RULES AND REGULATIONS

Title 28—HEALTH AND SAFETY

DEPARTMENT OF HEALTH

[28 PA. CODE CHS. 551, 553, 555, 557, 559, 561, 563, 565, 567, 569, 571 AND 573]

Ambulatory Surgical Facilities

Scope and Purpose

This final-form rulemaking amends the standards for the licensing and operation of ambulatory surgical facilities and implements the statutory mandate in section 806(f) of the Health Care Facilities Act (act) (35 P. S. § 448.806(f)) requiring the establishment of separate licensure criteria for office based surgical facilities and for comprehensive freestanding ambulatory surgical facilities. These amendments also reflect the modernization of ambulatory surgical facility standards which are appropriate given improvements in medical technology.

The act (35 P. S. §§ 448.101—448.904b) provides that, to be issued a license, the applicant shall 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 of Health (Department). (See section 808(a) of the act (35 P. S. § 448.808(a)).

With the sunset of the Certificate of Need (CON) program, the Department is adopting these amendments to assure that aspects of quality care and patient safety, previously addressed through the CON program, will now be enforced through the licensure process.

Public Comments

Notice of proposed rulemaking was published at 27 Pa.B. 3609 (July 19, 1997) with an invitation to submit written comments within 30 days.

Within the 30-day comment period, the Department received comments from the following respondents: The Pennsylvania Society of Physician Assistants; The Lowry Surgicenter; The Pennsylvania Ambulatory Surgical Association; The Hanover Surgicenter; The Lehigh Anesthesia Associates; Wyomising Hills Professional Center; Pennsylvania Dental Association; Hospital and Healthsystem Association of Pennsylvania; Pennsylvania Medical Society; Pennsylvania Podiatric Medical Association; Sacred Heart Hospital; Pennsylvania Association of Nurse Anesthetists; Kay Larkin, Esquire; Pennsylvania Psychological Association; Edward Dench, M.D.; Abington Surgical Center; HealthSouth; Senator Joseph Uliana; Representative Dennis M. O'Brien; and the State Board of Nursing.

After the comment period, the Department received comments from the Independent Regulatory Review Commission (IRRC). It also met with staff and counsel from IRRC prior to preparing the final rulemaking. Also, a stakeholder's meeting was held on May 19, 1999, to discuss a draft of the final-form regulations and a subsequent meeting to review those regulations was held with IRRC.

Following is a discussion of the comments received by the Department and the Department's response to them:

Chapter 551. General Information

§ 551.3 Definitions.

One person noted that the definition of "ambulatory surgical facility (ASF)" states a facility is not located on the premises of a hospital and asked for clarification of what is meant by "premises of a hospital." The Department considers the premises of a hospital to be that building and attachment covered by the hospital's license.

Another person requested that the definition of "ASF" exclude dental offices, because a definition would be consistent with § 551.2 (relating to affected institutions) which states that dentists' and oral surgeons' offices are excluded except if they are providing ambulatory surgery. The Department believes that since the exclusion is already contained in § 551.2, to repeat it in the definition would be redundant.

Finally, IRRC expressed a preference for amending the definition to track the definition in the act. The final rulemaking contains a definition of "ambulatory surgical facility" that is the same as that contained in section 802.1 of the act (35 P. S. § 448.802a).

Regarding the definition of "anesthesia," the Pennsylvania Medical Society and IRRC noted that the word "routine" should be replaced by the word "route." That change has been included in the final rulemaking.

Several comments were received with respect to the classification levels of ASFs and the distinctions between them for regulatory purposes.

David Bartos, D.P.M., requested that the Department accept accreditation by the Accreditation Association of Podiatric Surgical Facilities and the Pennsylvania Medical Society requested that the Department accept accreditation by the American Association for the Accreditation of Ambulatory Surgery Facilities, Inc. (AAAASF) for purposes of Class A designation. The act empowers the Department to combine surveys and inspections and make the dates of licensure expiration coincide with that of Medical Assistance and Medicare certification or the accreditation of an applicable Nationally recognized accrediting agency. (35 P. S. § 448.804(b)). As to Nationally recognized accrediting agencies, the Department relies upon those accrediting agencies designated by the Federal Medicare Program for deemed certification purposes. The accrediting agencies thus far recognized by the Federal Medicare Program are the Accreditation Association for Ambulatory Health Care (AAAHC) and the Joint Commission on the Accreditation of Health Care Organizations (JCAHO). The Federal Medicare Program has recently announced the approval of AAAASF as an accreditation organization for deemed certification purposes as of March 2, 1999. The accrediting agency proposed for inclusion by Dr. Bartos is not currently designated by the Federal Medicare Program, therefore, the Department has not made the suggested change. The Department, however, has included AAAASF as a Nationally recognized accrediting agency in the final rulemaking.

Dr. Edward Dench commented that the Class A facilities should be allowed to use intravenous general anesthesia because in limited circumstances certain local anesthetics could also cause suppressed breathing. By

contrast Senator Uliana requested that the Department clarify and expand upon its authority over Class A facilities. IRRC also asked that the Department respond to Dr. Dench and Senator Uliana.

In response to these comments, the Department has revised the definition of "Class A facilities" and their licensure requirements. The definition of a "Class A facility" will not include the proposed references to accreditation. The references and the Department's system for registering the facilities have been moved to § 551.31 (relating to licensure) which governs licensure of ambulatory surgical facilities. To draw the distinction between the types of procedures and anesthesia permitted in "Class A facilities," in contrast to Class B and Class C facilities, the Department is providing that those types of procedures which are performed in Class A facilities are those which require either no anesthesia, or local or topical anesthesia and during which reflexes are not obtunded. Therefore, certain procedures such as some endoscopies, removal of some foreign bodies and certain types of minor surgery would be permitted in Class A facilities. Certain types of surgery would not be permissible, even though a local or topical anesthetic might be used, because reflexes would be obtunded. Obtunded reflexes include the breathing reflex, the blinking reflex and the pupillary dilation and contraction reflex, or the involuntary joint extension or contraction reflex.

Representative O'Brien provided several comments with respect to classification levels including suggesting a requirement that Class A facilities be limited to one operating room and that accreditation by AAAHC or JCAHO be mandated. Representative O'Brien also suggested that Class B and Class C facilities should have a minimum of two operating rooms because this requirement would demonstrate a greater commitment to performing surgery at a higher volume of services raising the level of medical skill and service available in those ASFs. IRRC asked that the Department address these concerns as well.

The Department agrees that volume of procedures performed is related to quality but does not believe that quality is enhanced by the number of operating rooms in an ASF. Indeed, it is possible that mandating two operating rooms would encourage unnecessary procedures which would be both contrary to quality care and may also unnecessarily increase the cost of health care. The Department has amended the regulations to refer specifically to the standards of AAAHC and JCAHO. The Department currently works with JCAHO for the licensure of hospitals and will work with both AAAHC and JCAHO in the hopes of combining licensure and accreditation in one survey process. This is consistent with the Department's practice with respect to hospitals and is a matter that has already been discussed with these accrediting organizations. The Department will also consider working with other accrediting organizations as each becomes a Nationally recognized accrediting body. The Department has not amended the regulations to require ASFs to maintain a specific number of operation rooms.

§ 551.21. Criteria for ambulatory surgery.

The Department received comments from three sources, including IRRC, regarding the length of supervised recovery. Two of the commentators urged that up to 24 hours of supervised recovery be permitted at an ASF on the premise that the recovery would be safe and less expensive than hospital care. The Department believes that the extension of time to 4 hours of surgery and 4 hours of recovery, for surgery to be considered ambulatory surgery, is appropriate for the following reasons. First, the reason for extending the surgery time, but not the recovery time, is due to the development of newer anesthetic agents which enable surgeons to conduct longer periods of surgery. These same anesthetic agents also enable the patient to have a shorter recovery period.

Second, to extend the length of the permitted recovery time would require significant additional regulation by the Department of facility services, including housekeeping, nursing staff, social work staff and nutrition services. Once those items are added, the ASF regulations would be similar to hospital regulations. Therefore, entities that wish to provide 24-hour care should obtain hospital licenses.

Third, the work group, which included representatives of consumers, physicians and other providers, as well as representatives of the Pennsylvania Ambulatory Surgical Association (PASA), concluded that permitting 24-hour services would result in managed care organizations forcing patients to have complex procedures which require lengthy recovery, such as the now infamous "drive by mastectomies," in these settings. While the procedures might be physically safe in these settings, the group unanimously agreed that patient recovery would be better served by limiting cases that require that much recovery to hospitals.

Fourth, PASA provides no citation or other support for its statistics which do not account for complications, infections or other morbidity. Also, while PASA provides no support for its assertion that surgery in an ASF is less expensive than out-patient hospital procedures, that issue is not a quality of care consideration under the Department's purview.

IRRC suggested that the term "generally" should be stricken from this section as it does not establish a regulatory standard. While the Department agrees with IRRC, it also recognizes that, in certain unforeseen circumstances, the amount of time necessary may exceed 4 hours for either operation time or supervised recovery. Accordingly, the Department has added subsection (b) which provides that the time limits established 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 this additional time could not have been anticipated prior to surgery. This should address those rare cases when the extra time needed for proper treatment of the patient arises suddenly and unexpectedly. The Department expects the number of surgeries which exceed the 4-hour standard will be minimal and would question a facility where this standard is routinely violated.

Similarly, IRRC recommended striking the term "generally" in subsection (d)(1) and (4) which identify types of surgical procedures which may not be performed in an ASF. The Department has stricken the term in both instances, but has added language to subsection (d)(4), which stated, as proposed that surgical procedures may not be performed in an ASF if they are either emergency or life threatening in nature, to permit performance of this procedure in an ASF if no hospital is available for the procedure and the need for the surgery could not have been anticipated. The additional language has been added in recognition that an ASF may be located in a remote location where there is no nearby hospital to which the patient can be transported in time for appropriate treatment.

Finally, the Department believes that patients who undergo surgery in an ASF should be fully aware of the

risks associated with the administration of anesthesia and the surgery to be performed, as well as the option to have the surgery performed elsewhere. The Department has added subsection (e) requiring the surgeon to inform the patient of the risks, benefits and alternatives associated with the anesthesia to be administered, the procedure which will be performed and with performing the procedure in an ASF instead of in a hospital.

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

The Department received several comments on § 551.21(d)(5) which proposed that patients younger than 6 months of age and low birth weight babies up to 1 year of age could not be treated in an ASF.

The Hanover Surgicenter suggested amending the limitation on pediatric surgery by permitting surgery on infants classified as Class 1 patients with a gestational age of at least 48 weeks or those patients who are at least 6 months of age. The Department responds by noting that the proposed standard was developed after seeking advice from pediatric surgeons and reflects the minimum standard for safety.

On that particular requirement, the Pennsylvania Medical Society and IRRC proposed the use of the term "premature" rather than low birth weight babies. The work group decided, and the Department agrees, that the baby's condition, rather than the time of birth, should be the relevant factor. Whether or not a baby should be considered "low birth weight" is a professional judgment for the pediatrician.

The Hospital Association of Pennsylvania (HAP) recommended that ambulatory surgery should only be provided to pediatric patients if there is a pediatric anesthesiologist present and the physician is Board certified in pediatric surgery. IRRC suggested that the Department clearly specify separate criteria for pediatric patients in sections where pediatric treatments or requirements would be different than those required for adult patients.

To address these concerns appropriately, the Department has decided to create a new section which sets forth the criteria for performance of ambulatory surgery on pediatric patients. Subsection (a)(1) retains the requirement previously set forth in proposed § 551.21(d)(5) that no child under 6 months of age may be treated in an ASF. Subsection (a)(2) provides that the child's medical record shall contain documentation that the surgeon consulted with and sought an opinion from the child's primary care provider as to the appropriateness of performing the procedure in an ASF. If an opinion cannot be obtained (for example, child does not have a primary care provider), the record shall contain documentation providing an explanation. This will promote coordination of the surgery between the child's primary care physician and the surgeon. The primary care physician should be consulted by the surgeon. As the physician with the most comprehensive knowledge of the child's medical history, the primary care physician should be able to decide when the child's surgery should be not be performed in an ASF. Consultation between the primary care physician and surgeon is recommended by the American Academy of Pediatrics in its *Guidelines for the Pediatric Perioperative Anesthesia Environment* (issued February 1999) and also in a Policy Statement issued by the Academy in September, 1996 entitled *Evaluation and Preparation of Pediatric Patients Undergoing Anesthesia.*

Subsection (a)(3) sets forth requirements regarding the qualifications of the surgeon and the anesthetist who are involved in pediatric surgery in an ASF. Subsection (a)(3)(i) provides that the 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. This requirement is adopted from a similar standard in the *Guidelines* previously referenced. Subsection (a)(3)(ii) provides that the practitioner who performs the surgery shall be either board certified or have obtained preboard certification status. The Department believes that it is appropriate to require this higher level of training for the performance of surgery on children. The Department agrees with the statement that children are not "little adults" and that the performance of surgery on children in an outpatient setting requires that the surgical and anesthesia team have specialized training in the treatment of pediatric patients. Subsection (a)(4) requires that if a pediatric patient is present in the facility, a medical professional certified in advanced pediatric life support shall also be present in the facility. The subsection provides that the courses which the Department recognizes for certification in advanced pediatric life support are: 1) the course offered by the American Academy of Pediatrics and the American College of Emergency Physicians (commonly referred to as APLS); and 2) the course offered by the American Academy of Pediatrics and the American Heart Association (commonly referred to as PALS).

§ 551.31. Licensure.

While no comments were directly submitted on this particular section, the comments of Senator Uliana, the House Health and Human Services Committee and IRRC all impact on the relationship between the classification levels and licensure. The Department has amended this section to include a registration system for Class A ASFs which requires Class A ASFs to be accredited by a Nationally recognized accrediting agency. The Department has the ability to perform vigorous oversight if necessary and will not register a Class A ASF unless the facility has received this accreditation.

The Department believes that the risk of harm or injury to patients in these types of facilities should be minimal. To monitor Class A ASFs and to determine if this assumption is valid, the Department has added language which requires the applicant to complete a registration form and to provide the Department with information on the surgical procedures which will be performed in the ASF, the type of anesthetics to be administered and the current accreditation status of the facility. With this information, the Department will be in a position to assess whether the facility is properly classified as a Class A. The Department has also added a provision that the Class A ASF applicant shall provide other information the Department deems pertinent to registration requirements. Through this provision, the Department will be able to obtain any relevant information it needs to ensure that the ASF is meeting the criteria established for a Class A ASF.

The Department intends to monitor the performance of the Class A ASFs to determine if quality assurance concerns are raised at these facilities. Under subsection (f), the Department reserves the right to enter and inspect any ASF to investigate complaints. If the Department determines that registration is not the appropriate mechanism for these facilities based upon quality of care

problems that it identifies, it will seek amendment of these regulations to address that issue.

§ 551.34. Licensure process.

Several persons discussed the fee for licensure application. The Department is amending the regulation to conform to the fee as set by the act. It lacks the authority to impose fees inconsistent with the act.

§ 551.41. Policy.

PASA and Abington Surgical Center suggested that the time period for licensure should be changed. IRRC noted that the licensure period should follow the statute. The Department decided not to expand the licensure period to 2 years as proposed, and will continue to follow the statute which provides for a license to be issued for 1 year.

§ 551.61. Policy.

The House Health and Human Services Committee recommended that an ASF should be required to correct all deficiencies before a license is issued, because licensure requirements are ineffective without the ability to compel conformance.

The Department retains the discretion under §§ 551.82 and 551.83 (relating to regular license; and provisional license) to determine that the ASF is in substantial compliance with the regulations and that it has an acceptable plan of correction, prior to the Department issuing a provisional license. Absolute compliance is a standard unnecessary to assure the quality of health care and is inconsistent with not only the Department's requirements for other health care facilities but also Medicare standards and National accrediting standards. The Department has not made the recommended change.

§ 551.81. Principle.

IRRC requested an explanation of whether an ASF may continue to operate under licensure when it is out of compliance but has filed a compliance plan. Under this section, the Department is permitted to issue an ASF license to a facility that "complies with this subpart." This subpart includes § 551.82 which allows the Department to review and approve a plan of correction and to determine whether or not a facility is in substantial compliance with the Department's regulations. If the Department determines that the ASF is not in substantial compliance or if the Department has not approved the plan of correction, a regular license will not be issued. Under the act, the Department may issue a provisional license to ASF which is found to have deficiencies, but which is taking appropriate steps to correct those deficiencies. This is further explained in § 551.91 (relating to grounds) which addresses reasons why the Department may refuse to issue, renew, suspend, revoke or limit a license.

§ 551.82. Regular license.

As with the time period for a license discussed in § 551.61 (relating to policy), the Department decided not to expand the licensure period to 2 years as proposed, and will continue to follow the statute which provides for a license to be issued for 1 year.

§ 551.91. Grounds.

The Pennsylvania Medical Society asked for more detail on the investigation and adjudication process for the removal or revocation of an ASF license. The regulations as written in § 551.111 (relating to hearings relating to licensure) require that the hearings for the removal or revocation of a license be conducted by the State Facility Hearing Board. That reference has been changed to the Health Policy Board. The State Health Facility Hearing Board conducted hearings under 37 Pa. Code 197 (relating to practice and procedure). Those regulations will continue to apply. Those provisions are applicable for all administrative hearings and are sufficient for these purposes. The investigation process is consistent with that for other facilities, as outlined in section 813 of the act (35 P. S. § 448.813).

The House Health and Human Services Committee suggested that the Department add a provision whereby it may deny or revoke a license if any owner of the applicant is not fit to operate an ASF. The comment also asserted that the Department should consider the applicant's prior history of at least 5 years in operating health care facilities in any jurisdiction, including violations of licensure regulations or other health related laws. The rationale for this suggestion is that the extent of the health related offenses, licensure violations and other improper conduct, both in this Commonwealth and in other jurisdictions, is an indication of whether a health care provider/organization should be entrusted with the health and well being of Commonwealth patients.

The Department agrees with the rationale, but believes that it already has sufficient authority to implement the quality control rightfully requested by the House Health and Human Services Committee. First, section 808(a)(1) of the act provides that the Department must be satisfied that, among other things, "the health care provider is a responsible person." To list offenses would unnecessarily restrict the Department's discretion with respect to determining whether or not an applicant or provider is a responsible person.

Second, under subsection (b)(1) the Department may refuse to renew, or may suspend, revoke or limit a license for noncompliance with the act. Therefore, if the Department were to determine that the owners or providers of an ASF were no longer responsible persons, as mandated by the act, the ASF would be noncompliant and subject to revocation or suspension of the license.

Chapter 553. Ownership, Governance and Management

§ 553.3. Governing body responsibilities.

HAP, Lowry Surgicenter, the House Health and Human Services Committee and IRRC, recommended adding a requirement for pediatric advance life support when pediatric surgery is performed. The Department agrees with this recommendation and has amended paragraph (16) to reflect this requirement.

Subsection (b)(17) which required that all ASF personnel wear identification tags which include the person's name and professional designation, has been deleted as this requirement is now in § 51.6 (relating to identification of personnel).

§ 553.4. Other functions.

One person recommended the removal of the requirement that an ASF have a board certified medical director. IRRC requested that the Department demonstrate flexibility in this regard. The Department stands behind the mandate for a board certified medical director as an index of the quality of care that shall be provided in the ASF. Board certification is available to all trained surgeons and serves as an independent peer review acknowledgment of the qualifications of the physician. The Department has amended this regulation in subsection (h) to require that the medical director shall be board certified by an American Board of Medical Specialities recognized board

or the dental, podiatric or osteopathic equivalent and to allow a board eligible or similarly qualified physician to serve as an interim medical director during the period of time between the departure of a director and the selection of a new director. This interim medical director shall be a physician who is able to demonstrate qualifications acceptable to the medical staff of the ASF and to the Department.

§ 553.21. Principle.

HealthSouth requested that the Department permit transfer and discharge of a patient, by an ASF, to a rehabilitation hospital. The regulations do not prohibit transfer of a patient from an ASF to a rehabilitation hospital. Counsel to HealthSouth agreed with that analysis. No change has been made to this section, other than as proposed.

The House Health and Human Services Committee recommended that the Department add a provision mandating that ASFs provide minimum levels of care to the indigent and to Medical Assistance recipients. This recommendation was not adopted. While the Department appreciates the importance of having medical care available to all persons, mandating access is not authorized by the act. The Department's ability to enforce market controls in health care terminated with the sunset of the CON Program. However, most physicians participate in both the Medicare and Medicaid programs, which do not permit them to refuse to treat patients without threatening the physicians' participation in these programs. In addition, there is currently no evidence to suggest that the emergence of ASFs would limit care to the poor or indigent. Finally, the Department will continue to require that ASFs continue to abide by the Commonwealth's nondiscrimination laws.

Chapter 555. Medical Staff

§ 555.1. Principle.

The Pennsylvania Psychological Association recommended the addition of psychologists to the definition of "medical staff." Psychologists are not permitted to perform surgery in this Commonwealth. The Department has not revised this section.

§ 555.2. Medical staff membership.

The Pennsylvania Medical Society recommended board certification for medical staff membership on an ASF. The Department has required board certification for the medical director of an ASF. This requirement would be higher than that which is required of hospitals. The Department rejected this recommendation.

§ 555.12. Oral orders.

One commentor suggested substituting the phrase "verbal orders" for "oral orders" because this reference is consistent with current usage. The Department has not made this change. The phrase "oral orders" most accurately describes the type of orders discussed in this section.

The Department has added language to clarify that administration of medications through an oral order is restricted to only those individuals who are qualified to do so by their professional license or certification issued by the Commonwealth. The scope of practice of these individuals is the appropriate determinant as to their ability to administer medication.

There was some objection to the proposed requirement of a countersignature being placed in the medical record within 24 hours of the order. The objection was that this period was not long enough. The Department has amended this time frame to 48 hours and added a provision that countersignatures may be received by facsimile transmission. The Department believes that this requirement is not unduly burdensome. With the proliferation of fax machines there should be no reason for failure to obtain countersignatures within the required period of time.

§ 555.13. Administration of drugs.

The Pennsylvania Society of Physician Assistants and IRRC suggested that the regulation should reflect that it is within the scope of practice of physician assistants (PAs), certified registered nurse practitioners (CRNPs), and registered nurses to administer drugs in an ambulatory surgical facility. The Department has amended this section accordingly.

§ 555.22. Preoperative care.

Sacred Heart Hospital recommended that the ASF should be required to arrange for patients who receive regional anesthesia to have a responsible person escort them home. The Department agrees with this recommendation and has amended this section to require that a medical decision be made in advance regarding whether patients who receive local or regional anesthesia require a responsible person to escort them home.

Sacred Heart Hospital asserted the need to identify necessary preoperative studies in the regulations. The recommendation was rejected because of the wide variety of procedures which may be performed in an ASF setting. It would be impossible to identify the preoperative studies that would be required in each case.

HAP suggested that a third person, in addition to the physician and the individual administering the anesthesia, should identify the patient prior to the administration of the anesthesia. The recommendation was rejected. While the Department agrees that making a third person responsible for identification of the patient may add another mechanism for certainty, this requirement would be cost prohibitive for many ASFs.

§ 555.23. Operative care.

Three persons, including IRRC, suggested that the Department modify the dual requirement that an ASF have a written transfer agreement and that the operating surgeon have surgical privileges at a hospital in close proximity to the ASF. The Department agrees that either a written transfer agreement or the operating surgeon having clinical surgical privileges at a nearby hospital will be an adequate protection, and has amended this section accordingly.

§ 555.24. Postoperative care.

One person suggested that when a CRNP or PA dictates the operative report, the report should be countersigned by the surgeon. The Department agrees with this recommendation and has amended this section accordingly.

PASA and Abington Surgical Center suggested that the ASF should ensure that all patients who receive anesthesia are observed in recovery. The regulation has been amended to require observation of all patients who receive anesthesia without distinction between types of anesthesia. The regulation requires that all patients who receive any type of anesthesia be observed in recovery.

Sacred Heart Hospital recommended that the Department should mandate that only a physician may discharge a patient. Subsection (g) addresses this concern, in part, by requiring that patients be discharged from an

ASF on the written signed order of a practitioner. "Practitioner" is defined in § 101.4 (relating to definitions) to include podiatrists, dentists and physicians.

Three organizations suggested that the anesthetist who provides anesthesia need not remain at the ASF during recovery so long as an anesthetist is present. The Department agrees with this, and has amended subsection (d) to require that if a patient receives general anesthesia or conscious sedation, an anesthetist shall remain present in the facility until that patient has been discharged.

The Lowry Surgicenter recommended retaining a requirement that an anesthesiologist or physician qualified in resuscitative techniques be required rather than a medical professional certified in ACLS. The work group concluded, and the Department agrees, that a medical professional certified in ACLS provides greater protection than a physician who lacks this training and certification. The Department has not made the suggested change.

Another person recommended that discharge instructions also include care of wound dressing, follow up appointments, emergency phone numbers and diet. The regulations as written already include a provision for follow up appointments and emergency contacts. The Department has added provisions requiring instructions on care of wound dressing and dietary limitations.

§ 555.31. Principle.

The Pennsylvania Medical Society requested that the Department delete the reference to the degree of supervision required and the scopes of responsibilities delegated to anesthesiologists and supervising physicians. Each individual ASF is permitted to enhance quality assurance by using protocols it may develop for the administration and supervision of anesthesia. The Department has not made the suggested deletion.

§ 555.32. Administration of anesthesia.

Several associations, including the Pennsylvania Association of Nurse Anesthetists (PANA), have opposed the requirement that when a nonphysician administers anesthesia, the anesthetist shall be under the medical direction of an anesthesiologist or a qualified physician or dentist. The Department has changed the language of this section, in part, to reflect that a nonphysician shall be under the overall direction of an anesthesiologist or a physician or dentist who is present in the facility.

The House Health and Human Services Committee recommended adding a provision that for pediatric patients anesthesia shall be administered by an anesthesiologist who has been trained in pediatric anesthesiology. The Department has amended this section by requiring that pediatric surgery be performed only if a pediatric anesthesiologist is present in the ASF and the physician is either board certified or has obtained a preboard certification status in pediatric surgery.

The same committee also recommended that anesthesia not be administered by nonphysicians unless an anesthesiologist or qualified physician directly supervises the nonphysician. This change was not made. This approach would contradict the current regulations for CRNAs and dentists. The Department is seeking to make these regulations as consistent as possible with those of the health profession licensing boards.

PANA, IRRC and the State Board of Nursing commented that a CRNA who administers anesthesia should be required to be under the overall direction of an anesthesiologist, physician or dentist. The Department agrees with this comment and the regulation has been changed accordingly.

Abington Surgical Center requested that the regulation be amended to be consistent with the proposed Board of Medicine regulation for medical supervision of anesthesia. This recommendation was rejected. The Department's regulations reflect existing laws and not proposed ones.

§ 555.33. Anesthesia policies and procedures.

Lehigh Anesthesia Associates recommended that CRNAs be permitted to serve as directors of anesthesia services for an ASF. The Department notes that 49 Pa. Code § 21.17(3) (relating to anesthesia) requires that the CRNAs' performance be under the overall direction of the chief or director of anesthesia services who has been defined in this subpart as an anesthesiologist or a qualified physician or dentist. Further, the director of anesthesia services of an ASF should be an independent practitioner, not one who is under the direction of someone else. Therefore, no change was made.

Lehigh Anesthesia Associates and Blank Rome Comisky & McCauley recommended the removal of the requirement for "one or more health care professionals, besides the one performing surgery, to be present and trained in the administration of anesthesia." One justification was that dentists are certified to perform both surgery and anesthesia. Under § 551.2 (relating to affected institutions), dentists and oral surgeons offices are specifically excluded unless they seek licensure or certification as ASFs. The Pennsylvania Dental Society agreed to this rule. With respect to other surgeons, the point of the requirement is that surgeons should focus on the surgery while another professional, trained to administer anesthesia, monitors the patient's condition. Therefore, the Department has amended the regulation to require that one or more additional health care professionals are present in the ASF besides the one performing surgery.

Blank Rome Comisky & McCauley recommended the removal of the requirement that the administering anesthesiologist evaluate the patient prior to discharge. The Department has amended this section to state that prior to discharge from the ASF, a patient shall be evaluated by an anesthetist, the operating room surgeon, anesthesiologist or dentist.

The Pennsylvania Medical Society suggested replacing the term "pulse oximeter" with "oxygen saturation by pulse oximetry." The Department agrees and has amended the section to follow that suggestion.

Chapter 557. Quality Assurance and Improvement

§ 557.3. Quality assurance and improvement program.

HAP suggested that data be specific to age group so that the data on pediatric patients can be segregated and analyzed separately. The Department has incorporated this suggestion into the regulation.

Chapter 559. Nursing Services

§ 559.2. Director of nursing.

Sacred Heart Hospital asked for further definition of the qualifications for the director of nursing. The only qualification is that the director of nursing be a registered nurse. This is consistent with the hospital regulations.

§ 559.3. Nursing personnel.

Sacred Heart Hospital asked for clarification of the required number of licensed and unlicensed personnel. The work group chose to leave the judgment of what constitutes an adequate number of licensed and unlicensed personnel to each ASF, given the other requirements in the regulations for personnel to supervise

anesthesia and recovery. The language in these regulations is consistent with the language in the hospital regulations.

HAP recommended that if pediatric services are provided, the regulation should require nursing staff with experience in the postoperative care of children. The Department agrees and has included such a requirement for Class B and Class C facilities. This requirement provides that the nursing staff shall have documented experience in the postoperative care of pediatric patients, when the patients are treated in the ASF.

One ambulatory surgical facility recommended eliminating the requirement for a registered nurse to be present during all hours of operation. The Department amended the regulation to require that a registered nursed be in attendance in the ASF during the hours that patients are present.

Chapter 563. Medical records

§ 563.1. Principle (medical records).

Blank Rome Comisky & McCauley and IRRC, suggested permitting combined ASF records with physician office or health system records. The Department specifically requires that the ASF medical record be onsite to promote quality assurance and to protect patient confidentiality. The Department will permit a medical information system in which the relevant part of a patient's medical record is made available to or in the ASF and the remaining part of the record could be stored elsewhere.

Chapter 565. Laboratory and Radiology Services

§ 565.15. Records.

The Pennsylvania Medical Society and Lowry Surgicenter suggested that the 24-hour requirement for inclusion of ancillary service reports is not workable and recommended that the Department continue to require that dated reports of service be made a part of the medical record in a timely manner. While the Department agrees that 24 hours may not provide adequate time, it believes that a finite period of time shall be established. The Department has restored the provision that these reports shall be made a part of the medical record in a timely manner, but requires that this period of time may not exceed 30 days.

Chapter 567. Environmental Services

§ 567.11. Operating suite equipment.

The House Health and Human Services Committee suggested adding a provision requiring the use of age appropriate equipment and supplies. The Department agrees that age appropriate equipment and supplies should be used. The Department has amended the regulation to include such a requirement.

One ambulatory surgical facility recommended that the requirement for a thoracotomy set should not be deleted as proposed. This recommendation was rejected. The physicians and nurses on the work group could not think of any circumstance in which a thoracotomy set rather than some other type of required equipment would be used.

Chapter 571. Construction Standards

§ 571.1. Minimum standards (Life Safety Code).

The House Health and Human Services Committee recommended adding a provision that requires ASF physical plants to conform to local building codes. The Department has amended the regulations to require that ASF construction be in accordance with the latest edition of the "Guidelines for Design and Construction of Hospital and Health Care Facilities," as published by the American Institute of Architects/Academy of Architecture for Health (AIA Guidelines). Where renovation or replacement work is performed within an existing facility, all new work or additions shall comply with the requirements for new construction. These AIA Guidelines are generally recognized as the standard in health care and are used for hospitals and long-term care facilities.

The Department received several comments that the AIA Guidelines are not appropriate for certain facilities, particularly Class B facilities which perform endoscopic surgery exclusively. The Department has added language to provide that in applying the AIA Guidelines, it will consider those portions of the AIA Guidelines which establish criteria for various outpatient facilities. Those criteria include guidelines for design and construction of endoscopic suites. Additionally, the Department is willing to recognize other authoritative sources for design and construction standards of different types of ASFs. A provision has been added that, as an alternative to the AIA Guidelines, an ASF applicant may meet the construction guidelines for specified types of surgical procedures as listed in Appendix A. Organizations interested in having their standards for design and construction recognized by the Department should provide the Department with specific guidelines established by other organizations and the reason why these guidelines should be considered authoritative (for example, adoption by a Nationally recognized accrediting agency, widespread use in the industry). The Department will review these guidelines and, as appropriate, will add them to Appendix A. The Department has been provided with two sets of guidelines by the Pennsylvania Society of Gastroenterology for the construction of ASFs which will provide only endoscopic surgery. Those have been found acceptable by the Department and are included in Appendix A. Applicants should be aware that if the procedures performed at the ASF should change, other design and construction standards may become relevant. Under § 51.3(a) (relating to notification), owners of ASFs are required to provide the Department with at least 60 days advance notification of the commencement of a health care service which has not been previously offered at that facility.

Fiscal Impact

These amendments, to ensure the quality of services being provided at an ASF, will result in minimal costs to the Department. 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 an ASF previously had to undergo CON review prior to commencement of that activity. This review involved expenses for the Department in the employment of an entire division to process and review CON applications. With the sunset of the CON Program, staff were reassigned to various divisions, including the Bureau of Facility Licensure and Certification which should offset these identified costs.

The amendments to the Department's licensure regulations will impose additional costs on health care providers to some degree. The regulations require that medical directors of ASFs shall be board certified. 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 ASFs are already meeting if they provide these services.

These costs must be compared to prior costs associated with the CON program which 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 amendments will not eliminate all of the costs which ASFs 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 ASF 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 desiring to operate an ASF were required to submit detailed applications which could be quite lengthy and require extensive documentation.

Effective Date/Sunset Date

The amendments will become effective 30 days after publication in the *Pennsylvania Bulletin.*

Statutory Authority

Section 803(2) of the act (35 P. S. § 448.803(2)) authorizes the Department to promulgate 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 section 806(f) of the act (35 P. S. § 806(f)) to provide for separate licensure criteria for office-based surgical facilities and for comprehensive freestanding ambulatory surgical facilities confers upon the Department the authority to employ regulations as necessary to assure quality care delivery in those facilities.

Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), the Department submitted a copy of the notice of proposed rulemaking, published at 27 Pa.B. 3648 (July 19, 1997), to IRRC and the Chairpersons of the House Committee on Health and Human Services and the Senate Committee on Public Health and Welfare. In compliance with section 5(c) of the Regulatory Review Act, the Department also provided IRRC and the Committees with copies of all comments received, as well as other documentation.

In compliance with section 5.1(a) of the Regulatory Review Act (71 P. S. § 745.5a(a)), the Department submitted a copy of the final-form regulations to IRRC and the Committees on March 30, 1999. In addition, the Department provided IRRC and the Committees with information pertaining to commentators and 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.

In preparing these final-form regulations, the Department has considered all comments received from IRRC, the Committees and the public.

These final-form regulations were deemed approved by the House Health and Human Services Committee and deemed approved by the Senate Public Health and Welfare Committee. IRRC met on September 9, 1999, and approved the final-form regulations in accordance with section 5.1(e) of the Regulatory Review Act.

Contact Person

Questions regarding these amendments may be submitted to: James T. Steele, Jr., Senior Counsel, Department of Health, P. O. Box 90, Harrisburg, PA 17108-0090, (717) 783-2500. Persons with disabilities may submit questions in alternative formats such as by audiotape, braille or by using V/TT: (717) 783-6514 or the Pennsylvania AT&T Relay Service at (800) 654-5984 (TT).

Persons with disabilities who would like to obtain this document in an alternative format (that is, large print, audiotape, braille) should contact James Steele so that he can make the necessary arrangements.

Findings

The Department finds that:

(1) Public notice of intention to adopt these amendments has been given under sections 201 and 202 of the act of July 31, 1968 (P. L. 769, No. 240) (45 P. S. §§ 1201 and 1202), and the regulations thereunder, 1 Pa. Code §§ 7.1 and 7.2.

(2) A public comment period was provided as required by law and all comments were considered.

(3) The adoption of the final-form regulations in the manner provided by this order is necessary and appropriate for the administration of the authorizing statute.

Order

The Department, acting under the authorizing statute, orders that:

(a) The regulations of the Department, 28 Pa. Code Chapters 551, 553, 555, 557, 559, 561, 563, 565, 567, 569, 571 and 573, are amended by adding §§ 551.22, 553.25, 555.13 and Chapter 573, Appendix A by amending §§ 551.1—551.3, 551.21, 551.31, 551.33, 551.34, 551.41, 551.43, 551.53, 551.81—551.83, 551.91, 551.93, 551.111, 553.2—553.4, 553.21—553.22, 553.31, 555.3, 555.4, 555.11, 555.12, 555.21—555.24, 555.31—555.33, 555.35, 557.1—557.4, 559.2, 559.3, 561.1, 561.2, 561.13, 561.21, 561.23, 563.8, 563.12, 563.13, 565.12, 565.13, 565.15, 567.1, 567.3, 567.11, 567.32, 569.2, 569.11, 569.21, 569.33, 569.35, 571.1, 571.2, 571.11, and by deleting §§ 551.11—551.13, 551.32, 551.42, 551.121—551.123, 571.13, 573.1—573.2 to read as set forth in Annex A.

(b) The Secretary of Health shall submit this order and Annex A to the Office of General Counsel and the Office of Attorney General for approval as required by law.

(c) The Secretary of Health shall submit this order, Annex A and a Regulatory Analysis Form to IRRC, the House Committee on Health and Human Services and the Senate Committee on Public Health and Welfare for their review and action as required by law.

(d) The Secretary of Health shall certify this order and Annex A and deposit them with the Legislative Reference Bureau as required by law.

(e) This order shall take effect November 22, 1999.

ROBERT S. ZIMMERMAN, Jr.,
Secretary

(*Editor's Note:* For the text of the order of the Independent Regulatory Review Commission relating to this document, see 29 Pa.B. 5031 (September 25, 1999).)

Fiscal Note: 10-149B. No fiscal impact; (8) recommends adoption.

Annex A

TITLE 28. HEALTH AND SAFETY

PART IV. HEALTH FACILITIES

Subpart F. AMBULATORY SURGICAL FACILITIES

CHAPTER 551. GENERAL INFORMATION

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.

§ 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.

§ 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 noncompliance 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.

§§ 551.11—551.13 (Reserved).

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.

§ 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.

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 survery 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.

§ 551.32. (Reserved).

§ 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.

§ 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.

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.

§ 551.42. (Reserved).

§ 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.

INSPECTION AND SURVEY ACTIVITIES

§ 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.

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.

§ 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.

§ 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.

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.

§ 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.

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).

§ 551.121. (Reserved).

§ 551.122. (Reserved).

§ 551.123. (Reserved).

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.

(b) A complete list of the names and addresses of owners, directors, officers and managers shall be submitted with the application.

(c) 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.

(d) A physically noncontiguous branch of the ASF shall meet the requirements for licensure and shall be independently licensed.

§ 553.3. Governing body responsibilities.

Governing body responsibilities include:

(1) Conforming to applicable Federal, State and local law.

(2) Determining the goals and objectives of the ASF.

(3) Assuring that facilities and personnel are adequate and appropriate to carry out the goals and objectives.

(4) Establishing an organizational structure and specifying functional relationships among the various components of the ASF.

(5) Adopting bylaws or similar rules and regulations for the orderly development and management of the ASF, which:

(i) Describe the authority delegated to the person in charge and to the medical staff.

(ii) Require the governing body to review and approve the bylaws, or similar rules and regulations, of the medical staff.

(6) Adopting policies or procedures necessary for the orderly conduct of the ASF.

(7) Assuring that the quality of care is evaluated and that identified problems are appropriately addressed.

(8) Establishing personnel policies and practices which adequately support sound patient care to include the following:

(i) Require the employment of personnel with qualifications commensurate with a job's responsibilities and authority, including appropriate licensure and certification.

(ii) Applicants for positions requiring a licensed person shall be hired only after obtaining verification of their licenses, records of education and written references.

(iii) Personnel records shall include current information relative to periodic work performance evaluations.

(iv) Compliance with Occupational Safety and Health Administration (OSHA) Universal Precautions for prevention of transmission of diseases.

(v) Written job descriptions shall exist for each type of job in the ASF.

(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.

(9) Reviewing legal and ethical matters concerning the ASF including the reports and disposition of unusual incidents.

(10) Maintaining effective communication throughout the ASF.

(11) Establishing a system of financial management and accountability that includes an audit appropriate for the ASF.

(12) Establishing a procedure for implementing, disseminating and enforcing a patient's bill of rights in compliance with § 553.13 (relating to procedures for distribution).

(13) Approving major contracts or arrangements affecting the medical care provided under its auspices, including those concerning:

(i) The employment 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.

(iv) The provision of education to students and postgraduate trainees.

(14) Formulating long-range plans in accordance with the goals and objectives of the ASF.

(15) Operating the ASF without limitation because of age, race, creed, color, sex, national origin, religion, handicap or disability.

(16) Assuring that at least one medical professional in the facility when patients are present is currently and on an ongoing basis certified in advanced cardiac life support, or its successor. If a pediatric patient is present in the facility, the certification of the medical professional shall be in advanced pediatric life support as defined in § 551.22(A)(4) (relating to criteria for performance of ambulatory surgery on pediatric patients).

§ 553.4. Other functions.

(a) The governing body shall meet at least annually and keep minutes or other records necessary for the orderly conduct of the ASF.

(b) If the governing body elects, appoints or employs officers and administrators to carry out its directives, the authority, responsibility and functions of the positions shall be defined.

(c) If 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—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—initial appointments, reappointments and assignment or curtailment of clinical privileges of the practitioners.

(e) If students and postgraduate trainees are present in the facility, their role and functions shall be defined.

(f) The governing body shall ensure that personnel are provided with continuing education which is relevant to their responsibilities within the organization.

(g) The governing body shall ensure that the licensee provides to the Department, the documents under § 551.53 (relating to presurvey preparation).

(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. The governing body may appoint an interim director during the period of time between the departure of a director and the selection of a new director.

(1) The interim director shall be a physician who is able to demonstrate qualifications acceptable to the medical staff of the ASF and to the Department.

(2) If the interim director is not board certified, the Department will specify the maximum period of time for which the interim director may serve.

ADMISSION, TRANSFER AND DISCHARGE

§ 553.21. Principle.

(a) The ASF shall have written policies for the admission, discharge, transfer and proper referral of patients.

(b) The ASF may not provide beds or other accommodations for an overnight stay of patients.

(c) A patient shall be discharged in a conscious and coherent condition and able to maintain vital life functions or shall be transferred to a hospital.

(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 the patient's usual level considering limitations imposed by the surgical procedure.

(3) *Mental status.* The patient is awake, alert or functions at the patient's 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.

(a) A full time person in charge shall be appointed who has authority and responsibility for the operation of the ASF at all times. Qualifications, authority, responsibilities and duties of the person in charge shall be defined in a written statement adopted by the governing body.

(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.

(a) To receive favorable recommendation for appointment, or reappointment, members of the medical staff shall always act in a manner consistent with the highest ethical standards and levels of professional competence.

(b) Privileges granted shall reflect the results of peer review or utilization review programs, or both, specific to ambulatory surgery.

(c) Privileges granted shall be commensurate with an individual's qualifications, experience and present capabilities.

(d) Granting of clinical privileges shall follow established policies and procedures in the bylaws or similar rules and regulations. The procedures shall provide the following:

(1) A written record of the application, which includes the scope of privileges sought and granted. The delineation "clinical privileges" shall address the administration of anesthesia.

(2) A review, summarized on record with appropriate documentation, of the qualifications of the applicant.

(e) Reappraisal and reappointment shall be required of every member of the medical staff at regular intervals no longer than every 2 years.

(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 certified registered nurse practitioners.

(a) If the ASF assigns patient care responsibilities to physician assistants and nurse practitioners, the medical staff shall have established policies and procedures approved by the governing body, for overseeing and evaluating their clinical activities. The training, experience and demonstrated current competence of physician assistants and nurse practitioners shall be commensurate with their duties and responsibilities.

(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) and the Osteopathic Medical Practice Act (63 P. S. §§ 261—271). Certified registered 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 State Boards of Medicine and Nursing.

(c) Physician assistants and nurse practitioners shall be licensed or certified as applicable.

MEDICAL ORDERS

§ 555.11. Written orders.

(a) Medication or treatment shall be administered by authorized persons to administer drugs and medications only upon written and signed orders of a practitioner acting within the scope of the practitioner's license.

(b) Physician assistants and certified registered nurse practitioners may write orders for medication or treatment in accordance with their legally authorized scope of practice and policies and procedures of the ASF.

(c) Written orders may be issued by facsimile transmission.

§ 555.12. Oral orders.

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 by their professional license or certification issued by the Commonwealth and 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 48 hours of the order. If the practitioner is not the attending physician, the practitioner shall be authorized by the attending physician and shall be knowledgeable about the patient's condition. Countersignatures may be received by facsimile transmission.

§ 555.13. Administration of drugs.

Drugs shall be administered only upon the proper order of a practitioner acting within the scope of the practitioner's 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. Physician assistants and certified registered nurse practitioners shall be permitted to administer drugs within their authorized scope of practice. 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, upon the recommendation of the medical staff and congruent with ASF classification as stated on its 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 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 30 days prior to date of surgery.

(2) 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 practitioner, and signed by the patient, or responsible person, for the performance of the specific 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 patient. It shall also identify any practitioner who will participate in the surgery.

(c) Written instructions for preoperative procedures, which have been approved by the medical staff, shall be given to the patient or responsible person, and shall include:

(1) Applicable restrictions upon food and drink before surgery.

(2) Special preparations to be made by the patient.

(3) The required proximity of the patient to the ASF for a specific time following surgery, if applicable.

(4) An understanding that the patient may require admission to the hospital in the event of medical need.

(5) Upon discharge of a patient who has received sedation or general anesthesia, a responsible person shall be available to escort the patient home. With respect to patients who receive local or regional anesthesia, a medical decision shall be made regarding whether these patients require a responsible person to escort them home.

(d) Preoperative diagnostic studies, if performed, shall be evaluated, annotated, signed and entered into the patient's medical record before surgery.

(e) 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 the procedure to be performed 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 the practitioner's defined specific practice privileges. Physician assistants and certified registered 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.

(b) Tissues and exudates removed during a surgical procedure shall be properly labeled and sent to a laboratory for examination by a pathologist. The specimen shall be accompanied by pertinent clinical information, including its source and the preoperative and postoperative surgical diagnosis. The pathologist's signed report of the examination shall be made a part of the patient's medical record. Certain tissues and exudates may be exempt from laboratory examination. The exemptions shall be those that are consistent with current medical practices and are in writing and approved by the governing body.

(c) An ASF shall be prepared to initiate immediate onsite resuscitation or other appropriate response to an emergency which may be associated with procedures performed there.

(d) The ASF shall have an effective procedure for the immediate transfer to a hospital of patients requiring emergency medical care beyond the capabilities of the ASF.

(e) The ASF shall have a written transfer agreement with a hospital which has emergency and surgical services available, or physicians performing surgery in the ASF shall have admitting privileges at a hospital in close proximity to the ASF, to which patients may be transferred.

(f) There shall be a written agreement in effect with an ambulance service staffed by certified EMT personnel, for the safe transfer of a patient to a hospital in an emergency situation, or as the need arises.

§ 555.24. 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 certified registered nurse practitioner performed part of the operation, the findings and techniques of the procedure shall be accurately recorded and the report shall be countersigned by the medical staff member. This description shall become a part of the patient's medical record.

(b) A patient who has received anesthesia shall be observed in the facility by a registered nurse, physician assistant or a practitioner for a period of time which is sufficient to ensure that no immediate postoperative complications are present.

(c) Patients in whom a complication is known or suspected to have occurred during or after the performance of a surgical procedure shall be informed of the condition and arrangements made for treatment of the complication. In the event of admission to an inpatient facility, a summary of care given in the ASF concerning the suspected complication shall accompany the patient.

(d) 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, regional anesthesia or IV sedation, an anesthetist shall remain present until that patient has been discharged from the facility.

(e) Patients shall be discharged in the company of a responsible person, if one is deemed to be necessary under § 555.22(c)(5) (relating to preoperative care).

(f) Protocols approved by the medical staff shall be established for instructing patients in self-care after surgery including written instructions which, at a minimum, include the following:

(1) The symptoms of complications associated with procedures performed.

(2) An explanation of prescribed drug regime including directions for use of medications.

(3) The limitations and restrictions on activities of the patient, if necessary.

(4) A specific telephone number to be used by the patient, if a complication or question arises.

(5) A date for follow-up or return visit after the performance of the surgical procedure.

(6) Instructions on the care of dressing and wounds.

(7) Instructions on dietary limitations.

(g) Patients shall be discharged only on the written signed order of a 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 shall define the degree of supervision required and the scope of responsibilities delegated to anesthesiologists, certified registered nurse anesthetists 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 practitioners as defined in § 551.3 (relating to definitions).

(b) If a nonphysician administers the anesthesia, the anesthetist shall be under the overall direction of an anesthesiologist or a 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 overall direction of the anesthetist.

§ 555.33. Anesthesia policies and procedures.

(a) In ASFs where an anesthesiologist is present, the anesthesiologist shall be designated the Director of Anesthesia Services and shall be responsible for directing the anesthesia services and establishing the general policies and procedures for the administration of anesthesia in the ASF which shall be approved by the governing body.

(b) In ASFs where there is no anesthesiologist, the governing body shall designate a physician or dentist to function as the Director of Anesthesia Services, who shall be responsible for directing the anesthesia 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.

(d) Anesthesia procedures shall provide at least the following:

(1) A patient requiring anesthesia shall have a preanesthesia evaluation by a 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 preanesthesia medications.

(3) Prior to beginning the administration of anesthesia, the anesthetist shall check equipment to be used in administration of anesthetic agents. An anesthetic gas machine in anesthetising areas shall have a pin-index safety system.

(4) Following the procedure for which anesthesia was administered, the anesthetist shall remain with the patient as long as necessary to insure safe transport to the recovery area and shall advise personnel responsible for postanesthetic care of the condition of the patient.

(5) A patient receiving anesthesia shall have an anesthetic record maintained. This shall include a record of vital signs and all events taking place during the induction of, maintenance of and emergence from anesthesia, including the dosage and duration of anesthetic agents, other drugs and intravenous fluids.

(6) Intraoperative physiologic monitoring shall include the following at a minimum:

(i) The use of oxygen saturation by pulse oximetry.

(ii) The use of End Tidal CO_2 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.

(8) Before discharge from the ASF, a patient shall be evaluated for proper anesthesia recovery by an anesthetist, the operating room surgeon, anesthesiologist or dentist. Depending on the type of anesthesia and length of surgery, the postoperative check shall include at least the following:

(i) Level of activity.

(ii) Respirations.

(iii) Blood pressure.

(iv) Level of consciousness.

(v) Oxygen saturation by pulse oximetry.

§ 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. 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 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) Peer-based review of clinical performance of individuals with clinical privileges.

(ii) Surgical case and tissue review.

(2) Anesthesia services.

(3) Nursing services.

(4) Pharmaceutical services.

(5) Pathology and radiology services.

(6) Infection control procedures.

(7) Procedures performed in the ASF and their necessity.

(8) Reports of accidents, injuries and safety hazards.

(d) The plan shall include participation of 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. Facilities that treat pediatric patients shall segregate data regarding these patients.

(b) The quality assurance program shall provide for the identification of problems and actions taken—through the monitoring and evaluation process—which improve the quality of patient care.

(c) The frequency, severity and source of suspected problems or concerns are evaluated by practitioners and nurses.

(d) 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. Measures which may be taken include:

(1) Changes in policies and procedures.

(2) Staffing and assignment changes.

(3) Appropriate education and training.

(4) Adjustments in clinical privileges.

(5) Changes in equipment or physical plant.

(e) The program shall include a mechanism to assure that activities are documented and reports of the quality assurance activities are brought to the attention of the governing body. There shall be a periodic reappraisal of the program.

(f) The quality assurance program shall include the establishment of a quality assurance committee.

§ 557.4. Quality assurance and improvement committee.

(a) The Committee shall consist of the following:

(1) A practitioner who is not an owner.

(2) A representative of administration.

(3) A registered nurse.

(4) Other health care personnel, as appropriate.

(b) Committee functions shall include:

(1) Evaluating data submitted as part of the quality assurance program.

(2) Reviewing credentials.

(3) Reviewing tissue examination reports.

(4) Reviewing infection control program.

(5) Reviewing the standards of practice in all specific areas of the ASF.

(c) Committee records of the activities shall include:

(1) Reports made to the governing body.

(2) Minutes of committee meetings including date, time, persons attending, description and results of cases reviewed and recommendations made by the committee.

(3) Corrective actions taken including appropriate orientation, training or education programs necessary to correct deficiencies which are uncovered as a result of the quality assurance program.

CHAPTER 559. NURSING SERVICES

§ 559.2. Director of nursing.

The director of nursing shall be currently licensed as a registered nurse in this Commonwealth and be responsible and accountable to the person in charge of the ASF for:

(1) Delivery of nursing services to patients.

(2) Development and maintenance of nursing service goals and objectives, standards of nursing practice, nursing policy and procedure manuals and written job descriptions for each level of personnel.

(3) Coordination of nursing services with other patient services.

(4) Establishment of a means of assessing the nursing care needs of patients and staffing to meet those needs.

(5) Staff development.

§ 559.3. Nursing personnel.

(a) An adequate number of licensed and assistive 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. Class B and Class C ASFS which provide surgical services to pediatric patients shall have nursing staff with documented experience in the postoperative care of these patients.

(b) At least one registered nurse shall be in attendance during the hours patients are present. Nursing personnel shall be assigned to duties consistent with their education, training and experience.

(c) 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 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) 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 use shall be obtained.

§ 561.23. Use of 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 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.

CHAPTER 563. MEDICAL RECORDS

§ 563.8. Automation or computerization of medical records.

Nothing in this subpart 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:

(1) Patient identification.

(2) Pertinent medical history and results of physical examination.

(3) Preoperative diagnostic studies—entered before surgery—if performed.

(4) 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.

(5) Documentation of properly executed, informed patient consent.

(6) Entries related to anesthesia administration.

(7) Findings and techniques of the operation, including a pathologist report on tissue removed during surgery.

(8) Notes by authorized staff members and individuals who have been granted clinical privileges, nurses' notes and entries by other professional personnel.

(9) Written and verbal disposition recommendations and instructions given to the patient.

(10) Significant medical advice given to a patient by telephone.

(11) Discharge summary including discharge diagnosis.

§ 563.13. Entries.

(a) Entries in the record shall be dated and authenticated by the person making the entry.

(b) Symbols and abbreviations may be used only when they have been approved by the medical staff and when a legend exists to explain them.

(c) A single signature on the fact sheet of a record does not suffice to authenticate the entire record. Each entry shall be individually authenticated.

(d) Notation of unusual incidents shall be entered in the medical record.

(e) Necessary documentation on the patient's medical record as specified in § 563.12 (relating to form and content of record) shall be completed in a timely manner not to exceed 30 days.

CHAPTER 565. LABORATORY AND RADIOLOGY SERVICES

RADIOLOGY SERVICES

§ 565.12. Radiology service policy.

(a) The service shall be provided by contract or directly by the ASF.

(b) Applicable provisions of the Department of Environmental Protection regulations in 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 in 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.

(a) Radiology services provided by the ASF shall be directed by a person who is qualified to assume professional, organizational and administrative responsibility for the quality of services rendered.

(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 not to exceed 30 days.

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 the following:

(1) Medical asepsis.

(2) Surgical asepsis.

(3) Sterilization and disinfection, including suitable equipment for routine and rapid sterilization.

(4) Sterilized materials are packaged, labeled and dated in a consistent manner.

(5) Housekeeping.

(6) Cleaning of surgical suites prior to each operation.

(7) Clean and soiled linen and utility rooms.

(8) Linen.

(9) Traffic flow patterns.

(10) Isolation protocols.

(11) Staff health status requirements.

(12) Infection control in-service education for personnel.

(13) Recording and reporting of potential infection.

(14) Bacteriological testing of potential infections, recording results and reporting to the quality assurance committee.

(15) Admission criteria for patients with specific or suspected infections.

(16) Patient postdischarge investigation.

(17) Reporting of communicable diseases as required by § 27.2 (relating to reportable diseases).

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 postanesthesia recovery of surgical patients. All equipment and supplies shall be age and size appropriate for the patients treated. The following equipment shall be available in the operating suite and recovery area.

(1) Suitable surgical instruments customarily available for the planned surgical procedure.

(2) Emergency call system.

(3) Airways, breathing bag and device for the provision of positive pressure rescue breathing.

(4) Cardio-pulmonary drugs and intubation equipment.

(5) Cardiac monitor and defibrillator.

(6) Resuscitator including oxygen and suction equipment.

(7) Tracheostomy and necessary pulmonary reexpansion supplies.

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

GENERAL PROVISIONS

§ 569.2. Fire safety standards.

(a) An ASF shall meet the applicable edition of National Fire Protection Association 101 *Life Safety Code*, which is currently adopted by the Department.

(b) An ASF previously in compliance with prior editions of the *Life Safety Code*, is deemed in compliance with subsequent *Life Safety Codes*, except renovation or new construction shall meet the current edition adopted by the Department.

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 firefighting equipment, exits, patient rooms, storage places of flammable and information that the fire department requires or as may be necessary.

EVACUATION DRILLS

§ 569.21. Fire drills.

(a) Fire, internal disaster and evacuation drills shall be held at least quarterly for ASF personnel and under varied conditions.

(b) 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 firefighting equipment in the ASF.

(3) Enable the chief executive officer to evaluate the effectiveness of the plan.

(c) A written report and evaluation of drills conducted since the last survey shall be kept on file.

(d) The actual evacuation of patients to safe areas during a drill is optional.

SAFETY PRECAUTIONS

§ 569.33. Smoking.

Smoking is not permitted in an ASF.

§ 569.35. General safety precautions.

The following safety precautions shall be met:

(1) Doorways, corridors and stairwells shall be properly lighted and free of obstructions.

(2) Doors into patient rooms may not be locked.

(3) Exit doors may not be locked from the inside while patients are in the ASF.

(4) Doors opening to shafts shall be equipped with self-closing devices and positive latches.

(5) Wastebaskets, cubicle curtains, window shades and drapes shall be rendered flame retardant.

(6) Call bells in the shower, tub room or water closet shall be easily accessible to patients.

(7) Only nonflammable agents may be present in a surgical suite.

CHAPTER 571. CONSTRUCTION STANDARDS

GENERAL PROVISIONS

§ 571.1. Minimum standards.

ASF construction shall be in accordance with the latest edition of the "Guidelines for Design and Construction of Hospital and Health Care Facilities," as published by the American Institute of Architects/Academy of Architecture for Health including those guidelines established for various outpatient facilities. In the alternative, a facility shall meet the construction guidelines for specified types of surgical procedures as listed in Appendix A (relating to alternative construction guidelines). Where renovation or replacement work is performed within an existing facility, all new work or additions shall comply with the requirements for new construction.

§ 571.2. Modifications to HHS requirements.

(a) Life Safety Code means the standard as defined in § 569.2 (relating to fire safety standards).

(b) Adequate storage areas shall be provided to meet the needs of the facility.

(c) Patient privacy shall be provided in preoperative and postoperative areas.

(d) In multistory buildings, where the ASF may be provided on floors other than at grade level, at least one hospital type elevator shall be provided.

(e) Elevators shall conform to "HHS Requirements" and 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

§ 571.11. Principle.

Plans and specifications shall be submitted to the Division of Safety Inspection of the Department for approval prior to construction of an ASF, in accordance with § 51.5 (relating to building occupancy). Submission shall be in three stages.

§ 571.13. (Reserved).

CHAPTER 573. (Reserved)

§ 573.1. (Reserved).

§ 573.2. (Reserved).

APPENDIX A. ALTERNATIVE CONSTRUCTION GUIDELINES

ENDOSCOPY

1) Office Endoscopy, edited by Bergein F. Overholt and Sarkis J. Chobanian.

2) Planning an Endoscopy Suite for Office and Hospital, by Jerome D. Waye and Martin E. Rich.

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