RULES AND REGULATIONS

Title 28—HEALTH AND SAFETY

DEPARTMENT OF HEALTH
[28 PA. CODE CHS. 51, 136, 138, 139 AND 158]
Health Facility Licensure

The Department of Health (Department) amends Part IV (relating to health facilities) by adding Chapters 51, 136, 138 and 158 and by amending Chapter 139.

Scope and Purpose

This final rulemaking amends the standards a hospital needs to satisfy to secure authorization to perform open heart surgery, cardiac catheterizations, organ transplantation surgery and to provide services to newborns under its hospital license. They also prohibit open heart surgery, cardiac catheterizations and organ transplantation surgery from being performed at nonhospital locations. Finally, they add a general information chapter which sets forth regulations which are applicable to all health care facilities.

The Health Care Facilities Act (act) (35 P. S. §§ 448.101—448.904b) provides that, to be issued a license, the applicant must show that: 1) it is a responsible person; 2) the place to be used as a health care facility is adequately constructed, equipped and maintained and safely and efficiently operated; 3) it will provide safe and efficient services adequate for the care and treatment of patients or residents; and 4) it is in substantial compliance with the rules and regulations of the Department. See 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 of 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. 2703 (May 31, 1997) with an invitation to submit written comments within 30 days.

Within the 30-day comment period, the Department received 26 letters from various individuals and organizations involved in health care.

The Department also received comments from Senators Robert Mellow and Hardy Williams and the Independent Regulatory Review Commission (IRRC). The Department considered these comments, prepared final rulemaking and processed the final-form regulations through the regulatory process.

IRRC disapproved the proposed final-form regulations and communicated its concerns to the Department. Thereafter, the Department reviewed IRRC's concerns, contacted several entities and revised and resubmitted the final-form regulations.

The following is a discussion of the comments which the Department received and the Department's response to them:

Chapter 51. General Information

§ 51.3. Notification.

The Department received several comments from various health care organizations concerning the proposed provisions of this section which discussed the occurrence of events at health care facilities which require providing the Department with some type of notice.

Subsections (a)—(d) proposed that when any health care facility wishes to commence the provision of a new health care service, provide services in new beds, cease providing a health care service, reduce its licensed bed complement or initiate the design phase of any proposed new construction, alteration or renovation of the facility, it must first provide notice to the Department of its intention.

Most of the comments concerned the Department's response to these notification requests. The Hospital Association of Pennsylvania (HAP), Temple University Hospital (Temple), Shriner's Hospital for Children (Shriner's) and Pennsylvania Association of County Affiliated Homes (PACAH) stated that the Department should set forth a period of time within which it would respond to the facility's notification letter and questioned whether the response would constitute an approval or disapproval of the subject matter of the notification. IRRC also stated that the Department should establish such a time table.

HAP, IRRC and Allegheny Health, Education and Research Foundation (AHERF) also questioned how the Department would conduct its reviews and what criteria would be used to determine if the activity which was the subject of the notification would be approved or disapproved.

The purpose of these subsections is to assure that the Department receives proper notification of the ongoing changes occurring at health care facilities and that these changes are not inconsistent with the requirements of the Department's regulations. Thus, the criteria and standards which will be used to determine the propriety of these activities are those contained in the regulations. With the sunset of the CON provisions of the act, the Department no longer approves or disapproves activities at health care facilities, but, rather, monitors those activities for quality assurance and patient safety purposes. Receiving notification of these changes will enable the Department to remain current as to the status of the health care facilities in this Commonwealth and also assist the Department in future licensure surveys.

Subsection (l) (proposed subsection (h)) provides that no health care facility may commence the provision of new health care services or provide services in new beds until the facility has been informed by the Department that it is in compliance with all licensure requirements. This applies to the notification requirements mandated in subsections (a) and (b). Upon being informed that a new service or new beds will be provided at a health care facility, the Department may need to conduct an onsite visit to assure that any life safety code or other occupancy criteria have been met. This visit would occur shortly before the actual occupancy of the beds or commencement of the service is expected. The visits are usually coordinated with the health care facility. While the health care facility may not provide new services or open new beds until after this visit, the Department is not approving the facility for these purposes, but is assuring that the

relevant criteria have been met. The Department has followed this procedure through its licensure activity for many years.

Subsections (a)—(c) have been amended to require that the facility provide the Department with notice 60 days before the expected commencement of a new health care service, addition of new beds, reduction of the licensed bed complement or cessation of the provision of a health care service. This will give the Department and the facility sufficient time to determine that all licensure criteria have been met before the effective date occurs.

Subsection (d) has been amended after several commentators noted that providing notice prior to the initiation of the design phase of any proposed new construction, alteration or renovation to the facility would not be appropriate. At this stage, any design plans are likely to be incomplete and subject to numerous changes. The Department is concerned with receiving notification of the actual plans, rather than with plans which are still being formulated. Accordingly, the subsection has been amended to provide that architectural plans and blueprints shall be submitted to the Department at least 60 days prior to expected initiation of construction, alteration or renovation. The Department will then review these documents for compliance with the relevant life safety code and other regulatory requirements and, within 45 days of their receipt, will notify the facility of either an approval or disapproval. If the material submitted is not sufficient to determine if regulatory requirements have been met, the Department will ask the facility to submit further information. The facility may not initiate construction, alteration or renovation unless the Department has issued an approval. Again, this procedure of review and approval of architectural plans has been followed by the Department for many years. While the time frames announced are new, the procedure to be applied has been in place and is familiar to health care facilities. The Department is generally able to work with a facility to assist it in assuring that all necessary regulatory requirements are met.

Temple, AHERF, Chester County Hospital and Senator Mellow inquired as to whether the proposed requirement in subsection (a) regarding notification of a health care service which has not been previously provided at that facility is referring to those services which were previously reviewable under the CON Program.

Under CON, a list of 23 clinically reviewable health services set forth those health care services which required Department approval. As stated in the previous paragraph, the Department's interest in maintaining quality assurance is separate from its previous role in CON reviews. For quality assurance purposes, the Department needs to be informed of all of the services, additions or terminations of beds, renovations, and the like, which are occurring at a facility. By fully informing the Department of all of its ongoing changes, the facility can assure that the Department is in possession of all relevant information which it will need to assess quality assurance and to conduct an upcoming licensure survey. Thus, the reporting of health care services includes and goes beyond those previously covered under the CON Program. In determining if the Department should receive notification of a service, the facility should be guided by the understanding that it should inform the Department as much as possible of the ongoing changes at the facility so that the Department will be adequately informed and prepared for the next licensure survey.

Subsections (e) and (f) in the proposed rulemaking provided that if a facility became aware that it was not in compliance with the Department's regulations or if it became aware of a situation which could compromise quality assurance or patient safety, it was required to notify the Department of the event and the steps which the facility had taken to rectify the situation.

The comments to these proposed subsections, from HAP, AHERF, PACAH, Pennsylvania Health Care Association (PHCA) and John Reiss, Esq., centered around concerns that the regulations would be too broad and vague and that it would be unclear what type of events needed to be reported.

As explained in the previous discussion, it is the Department's intent that a facility provide the Department with all relevant information to determine if the facility is in compliance with the Department's regulations and if any situations are present which could affect patient care. Quality assurance and patient care are at the very core of the Department's mandate from the General Assembly under section 801a of the act (35 P. S. § 448.801a).

The Department does not agree with comments suggesting that only events which directly affect patient care should be reported. The Department's focus is on patient safety. Even events which indirectly affect patient care, such as, failure of the sprinkler system in a facility, can still place a patient or resident at risk. Some commentators asserted that these incidents are already reported to other agencies or entities. However, it is the Department's role to assure safe, adequate and efficient facilities and services, and to promote the health, safety and adequate care of the patients or residents of these facilities. The Department must be informed of all significant untoward events at a facility to carry out this mandate. A facility should err on the side of over-notification so as to assure that the Department will not subsequently learn of an event from another source.

However, the Department does not intend that health care facilities be required to report every possible instance of noncompliance with the regulations. A task could prove to be overly burdensome on the facilities and could also flood the Department with unnecessary information. The Department is concerned with those violations which pose imminent risks to the safety of the patients or residents in the facility. The Department has amended subsections (e) and (f) to provide that a health care facility shall provide notification of a regulatory violation or a situation or occurrence at the facility which seriously compromises quality assurance or patient safety. The addition of the word "seriously" addresses the concerns of the commentators yet still assures that the Department will receive the necessary notification to fulfill its statutory mandate.

To assist facilities in determining which incidents or violations may seriously compromise quality assurance or patient safety, the Department has added subsection (g). This subsection provides a partial list of events which would meet that standard. This list is meant to be illustrative and not exhaustive as is clearly indicated by use of the terminology "events which seriously compromise quality assurance or patient safety include, but are not limited to, the following." All facilities should be aware that incidents or violations other than those listed will also be reportable under subsections (e) and (f). Those incidents found in subsections (g)(1)—(6), (11) and (14) are taken from reportable incidents presently listed in the regulations for long-term care facilities. See

§ 201.14(c)—(e) (relating to responsibility of license). The Department has also added several other illustrations of reportable incidents or violations. Subsection (a)(13) provides that the facility's awareness of the unlicensed practice of a regulated profession shall be reported to the Department. In most instances, this refers to those professionals who are licensed to practice by the Department of State, Bureau of Professional and Occupational Affairs (such as, medical doctors, osteopaths, chiropractors, psychologists, registered nurses). While most of the list is self-explanatory, the facility should contact the Department if there is any question concerning the reportability of an incident.

The Department has also added several subsections to set forth the use which will be made of the information reported by health care facilities under subsections (e) and (f). Subsection (i) provides that the information contained in the notification will be used only by the Secretary or a representative and will only be provided to another government agency, unless a court order otherwise. This limitation on the sharing of information applies only to the actual notification report. If the facility's notification results in an investigation with the issuance of a plan of corrections and order, the information contained in the original notification may also be contained in the plan of corrections or order. These documents are public documents and are generally provided by the Department upon request. Subsection (j) provides that the information contained in the notification will be used by the Department to enforce its responsibilities under the act and other statutes within the Department's jurisdiction. While this would describe the usage of the information by the Department, under subsection (i) the Department may find that another government agency should also be provided with the information contained in the notification. Any limitations upon these agencies is not discussed in these regulations. Finally, under subsection (k), in providing the Department with the notifications required under subsections (e) and (f), facilities do not have to report any information which may be deemed confidential and not reportable to the Department under other provisions of Federal or State law or regulations. In rare instances, a facility may find that certain information is not reportable to the Department, due to other statutory or regulatory provisions. This would generally not excuse the facility from reporting the incident or violation to the Department, but may bar the facility from providing certain information to the Department which would be reported to another entity. The Department believes that the provisions of this subsection will have limited applicability and will expect a health care facility claiming the confidentiality restrictions to provide a cogent argument supporting its position.

Another issue raised was the penalty that facilities could face for failure to notify the Department as required under this section. In its comments, IRRC stated that the Department needed to indicate what action it would take when it was notified of the occurrences in this section.

The act provides for a wide range of actions which can be instituted against a health care facility for violation of the act or the Department's regulations, including assessment of a civil penalty (35 P. S. § 448.817) and revocation or nonrenewal of a license (35 P. S. § 448.811). The Department intends to rely on these statutory provisions in determining what sanctions it may levy for failure to comply with the requirements of this section. To address the concerns of IRRC and other commentators who raised the issue of sanctions, the Department has added § 51.41 (relating to change in ownership; change in management), which sets forth the sanctions which the Department may assess for a violation of its regulations.

§ 51.4. Change in ownership; change in management.

Proposed subsection (b) required notification of a planned change in ownership of a health care facility at least 90 days prior to the actual change. Both HAP and AHERF commented that the 90 day requirement was unrealistic in today's health care environment and that the Department should change the requirement to timely notification.

While the Department understands that the ownership of health care facilities can change rapidly, the purpose of this section is to assure that the Department is aware of these changes so that it can carry out its function to assure quality health care. To perform this function, the Department must have advance notice of expected changes of the ownership of health care facilities so that it can determine the possible impact. The Department has revised subsection (b) to require notification 30 days prior to the expected date of the change of ownership.

The PACAH commented that the requirement of notification of a change of management in proposed subsection (c) could be interpreted to mean every department head at the facility; it recommended that the phrase be amended to a change in administrator.

The Department does not accept this suggestion. While a change in administrator may have a particular meaning in a long-term care facility, it has a different application in a hospital and in other health care facilities. The Department is to receive notification when a change occurs in persons onsite charged with the responsibility of running the facility. The Department believes that the second sentence accurately expresses this explanation by stating that: "A change in management occurs when the person or persons responsible for the day to day operation of the health care facility changes."

§ 51.5. Building occupancy.

Comments on this section were received from HAP, AHERF and PACAH. The PACAH recommended that the Department delete proposed subsection (b) as the same language appeared in proposed subsection (c). The Department agrees and has made this deletion.

Other concerns centered on subsection (b) (proposed subsection (c)), which would have required a health care facility to request a preoccupancy survey at least 2 weeks prior to the anticipated occupancy of the facility. HAP believes that the 2-week time frame is insufficient for an occupancy survey to be completed. The AHERF questioned the activities which must occur within the 2 week time frame and the PACAH requested further clarification of when the Department will conduct the survey. The Department's position is that the facility should be in contact with the Department prior to the anticipated date of opening and that actual occupancy should not occur until the Department has informed the facility that occupancy may commence.

In response to comments that the proposed 2 week requirement is insufficient, it should be noted that this would have been the minimal standard. It is anticipated, and experience has shown, that most health care facilities contact the Department in the early stages of their construction projects. When this occurs, the Department is able to work with the facility and inform it of any potential problems, before actual construction or renovation commences. If the health care facility and the Department have been in contact from these early stages,

the preoccupancy survey should proceed smoothly and a lengthy period of time would not be needed to correct deficiencies revealed during the survey. However, in recognition of the concerns over the 2 week minimum, the Department has revised subsection (b) to provide that the request must be made at least 30 days prior to the date of anticipated occupancy. This should ensure that the facility has sufficient time to address deficiencies revealed through the survey before the scheduled opening is to occur.

The Department has also revised the language in subsection (b) concerning the method by which facilities will be informed of the Department's determination as to occupancy. The proposal stated that the Department could provide oral authorization, which would then be followed by a written confirmation within 30 days. The Department has decided that a more appropriate method would be to provide written authorization, which although it might not address all of the outstanding issues pertaining to the building occupancy, would give the facility the approval to commence occupancy. This would provide the facility with written proof of the determination to permit occupancy. If this written authorization indicates that other issues are outstanding and are still under review, this document will be followed by a formal authorization which will discuss these other issues and provide the Department's concerns on these ancillary matters.

§ 51.6. Identification of personnel.

This section was not contained in the proposed rulemaking, but the Department believes it is an appropriate addition to the general information chapter. Under this section, all health care personnel working in a health care facility must wear identification labels which state their name and position. Only those persons whose professional designation is recognized by a Commonwealth agency may use an abbreviation on the name tag. For example, the abbreviations of "M.D," "R.N.," "D.M.D." and "D.O." would be appropriate for, respectively, a medical doctor, registered nurse, dentist and doctor of osteopathy. However, an abbreviation of "P.C.A." for a personal care assistant would not be appropriate—the entire title must be printed. The language of this section closely mirrors that used in H.B. 402, currently pending in the General Assembly. This identification of personnel will assist patients, residents and their families in keeping track of the individuals who are providing treatment.

§ 51.13. Civil rights compliance records.

Comments on this section were received from the PACAH and John Reiss, Esq. The PACAH questioned whether the language used in proposed subsection (a)(1) meant that all of the nondiscriminatory practices must be contained in one document. The purpose of this subsection is to assure that the nondiscriminatory statements exist and are readily available to the public and to the Department. While it is not necessary that all of these statements appear on one document, they all must be issued by the facility and, under subsection (b), posted in locations accessible to the facility's staff and the general public.

The remaining comments from the PACAH and those of Attorney Reiss concerned the proposed requirements for annual publication of the nondiscriminatory policy and annual notification to physicians, social workers and others who normally refer patients or residents to the facility. IRRC recommended that the Department review reporting requirements of other agencies and assure that no duplication is involved.

The Department notes that the General Assembly specifically mandated that discrimination be prohibited in all health care facilities. See section 804(a) of the act (35 P. S. § 448.804(a)). While other agencies may enforce some aspect of civil rights protection, it is the Department's duty to ensure that the relevant nondiscriminatory policies are in place. Therefore, it is an appropriate exercise of the Department's regulatory authority to require formulation and dissemination of these policies. The Department does appreciate that annual notification requirements could prove burdensome to the facilities. Also, most physicians, social workers and others who make referrals to the facilities are aware of these nondiscriminatory requirements from other sources. The Department will delete proposed subsection (a)(2), which would have required annual notification to these individuals. The proposed subsection (a)(3) (now subsection (a)(2)) would have required annual notification to employes of the facility's nondiscriminatory policy. This subsection has been revised to remove the requirement that the notification occur annually. Also, in accordance with the PACAH's recommendation, the Department has revised subsection (a)(3) (proposed subsection (a)(4)) to require publication of the nondiscriminatory policy every 3 years, instead of annually. This is the same period of time which is required for publication of nondiscriminatory policies by long-term care facilities. See § 201.28(c)(4) (relating to nondiscriminatory policy).

IRRC also recommended that the Department either eliminate proposed subsection (a)(5) or provide a specific list of records or reports which would be required by the Department. The Department has deleted this subsection.

§ 51.31. Principle.

IRRC recommended that the Department clarify that exceptions cannot be granted to permit departures from provisions of the act and other State and Federal statutes. The Department has added language to this effect.

§ 51.32. Exceptions for innovative programs.

The PACAH recommended that the proposed section be deleted because of its concern that, without published structured guidelines, exceptions would not necessarily be granted based on the unmet needs of a community.

The Department will not delete this section. The act directs the Department to "administer [the licensure provisions of the act] to encourage innovation and experimentation in health care and health care facilities..." 35 P. S. § 448.804(c).

§ 51.33. Requests for exceptions.

Comments on this section were received from several sources, including Temple, the PACAH and Senator Hardy Williams. Most of these comments centered on proposed subsection (c), stating that the Department may request public comment on exception requests by publishing a notice in the *Pennsylvania Bulletin*. The commentators suggested that the Department should publish all requests for exceptions, or at least those requests which the Department intends to approve.

The Department is in agreement with this request. The Department will publish these requests for exceptions and will establish a limited period of time during which it will receive comments. By publishing requests for exceptions, the Department can assure that it has all relevant information in making a determination, as well as a method of conveying to the health care community the requests for exceptions which are received. However, in certain emergency situations, (such as fire, water dam-

age) the Department must act on the exception request immediately and the time necessary for receipt and review of public comment should not be imposed under those circumstances. Accordingly, the Department has revised subsection (c) to state that it will publish all requests for exceptions in the *Pennsylvania Bulletin* and the Department will review any comments which it receives before making a determination to approve or disapprove an exception. Subsection (c) has also been revised by adding a sentence stating that although the Department will publish requests for exceptions, in emergency situations it will not establish a public comment period.

Finally, the Department has added subsection (d) which states that all approved exceptions will be published in the *Pennsylvania Bulletin*. Although no written comments were received on this issue, the Department has become aware of the interest of the health care community in obtaining information on the exceptions which the Department has granted. At present, some health care facilities are aware of certain types of exceptions generally granted by the Department, while other health care facilities are not as well informed. This degree of knowledge varies depending upon which facility's representatives happen to possess information regarding the exceptions which the Department has granted. To assure that all facilities will be kept equally informed, the Department will publish notice of all exceptions granted. This publication will occur on a periodic basis in the *Pennsylvania Bulletin*.

IRRC recommended that the Department provide clarification as to what types of exceptions may be granted and what criteria it would use in making a decision on a request for an exception.

A facility may request an exception from any of the regulations promulgated by the Department. The criteria which the Department would use may vary depending upon the type of exception being requested. Paramount in any determination would be the consideration of the manner in which the exception would impact on quality assurance and patient safety at the facility. If the exception would negatively affect these areas, it would not be approved. Beyond these areas, the Department has to evaluate each request on its own merits to determine if an exception from the regulations is appropriate. Certainly those requests which present an innovation or improvement in the delivery of health care services and do not compromise either quality assurance or patient safety, are most likely to be favorably received by the Department. Consequently, the requested clarification has not been inserted.

§ 51.34. Revocation of exceptions.

Senator Hardy Williams noted that subsection (a) states that an exception may be revoked for any good reason. He noted that this differs from the requirement in § 101.14(a) (relating to revocation of exceptions) which states that exceptions could be revoked for any justifiable reason. He raises a concern that the word "good" could make it more difficult for the Department to revoke an exception. It was not the Department's intent to limit its ability to revoke exceptions. The Department has revised subsection (a) to substitute the word "justifiable" in place of "good."

§ 51.41. Violations; penalties.

Several commentators, including Senator Williams and IRRC, wanted to know what type of sanctions the Department would apply for violations of specific provisions. The sanctions which the Department can issue for a violation of its regulations are in sections 811, 812, 814 and 817 of the act (35 P. S. §§ 448.811, 448.812, 448.814 and 448.817).

These sections state that the Department may refuse to renew a license or may suspend or revoke or limit a license for all of any portion of a health care facility or for any particular service offered by a facility or may suspend admissions if the licensee commits a serious violation of the regulations for licensure. A serious violation of the regulations is defined as one which poses a significant threat to the health or safety of patients or residents. See sections 811(1) of the act. Section 812 of the act provides that the Department may issue a provisional license when it finds that a health care facility has committed a serious deficiency or numerous deficiencies in failing to comply with the Department's regulations. Section 814(a) of the act states that when a violation of the Department's regulations exist, the Department can require the offending facility to submit a plan of corrections to show what action the facility will take to bring it into compliance with the regulations. Finally, section 817 of the act provides that any person who violates a provision of the regulations may be subject to a civil penalty of up to $500 for each deficiency for each day that each deficiency continues.

Although it is not mandatory that these sanctions be repeated in the regulations, the Department has decided to include them in this chapter. This should address the concerns of those commentators as to what sanctions could be faced by those facilities or individuals who violate these regulations and any of the regulations contained in Part IV. These sanctions are in sections (b) and (c). Subsection (a) states that the Department will work with the health care facility to rectify a violation, where appropriate. The degree to which the Department will pursue this course depends on a variety of factors, including the seriousness of the violation and the degree of danger which is posed to the health and safety of the public. Also, the Department's election to work with a facility to rectify a violation does not preclude it from subsequently concluding that the levying of a sanction would be appropriate.

Chapter 136. Open Heart Surgical Services.

§ 136.2. Definitions.

Board eligible—Subsequent to issuance of these regulations as proposed, the Department learned that the terminology of "board eligible" was no longer recognized by the American Board of Medical Specialties. As various specialty boards used the term "board eligible" to describe the status of physicians who were not yet certified, but who were at varying stages in the process of board certification, the term became confusing and it the exact status of these physicians was unclear. The Department has avoided this problem by providing its own definition for "board eligible," which is that the physician has completed the requirements necessary to take the certification examination (usually completion of a residency program) and no more than 3 years has passed since that event occurred. To avoid terminology which is no longer recognized by the American Board of Medical Specialties and which could cause confusion to the health care community, the Department has decided to substitute the term "preboard certification status" for "board eligible." This should assure that health care facilities understand that certain health care services may be provided only by physicians who have obtained specific qualifications.

The Department has changed all of the references in these regulations from "board eligible" to "preboard certification status." These changes have been made in the following sections: §§ 136.12(1), 138.2, 138.12(b), 138.17(a), 138.18(a), 139.2, 139.22, 158.2, 158.13(a), (b)(1)—(3) and (6), 158.31(d), 158.32(c), 158.33(c), 158.34(c) and 158.37(d),(e)(1), (3) and (5) and (g).

Temple commented that the definition as proposed was confusing and suggested that the Department use the definition for "board eligible" contained in the vital organ transplantation chapter (§ 158.2 (relating to definitions)). The Department agrees that the proposed terminology was confusing and has amended the language to clarify that, for purposes of this chapter, a physician will be considered board eligible for 3 years immediately following the date upon which eligibility is first attained. After that date, the physician will no longer meet this definition of "board eligibility." The Department has also revised the proposals to place this same terminology in the chapters relating to cardiac catheterization (§ 138.2 (relating to definitions)), neonatal services (§ 139.2a (relating to definitions)) and vital organ transplantation (§ 158.2 (relating to definitions)).

This definition is designed to place a limitation on the amount of time that a physician is considered board eligible. If a physician has been eligible to take a certification examination for a period of time in excess of 3 years and has not taken and passed the examination, that person no longer meets the requirements of this definition and could not serve in any of the positions which require board certification or board eligibility. The word "preliminary" has been removed as it is redundant in the context in which it is used.

Open heart surgery—The Department has added a sentence to this definition to clarify that any open heart surgery program which treats adults can perform surgery on any individual who is not contained in the definition of "pediatric heart surgery." As the proposed amendments only discussed criteria for those patients who are to be treated by a pediatric heart surgery program, IRRC recommended that language be added to the scope of treatment for adult open heart surgery programs.

Pediatric heart surgery—Children's Hospital of Philadelphia (CHOP) took issue with the definition in the proposed amendments. That definition stated that pediatric patients were those patients under 18 years of age whose physical development precluded them from being handled as adults. CHOP stated that this definition did not reflect accepted medical standards and that, as most pediatric heart surgery deals with congenital defects, specialized training is required.

The Department recognizes that pediatric heart surgery is a highly specialized type of surgery and data shows that this type of surgery is almost exclusively done in hospitals which have developed cardiac care programs focusing specifically on pediatric patients (such as, CHOP, Children's Hospital of Pittsburgh and the Hershey Medical Center). The Department agrees that patients under 18 years of age are almost always considered pediatric patients and are best treated in facilities with these types of programs. In the final-form regulations, the Department amended the definition of "pediatric heart surgery" to indicate that patients under 18 years of age would be considered pediatric patients, unless their physical development precludes them from being treated as such.

Prior to the public hearing at IRRC, the Department received letters from Abington Memorial Hospital and Senators Loeper and Greenleaf objecting to the definition of "pediatric heart surgery." Specifically, Abington objected to the lack of explanation as to what types of indicia would be used to determine the patient's physical development. Abington suggested that the definition be expanded to include consideration of body mass, weight and other physiologic characteristics. In its disapproval order, IRRC expressed its concern that the definition of "pediatric heart surgery" could limit the care of some patients, who, although they might technically meet the requirements for treatment in a pediatric heart program, might be more appropriately treated in an adult program.

While the Department does not intend to be overly prescriptive in this area, it believes that the definition originally suggested by Abington could actually serve limit those physical developments which could be considered by the physician. The Department believes that the decision as to whether a person should be treated in a pediatric or adult program most properly belongs with the patient's physician. The treating physician is the individual best qualified to assess the patient's medical condition and needs. The physician is also able to determine which type of program best meets those needs. In making this determination, the issue of the physical development of the patient will no doubt be a prime consideration. While the Department has not included a specific requirement in this area, it expects that the physician will also consider the patient's psychosocial development, that is the extent to which the adolescent is psychologically and emotionally prepared to be treated in an adult program.

As stated previously, Abington Memorial Hospital had recommended that the term "physical development" be defined to include consideration of body mass, weight and other physiologic characteristics. However, after the public hearing, the Secretary received a letter from Abington noting that its recommendations may have been too prescriptive. Abington suggested that the definitions of "pediatric heart surgery" and "pediatric cardiac catheterization" be modified to provide that the patient's physician will be entrusted with the determination of those patients whose physical development allows the patient to receive treatment safely and appropriately in other than pediatric centers.

The Department has amended the definition of "pediatric heart surgery" in § 136.2 to state that this term "includes both open heart and closed heart procedures for patients under 18 years of age except for those whose physical development, in the judgment of the patient's physician, allows the patient to receive treatment safely and appropriately in hospitals which do not have a pediatric heart program."

§ 136.11. Director.

Comments were received from HAP, the AHERF and CHOP as to the appropriate terminology to be used in describing the type of certification required. The AHERF suggested that the phrase "Board certified cardiovascular surgeon" be used. CHOP suggested that, for pediatric heart surgery programs, a sentence be added requiring the director to be a "Board certified thoracic and cardiac surgeon with an expertise in pediatrics." The Department consulted with a group of cardiologists and surgeons to determine the appropriate language to be used. The consensus was that the most appropriate terminology is "thoracic surgeon" as this is the specialty field in which open heart surgeons are trained. These specialists also agreed that the correct terminology for surgeons practicing in pediatric heart surgery programs is "pediatric and

thoracic surgeon." This assures Board certification in the two necessary specialty areas. The Department revised subsection (a) accordingly.

The Pennsylvania Medical Society (PMS) also provided comments on this section which applied generally to all of the sections in the remaining chapters which discuss the appointment of a medical director. The concern raised by the PMS is that there are situations in which, due to the termination or departure of the existing medical director, the hospital is faced with the task of immediately filling that position with a qualified physician. The PMS believes that the requirement that the physician be Board certified will prove burdensome to the hospital and will hinder its ability to fill the position on an interim basis. IRRC suggested that the Department allow for an interim period of time for the employment of a director who is neither Board certified nor Board eligible.

The Department has some concerns regarding the waiver of the Board certified director. This requirement was proposed to help assure that patients receive quality care and that the staff involved in treating patients are under the direction of a qualified physician in the specialty area. (Each of the chapters being amended or revised by this order require Board certified directors.) Any patient should expect this quality assurance aspect at any time, regardless of whether there is a permanent director or not. In most instances, the hospital should have sufficient notice from the departing director so that arrangements can be made to either hire a new qualified director or make arrangements with another health care facility to provide the temporary assistance of its director. However, in those instances where the director's departure is sudden or unexpected, the Department recognizes that these arrangements may be difficult to make.

Therefore, the Department is amending all of the sections of these regulations discussing directors to allow for the appointment of an interim director who is not Board certified. See, also §§ 138.11(b), 139.3(b) and 158.11(b) (all relating to directors). Although Board certification will not be required, the physician must demonstrate qualifications to the medical staff of the hospital and to the Department which establish that the physician is capable of fulfilling the functions of the director, even if only for a short period of time. To receive approval for this appointment, the hospital must submit a request for an exception, as detailed under §§ 51.31—51.34. The hospital provides the Department with specific and detailed information concerning the circumstances requiring the appointment of an interim director who is not Board certified. This information includes the curriculum vitae of the interim director as well as any supporting documentation of the director's qualifications. If the request for an exception is approved, the Department will include a maximum period of time for which the appointment may last.

§ 136.12. Medical staff.

The AHERF and CHOP both commented as to the correct terminology. Consistent with the revisions to previous section on the qualifications of the medical director, the Department has revised this section to provide that the medical staff shall include thoracic surgeons who are either board certified or who have attained precertification board certification status. See discussion under § 136.2, relating to definitions, regarding use of preboard certification status. Similarly, a pediatric heart surgery program shall include Board certified or Board eligible pediatric and thoracic surgeons.

IRRC commented upon § 136.12(1), which requires a sufficient number of surgeons within the service to allow for 24-hour per day continuous coverage. IRRC noted that there was no definition of the term "sufficient" and requested that the Department provide further guidance on this matter.

The Department has discussed this matter with a group of cardiologists and thoracic surgeons. To their knowledge, there is no universal standard such as a ratio of patients per surgeon dealing with this issue. The Department believes that the open heart program will be able to determine the appropriate number of medical staff which will amount to sufficient coverage of the unit. Obviously, this number will change depending on the number of patients in the program and the severity of their medical condition. The purpose of this requirement is to assure that the hospital reasonably provides for medical staff coverage of the patients in the open heart surgical program. The experience of the service and the expertise of the staff should be evaluated by the hospital in order to determine appropriate and sufficient coverage. Consequently, no definition of the term "sufficient" has been included.

§ 136.13. Nursing staff; other health care personnel.

Comments on this section were received from the Pennsylvania Nurses Association (PNA). This organization was represented on the original task forces which were organized in early 1997 to discuss the need for additional regulations as a consequence of the sunset of CON. At that time, the PNA recommended language regarding the qualifications of the nursing staff for insertion in each of the proposed chapters. That language was in this section. See also §§ 138.13, 139.4 and 158.14 (relating to nursing staff; other health care personnel.) In its comment, the PNA requested that the Department revise the provisions which it had previously recommended and provided alternative language.

Most of the recommended changes do not vary the intent of the proposed language. The Department does have concerns with the PNA's request to define "unlicensed assistive personnel" as "individuals who are trained to function in an assistive role to the registered professional nurse in the provision of patient/client care activities as delegated by and under the supervision of the registered nurse." This definition does not provide for the direction and supervision of unlicensed assistive personnel by other health care workers, in particular, physicians.

Rather than adopt changes to the nursing personnel language, the Department believes that this issue is best addressed through a review of Chapter 109 (relating to nursing services) which discusses nursing services in a hospital. See §§ 109.1—109.68. The Department is presently engaged in a full review of all of the hospital licensure regulations and will be addressing this issue. A work group has been formed to make recommendations to the Secretary. The PNA is a member of this work group. The Department will address any necessary changes to the nursing staff regulations through this mechanism.

However, the Department has added language to this section to discuss the need for other health care personnel in the program in subsection (d)(1)—(4). This language was adapted from similar language suggested by Geisinger Medical Center in the cardiac catheterization chapter. See § 138.13 (relating to nursing staff; other personnel). These additional provisions require that hospitals assure that the open heart program contain ad-

equate health care personnel to address the needs of the patients. In establishing standards for physicians, nurses and other health care personnel, the Department's goal is to provide a framework to assist the hospital in providing an open heart surgery program that will meet quality assurance criteria.

§ 136.14. Support team in the operating room.

The Department has eliminated the word "preferably" in the third sentence of proposed subsection (a)(2) so that all perfusionists participating in open heart surgery programs are required to possess certification. This change was made after consultation with cardiologists and thoracic surgeons who stated that most perfusionists do obtain certification. As the perfusionist's duties include the critical function of operating and monitoring the heart-lung machine during open heart surgery, the Department agrees that the certification requirement is appropriate.

In an effort to determine the appropriate level of education, training and experience which should be required, the Department found that most perfusionists attend an educational institution or School of Perfusion which specifically trains individuals in this area. Most of these schools require that the individual has obtained a bachelor degree and have some type of medical background and experience. These institutions generally issue a certificate of completion. The graduates from these schools are eligible to take a two part examination offered by the American Board of Cardiovascular Perfusion (ABCP). The graduates must first successfully complete a written basic science examination and are then eligible to take a clinical competency examination. Prior to taking this second examination, the perfusionist must document the performance of 50 independent clinical perfusions which occurred after graduation. After the graduate has passed both of these examinations, the graduate is considered board certified.

Subsection (a)(2) has been revised to require that all perfusionists obtain certification from the ABCP. In recognition of the fact that certification will not be obtained until sometime after graduation from a school of perfusion, the perfusionist is given 2 years from the start of employment at the hospital to obtain this certification. The ABCP does not recognize the concept of board eligible. The organization will report the status of a perfusionist as board certified, not certified or has been accepted for examination. As the term "board eligible" is not applicable, the Department has placed a time limit on the number of years which a hospital can employ a perfusionist who is not board certified (2 years) and has required that a perfusionist who is not board certified shall work under the supervision of a certified perfusionist, cardiologist or cardiac surgeon, until the perfusionist obtains board certification.

The other change which was made in this section was to require that the perfusionist operate the heart-lung machine in accordance with the requirements of the hospital, instead of the operating surgeon. Perfusionists should not be expected to change methods or practices at the discretion of each surgeon with whom they may work. Compliance with the hospital's standards is a more appropriate standard.

§ 136.15. Other support services.

The Department received a general comment from the AHERF on this section. As proposed and adopted, each of the various support services is qualified with the requirement that it be either available or onsite. The term "onsite" is defined as "in the physical structure at which open heart surgical services are being offered or in an adjoining structure." The AHERF noted that no corresponding definition for "available" was proposed and requested that one be provided. The Work Groups and the Department were unable to arrive at a definition for this term, as the services listed vary greatly. For example, the availability of bio-engineering services (subsection (a)(15)) may differ from the availability of a cardiographic laboratory (subsection (a)(10)). Whereas the term "onsite" indicates a service that must be immediately accessible, the services required to be available, may be located on the same campus as the building housing the open heart surgery site or may be located at some distance. Therefore, the requested change was not included.

The Department expects that most hospitals who provide open heart surgery will have all of the support services listed in this section available somewhere within the hospital's facility or have some type of contractual arrangement with a facility located nearby. The important aspect is that these support services are accessible by the cardiac surgical service, as needed. The Department expects that the training and expertise of those personnel involved in the delivery of open heart surgical services will help to ensure that these support services are appropriately located.

As to specific subsections, the AHERF commented that the cardiac catheterization and interventional angiography laboratory (subsection (a)(5)), should be onsite and not available, as a hospital must be capable of performing all types of cardiac catheterization to also operate an open heart surgery program. The Department agrees and has made this change.

HAP requested clarification and justification for the requirement that the hospital contain an emergency department, staffed onsite with an advanced cardiac life support certified physician (subsection (a)(9)). After reviewing this matter, the Department has revised this subsection to provide that a physician with an advanced cardiac life support certification must be onsite. The important aspect of this requirement is that a physician with ACLS certification be nearby for those pre and post operative open heart patients who need immediate resuscitation. The full services of an emergency department are not necessary to assure that open heart patients will receive appropriate care.

In subsection (b)(2), the word "should" has been changed to "shall" to clarify the requirement that the operating room and support facilities must meet the requirements of either the Inter-society Commission on Heart Disease or the American College of Cardiology/ American Hospital Association Guidelines.

§ 136.20. Pediatric heart surgery—supplementary criteria.

Temple noted that another proposed section of this chapter, § 136.2, defined "pediatric heart surgery" as including both open and closed heart surgery on pediatric patients, but that this section referred only to pediatric open heart surgery. Temple questioned whether the title of this section and the references in subsections (a) and (b) should be changed from "pediatric open heart surgery" to "pediatric heart surgery." The Department agrees and has made these changes.

CHOP requested that the Department add a supplementary criterion requiring the provision of special support services unique to assisting children in coping with their illness, such as a Child Life program. While the Department agrees that pediatric heart patients have

special needs and require support services different from or in addition to those needed by adult open heart patients, it believes that this criteria should be stated in terms of required training of personnel involved in the pediatric heart program, rather than in requiring the presence of a particular program. The Department has revised proposed subsection (b)(5) to provide that "all staff responsible for care of the pediatric patient shall have experience and training in pediatrics, including both physiological and psychosocial needs of the patient." The elimination of extraneous language in this subsection reflects the Department's intent that all staff be adequately and appropriately trained in caring for the pediatric heart patient.

§ 136.21. Quality management and improvement.

The Department received comments on this section from Temple, Sharon Regional Health System (Sharon), Valley Health System (Valley), Hershey Medical Center (Hershey), the AHERF and Senator Hardy Williams.

Sharon, Valley and Hershey took issue with proposed subsection (a)(4) which stated that the hospital must maintain and submit data on the volume of procedures performed. Proposed subsection (c) stated that the Department will publish by statement of policy the values or standards, or both, for each of the factors in subsection (a). These hospitals maintained that minimum volume standards should have been included in the regulations and that the standards are necessary to ensure quality of care. Without the establishment of a minimum number of open heart procedures which must be performed by each program, these hospitals argued, open heart programs will proliferate and compromise patient outcomes. Temple and Senator Williams questioned the Department's intent to publish the proposed values or standards, or both, through a statement of policy as the Department may not be able to enforce these standards. IRRC also commented that a statement of policy is not binding on an agency or on anyone subject to the agency's jurisdiction. IRRC recommended that if the Department intended to establish minimal volume standards and establish an enforceable quality review standard, it should publish these standards in the regulations.

In reviewing this issue, the Department has determined that there are no definitive numbers that can be assigned to the factors listed in subsection (a), which in and of themselves can prove that a program that does not meet these numbers is absolutely shown to be providing substandard care. Rather than focus on specific numbers, the Department's review is intended to identify trends of performance in the areas listed in subsection (a), so that a determination can be made if further review of that program may be appropriate. With the sunset of the CON Program, the focus of the Department is not on stopping open heart surgery programs from developing, but in assuring that the services provided in these programs meet quality standards and that the patients are receiving the proper and appropriate treatment. The main test of these criteria will be a review of the outcomes of the open heart surgery programs which will reflect whether the care there meets quality assurance standards. Therefore, instead of issuing specific values and standards for these various factors, the Department will look to the program's overall performance and any problems with quality assurance aspects of that program which may be indicated by review of the program's outcomes in these areas.

The AHERF commented that the data requested by the Department may already be available from other agencies, such as the Health Care Cost Containment Council (HCCCC). The Department does not intend to burden health care facilities with compiling a report for the Department when it is already being supplied to another regulatory body and can be easily accessed by the Department. The Department will work with other regulatory agencies and with health care facilities to determine if this data is available from other sources and what the best method would be for the Department to obtain this data promptly and on a regular periodic basis.

However, the Department intends to fulfill its statutory obligation to promote and protect the public health and welfare. The Department is the agency charged with setting standards to assure safe, adequate and efficient facilities and services and to assure quality health care to patients in these facilities. See section 801a of the act. The Department believes that the collection of this data is essential to review the outcomes in open heart surgery programs and assure that quality treatment is being provided. Regardless of the functions of other agencies, the Department intends to collect this data in a timely manner from the affected health care facilities. Any burden which may occur due to the necessity of compiling and reporting this information is far outweighed by the benefit of oversight of quality assurance standards.

The Department consulted with cardiologists and thoracic surgeons regarding the requirements of this section. They advised the Department that the information which is mentioned in this section is similar to information which is voluntarily provided by most thoracic surgeons to the Risk Stratification Program run by the Society of Thoracic Surgeons. Due to this fact, the Department has added subsection (c), which permits a hospital to submit the surgeon's report to the Risk Stratification Program in lieu of the information listed in subsection (b). This information shall be submitted on a quarterly basis, as set forth in subsection (b). Those hospitals or surgeons who do not report to the Risk Stratification Program are encouraged to contact the Society of Thoracic Surgeons and obtain information on this program and the forms which are used for the submission of information.

IRRC objected to the Department's use of the term "and the like" as a descriptive phrase in proposed subsection (a)(2) and (3) and recommended that the Department list specific factors for which information may be requested. The terms for which this phrase was used are "patient risk factors" and "infections and complications." Both of these terms comprise broad categories encompassing a variety of contributing factors. An attempt to list all possible patient risk factors or all potential infections and complications would prove difficult and the inadvertent failure to list a risk factor or infection/complication does not mean that the existence of that factor in a particular patient should not be reported. Rather than attempt an exhaustive list, the Department has eliminated the examples cited in proposed subsection (a)(2) and (3) and will rely on the thoracic surgeons and the hospitals to report all relevant risk factors and infections/complications.

Senator Williams raised concerns as to what enforcement mechanisms the Department would use if it determines that the open heart surgery program is not in compliance. Section 811 of the act provides that the Department may refuse, suspend, revoke or limit a license if the facility commits a serious violation of the act or of the regulations for licensure. See section 811(1). Also, section 817 of the act provides that the Department may bring an action for an injunction against any individual who violates the regulations as well as assess a

civil penalty against a facility who violates a regulation and fails to take corrective action. See 817(a) and (b). Thus, the General Assembly has given the Department the authority to enforce its regulations by pursuing various sanctions. The Department intends to use the full range of the available sanctions in enforcement of these regulations. IRRC also raised the issue of possible sanctions which a facility could face for violation of this provision. In response to these concerns, the Department has added § 51.41 in the general information chapter, which sets forth the sanctions which can be assessed by the Department for a violation of its regulations.

Chapter 138. Cardiac Catheterization Services

§ 138.1. Principle.

Both HAP and Gnadden Huetten Memorial Hospital suggested that the Department permit catheterizations to be performed in mobile catheterization laboratories ("cath labs"). The recommendation was rejected.

The Department is not inclined to permit mobile cath labs which are entirely freestanding and unattached to a hospital, thus without the presence of immediate emergency and surgical back-up. This position is supported by the Guidelines of the American College of Cardiology and American Heart Association for Cardiac Catheterization and Cardiac Catheterization Laboratories.

The Department does recognize that a situation may arise where a hospital which already possesses a cardiac cath lab may need to temporarily close the lab for renovation or other purposes. In order not to disrupt cath lab services, the hospital may utilize a mobile cath lab which is brought onto the grounds of the hospital and usually connected to the hospital by a temporary corridor. In these instances, the Department does not object to the use of a mobile cath lab as it is only a temporary measure and treatment is rendered by qualified physicians and staff. Also, the full services of the hospital are immediately available. This position is reflected in § 138.14(c) (relating to program services) which states that "to allow for continuity of care, mobile cardiac catheterization laboratories may be utilized onsite at a hospital which is already providing cardiac catheterization services while the existing, fixed cardiac catheterization laboratory is being renovated or its equipment upgraded."

§ 138.2. Definitions.

Board eligible—Due to the discontinuance of the use of the term "board eligible" by the American Board of Medical Specialties, the Department has substituted the term "preboard certification status." See discussion under § 136.2 for open heart surgical services, for further information.

Both Temple and the PMS questioned why no definition of "board eligible" was proposed in this chapter, as other proposed chapters in these regulations allowed for both board certified and board eligible physicians.

As discussed previously, the Department has determined that all chapters should allow for medical staffs with both board certified and preboard certification status physicians. See previous discussion under § 136.2. Accordingly, this section has been amended to include a definition for "preboard certification status" consistent with the definitions in the other chapters.

Cardiac catheterization area—Subsequent to IRRC's disapproval, the Department revised § 138.13 (relating to nursing staff; other health care personnel). In that revised section, the Department distinguishes between staffing requirements in the cardiac catheterization laboratory and in the cardiac catheterization area. To clarify this distinction, the Department has added a definition of "cardiac catheterization area" which indicates that this area includes the cardiac catheterization laboratory and any preoperative and postoperative recovery units. For further discussion of this definition, see § 138.13.

"EPS—electrophysiology study—diagnostic" and *"EPS—electrophysiology study—therapeutic"*—The wording of these definitions has been changed to clarify the distinction between diagnostic and therapeutic electrophysiology studies. A comment was received from a cardiologist, Ancil A. Jones, M.D., recommending this distinction. Dr. Jones also suggested that the phrase "procedures designed to induce ventricular or supraventricular tachycardia; activation sequence mapping of cardiac tachyarrhythmias" be moved from the definition of "therapeutic EPS" to "diagnostic EPS," as induction and sequence mapping of arrhythmias are properly considered diagnostic and not therapeutic. In reponse to this suggestion, the Department consulted with a group of thoracic surgeons and cardiologists. They agreed that induction and mapping are considered to be diagnostic, rather than therapeutic. The Department has revised the proposed definitions accordingly.

Pediatric cardiac catheterization—Similar to the definition of "pediatric heart surgery" comments were received from HAP requesting clarification and from CHOP requesting that the definition be changed to state that patients from ages 0-18 should be treated in a pediatric program. See discussion under § 136.2. The Department agrees that children should be treated in pediatric cardiac catheterization programs and has amended the definition to indicate that. Except for those instances where physical development precludes treating the individual as a pediatric patient, children aged 0-18 should be treated in a pediatric cardiac catheterization program.

As discussed in § 136.2, IRRC disapproved the proposed final-form regulations in part because of the definition of "pediatric heart surgery." The Department has revised that definition. As the definition of "pediatric cardiac catheterization" is virtually identical to the definition of "pediatric heart surgery" and similar reasoning for these definitions existed during their development, the Department has revised the definition of "pediatric cardiac catheterization" to reflect that children up to age 18 shall be treated in a hospital with a pediatric cardiac catheterization program except for those patients whose physical development, in the judgment of the patient's physician, allows the patient to receive treatment safely and appropriately in hospitals that do not have pediatric cardiac catheterization programs. As discussed more extensively in § 136.2, the Department has determined that the physician is the most appropriate person to assess whether an adolescent should receive treatment in a pediatric or adult program.

§ 138.11. Director.

The PMS and IRRC both questioned the provisions of this proposal which would have permitted only board certified cardiologists to serve as medical directors. Both entities stated that this varied from the requirements for directors in the remaining chapters of the proposed amendments, as board eligible directors were permitted.

A review of the proposed amendments indicates that the open heart and cardiac catheterization chapters both permitted only board certified physicians to serve as medical directors of the respective programs. The Department believes that this requirement is justified. The

medical director is responsible for the operations of the program and will often be called upon to make determinations based upon the director's medical knowledge and judgment. The presence of a board certified director will assure that a competent and qualified individual fills this important position. The Department has amended the neonatal services chapter and revised the proposed vital organ transplantation services chapter to require that the medical directors of those programs also be board certified in the appropriate specialty.

A minor amendment was made to this provision in adding the words "as appropriate" after the statement that "the director of the cardiac catheterization service shall be Board certified in cardiology or pediatric cardiology." This will clarify the Department's intent that the director of an adult cardiac catheterization service will be Board certified in cardiology and the director of a pediatric cardiac catheterization service will be Board certified in pediatric cardiology.

Both the PMS and IRRC also recommended that the Department permit the appointment of interim directors who are not board certified. This issue was discussed in the section dealing with the requirements for the director of an open heart surgical services program. See discussion in this preamble under § 136.2 (relating to definitions for open heart surgical services). The Department has added subsection (b), setting forth requirements for the appointment of an interim director.

§ 138.12. Medical staff.

Both the HAP and AHERF questioned the appropriateness of the terminology in the proposed regulation which stated that the physicians on staff shall have graduated from an accredited training program in cardiac catheterization.

The Department consulted with a group of cardiologists who advised that the correct language to be used is board certified or board eligible in cardiovascular diseases with specialized training in invasive procedures. This reflects the appropriate certification and the area in which the staff member must obtain additional or specialized training. The proposed language has been revised. See discussion in § 136.2 regarding substitution of preboard certification status for board eligible.

§ 138.13. Nursing staff; other health care personnel.

The Department received comments from nine organizations objecting to the failure to mention the role of registered cardiovascular technologists (RCVTs). These individuals receive special training and education to assist physicians in the cardiac cath lab. Most of the commentators believe that requiring a registered nurse (RN) in the cath lab does not assure that appropriate personnel are present. They claim that the RCVT is often better qualified and more appropriate to assist a physician in the cath lab than an RN. Several commentators feared that the specific requirement of an RN in the cath lab will serve to exclude RCVTs, that is, a hospital may not be able to afford to employ both, so it will hire an RN for the cath lab because of the specific regulatory requirement. Some commentators suggested that the proposal be specifically revised to require that a RCVT be present in the cath lab.

After reviewing these comments and consulting with a group of cardiologists, the Department has determined that the services of RCVTs are regularly used in the cath lab. The RCVT works closely with the physician in the cath lab in assisting in the performance of the catheterization. However, RCVTs are neither registered nor licensed by the Commonwealth and there could be a wide variance in each individual's level of education and training. Conversely, all RNs receive standardized training in all areas of health care and must demonstrate proficiency in these areas in order to receive and maintain a license. This consistency in education and training assures the Department that the RN is capable of providing assistance to the physician in the cardiac catheterization laboratory.

The requirements of this section were not meant to exclude any qualified personnel from participating or assisting in the catheterization procedure. The Department still believes that at least one RN should be present in the cath lab. Due to the scope of practice of an RN, the presence of this individual in the cath lab setting will assist in the provision of quality care and will also impact on patient safety. However, other personnel may still be employed in the cath lab to assist the physician. Geisinger Medical Center suggested language establishing minimum requirements for other health care personnel involved in the cardiac catheterization service. The Department has amended this section to include this language. See § 138.13 (c).

At the public hearing before IRRC, several individuals testified regarding this issue. Most of these individuals were RCVTS or represented hospitals which use technologists in their cardiac catheterization programs. In its order disapproving the final-form regulations, IRRC noted that it had received letters and testimony from a number of hospitals which indicated that they were staffing their cardiac catheterization laboratories with RCVTs, who received extensive training and examination in this specialized area. In requiring these hospitals to hire a nurse to work in the catheterization laboratory, IRRC was also concerned of potential adverse economic impact on these hospitals and on the trained personnel currently working in this field.

After review of the information submitted and the Guidelines for Cardiac Catheterization and Cardiac Catheterization Laboratories issued by the American College of Cardiology and the American Heart Association, the Department has concluded that a distinction can be made between the provision of nursing care and the assistance of a physician in the performance of the catheterization procedure. Nursing care, which is generally provided in the preoperative and postoperative setting and involves monitoring and assessment of the patient's medical condition, is performed by a hospital's nursing staff. However, providing assistance to a physician in conducting the actual catheterization procedure, can be performed by technicians, as this activity involves specialized knowledge of the procedure and the equipment used in that procedure. While nurses who have been trained in monitoring this equipment may assist a physician, it is also appropriate for technicians with appropriate education, training and experience to assist the physician in conducting the catheterization procedure.

The Department has revised § 138.13 to reflect the distinction between nursing care of the patient and assistance of the physician in performance of the cardiac catheterization procedures. Section 138.13(a) states that "there shall be at least one registered nurse assigned to provide nursing care for patients in the cardiac catheterization area at all times who shall have intensive care or coronary care experience and knowledge of cardiovascular medications, and experience with cardiac catheterization patients." This subsection was changed to clarify that a nurse must be assigned to the cardiac

catheterization area, rather than to the cardiac catheterization laboratory. A definition has been added to § 138.2 for the term "cardiac catheterization area." This term has been defined as "that portion of the hospital dedicated to the performance of cardiac catheterizations, including the cardiac catheterization laboratory where the invasive procedures are performed by the physician, and any preoperative and postoperative recovery units used for treatment of the cardiac catheterization patient." The addition of this term clarifies that the nurse must be assigned to the general cardiac catheterization area, and not necessarily to the cardiac catheterization laboratory itself.

Section 138.13(d) has been added to clarify the types of care which can be provided by various health care personnel and the areas in which that care can be provided. The first sentence of this section states that: "The patient's preoperative and postoperative nursing care in the cardiac catheterization area shall be provided by a registered nurse and other nursing staff as required to meet patient care needs." This statement clarifies that the care provided to cardiac catheterization patients in those areas outside of the cardiac catheterization laboratory must be provided by the nursing staff, including a registered nurse, as it involves monitoring, assessment and other duties which constitute nursing care. The second sentence of this section states that: "Either nursing personnel or other health care personnel with appropriate education, training and experience shall assist the physician in the performance of the cardiac catheterization procedures in the cardiac catheterization laboratory." This statement permits nursing personnel and other health care personnel, who are appropriately equipped to assist the physician in the performance of the catheterization in the catheterization laboratory. The Department has decided not to limit the description of "other health care personnel" to any particular group or classification, but to allow the hospital and the physician to determine those personnel who will be able to safely and appropriately assist the physician in the catheterization laboratory.

§ 138.16. Transfer agreements for low-risk cardiac catheterization hospitals.

The Department has corrected an inadvertent deletion which appeared in subsection (a) of the proposed regulations. The requirement is that a hospital which performs low-risk cardiac catheterizations shall have a transfer agreement with at least one hospital which performs open heart surgery. This requirement assures that the hospital in which the patient is receiving the cardiac catheterization will be able to transfer the patient to another hospital with more extensive surgical capabilities should the need arise.

HAP provided comment on this section. HAP questioned the justification for the inclusion of the requirement in subsection (a)(5) that a hospital receiving a transferred patient should not duplicate the already performed diagnostic cardiac catheterization. HAP argued that there is no need for the proposed requirement in a transfer agreement as it is controlled through other mechanisms such as utilization review and approval processes by insurers and payors.

While the Department's focus is on quality of care rather than utilization requirements, it agrees that this particular requirement can be deleted. Whether or not it may be necessary or appropriate to duplicate a cardiac catheterization will be up to the medical judgment of the physician at the hospital to which the patient is transferred. This medical judgment is subject to sufficient review mechanisms to assure that any unnecessary duplications should not occur. The questioned provision has been deleted.

§ 138.17. Percutaneous transluminal coronary angioplasty (PTCA).

The AHERF commented that the proposed terminology is incorrect and suggested language requiring graduation from an accredited cardiovascular training program and at least 2 years experience in cardiac catheterization and catheter interventions. The Department consulted with a group of cardiologists and thoracic surgeons on this issue. They agreed that a physician who performs PTCAs should be Board certified or Board eligible in cardiovascular diseases. However, they stated that there was nothing as an accredited training program in PTCA which was an additional requirement contained in the proposed amendments. The cardiologists did believe that training in the area of interventional cardiology was needed. The training should be specific to the type of procedure which the physician will be performing in the cath lab. Accordingly, the Department determined that a requirement that the physician must be either Board certified or have attained preboard certification status and have received "specialized and appropriate training in interventional cardiology procedures" would assure that a physician performing PTCAs will be properly educated and trained. The Department has amended subsection (a) to reflect this language. See discussion in § 136.2, relating to definitions for open heart surgical services, for further information on substitution of preboard certification status for board terminology.

The AHERF and Temple both objected to the proposed inclusion of subsection (c), which provides that a hospital which performs an emergency PTCA procedure and which does not have an open heart surgery program onsite shall report these circumstances to the Department in writing within 72 hours of the performance of the PTCA. Their argument was that inclusion of this language will encourage the performance of PTCAs at hospitals without an open heart surgery program. Another commentator, Community Hospital of Lancaster, suggested that this language was too limiting, and that PTCAs can be performed safely at hospitals without an open heart surgery program.

The Department consulted with cardiologists and thoracic surgeons who confirmed that, in certain emergency cases it may be necessary for a low-risk catheterization lab to perform an emergency PTCA. These low-risk cath labs may be located in hospitals without the presence of an open heart surgery program. However, the performance of PTCAs in such a situation should be rare. If the candidates for low-risk catheterization are properly screened, a patient who may potentially require a PTCA would be receiving a catheterization at a hospital with open heart surgery capacity.

Temple's and AHERF's concerns raise a quality assurance issue which the Department can address by monitoring the performance of the cardiac cath labs. Under § 138.20 (relating to quality management and improvement), the Department will be collecting data from the cardiac catheterization programs. One of the areas which will be reviewed is the number of emergency PTCAs which are performed at a hospital without open heart surgery. If the reports from these low-risk cath labs indicate a trend towards an increasing number of factors showing that a procedure performed on this patient should be considered a high-risk catheterization and

there are a number of so-called emergency PTCAs performed by this program, the Department will have serious concerns as to whether the cath lab is properly screening and selecting only those patients who are appropriately treated in a low-risk cath lab. A high number of emergency PTCAs may also suggest that the low-risk cath lab is not performing its catheterizations appropriately.

§ 138.18. Electrophysiology studies.

The AHERF questioned the terminology used in proposed subsection (a) regarding physician qualifications. The AHERF suggested that each physician should be required to have graduated from an accredited training program with at least 2 years dedicated to electrophysiology. The Department consulted with a group of cardiologists concerning this issue. They advised that the standard applied in most facilities for physicians to perform electrophysiology studies is board certification or board eligibility in cardiovascular diseases and board certification or board eligibility in clinical cardiac electrophysiology. Completion of these studies should assure qualified physicians in this area. The Department has amended subsection (a) to reflect this language. This standard is supported by the "American College of Physicians/American College of Cardiology/American Heart Association Task Force on Clinical Privileges in Cardiology" issued in April 1994. The Department has amended subsection (a) to provide that a physician performing electrophysiology studies shall be either board certified or shall have attained preboard certification status in cardiovascular diseases and shall be either board certified or shall have attained preboard certification status in clinical electrophysiology.

A cardiologist, Ancil A. Jones, M.D., suggested that the requirement in subsection (b) that implantation of automatic implantable cardioverter defibrillators be performed in hospitals with an open heart surgery program was not necessary and that this particular therapeutic electrophysiology procedure could be performed in a hospital without an open heart surgery program. The Department discussed this issue with several cardiologists. Their unanimous opinion was that this procedure does require the onsite presence of an open heart surgery program. These cardiologists agreed with the other requirements set forth in subsection (b). The Department has not made any revisions to this subsection.

§ 138.20. Quality management and improvement.

Most of the comments on this section were similar to those received for § 136.21 (relating to quality management and improvement for open heart surgical services), which discusses quality management and improvement for open heart surgical services. Reference should be made to that section in this Preamble for a fuller explanation of the matters discussed as follows.

The Department received comments on this section from the AHERF, Valley, Sharon, Geisinger, Ancil A. Jones, M.D. and Senator Hardy Williams.

Sharon and Valley took issue with proposed subsection (a)(4) which stated that the hospital must maintain and submit data on the volume of procedures performed. These hospitals maintained that minimum volume standards should have been included in the regulations, rather than being published in a statement of policy, as proposed in subsection (c). Senator Williams also questioned the Department's intent to publish standards and values in a statement of policy as the Department may not be able to enforce these standards. IRRC recommended that, if the Department intended to establish minimal volume standards and establish an enforceable quality review standard, it should publish these standards in the regulations.

The recommended revisions have not been made. As with the issue of volume for open heart surgical services, the Department has determined that there are no definitive numbers that can be assigned to the factors in subsection (a) which in and of themselves can prove that a program that does not meet these numbers is absolutely shown to be providing substandard care. The focus of the Department is on trends of performance in the areas listed in subsection (a) and not on compliance with some arbitrary value or standard. With the sunset of CON, the Department is reviewing the quality assurance aspects of the provision of health care services. The chief test of the criteria contained in subsection (a) will be a review of the outcomes of the cardiac catheterization programs. These outcomes will indicate if the care provided meets appropriate quality assurance standards. Therefore, instead of issuing specific values and standards for these various factors, the Department will look to the program's overall performance and any problems with quality assurance aspects of that program which may be indicated by review of the program's outcomes in these areas.

The AHERF commented that the data the Department proposed to request may already be available from other agencies, such as the HCCCC. Dr. Jones also suggested that the Department seek input from cardiologists in gathering this information and stated that the Pennsylvania Chapter of the American College of Cardiology would provide representation on a restructured advisory committee. Dr. Jones' reference is to the oversight committee which was formed in 1991 under the provisions of the cardiac catheterization chapter of the SHSP. Working with this committee, the Department developed a Cardiac Catheterization Report which provided relevant information on each catheterization performed. These forms were completed by the cath labs and returned to the Department for use in assuring compliance with the requirements of the SHSP. The Department has determined that this report provides adequate information to assess the performance of a cardiac catheterization program. As those programs which obtained a CON for cardiac catheterization since 1991 have been submitting these reports regularly, continued use of this report would appear to be of minimal fiscal impact upon these hospitals. Those programs in operation prior to 1991 should find this form relatively straightforward. As the Department gathers this information, it may determine that changes should be made to the report. All parties will be notified of any changes in the forms used to report this information.

While the Department does not intend to duplicate the reports and information being supplied to other regulatory bodies, it intends to fulfill its statutory obligation to promote and protect the public health and welfare. The Department is the agency charged with setting standards to assure safe, adequate and efficient facilities and services and to assure quality health care to patients in these facilities. See section 801a of the act. The Department believes that the collection of this data is essential to review the outcomes of cardiac catheterization programs and assure that quality treatment is being provided. Another important aspect of this assessment will be to assure that high-risk catheterizations and PTCAs are performed in facilities with open heart surgery programs. As mentioned in the discussion in this Preamble on § 138.17 (relating to percutaneous transluminal coro-

nary angioplasty), the Department will be able to monitor the location of the performance of these more complex types of catheterizations and take action if a cath lab without onsite open heart surgery back-up appears to be performing an inordinate amount of high-risk catheterizations, either on a routine or emergency basis.

The Department consulted with a group of cardiologists regarding the requirements of this section. Unlike the similar requirements for open heart surgery programs, the cardiologists were unaware of any organization which collected this type of data. Although the Department has discussed this matter with HCCCC and will do so again before issuance of any report form, it does not appear that HCCCC collects this data in a manner which would prove to be of sufficient detail and timeliness for the Department's purposes.

IRRC objected to the Department's use of the term "and the like" as a descriptive phrase in proposed subsections (a)(2) and (3) and recommended that the Department list specific factors for which information may be requested. The terms for which this phrase are used are "infections and complications" and "patient risk factors." Both of these terms comprise broad categories encompassing a variety of contributing factors. Geisinger noted that there are a multitude of patient risk factors. An attempt to list all possible patient risk factors or all potential infections and complications would prove difficult and the inadvertent failure to list a risk factor or infection/complication does not mean that the existence of that factor in a particular patient should not be reported. While the previously mentioned Cardiac Catheterization Report contains a list of possible risk factors and major complications, it is recognized that even this list is not exhaustive. Rather than attempt to construct such a list for these regulations, the Department has eliminated the examples cited in proposed subsections (a)(2) and (3) and will rely on the cardiologists and the hospitals to report all relevant risk factors and infections/complications. Any form prepared by the Department will give the hospital opportunity to provide information regarding these criteria.

Senator Williams raised concerns as to what enforcement mechanisms the Department would use if it determines that the cardiac catheterization lab is not in compliance with these regulations. Section 811 of the act provides that the Department may refuse, suspend, revoke or limit a license if the facility commits "a serious violation of provisions of this act or of the regulations for licensure." See section 811(1) of the act. Also, section 817 of the act provides that the Department may bring an action for an injunction against an individual who violates the regulations as well as assess a civil penalty against a facility that violates a regulation and fails to take corrective action. See section 817(a) and (b) of the act. Thus, the General Assembly has given the Department the authority to enforce its regulations by pursuing a variety of sanctions. The Department intends to use the full range of these available sanctions in enforcement of the regulations. IRRC also raised the issue of possible sanctions. To address these concerns, the Department has added § 51.41 in the general information chapter, which sets forth the sanctions which the Department can assess for violation of its regulations.

Chapter 139. Neonatal Services

General Comments

The Department received a comment noting that the Work Group had recommended, and the Department had agreed, to eliminate the term "newborn" and replace it with the more current and appropriate term "neonatal." The commentator noted that in several instances in the text of the regulations the term "newborn" still appeared. The Department has replaced this term with either "neonatal" or "neonate" in the following sections: §§ 139.1, 139.4(b), 139.12(a) and (c), 139.15, 139.23(a), (b)(2), (6) and (7), 139.26(d) and § 139.27(c). In addition, the Department has added a definition of "neonate" to § 139.2a (relating to definitions) to clarify that this term refers to a baby or infant.

§ 139.2a. Definitions.

The PMS commented that the definitions for "board certified" and "board eligible" should refer to the American Board of Medical Specialties, instead of the American Board of Medical Specialists. The Department has made this change and has also substituted the term "preboard certification status" for "board eligible." See discussion in § 136.2 for further information.

Both the PMS and IRRC noted that the proposed definitions for the terms "board certified" and "board eligible" varied in this chapter from definitions used in other chapters in these regulations. IRRC recommended that the terms be defined consistently or a reason given for any differences. The Department has amended the definitions for "board certified" and "board eligible" in this chapter to conform with the definitions for those terms in the other chapters. See §§ 136.2, 138.2 and 158.2 (all relating to definitions). Consistent with the definition for "board eligible" in the other chapters, the word "preliminary" has been removed from the definition as it is redundant.

A definition of "neonate" has been added to clarify the use of this term in the chapter.

§ 139.3. Director.

The PMS and IRRC noted that the proposal would allow for the appointment of a director who is board eligible, while other chapters permitted only board certified physicians to serve in this capacity. The Department has reviewed this matter and determined that a director of neonatal services should be limited to those physicians who are board certified pediatricians. Subsection (a) has been amended accordingly. The appointment of a board certified director will assure that a qualified individual serves in this capacity. The Department notes that the current "Guidelines for Perinatal Care" issued by the American Academy of Pediatrics and the American College of Obstetricians and Gynecologists also permits only board certified pediatricians to serve as medical directors in neonatal care units. Similar to the provisions of the other chapters discussing a medical director's qualifications, this section has been amended to add subsection (b), which would permit a facility to appoint an interim director after the departure of the previous director and prior to the appointment of the next permanent director. Permission for the appointment of an interim director would be obtained through the exceptions process.

§ 139.4. Nursing services; other health care personnel.

The PNA provided comments suggesting general changes in the language in this section regarding duties of nursing personnel. The language which was added to this section in the proposed amendments was suggested by the PNA. At present, the Department is reviewing all of its hospital licensure regulations and will discuss the issue of nursing services during that review. A representative of the PNA is serving on the Work Group reviewing these regulations. The Department will address any

changes to the duties of nursing personnel in this current review process. See discussion under § 136.13 (relating to nursing services; other personnel for further explanation).

However, the Department has added language to this section to discuss the need for other health care personnel in the program in subsection (e)(1)—(4). This language was adapted from similar language suggested by Geisinger Medical Center in the cardiac catheterization chapter. See § 138.13 (relating to nursing services, other personnel). These additional provisions require that hospitals assure that neonatal services units contain adequate health care personnel to address the needs of the patients. In establishing standards for physicians, nurses, and other health care personnel, the Department's goal is to provide a framework to assist the hospital in providing neonatal services that will meet quality assurance criteria.

Chester County Hospital noted that the proposed amendment of this section did not provide guidance for facilities that utilize a mother/baby couplet care model. Under this model, one registered nurse delivers care to a mother and baby who are both located in the mother's room. However, the baby is not under the constant surveillance of the registered nurse and the mother may send the baby to the neonatal unit if she wishes to rest, shower, and the like. As the baby is not physically present in the neonatal care unit, the requirements of subsection (b) would not be applicable. Even though the baby is not under constant surveillance, it would still be expected that the nursing staff would regularly check on the baby and monitor the infant's condition. When the baby is returned to the neonatal care unit at periodic intervals, subsection (b) would apply.

§ 139.13. Equipment and supplies.

At the suggestion of a licensure surveyor in the Department, subsection (c) has been amended to replace wash basin with sink so as to more accurately reflect the equipment which should be present in the neonatal care unit.

Also, in subsection (d), the word "neonatal" has been inserted before "care units" to provide a more precise reference.

Chapter 158. Vital Organ Transplantation Services

§ 158.2. Definitions.

As discussed previously (see discussion in § 136.2, relating to definitions for open heart surgical services), the Department has substituted the term "preboard certification status" for "board eligible" throughout these amendments.

Also as discussed in previous chapters, the Department has changed the definition of "preboard certification status," to clarify that a physician is considered board eligible for the 3 years immediately following attainment of that eligibility. Also, consistent with the definition for "preboard certification status" in the other chapters, the word "preliminary" has been removed from the proposed definition as it is redundant.

The AHERF noted that the Department had defined "pediatric" in the proposed open heart surgery and cardiac catheterization services chapters, but had not provided a definition in this chapter. The Department has added a definition of a "pediatric transplantation program" and defining it as a "program where vital organ transplantation services are provided to all patients under 18 years of age, except for those whose physical development precludes them from being handled as a pediatric patient when receiving transplantations."

§ 158.11. Medical director.

The proposed amendments would have permitted board eligible medical directors. Some commentators noted that this was inconsistent with the requirements of the proposed open heart and cardiac catheterization chapters. In reviewing this matter, the Department believes that the director of the transplantation program should be board certified so as to assure that a qualified individual serves in this capacity. The language permitting board eligible medical directors has been deleted from subsection (a).

As discussed previously, both the PMS and IRRC commented on the possibility of an interim director who is not board certified. This person would serve as director after the departure of the previous director, until a board certified director could be appointed. Through utilization of the exceptions process (§§ 51.31—51.34), the Department will permit an interim director to serve for a limited period of time. (For further discussion of this issue, see this preamble at § 136.11 (relating to medical director)).

§ 158.12. Transplantation coordinator.

HAP commented that the Department should revise the proposal that transplantation coordinators be certified by the American Board of Transplant Coordinators (ABTC) to state that the transplant coordinator shall have appropriate education and experience to fulfill the obligations of the position

In reviewing this issue, the Department contacted representatives of the United Network for Organ Sharing (UNOS) and transplantation personnel at several hospitals. The bylaws of UNOS do not contain any specific requirements regarding transplant coordinators. However, it is apparent that the transplant coordinator fills a vital role in the transplant program. The coordinator is generally responsible for assuring the performance of necessary preoperative tests to determine if the patient is an appropriate transplant candidate and if there are any contraindications to the performance of a transplant (such as, absence of chronic infections). While the patient is listed as a transplant candidate, the coordinator is responsible for monitoring the patient's condition to evaluate if the patient remains a viable candidate. The coordinator also evaluates and monitors living donors (kidney transplants) for suitability. For posttransplant patients, the coordinator serves as a tracker and clearing house to assure the patient is receiving the appropriate medication, evaluates the patient's health and progress, and channels any issues or questions regarding the patient to the appropriate person.

These functions are crucial to a successful transplantation. It appears that many transplant coordinators are registered nurses and have a bachelor's or master's degree. However, there does not appear to be a universal standard; some hospitals employ coordinators with experience in health care. As these coordinators can come from various backgrounds regarding training and experience, the Department has concerns that all persons who serve in this capacity have the basic training, experience and education necessary.

The test administered by the ABTC appears to fulfill this requirement. This test covers basic issues which confront transplant coordinators and, at a minimum, serves to verify their qualifications to hold this position. Additionally, to retain certification status, continuing education courses are required. The Department believes that HAP's suggestion is not sufficient to assure that a

qualified individual is serving in this position. According to the individuals contacted by the Department, most hospitals require their coordinators to successfully complete this examination. The exam is offered biannually and, in order to sit for the exam, the candidate must have at least 1 year's experience as a coordinator. The Department believes that requiring an individual to pass this examination within 2 years of assuming the position of a transplant coordinator will allow sufficient time for the coordinator to meet the preliminary requirements of the ABTC and to successfully complete the examination.

Accordingly, the Department has revised this section to require that all transplant coordinators obtain certification from the ABTC within 2 years of their employment as a coordinator. The language in this section has also been modified to reflect the fact that most transplantation centers hire more than one coordinator. Generally, each transplantation program has at least one coordinator, depending upon the size of the program. The first sentence has been revised to require that each transplant center have at least one coordinator.

§ 158.13. Medical staff.

This section has been revised to clarify that transplantation surgeons and transplantation physicians who serve on the medical staff shall be either board certified or shall have attained preboard certification status.

§ 158.14. Nursing staff; other health care personnel.

The Department has added this section to the organ transplantation chapter as proposed. As previously discussed, the chapters on open heart surgical services, cardiac catheterization services and neonatal services all contain sections discussing general requirements for nursing staff and other health care personnel. See §§ 136.13, 138.13 and 139.4 (all relating to nursing staff; other health care personnel). To be consistent, the Department has determined that a similar section should be added to this chapter.

§ 158.19. Volume of procedures.

Comments on this section were received from Temple, the AHERF and HAP. Most of the comments concerned the requirement that transplantation programs meet volume standards established by the OPTN. It was noted that the current organization which is the designated OPTN—the United Network for Organ Sharing (UNOS)—does not establish a volume standard for any transplantation program. Instead of reviewing volumes, the UNOS looks at the survivability rate of transplantation patients. In its bylaws, the UNOS sets forth a formula to determine if the actual observed patient survival rate falls below the expected rate by more than a threshold amount. If a transplantation program does fall below the threshold, the UNOS reviews that program to determine if the low survival rate can be accounted for by patient mix or some other unique clinical aspect of the transplantation program in question. As explained more fully in the preamble to the proposed regulations, organ transplantation is unique in that every transplantation program must belong to the OPTN in order to receive organs for transplantation. Thus, all transplantation centers and programs are subject to the bylaws of the UNOS.

The Department has redrafted subsections (b) and (c) to provide that each transplantation program shall meet the expected survival rate as established by the OPTN. Failure to meet this survival rate will result in a review to determine if there is an explanation, such as a higher amount of sicker patients or use of more marginal organs. The transplantation program should provide any evidence of these factors to the Department for its review and assessment. If the review of this material does not adequately explain the low survival rate, concerns will be raised regarding the quality of care provided in that program. The Department would then undertake a complete review of the program to determine if these concerns are justified. As set forth more fully in previous discussions of quality management for open heart (§ 136.21) and cardiac catheterization (§ 138.20) (both relating to quality management and improvement), the Department has a wide range of sanctions available if the review of the transplantation program would show that it was not in compliance with these regulations. In addition to the Department's review of the transplantation program, the UNOS has indicated that it will inform state health department officials when it determines that a transplantation program has failed to conform to institutional membership requirements.

Subsection (c) has also been amended to specifically state that the Department will conduct a full review of a transplantation program if it is unable to explain why it did not meet the expected survival rate. This review will focus on the program's compliance with the criteria set forth in the vital organ transplantation services chapter. This should address the concerns of HAP and IRRC, which questioned the original language providing that the Department would "review the transplantation program [and] to determine its compliance with other quality assurance criteria." Both HAP and IRRC requested more specificity and clarity as to which criteria would be used in the Department's assessment.

The process in subsections (b) and (c) should ensure that the Department has a mechanism to assure that the appropriate quality of care at the transplantation program is being provided. The Department has eliminated the proposed requirement in subsection (b) that a program would have to meet the volume requirements established by the HCFA. These volume requirements had been established for only three types of organs (liver, heart and lung) and the Department was unable to find an explainable basis for the selection of these numbers.

§ 158.37. Pediatric transplantation programs.

The AHERF commented that the Department should clarify that transplantation of vital organs in pediatric patients should be performed in facilities where a full array of board certified pediatric subspecialists are available to attend to any possible untoward effect or complication of surgery.

The Department believes that a review of this chapter and of this section will impress upon all facilities the need to have a fully developed pediatric program when treating pediatric organ transplantation patients. This section indicates that a pediatric program must comply with all of the general and supplementary criteria in this chapter. Additionally, subsection (d) contains a specific list of specialists which must be on staff depending on the type of organ which is transplanted in the facility. Any hospital which performs pediatric transplantations is expected to have all appropriate and necessary support services available for treatment of the pediatric patient.

Fiscal Impact

These amendments, to ensure the quality of services being provided at licensed health care facilities, will result in some additional costs to the Department. Increased staffing may be necessary to implement the expanded quality assessment process. These resources would be needed to review submitted documentation

supporting the licensure requests, to conduct on site surveys of health care facilities and process licensure applications. Additional costs may also include stipends/fees or expenses, or both, for persons not part of the Department staff who may assist the Department in the licensure and quality assurance assessment process.

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

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

Paperwork Requirements

The Department will experience some increase in paperwork related to reviews in processing licensure requests and additional regulatory requirements. Particularly in the areas of cardiac catheterization and open heart surgical services, Department staff will be reviewing additional data, not currently collected, from providers of these services, to generate reports which will be used to assess quality.

In general, there will not be a significant paperwork burden on providers to comply with the expanded licensure requirements. There will also be additional reporting responsibilities for providers of cardiac catheterization and open heart surgical services, to submit data on outcomes to the Department. Options are being explored to implement the least burdensome reporting process possible consistent with obtaining the data needed to assess quality performance.

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

Effective Date/Sunset Date

The final-form regulations will become effective upon final publication in the *Pennsylvania Bulletin*.

Statutory Authority

Section 803(2) of the act (35 P. S. § 448.803(2)) authorizes the Department to promulgate, after consultation with the Health Policy Board, regulations necessary to carry out the purposes and provisions of the act. Section 801.1 of the act 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 the facilities.

These provisions, in combination with the Department's express authority under the definition of "health care facility" in section 802.1 of the act to employ regulations to create new categories of health care facilities as may be required due to the emergence of new modes of health care, confer upon the Department the necessarily implied authority to employ regulations to restrict certain modes of health care services to specified health care facilities to ensure the health, safety and adequate care of patients.

Final Rulemaking

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on May 21, 1997, the Department submitted a copy of notice of proposed rulemaking, published at 27 Pa.B. 2703 to IRRC and the Chairpersons of the House Committee on Health and Human Services and the Senate Committee on Public Health and Welfare for review and comment. 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, the Department submitted a copy of the final-form regulations to IRRC and the Committees on January 22, 1998. 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.

On February 13, 1998, the Commission considered the final-form regulations at its public meeting and voted to disapprove them. On February 18, 1998, the Commission served the Department with an order both disapproving and barring publication of the regulations. Its reasons for doing so were included with its order.

Under section 7(a) of the Regulatory Review Act (71 P. S. § 745.7(a)), within 7 days of receipt of that notice the Department notified the Governor and IRRC of its intent to resubmit revised final-form regulations. On March 30, 1998, under section 7(c) of the Regulatory Review Act, the Department submitted a report to IRRC which contained the revised final-form regulations set forth in Annex A to this order, the finding of IRRC and the Department's response to IRRC's comments. The final-form regulations were approved by the Commission on April 23, 1998.

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

Contact Person

Questions regarding these final-form regulations may be submitted to: James T. Steele, Jr., Acting Chief

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 audio tape, braille or by using TDD: (717) 783-6514.

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

Findings

The Department finds that:

(1) Public notice of intention to adopt the regulations adopted by this order 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 51, 136, 138, 139 and 158, are amended by adding §§ 51.1—51.6, 51.11—51.13, 51.21—51.24, 51.31—51.34, 51.41, 136.1, 136.2, 136.11—136.21, 138.1, 138.2, 138.11—138.20, 139.2a, 158.11—158.20 and 158.31—158.37 and by amending §§ 139.1, 139.2, 139.3, 139.4, 139.11—139.17, 139.21—139.29 and 139.31—139.34 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 upon publication in the *Pennsylvania Bulletin*.

DANIEL F. HOFFMANN,
Secretary

Fiscal Note: Fiscal Note 10-148 remains valid for the final adoption of the subject regulations.

(*Editor's Note*: For the text of the order of the Independent Regulatory Review Commission relating to this document, see 28 Pa.B. 2189 (May 9, 1998).)

Annex A

TITLE 28. HEALTH AND SAFETY

PART IV. HEALTH FACILITIES

Subpart A. GENERAL PROVISIONS

CHAPTER 51. GENERAL INFORMATION

GENERAL PROVISIONS

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CIVIL RIGHTS

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RESTRICTION OF PROVISION OF HEALTH CARE SERVICES

51.21. Surgery.
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GENERAL PROVISIONS

§ 51.1. Legal base, scope and definitions.

(a) This subpart implements the act.

(b) This subpart contains standards which are applicable to all entities licensed as health care facilities under the act. It also identifies specific health care services which are restricted to specified health care facilities.

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

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

Department—The Department of Health of the Commonwealth.

§ 51.2. Licensed facilities.

The Department licenses the following health care facilities under the act:

(1) Ambulatory surgical facilities.

(2) General hospitals.

(3) Special hospitals.

(4) Long-term care nursing facilities.

(5) Birth centers.

(6) Home health care agencies.

(7) Cancer treatment centers.

§ 51.3. Notification.

(a) A health care facility shall notify the Department in writing at least 60 days prior to the intended commencement of a health care service which has not been previously provided at that facility.

(b) A health care facility shall notify the Department in writing at least 60 days prior to the intended date of providing services in new beds it intends to add to its approved complement of beds.

(c) A health care facility shall provide similar notice at least 60 days prior to the effective date it intends to cease providing an existing health care service or reduce its licensed bed complement.

(d) A health care facility shall submit to the Department architectural plans and blueprints of proposed new construction, alteration or renovation to the facility. This material shall be submitted at least 60 days before the initiation of construction, alteration or renovation. The Department will review these documents to assure compliance with relevant life safety code and other regulatory

requirements. The Department will respond to the facility by either issuing an approval or disapproval or requesting further information within 45 days of receipt of the facility's submission. The facility may not initiate construction, alteration or renovation until it has received an approval from the Department.

(e) If a health care facility is aware of information which shows that the facility is not in compliance with any of the Department's regulations which are applicable to that health care facility, and that the noncompliance seriously compromises quality assurance or patient safety, it shall immediately notify the Department in writing of its noncompliance. The notification shall include sufficient detail and information to alert the Department as to the reason for the failure to comply and the steps which the health care facility shall take to bring it into compliance with the regulation.

(f) If a health care facility is aware of a situation or the occurrence of an event at the facility which could seriously compromise quality assurance or patient safety, the facility shall immediately notify the Department in writing. The notification shall include sufficient detail and information to alert the Department as to the reason for its occurrence and the steps which the health care facility shall take to rectify the situation.

(g) For purposes of subsections (e) and (f), events which seriously compromise quality assurance or patient safety include, but are not limited to, the following:

(1) Deaths due to injuries, suicide or unusual circumstances.

(2) Deaths due to malnutrition, dehydration or sepsis.

(3) Deaths or serious injuries due to a medication error.

(4) Elopements.

(5) Transfers to a hospital as a result of injuries or accidents.

(6) Complaints of patient abuse, whether or not confirmed by the facility.

(7) Rape.

(8) Surgery performed on the wrong patient or on the wrong body part.

(9) Hemolytic transfusion reaction.

(10) Infant abduction or infant discharged to the wrong family.

(11) Significant disruption of services due to disaster such as fire, storm, flood or other occurrence.

(12) Notification of termination of any services vital to the continued safe operation of the facility or the health and safety of its patients and personnel, including, but not limited to, the anticipated or actual termination of electric, gas, steam heat, water, sewer and local exchange telephone service.

(13) Unlicensed practice of a regulated profession.

(14) Receipt of a strike notice.

(h) A health care facility shall send the written notification required under subsections (a)—(f) to the director of the division in the Department responsible for the licensure of the health care facility.

(i) Information contained in the notification submitted to the Department by a facility under subsection (e) or (f) may not, unless otherwise ordered by a court for good cause shown, be produced for inspection or copying by, nor may the contents thereof be disclosed to, a person other than the Secretary, the Secretary's representative or another government agency, without the consent of the facility which filed the report.

(j) The Secretary and the Secretary's representative shall use the information contained in the notification from the facility only in connection with the enforcement of the Department's responsibilities under the act, or other applicable statutes within the Department's jurisdiction.

(k) The notification requirements of this section do not require a facility, in providing a notification under subsection (e) or (f), to include information which is deemed confidential and not reportable to the Department under other provisions of Federal or State law or regulations.

(l) A health care facility may not commence the provision of new health care services or provide services in new beds until it has been informed by the Department that it is in compliance with all licensure requirements.

§ 51.4. Change in ownership; change in management.

(a) A health care facility shall notify the Department in writing at least 30 days prior to transfer involving 5% or more of the stock or equity of the health care facility.

(b) A health care facility shall notify the Department in writing at least 30 days prior to a change in ownership or a change in the form of ownership or name of the facility. A change in ownership shall mean any transfer of the controlling interest in a health care facility.

(c) A health care facility shall notify the Department in writing within 30 days after a change of management of a health care facility. A change in management occurs when the person responsible for the day to day operation of the health care facility changes.

§ 51.5. Building occupancy.

(a) New construction, alterations or renovations that provide space for patient or resident rooms or services may not be used or occupied until authorization for the occupancy has been received from the Department.

(b) A health care facility shall request a preoccupancy survey at least 30 days prior to the anticipated occupancy of the facility or an addition or remodeled part thereof. The Department will conduct an onsite survey of the new or remodeled portion of the health care facility prior to granting approval for occupancy. The Department may give the authorization to occupy the new or remodeled portion of the health care facility by an interim written authorization. If interim authorization for occupancy is given, the Department will provide the health care facility with formal authorization within 30 days.

§ 51.6. Identification of personnel.

(a) When working in a health care facility and when clinically feasible, the following individuals shall wear an identification tag which displays that person's name and professional designation:

(1) Health care practitioners licensed or certified by Commonwealth agencies.

(2) Health care providers employed by health care facilities.

(b) The identification tag shall include the individual's full name. Abbreviated professional designations may be used only when the designation indicates licensure or certification by a Commonwealth agency, otherwise the full title shall be printed on the tag.

(c) The last name of the individual may be omitted or concealed when treating patients who exhibit symptoms of irrationality or violence.

CIVIL RIGHTS

§ 51.11. Civil rights compliance.

A health care facility shall comply with all civil rights laws. The Department may make onsite visits at its discretion to verify the civil rights compliance status of the health care facility.

§ 51.12. Nondiscriminatory policy.

(a) A health care facility shall have a nondiscriminatory policy which applies to all patients or residents and staff. The policy shall include a prohibition on the segregation of buildings, wings, floors and rooms for reasons of race, color, national origin, ancestry, age, sex, religion, handicap or disability. The nondiscriminatory policy shall also address the following:

(1) Inpatient or outpatient admission or care.

(2) Assigning patients or residents to rooms, floors and sections.

(3) Asking patients or residents about roommate preferences.

(4) Assignments of staff to patient or resident services.

(5) Staff privileges of professionally qualified personnel.

(6) Utilization of the health care facility.

(7) Transfers of patients or residents from their rooms.

(b) A health care facility is required to comply with Title VI of the Civil Rights Act of 1964 (42 U.S.C.A. §§ 2000e—2000e-17) and the Pennsylvania Human Relations Act (43 P. S. §§ 951—962.2) and to sign the following statement prior to receiving an initial license:

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

§ 51.13. Civil rights compliance records.

(a) A health care facility shall maintain the following records to show compliance with § 51.12 (relating to nondiscriminatory policy):

(1) A copy of the health care facility's admission policy which includes the date of its adoption, which sets forth in clear terms nondiscriminatory practices with regard to race, color, national origin, creed, ancestry, age, sex, religion, handicap or disability.

(2) A copy of a signed and dated notification to employes of the health care facility's nondiscrimination policy.

(3) Evidence that the nondiscriminatory practices of the health care facility have been publicized in the community at least every 3 years by one of the following methods: newspapers, television, radio, brochure or yellow pages.

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

(c) The health care facility shall provide the Department with a signed and dated copy of the nondiscriminatory policy within 30 days of the effective date of any change in the policy.

RESTRICTION OF PROVISION OF HEALTH CARE SERVICES

§ 51.21. Surgery.

Surgery shall be performed only in an acute care hospital or in a Class A, Class B or Class C ambulatory surgical facility.

§ 51.22. Cardiac catheterization.

Cardiac catheterization shall be performed only in an acute care hospital.

§ 51.23. Positron emission tomography.

Positron emission tomography (PET) scanning services shall be provided only in a hospital which complies with the regulations of the Department governing radiology and nuclear medicine services.

§ 51.24. Lithotripsy.

Lithotripsy services shall be provided only in a hospital or ambulatory surgical facility authorized to provide anesthesia services under its license.

EXCEPTIONS

§ 51.31. Principle.

The Department may grant exceptions to this part when the policy and objectives contained therein are otherwise met, or when compliance would create an unreasonable hardship and an exception would not impair or endanger the health, safety or welfare of a patient or resident. No exceptions or departures from this part will be granted if compliance with the requirement is provided for by statute.

§ 51.32. Exceptions for innovative programs.

This part is not intended to restrict the efforts of a health care facility to develop innovative and improved programs of management, clinical practice, physical renovation or structural design. Whenever this part appears to preclude a program which may improve the capacity of the health care facility to deliver higher quality care and services or to operate more efficiently without compromising patient or resident care, the Department encourages the health care facility to request appropriate exceptions under this chapter.

§ 51.33. Requests for exceptions.

(a) A health care facility shall make requests for exceptions to the Department in writing.

(b) The Department will retain the requests on file and document whether they have been approved or disapproved.

(c) Upon receipt of a request for exceptions, the request will be published in the *Pennsylvania Bulletin* with a public comment period. The Department will review these comments before making a determination to approve or disapprove an exception. The Department will publish requests for exceptions in emergency situations, but will not include a public comment period.

(d) The Department will publish notice of all approved exceptions in the *Pennsylvania Bulletin* on a periodic basis.

(e) The health care facility shall retain approved requests on file during the period the exception remains in effect.

§ 51.34. Revocation of exceptions.

(a) An exception granted under this chapter may be revoked by the Department for justifiable reason. The Department will provide notice of the revocation in writing and will include the reason for the revocation and the date upon which the exception will be terminated.

(b) In revoking an exception, the Department will provide for a reasonable period of time between the date of written notice of the revocation and the date of termination of an exception to afford the health care facility an opportunity to come into compliance with the applicable regulations.

(c) If a health care facility wishes to request a reconsideration of a denial or revocation of an exception, it shall do so in writing to the director of the appropriate division within 30 days after service of the adverse notification.

SANCTIONS

§ 51.41. Violations, penalties.

(a) When appropriate, the Department will work with the health care facility to rectify a violation of this part.

(b) A health care facility that violates this part may be subject to sanctions by the Department, which include:

(1) Suspension of its license.

(2) Revocation of its license.

(3) Refusal to renew its license.

(4) Limitation of its license as to operation of a portion of the health care facility or to the services which may be provided at the health care facility.

(5) Issuance of a provisional license.

(6) Submission of a plan of correction.

(7) Limitation or suspension of admissions to the health care facility.

(c) A person who violates this part may be subject to a civil penalty, not to exceed $500 per day.

Subpart B. GENERAL AND SPECIAL HOSPITALS

CHAPTER 136. OPEN HEART SURGICAL SERVICES

GENERAL PROVISIONS

Sec.
136.1. Principle.
136.2. Definitions.

PROGRAM, SERVICE AND PERSONNEL REQUIREMENTS

136.11. Director.
136.12. Medical staff.
136.13. Nursing staff; other health care personnel.
136.14. Support team in the operating room.
136.15. Other support services.
136.16. Rapid mobilization.
136.17. Observation of patients.
136.18. Postoperative care.
136.19. Education and training.
136.20. Pediatric heart surgery—supplementary criteria.
136.21. Quality management and improvement.

GENERAL PROVISIONS

§ 136.1. Principle.

Adult open heart surgical services and pediatric open and closed heart surgical services shall be performed only in hospitals and shall be performed in accordance with accepted and prevailing standards of medical practice.

§ 136.2. Definitions.

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

Board certified—A physician licensed to practice medicine in this Commonwealth who has successfully passed an examination and has maintained certification in the relevant medical 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).

CABG—Coronary artery bypass graft—A type of open heart procedure wherein a section of a blood vessel is taken from another part of the body to create an alternative path for blood to flow around a narrow or blocked portion of a coronary artery.

Cardiac intensive care service—Service provided to an open heart surgery patient immediately after surgery. This service is provided in a specially equipped area in a facility wherein the highest level of medical care is available. This area shall be equipped to provide invasive monitoring, including arterial pressure, Swan-Ganz catheters and intra-aortic balloon pumps.

Cardiac surgical service—Those personnel involved in the preparation, operation and postoperative care of patients receiving cardiac surgery.

Onsite—In the physical structure at which open heart surgical services are being offered or in an adjoining structure.

Open heart surgery—A surgical procedure to repair acquired or congenital diseases of the heart. The procedure shall do one of the following:

(i) Include the use of an extracorporeal pump oxygenator (heart lung machine) to perform the functions of the circulatory system during the surgery.

(ii) Employ minimally invasive procedures, which do not routinely involve the use of the extracorporeal pump oxygenator to perform the same types of surgical procedures, although its presence is required because, in a certain number of cases, this approach may have to be abandoned in favor of the other method.

Open heart surgery program—A service established by a hospital to evaluate, operate on and provide postoperative care to individuals with cardiovascular illness who require surgical intervention. Adult open heart surgery programs may perform any open or closed heart surgery not defined as pediatric heart surgery.

Operating room—The room wherein the open heart surgery is performed.

Pediatric heart surgery—Includes both open heart and closed heart procedures for patients under 18 years of age except for those whose physical development, in the judgment of the patient's physician, allows the patient to receive treatment safely and appropriately in hospitals which do not have a pediatric heart program.

Preboard certification status—A physician licensed to practice medicine in this Commonwealth who has completed the requirements necessary to take a certification examination offered by a medical specialty board recognized by the American Board of Medical Specialties, the American Osteopathic Association or the foreign equiva-

lent of either group, and who has been eligible to take the examination for no longer than 3 years.

Surgical suite—That area of the hospital wherein the patient is brought for open heart surgery and which is dedicated to the preparation of the surgical team and the patient for open heart surgery and to the actual performance of that surgery.

Twenty-four hours per day—Refers to the availability or onsite presence of specific personnel, support services or equipment on a 24-hour-per-day, 7-days-a-week basis.

PROGRAM, SERVICE AND PERSONNEL REQUIREMENTS

§ 136.11. Director.

(a) The Director of the open heart surgery program shall be a Board certified thoracic surgeon. The director of a pediatric heart surgery program shall be a Board certified pediatric and thoracic surgeon.

(b) An interim director may be appointed during the period of time between the departure of the prior director and the selection of a new director. The interim director shall be a physician who is able to demonstrate qualifications acceptable to the medical staff of the hospital and to the Department. The hospital shall apply to the Department for an exception under the procedures in §§ 51.31—51.34. If the exception is granted, the Department will specify the maximum period of time for which the interim director shall be appointed.

§ 136.12. Medical staff.

Supporting medical staff of the service shall include:

(1) Thoracic surgeons who are either Board certified or who have attained preboard certification status. There shall be a sufficient number of surgeons within the service to allow for 24-hour-per-day continuous coverage. In a pediatric service, the medical staff shall include pediatric and thoracic surgeons who are either Board certified or who have attained preboard certification status.

(2) A Board certified medical cardiologist with subspecialty certification in cardiovascular disease or who has demonstrated competence as determined by peer review. A pediatric open heart surgery program shall include a board certified pediatric cardiologist.

(3) A cardiac catheterization team with interventional ability on call 24 hours per day.

(4) A Board certified anesthesiologist experienced in open heart anesthesia. There shall be a sufficient number of anesthesiologists within the service for 24 hour per day continuous coverage. The anesthesiologists in a service performing pediatric surgery shall have experience in pediatric anesthesia.

(5) A physician who is Board certified in anatomic and clinical pathology.

§ 136.13. Nursing staff; other health care personnel.

(a) Nursing personnel shall include nurses with specialized education which includes theory, advanced technical skills, and supervised experience in a surgical intensive care unit or in a postoperative cardiovascular unit before assuming primary responsibility for the nursing care of open heart patients.

(b) There shall be nursing service goals and objectives, standards of nursing practice, procedure manuals and written job descriptions for each level of personnel which shall include the following:

(1) A means for assessing the nursing care needs of the patients and determining adequate staffing to meet those needs.

(2) Staffing patterns that are adequate to meet the nursing goals, standards of practice and the needs of the patients.

(3) An adequate number of licensed and unlicensed assistive personnel to assure that staffing levels meet the total nursing needs of the patient.

(4) Nursing personnel assigned to duties consistent with their training, experience and scope of practice, when applicable.

(c) Surgical suite nursing services shall be under the direction and supervision of a registered professional nurse with specific education and experience in dealing with cardiovascular patients.

(d) In addition to the requirements for the nursing staff in subsections (a)—(c), there shall be service goals and objectives, standards of patient care, procedure manuals and written job descriptions for each level of other health care personnel which includes the following:

(1) A means for assessing the needs of patients and determining adequate staffing to meet those needs.

(2) Staffing patterns that are adequate to meet patient care goals, standards of practice and needs of patients.

(3) An adequate number of licensed and unlicensed health care personnel to assure that staffing levels meet the total needs of patients.

(4) Health care personnel in the open heart surgical services program shall be assigned to duties consistent with their training, experience and scope of practice where applicable.

§ 136.14. Support team in the operating room.

(a) The operating room support team shall include:

(1) A circulating registered professional nurse and additional nursing personnel as required.

(2) A perfusionist. Each open heart procedure shall have a designated perfusionist in attendance. This individual shall meet the requirements for Board certification as established by the American Board of Cardiovascular Perfusion. If the perfusionist is not Board certified, all duties shall be performed under the supervision of a certified perfusionist, cardiologist or cardiac surgeon, until the perfusionist obtains Board certification. This certification shall be obtained within 2 years of the commencement of the perfusionist's employment at the hospital. The perfusionist's duties shall include the operation of the extracorporeal pump oxygenator (heart-lung machine) in accordance with the requirements of the hospital. The perfusionist shall have immediate access to hospital and surgeon specific procedure manuals for the conduct of cardiopulmonary bypass during all open heart procedures.

(b) There shall be a sufficient number of extracorporeal pump oxygenators and perfusionists to allow 24-hour-per-day coverage.

(c) A back-up extracorporeal pump oxygenator shall be available during all open heart procedures.

§ 136.15. Other support services.

(a) Supportive services within the hospital shall include the following, which shall be provided 24 hours per day and shall be either available or onsite, as noted:

(1) Medicine (cardiology onsite; availability of nuclear cardiology; hematology; pulmonary; nephrology; neurology; and infectious disease).

(2) Anesthesiology—available.

(3) Clinical laboratory services, onsite for blood banking, hematology, blood chemistry and urinalysis. These services shall be under the same direct management and quality assurance programs as the main hospital laboratories.

(4) Diagnostic radiology, including bedside X-rays—onsite.

(5) Cardiac catheterization and interventional angiography laboratory—onsite.

(6) Respiratory care services—available.

(7) Cardiac intensive care service—onsite.

(8) Inpatient service for continuing care after transfer from the intensive care unit.

(9) An advanced cardiac life support certified physician—onsite.

(10) Cardiographic laboratory, including continuous electrocardiogram monitoring—available.

(11) Echocardiography service (this may or may not be a part of the cardiographic laboratory)—available.

(12) Installation of pacemakers—available.

(13) Organized and designated cardiopulmonary resuscitation team—onsite.

(14) Bioengineering service—available.

(15) Peripheral vascular surgery and a noninvasive vascular laboratory—available.

(16) Acute inpatient dialysis—available.

(b) An operating room shall be specifically equipped for cardiac surgery, and the room and support facilities shall be of adequate size, as per Inter-society Commission on Heart Disease requirements or American College of Cardiology/American Hospital Association Guidelines.

§ 136.16. Rapid mobilization.

(a) An open heart surgery program shall have the capability for rapid mobilization of the cardiac surgical service and support team members for emergency procedures, 24 hours per day.

(b) There shall be an on-call schedule of physicians established and posted at each patient unit and other areas where cardiac surgical patients are admitted and at the communications center of the hospital to ensure that there is 24-hour-per-day emergency care and perioperative care available.

§ 136.17. Observation of patients.

A cardiac surgical care service shall include the capability of visual observation of all patients.

§ 136.18. Postoperative care.

(a) An intensive surgical care service shall be available immediately after surgery to provide invasive monitoring, including Swan-Ganz catheter, arterial pressure and intra-aortic balloon pumps.

(b) The cardiac surgical service shall be responsible for postoperative care and involved in discharge planning of patients.

§ 136.19. Education and training.

The staff of the open heart surgical program shall engage in the following activities:

(1) Ongoing programs of continuing education in cardiovascular care.

(2) Provision of training and consultation services with other providers of cardiovascular care and others.

(3) Patient and family education.

§ 136.20. Pediatric heart surgery—supplementary criteria.

(a) A hospital which provides pediatric heart surgery shall meet the standards in this chapter for a cardiovascular surgery program for adults.

(b) In addition, the following criteria shall be met by a pediatric heart surgery program:

(1) The facility shall be capable of providing definitive diagnostic and therapeutic services for children with all types of cardiovascular disease.

(2) A diagnostic laboratory with radiographic and cardiac catheterization equipment generally similar to that for adults. Bi-plane cineangiography shall be readily available 24 hours per day, and laboratories (both catheterization and general chemical) shall be equipped for small volume samples.

(3) Surgical equipment appropriate for newborns, infants and children.

(4) Intensive care facilities for newborns (as defined by current American Academy of Pediatrics/American College of Obstetrics and Gynecology Guidelines for Perinatal Care), infants and children.

(5) All staff responsible for care of the pediatric patient shall have experience and training in pediatrics including both physiological and psychosocial needs of the patient.

§ 136.21. Quality management and improvement.

(a) A hospital performing open heart surgery shall maintain patient data on the following:

(1) Mortality/morbidity.

(2) Infections and complications.

(3) Patient risk factors.

(4) Volume of procedures performed.

(b) The hospital shall provide this information to the Department on a quarterly basis, on a form prescribed by the Department. This data shall be integrated into the hospital's quality assurance program and used to ensure necessary corrections to improve outcomes.

(c) In lieu of the information listed under subsection (a), a hospital may submit information provided by its thoracic surgeons to the Risk Stratification Program of the Society of Thoracic Surgeons.

(d) The Department will review the information submitted by the hospital and other relevant information which is available to assess the qualitative performance of the hospital's open heart surgery program.

(e) If the Department's review of this information raises concerns with the quality of care in an open heart surgery program, the Department will undertake a review of that program to determine if these concerns are valid. The hospital shall cooperate with the Department in this review.

CHAPTER 138. CARDIAC CATHETERIZATION SERVICES

GENERAL PROVISIONS

Sec.
138.1 Principle.
138.2. Definitions.

PROGRAM, SERVICE, PERSONNEL AND AGREEMENT REQUIREMENTS

138.11. Director.
138.12. Medical staff.
138.13. Nursing staff; other health care personnel.
138.14. Programs and services.
138.15. High-risk cardiac catheterizations.
138.16. Transfer agreements for low-risk cardiac catheterization hospitals.
138.17. PTCA.
138.18. EPS.
138.19. Pediatric cardiac catheterizations.
138.20. Quality management and improvement.

GENERAL PROVISIONS

§ 138.1. Principle.

Cardiac catheterizations shall be performed only in hospitals and shall be performed in accordance with accepted and prevailing standards of medical practice.

§ 138.2. Definitions.

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

Board certified—A physician licensed to practice medicine in this Commonwealth who has successfully passed an examination and has maintained certification in the relevant medical 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).

Cardiac catheterization—A procedure used to diagnose and treat various cardiac and circulatory diseases that involves inserting a thin, pliable catheter, which is viewable by X-ray, into a major blood vessel of the arm or leg, and manipulating the tip of the catheter through veins or arteries to the heart.

Cardiac catheterization area—That portion of the hospital dedicated to the performance of cardiac catheterizations, including the cardiac catheterization laboratory where the invasive procedures are performed by the physician, and preoperative and postoperative recovery units used for treatment of the cardiac catheterization patient.

Electrophysiology study (EPS)—diagnostic—The use of blood vessel access to position electrode catheters in various intra cardiac locations with the help of fluoroscopy for the purpose of recording the timing of electrical events to assess the location and direction of impulse propagation. The term includes procedures designed to induce ventricular or supraventricular tachycardia and activation sequence mapping of cardiac tachyarrhythmias.

Electrophysiology study (EPS)—therapeutic—EPS used as or in combination with a therapeutic procedure, which includes electrode catheter ablative procedures and implantation of antitachyarrhythmia devices and implantable cardiovertor defibrillators.

High-risk cardiac catheterization—Cardiac catheterization which presents a high risk of significant cardiac complication. The term includes diagnostic cardiac catheterization procedures that present a high risk of significant cardiac complication, PTCA, pediatric cardiac catheterization and therapeutic electrophysiology except for the implantation of routine permanent pacemakers.

Low-risk cardiac catheterization—Cardiac catheterization which is not high-risk cardiac catheterization.

Onsite—In the physical structure at which cardiac catheterization services are being offered or in an adjoining structure.

PTCA—Percutaneous transluminal coronary angioplasty—A procedure which uses a balloon catheter, plaque removing device, laser device or mechanical stent to re-open collapsed, blocked or partially blocked arteries.

Pediatric cardiac catheterization—The performance of cardiac catheterization on a person who is under 18 years of age except for those patients whose physical development, in the judgment of the patient's physician, allows the patient to receive treatment safely and appropriately in hospitals that do not have pediatric cardiac catheterization programs.

Preboard certification status—A physician licensed to practice medicine in this Commonwealth who has completed the requirements necessary to take a certification examination offered by a medical 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.

Twenty-four hours per day—Refers to the availability or onsite presence of specific personnel, support services or equipment on a 24-hour-per-day, 7-days-a-week basis.

PROGRAM, SERVICE, PERSONNEL AND AGREEMENT REQUIREMENTS

§ 138.11. Director.

(a) The director of the cardiac catheterization service shall be Board certified in cardiology or pediatric cardiology, as appropriate.

(b) An interim director may be appointed during the period of time between the departure of the prior director and the selection of a new director. The interim director shall be a physician who is able to demonstrate qualifications acceptable to the medical staff of the hospital and to the Department. The hospital shall apply to the Department for an exception under the procedures in §§ 51.31—51.34 (relating to exceptions). If the exception is granted, the Department will specify the maximum period of time for which the interim director shall be appointed.

§ 138.12. Medical staff.

(a) There shall be at least two physicians staffing the cardiac catheterization laboratory to perform angiographies.

(b) These physicians shall be either Board certified or shall have attained preboard certification status is cardiovascular diseases with specialized training in invasive procedures.

§ 138.13. Nursing staff; other health care personnel.

(a) There shall be at least one registered nurse assigned to provide nursing care for patients in the cardiac catheterization area at all times who shall have intensive care or coronary care experience and knowledge of cardiovascular medications, and experience with cardiac catheterization patients. In pediatric units, this nurse shall also have experience in pediatric cardiac surgery units.

(b) There shall be nursing service goals and objectives, standards of nursing practice, procedure manuals and written job descriptions for each level of personnel which shall include the following:

(1) A means for assessing the nursing care needs of the patients and determining adequate staffing to meet those needs.

(2) Staffing patterns that are adequate to meet the nursing goals, standards of practice and the needs of the patients.

(3) An adequate number of licensed and unlicensed assistive personnel to assure that staffing levels meet the total nursing needs of the patient.

(4) Nursing personnel assigned to duties consistent with their training, experience and scope of practice, where applicable.

(c) In addition to the requirements for the nursing staff in subsections (a) and (b), there shall be service goals and objectives, standards of patient care, procedure manuals and written job descriptions for each level of other health care personnel which includes the following:

(1) A means for assessing the needs of patients and determining adequate staffing to meet those needs.

(2) Staffing patterns that are adequate to meet patient care goals, standards of practice and needs of patients.

(3) An adequate number of licensed and unlicensed health care personnel to assure that staffing levels meet the total needs of patients.

(4) Catheterization laboratory health care personnel shall be assigned to duties consistent with their training, experience and scope of practice when applicable.

(d) The patient's preoperative and postoperative care in the cardiac catheterization area shall be provided by a registered nurse and other nursing staff as required to meet patient care needs. Either nursing personnel or other health care personnel with appropriate education, training and experience shall assist the physician in the performance of the cardiac catheterization procedures in the cardiac catheterization laboratory.

§ 138.14. Programs and services.

(a) To perform cardiac catheterizations a hospital shall be an acute care facility that:

(1) Has inpatient medical and surgical services onsite.

(2) Has a coronary care unit onsite with 24-hour per day monitoring capability.

(3) Has a peripheral vascular surgical program available.

(4) Provides noninvasive cardiac diagnostic modalities including exercise and pharmacologic stress testing, echo cardiography and nuclear cardiology.

(5) Has a setting in which ambulatory cardiac catheterization patients can be observed for 4 to 6 hours after the procedure.

(6) Has adequate physician coverage to manage postprocedure complications.

(b) Outpatient diagnostic cardiac catheterization services shall be performed if care is exercised in selecting only appropriate low risk patients as defined in this chapter.

(c) To allow for continuity of care, mobile cardiac catheterization laboratories may be utilized onsite at a hospital which is already providing cardiac catheterization services while the existing, fixed cardiac catheterization laboratory is being renovated or its equipment upgraded.

§ 138.15. High-risk cardiac catheterizations.

A hospital may perform high-risk cardiac catheterizations only if it has an open heart surgical program onsite.

§ 138.16. Transfer agreements for low-risk cardiac catheterization hospitals.

(a) A hospital that does not have an open heart surgical program onsite may perform low-risk cardiac catheterizations if the hospital has protocols for distinguishing between low and high-risk cardiac catheterization patients and a formal written agreement with at least one hospital that does have an open heart surgical program onsite, which agreement includes the following:

(1) Protocols addressing indications, contraindications and other criteria for the emergency transfer of patients in a timely manner.

(2) Assurance of transfer of patients to an open heart surgery program and initiation of open heart surgery in a timely manner.

(3) Provision for semiannual data exchange on performance between the hospitals party to the agreement.

(4) Specification of mechanisms for continued substantive communication between the hospitals party to the agreement, and between their sending and receiving physicians.

(b) The agreement shall remain continuously in effect and be reviewed at least annually.

§ 138.17. PTCA.

(a) In a hospital in which elective PTCA is performed, each physician performing PTCAs shall be either Board certified or shall have attained preboard certification status in cardiovascular diseases with specialized and appropriate training in interventional cardiology procedures.

(b) A rigorous mechanism for valid peer review shall be established and ongoing in a hospital offering PTCA services.

(c) If a hospital that does not have an open heart surgery program onsite performs an emergent PTCA, the hospital shall report the circumstances to the Department in writing within 72 hours.

§ 138.18. EPS studies.

(a) In a hospital in which EPS is performed, each physician performing EPS shall be either Board certified or shall have attained preboard certification status in cardiovascular diseases and shall also be either Board certified or have attained preboard certification status in clinical cardiac electrophysiology.

(b) Therapeutic electrophysiology, including ablation and the implantation of automatic implantable cardioverter defibrillators shall be performed in a hospital with an open heart surgery program, and not in another facility. Implantation of routine permanent pacemakers may be performed in hospitals that do not have an open heart surgery program onsite. Pediatric diagnostic electrophysiology procedures also shall only be performed at a hospital with onsite pediatric cardiovascular surgery.

§ 138.19. Pediatric cardiac catheterizations.

A hospital may perform pediatric cardiac catheterizations only if:

(1) It has a pediatric heart surgical program onsite.

(2) The physicians and other staff who participate in the pediatric cardiac catheterizations are trained and experienced in the care of the pediatric cardiac patient.

(3) The equipment used for pediatric cardiac catheterizations is appropriate to meet the needs of the pediatric patient. Bi-plane cineangiography shall be readily available 24 hours per day, and laboratories (both catheterization and general chemical) shall be equipped for small volume samples.

§ 138.20. Quality management and improvement.

(a) A hospital providing cardiac catheterization services shall maintain patient data on the following:

(1) Mortality/morbidity.

(2) Infections and complications.

(3) Patient risk factors.

(4) Volume of procedures performed (including separate volumes for diagnostic visualizations, PTCA and electrophysiology procedures).

(b) The hospital shall provide this information to the Department through the Pennsylvania Cardiac Catheterization Report. This data shall be integrated into the hospital's quality assurance program and used to ensure necessary corrections to improve outcomes.

(c) The Department will review the information submitted by the hospital and other relevant information which is available to assess the qualitative performance of the hospital's cardiac catheterization program.

(d) If the Department's review of this information raises concerns with the quality of care in a cardiac catheterization program, the Department will undertake a review of that program to determine if these concerns are valid. The hospital shall cooperate with the Department in this review.

CHAPTER 139. NEONATAL SERVICES

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GENERAL PROVISIONS

§ 139.1. Principle.

When a hospital provides neonatal services, they shall be provided in a manner that meets the medical needs of the neonates.

§ 139.2. Scope.

This chapter applies to hospitals which provide obstetrical or neonatal infant care, or both. The Department recognizes the following levels of neonatal care:

(1) Level I: (Normal Neonatal).

(2) Level II: (Neonatal Intermediate/Intensive Care).

(3) Level III: (Neonatal Intensive Care).

§ 139.2a. Definitions.

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

Board certified—A physician licensed to practice medicine in this Commonwealth who has successfully passed an examination and has maintained certification in the relevant medical specialty area 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).

Guidelines—The term refers to the current *Guidelines for Perinatal Care* issued by the American Academy of Pediatrics and the American College of Obstetricians and Gynecologists.

NICU—Neonatal intensive care unit—The term refers to a unit which is specifically equipped and staffed for the care and treatment of high-risk infants and those infants otherwise in need of intensive care.

Neonate—Patients treated in neonatal care units. The term is synonymous with baby or infant.

Preboard certification status—A physician licensed to practice medicine in this Commonwealth who has completed the requirements necessary to take a certification examination offered by a medical 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.

§ 139.3. Director.

(a) A member of the medical staff shall be appointed director of neonatal services. The director shall be certified by the American Board of Pediatrics or an equivalent board.

(b) An interim director may be appointed during the period of time between the departure of the prior director and the selection of a new director. The interim director shall be a physician who is able to demonstrate qualifications acceptable to the medical staff of the hospital and to the Department. The hospital shall apply to the Department for an exception under the procedures in §§ 51.31—51.34 (relating to exceptions). If the exception is granted, the Department will specify the maximum period of time for which the interim director shall be appointed.

§ 139.4. Nursing services; other health care personnel.

(a) Neonatal nursing services shall be provided in accordance with Chapter 109 (relating to nursing services) and this section.

(b) A registered professional nurse, especially trained and experienced in the care of normal and high-risk infants, shall be responsible for the neonatal care unit at all times when the unit is occupied. No neonate may be left unattended.

(c) Licensed nursing personnel shall be assigned to duties consistent with their legal scope of practice. Unlicensed assistive personnel shall be assigned duties consistent with standardized training and competency evaluation.

(d) Staffing shall be adequate to meet nursing care goals, standards of nursing practice and nursing care needs of patients. The appropriate number of staff necessary to accomplish these goals, standards and needs shall be established in the written policies of the neonatal service and shall be consistent with the Guidelines.

(e) In addition to the requirements for the nursing staff in subsections (a)—(d), there shall be service goals and objectives, standards of patient care, procedure manuals and written job descriptions for each level of other health care personnel which includes the following:

(1) A means for assessing the needs of patients and determining adequate staffing to meet those needs.

(2) Staffing patterns that are adequate to meet patient care goals, standards of practice and needs of patients.

(3) An adequate number of licensed and unlicensed health care personnel to assure that staffing levels meet the total needs of patients.

(4) Health care personnel in neonatal services shall be assigned to duties consistent with their training, experience and scope of practice when applicable.

FACILITIES

§ 139.11. Facilities and equipment.

The maternity and neonatal services shall be separate and apart from other hospital services and especially from potential sources of infection. Access to each neonatal care unit shall be controlled to insure security and safety of all infants.

§ 139.12. Neonatal care units.

(a) Hospitals with maternity services shall provide neonatal care units with areas for neonate recovery, observation and isolation and provisions or arrangements for the care of high-risk infants in a neonatal intensive care unit either at the facility of birth or at a transfer site. Space allocation and total number of bassinets shall be consistent with the Guidelines.

(b) There should be an isolation area for the reception and care of infants exposed to potential sources of infection and infants suspected of or having a communicable disease. Infants may be housed and nursed in the isolation area pending diagnosis, disposition or completion of treatment. This isolation area should be served by nursing personnel and shall meet the standards established in the Guidelines for this type of care.

(c) A neonatal intensive care unit is one which is specifically equipped and staffed for the care and treatment of high-risk infants and those otherwise in need of intensive care. The neonatal intensive care unit shall meet the standards established in the Guidelines for this type of care. If such a service is not provided at the facility of birth, arrangements shall be made with an existing neonatal intensive care unit in the area of appropriate referral. The judgment of the attending physician and the policies of the hospital's neonatal services department shall determine the need for consultation with and referral to the hospital with an existing neonatal intensive care unit. The term "high risk infant" means any infant who, on the basis of socioeconomic, genetic or patho-physiologic history prior to delivery or on the basis of findings in the neonate period, manifests or is likely to manifest persistent and significant signs of distress. This may include:

(1) An infant with a birth weight below 2,000 grams or of less than 34 weeks gestation and any other low birth weight or premature infant who shows any abnormal signs.

(2) An infant showing persistent and significant signs of illness. This includes those with respiratory distress, congenital anomalies, tumors, jaundice, seizures, infections, metabolic distress or other conditions which pose an immediate threat to neonatal survival.

(3) An infant with serious feeding difficulties, excessive lethargy or instability of body temperature.

(4) An infant whose mother is drug addicted or habituated, diabetic, toxemic, isoimmunized, or having any other illness or condition which may affect the fetus.

(5) An infant requiring major surgical procedures.

§ 139.13. Equipment and supplies.

(a) Required equipment and supplies shall be in accordance with this section, the Guidelines for Design and Construction of Hospital and Health Care Facilities issued by the American Institute of Architects and with written policies of the neonatal service which shall be consistent with the Guidelines.

(b) An individual bassinet and equipment for the exclusive use of the infant to whom it is assigned shall be provided for each infant. All necessary supplies shall be stored in covered containers to permit individualized infant care and minimize risk of infection.

(c) Each neonatal care unit shall have its own sink with hot and cold running water equipped with foot, knee or elbow control so that hand contact with the sink is avoided. A sufficient supply of an antiseptic cleansing agent and disposable towels shall be readily available. Where paper towels are used, a dispenser shall be provided.

(d) Neonatal intensive care units shall be equipped with all equipment and supplies required for other neonatal care units.

§ 139.14. Oxygen control.

Oxygen shall be administered only with proper apparatus for its safe administration and control of concentration. Concentration of oxygen should not exceed a safe level commensurate with current concepts of oxygen therapy as recommended by the Guidelines.

§ 139.15. Temperature control.

A stable year-round temperature and humidity shall be maintained in all neonatal care units in accordance with written neonatal service policies consistent with the Guidelines.

§ 139.16. Housekeeping and maintenance.

The neonatal care unit shall be maintained in a clean and sanitary manner at all times. An environmental services room shall be provided for the exclusive use of the neonatal unit and shall be directly accessible from the unit.

§ 139.17. Neonatal intensive care units (Levels II and III).

In addition to the general requirements for the equipment of neonatal care units, the following provisions shall be required for all new construction, renovation or expansion of neonatal intensive care units and shall be available to all present neonatal intensive care units:

(1) The construction and arrangement of the neonatal intensive care unit shall permit personnel to observe the infants and have immediate access to them. Total neonatal care unit space, exclusive of anteroom, shall provide adequate floor space consistent with the Guidelines.

(2) Each infant requiring heat or air control, or both, shall have a separate incubator or other warming device and an individual environment with individualized heat, oxygen, suction and air turnover controls, as appropriate. Any infant whose condition permits may be placed in a bassinet.

(3) At least one oxygen outlet shall be provided for each patient station. Suction apparatus shall be easily available for each infant. A source of medically pure compressed air shall be available.

(4) A double-grounded electrical outlet shall be provided for each incubator or radiant warmer. Sufficient extra outlets should be provided for other electronic patient care equipment. Some electrical outlets in the unit shall be on the emergency electrical circuit of the hospital and shall be so marked.

(5) Resuscitation equipment shall be available within the neonatal intensive care unit. An effective method for preventing heat loss by the infant shall be available while the infant is undergoing any treatment.

(6) Air within neonatal intensive care units may not be recirculated and shall be frequently turned over each hour.

POLICIES

§ 139.21. Policies and procedures.

The director of neonatal services shall be responsible for developing written policies and procedures for the provision of medical services within the neonatal care unit which shall be available to the medical and nursing staff. The policies and procedures shall be reviewed by the director once a year and revised as necessary, and dated to indicate the time of last review. They shall provide specifications to conform to §§ 139.22—139.29.

§ 139.22. Physicians' services.

(a) There shall be a physician available at all times. This physician shall be either certified by the American Board of Pediatrics or an equivalent board, have attained preboard certification status, or have successfully completed an approved residency in pediatrics.

(b) All infants shall have a complete physical examination at or near the time of delivery consistent with the recommendations contained in the Guidelines and the results of the examinations shall be recorded in the infant's medical record.

(c) An infant who displays abnormal signs and symptoms at any time shall be examined by a physician as soon as possible.

(d) Every infant shall be examined by the attending physician or his authorized delegate within 1 day prior to discharge, and the findings recorded shall be in the infant's medical record.

(e) There shall be a method for the proper identification of each infant and mother or other responsible person at the time of discharge from the hospital. Infants discharged or transferred to another neonatal care unit or hospital shall be carefully identified.

§ 139.23. Delivery suite services.

(a) Delivery suite facilities shall include a neonatal recovery area specifically equipped for evaluation and treatment of the infant immediately after birth. An area of the delivery room set aside for infant care is acceptable.

(b) The director of obstetrics and the director of neonatal services shall formulate policies and procedures for delivery room care of infants. These policies and procedures shall be written and shall include provisions for:

(1) Notification of the physician in charge of the infant and the nurse responsible for the provision of nursing services in the neonatal care unit when the delivery of a potentially high-risk infant is expected.

(2) Continuity of care for all infants and especially for high-risk infants to be initiated in the delivery area, with constant observation of neonates for distress.

(3) The umbilical cord to be clamped or tied in accordance with standard medical practice.

(4) The collection of sample of cord blood and performance of laboratory studies for blood type, Rh and Coombs Test on every infant born to an Rh negative mother or having a family history of blood incompatibility.

(5) Infant identification, by an accepted duplicate system, for both mother and infant to be carried out in the delivery room and checked by the nurse or physician and, if possible, by the mother.

(6) Prophylaxis with medication under § 27.98 (relating to prophylactic treatment of neonates), to be carried out as soon as the condition of the infant permits.

(7) Every neonate to be examined at the time of delivery and the following noted on his medical record:

(i) Condition at birth including Apgar score or its equivalent.

(ii) Time of sustained respirations.

(iii) Physical abnormalities or pathological states.

(iv) Evidence of distress.

(8) A carefully planned procedure to be instituted for the transportation of infants to the neonatal care unit from the delivery room to insure maximum protection of the infant. Transfer of distressed infants to the unit shall be done in a manner that minimizes heat loss and to insure adequate oxygenation.

(9) The record of the infant to accompany the infant from the place of delivery to the neonatal care unit and be immediately available to unit personnel. This record shall include information concerning prenatal history, course of labor, delivery, drug administration to mother and infant, Apgar score, relevant conditions of the

mother, procedures performed on the infant in the delivery room, complications of any type, and other facts and observations.

§ 139.24. Neonatal intensive care units (Levels II and III).

(a) In hospitals with neonatal intensive care units, the director of the neonatal services shall develop written policies and procedures regarding admission of infants to neonatal intensive care units.

(b) Policies for neonatal intensive care units shall include:

(1) Requirements, in accordance with the Guidelines, for staffing of neonatal intensive care units. In addition, these units shall be staffed on every shift by at least one registered professional nurse who has special training, experience and interest in infants requiring special care and who is assigned no other responsibilities.

(2) A requirement that a pediatrician designated by the director of the neonatal services shall be on call 24 hours a day.

(3) A provision that private physicians or specialists may care for their patients in neonatal intensive care units. However, the final authority for policy in neonatal intensive care units shall reside with the director of neonatal services.

(4) A requirement that ancillary personnel employed to meet the needs of infants shall have appropriate, specified skills and training.

(5) Provisions for physicians, nurses and social service staff to assist parents of special care infants to become acquainted with their infant and any problems during the infant's hospitalization.

(6) A definite written policy, developed by the director of neonatal services, which provides for the unique problems involved in the total care of infants in neonatal intensive care units to be met, by making arrangements with the hospital nursing and social service departments and community health and social agencies, and by specifying what provisions will be made for continuing care, follow-up and home assistance.

§ 139.25. Control of infection.

(a) The director of neonatal services through the hospital's infection control program shall establish procedures for the control of infection, governing matters such as appropriate attire, isolation and cleaning of equipment in the neonatal care unit. Infection control procedures for neonatal services may be included among the responsibilities of the committee established under other licensure regulations. These procedures shall be written, reviewed at least annually and dated to indicate the date of last review.

(b) Infection control procedures shall do the following:

(1) Prohibit common or group carriers from transporting infants to their mothers.

(2) Require and specify procedures for scrupulous hand cleansing by all neonatal care unit personnel and visitors before and after each infant contact.

(c) The infection control standards shall be consistent with the current Guidelines.

§ 139.26. Care given by parents.

(a) The obstetrical and neonatal care departments of any hospital which provides rooming-in services shall have written policies governing the services. These procedures shall be designed to prevent cross contamination.

(b) When rooming in is provided, it shall be under professional nurse supervision.

(c) "Rooming-in services," as used in this section, shall include any of a variety of arrangements which allows the mother and her infant to be cared for together in a setting that gives the mother access to her infant during all or a substantial part of the day and which allows the father to have extensive contact with the mother and the infant during their hospital stay.

(d) Whether or not a hospital provides rooming-in services, it shall provide new parents with orientation, instructions, and demonstration in neonatal care and hygiene.

§ 139.27. Laboratory services and radiological services.

(a) Laboratory services shall be available on a 24-hour-a-day, 7-day-a-week basis for, at a minimum, hemoglobin; hematocrit; Coombs test; blood type; Rh type; urinalysis; bacteriologic cultures; spinal fluid analysis; and microchemical determinations for bilirubin, blood glucose, sodium, potassium, chloride and total protein.

(b) Radiological equipment and services shall be available on a 24-hour-a-day, seven-day-a-week basis.

(c) Each hospital with a neonatal service shall provide immediately available blood transfusion services.

(d) A hospital in which a neonatal intensive care unit is located shall have a licensed blood bank, available or on call to the unit on a 24-hour-a-day, 7-day-a-week basis.

§ 139.28. Patient medical records.

Patient medical records shall be maintained in accordance with Chapter 115 (relating to medical records services). The following information shall also be included in the neonatal record if the entire maternal records are not maintained as the neonatal records in § 115.23(b) (relating to preservation of medical records):

(1) Obstetrical history of mother's previous pregnancies.

(2) Description of complications of pregnancy or delivery.

(3) List of complicating maternal disease.

(4) Drugs taken by the mother during pregnancy, labor and delivery.

(5) Duration of ruptured membranes.

(6) Maternal antenatal blood serology, rubella titer, blood typing, Rh factors, and, when indicated, a Coombs test for maternal antibodies.

(7) Complete description of progress of labor including reasons for induction and operative procedures, if any, signed by the attending physician or an authorized delegate.

(8) Anesthesia, analgesia and medications given to mother and infant.

(9) Condition of infant at birth, including the 1-and 5-minute Apgar Score or its equivalent, resuscitation, time of sustained respirations, details of physical abnormalities, pathological states observed and treatments given before transfer to the neonatal care unit.

(10) Abnormalities of the placenta and cord vessels.

(11) Date and hour of birth, birth weight and length, and period of gestation.

(12) A written verification of eye prophylaxis.

(13) Report of initial physical examination, including abnormalities, signed by the attending physician or an authorized delegate.

(14) Discharge physical examination, including head circumference and body length, unless previously done; recommendations; and signature of attending physician or a delegate.

(15) A listing of all diagnoses since birth, including discharge diagnosis.

(16) Specific follow-up plans for care of infant.

§ 139.29. Infant nursing records.

Upon admission to a neonatal care unit, nurses shall initiate and maintain records on all infants as to weight, type and volume of feedings; time of first voiding; time of passage of first stool; number, color and consistency of stools; and temperature. If abnormalities are suspected or recognized, nurses shall also make notations on respiratory rate, dyspnea, color, cyanosis, jaundice, pallor, lethargy, twitching, motor activity, skin and buttocks, vomiting, condition of the eyes and umbilical cord, and other relevant factors as indicated and warranted by the condition of the infant. Treatments, medication and special procedures ordered by a physician should also be recorded with time, date and the name and title of the individual who administers them.

NUTRITIONAL SERVICES

§ 139.31. Policies and procedures.

Written policies and procedures for infant feeding shall be established and shall be available to the medical and nursing staffs.

§ 139.32. Commercial formula.

Precautions shall be taken to prevent the contamination and expiration of commercial formulas.

§ 139.33. Formula preparation.

(a) A registered professional nurse or dietitian shall be in charge of formula preparation.

(b) Formula shall be individually bottled and sterilized by pressure method 230|DF. for 25 minutes, with the following exceptions:

(1) If hermetically sealed commercial formula products are used and the hospital's method of dispensing the formula has been approved by the Department.

(2) Special mixtures which cannot be subjected to terminal heating shall be prepared by aseptic technique.

(c) Each formula bottle shall be labeled with the identity of its contents.

(d) Bacteriologic examinations of the equipment used, and analysis of techniques shall be done at least once each month. Plate counts on random sample of 24-hour milk mixtures shall not exceed 25 organisms per milliliter. Results of the bacteriologic tests shall be recorded and maintained on file.

§ 139.34. Breastfeeding.

Management of breastfeeding mothers and infants shall be consistent with the Guidelines.

CHAPTER 158. VITAL ORGAN TRANSPLANTATION SERVICES

GENERAL PROVISIONS

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GENERAL PROVISIONS

§ 158.1. Principle.

Transplantation services shall be performed only in hospitals and shall be performed in accordance with accepted and prevailing standards of medical practice.

§ 158.2. Definitions.

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

Board certified—A physician licensed to practice medicine in this Commonwealth who has successfully passed an examination and has maintained certification in the relevant medical specialty area 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).

Onsite—In the physical structure at which vital organ transplantation services are being offered or in an adjoining structure.

Organ Procurement and Transplantation Network—A private nonprofit entity created under 42 U.S.C.A. § 274 to coordinate organ procurement and allocation for transplants in the United States and whose duties include the establishment of membership and medical criteria for institutions that perform vital organ transplants.

Pediatric transplantation program—Describes that program where vital organ transplantation services are provided to all patients under 18 years of age, except for those whose physical development precludes them from being handled as a pediatric patient when receiving transplantations.

Preboard certification status—A physician licensed to practice medicine in this Commonwealth who has completed the requirements necessary to take a certification examination offered by a medical specialty board recognized by the American Board of Medical Specialities, 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.

Transplantation center—The entire unit of a hospital which is devoted to the provision of vital organ transplantation services. Within a transplantation center, separate programs shall be established for each type of vital organ transplanted.

Transplantation program—The offering of a surgical service which involves the transfer of a vital organ from one individual to another. Each type of organ transplantation constitutes a separate transplantation program.

§ 158.3. Scope.

(a) When a hospital provides transplantation services, it shall make a sufficient commitment of resources and planning to all transplantation services which it provides. This commitment shall be demonstrated as follows:

(1) Commitment of the hospital to the transplantation service shall be present at all levels and broadly evident throughout the facility. This requires a major commitment of resources. These shall include many other departments, as well as the principal sponsoring departments.

(2) The hospital shall have both the expertise and the commitment for participation in medical, surgical and other relevant areas. The hospital shall identify individuals in these areas to achieve an identifiable and stable transplant team.

(3) The component teams shall be integrated into a comprehensive team with clearly defined leadership and corresponding responsibility.

(4) The hospital shall have active medical and surgical programs in the specific areas in which transplantation services are offered.

(5) The commitment to medical staff shall include the elements in § 158.13 (relating to medical staff).

(6) The nursing service shall identify a team trained not only in the support of the patient, but also in the special problems of managing immunosuppressed patients.

(7) Adequate social services resources shall be available.

(8) Mechanisms shall be in place for managing the transplantation program which assures that:

(i) Patient selection criteria are consistent with those set forth in the hospital's written patient selection criteria.

(ii) The hospital is responsible for the ethical and medical considerations involved in the patient selection process and application of patient selection criteria.

(9) Adequate plans exist for organ procurement which meet legal and ethical criteria.

(b) Each transplantation program shall be a participating member of the Organ Procurement and Transplantation Network and shall comply with its standards, guidelines and bylaws.

PROGRAM, SERVICE AND PERSONNEL REQUIREMENTS

§ 158.11. Medical director.

(a) The medical director of the transplantation center shall be an active member of the medical staff who is a qualified transplantation surgeon or transplantation physician and who is either certified by the American Board of Surgery or the American Board of Internal Medicine or an equivalent Board.

(b) An interim director may be appointed during the period of time between the departure of the prior director and the selection of a new director. The interim director shall be a physician who is able to demonstrate qualifications acceptable to the medical staff of the hospital and to the Department. The hospital shall apply to the Department for an exception under the procedures in §§ 51.31—51.34 (relating to exceptions). If the exception is granted, the Department will specify the maximum period of time for which the interim director shall be appointed.

§ 158.12. Transplantation coordinator.

Each transplantation center shall have onsite on a full time basis at least one transplantation coordinator. Transplantation coordinators shall be certified by the American Board of Transplant Coordinators within 2 years of obtaining this position.

§ 158.13. Medical staff.

(a) Each transplantation program shall have at least one transplantation surgeon and one transplantation physician who are either Board certified or who have attained preboard certification status, members of the hospital's active medical staff and who meet the requirements established by the Organ Procurement and Transplantation Network to serve in that capacity.

(b) Each transplantation center shall have supporting medical staff to provide necessary services to transplant patients. Required medical staff shall be available at all times and shall include the following:

(1) Nephrology services comprised of at least one nephrologist who is either Board certified or who has attained preboard certification status in nephrology with the American Board of Internal Medicine or an equivalent Board. The nephrologist may also serve as the transplant physician.

(2) Pathology services with a pathologist who is either certified or who has attained preboard certification status with the American Board of Clinical Pathology or an equivalent Board. The pathology service shall be available for studying and reporting promptly the pathological responses to transplantation.

(3) Anesthesiology services with an anesthesiologist who is either certified or who has attained preboard certification status with the American Board of Anesthesiology or an equivalent Board. Anesthesiology shall identify a team for transplantation that is trained in transplant surgery and is available at all times.

(4) Radiology services with a radiologist who is certified by the American Board of Radiology or an equivalent Board. A radiologist shall have 1 year of training or 2 years experience in imaging techniques used in transplantation of the applicable organ and shall be available at all times.

(5) An internist who is certified in infectious diseases by the American Board of Internal Medicine or an equivalent Board and who shall be readily available to transplant patients. The internist shall have both the professional skills and the laboratory resources needed to discover, identify and manage the complications from organisms encountered in transplant patients.

(6) Psychiatric services with a psychiatrist who is either currently certified or who has attained preboard certification status in psychiatry with the American Board of Psychiatry and Neurology or an equivalent Board. The psychiatrist shall be available to meet the psychiatric needs of transplant patients.

§ 158.14. Nursing staff; other health care personnel.

(a) Nursing personnel shall include nurses with specialized education which includes theory, advanced technical skills and supervised experience in a surgical intensive care unit or in a postoperative transplantation unit before assuming primary responsibility for the nursing care of transplantation patients.

(b) There shall be nursing service goals and objectives, standards of nursing practice, procedure manuals and written job descriptions for each level of personnel which shall include the following:

(1) A means for assessing the nursing care needs of the patients and determining adequate staffing to meet those needs.

(2) Staffing patterns that are adequate to meet the nursing goals, standards of practice and the needs of the patients.

(3) An adequate number of licensed and unlicensed assistive personnel to assure that staffing levels meet the total nursing needs of the patient.

(4) Nursing personnel assigned to duties consistent with their training, experience and scope of practice, when applicable.

(c) Surgical suite nursing services shall be under the direction and supervision of a registered professional nurse with specific education and experience in dealing with transplantation patients.

(d) In addition to the requirements for the nursing staff in subsections (a)—(c), there shall be service goals and objectives, standards of patient care, procedure manuals and written job descriptions for each level of other health care personnel which includes the following:

(1) A means for assessing the needs of patients and determining adequate staffing to meet those needs.

(2) Staffing patterns that are adequate to meet patient care goals, standards of practice and needs of patients.

(3) An adequate number of licensed and unlicensed health care personnel to assure that staffing levels meet the total needs of patients.

(4) Health care personnel in the transplantation program shall be assigned to duties consistent with their training, experience and scope of practice when applicable.

§ 158.15. Laboratories.

(a) The transplantation center shall maintain, or by agreement have access to, a tissue typing laboratory with appropriate space and resources to perform required histocompatibility testing and cross matches.

(b) The transplantation center shall maintain, or by agreement have access to, laboratory facilities capable of performing virology, cytology, clinical chemistry, microbiology and monitoring of immunosuppressive drugs.

(c) The transplantation center shall have blood bank support with the capacity to supply blood components for the number of transplants that are projected, the ability to irradiate blood components and the availability of a blood separator and central blood repository.

§ 158.16. Support services.

(a) The transplantation center shall maintain, or by agreement have access to, a rehabilitation center which can provide physical rehabilitation, psychological services and vocational and occupational therapy.

(b) The transplantation center shall maintain, or by agreement have access to, the social support services necessary for the care of transplant recipients and for the assistance to families coping with the transplant experience.

(c) The transplantation center shall maintain a service for counseling recipients which is directed to their particular needs and problems. Additionally, as appropriate, the transplantation service shall provide counseling to donors and to their relatives.

(d) The transplantation center shall maintain the following facilities:

(1) Adequately equipped operating rooms.

(2) Adequate equipment and supplies.

(3) Intensive care facilities capable of maintaining transplant patients.

(4) Facilities for acute hemodialysis.

§ 158.17. Selection criteria.

(a) The transplantation program shall have written procedures for selecting transplantation candidates and distributing organs in a fair and equitable manner. Selection criteria shall comply with the National Organ Procurement and Transplantation Network organ allocation priorities and shall be based on objective medical criteria and time on a waiting list.

(b) The transplantation program shall have written policies in place to assure that:

(1) Patient selection decisions are consistent with criteria set forth in the written patient selection criteria.

(2) The transplantation program is responsible for ethical and medical considerations in the patient selection process.

§ 158.18. Referrals, hours of operation.

(a) The transplantation center shall accept referrals from all physicians.

(b) Transplantation services shall be accessible 24-hours-a-day, 7-days-a-week.

§ 158.19. Volume of procedures.

(a) Each transplantation program shall perform an adequate number of procedures to maximize quality.

(b) Each transplantation program shall meet the expected survival rate as set forth by the Organ Procurement and Transplantation Network in its bylaws. Those programs whose actual survival rates fall below their expected survival rates will be reviewed by the Department to determine if this deviation can be accounted for by patient mix or some other unique clinical aspect of the transplantation program.

(c) If the transplantation program is unable to provide an explanation for its failure to meet the expected survival rate, the Department will undertake a review of that program to determine if it is in compliance with the criteria in this chapter. The hospital shall cooperate with the Department in this review.

§ 158.20. Post-transplantation care.

(a) The transplantation center shall maintain a program for continuing patient follow-up care throughout the recipient's life.

(b) This program shall include the following:

(1) A system for referring physicians that integrates patient referral and continued patient supervision.

(2) The interchange of medical and other information necessary in the care and treatment of patients transferred between physicians responsible for patient care and the transplantation surgery.

(3) The provisions of a discharge plan to the referring physician.

(4) An obligation to follow the patient at appropriate intervals to assess the outcome of the transplant and to provide consultative care as necessary.

SUPPLEMENTARY CRITERIA

§ 158.31. Kidney transplantation program.

(a) The general standards in §§ 158.1—158.19 apply to kidney transplantation programs. Additionally, the criteria contained in this section apply only to kidney transplantation programs.

(b) A kidney transplantation program shall have overall plans and resources to assure a reasonable concentration of experience.

(c) A kidney transplantation program shall participate in and be certified by the Federal ESRD (End Stage Renal Disease) (Medicare) program and as an ESRD center.

(d) A hospital which has a kidney transplantation program shall have a Division of Urology comprised of at least one urologist who is either certified by or who has attained preboard certification status with the American Board of Urology or an equivalent Board. The urologist shall be available to act as a consultant when appropriate for the preoperative, operative and postoperative surgical evaluation and management of transplant patients and living donors.

(e) In addition to dialysis facilities for acute hemodialysis, a kidney transplantation program shall be capable of providing peritoneal dialysis.

§ 158.32. Heart transplantation program.

(a) The general standards in §§ 158.1—158.19 apply to heart transplantation programs. Additionally, the criteria contained in this section apply only to heart transplantation programs.

(b) A heart transplantation program shall have overall plans and resources to assure a reasonable concentration of experience.

(c) A heart transplantation program shall have on staff and available at all times a cardiologist and a pulmonologist both of whom are either certified by or have attained preboard certification status with the respective appropriate American Board or an equivalent Board. Either of these specialists may also serve as the transplant physician.

(d) The hospital shall have a cardiac catheterization service which meets all of the regulatory requirements for this service. The cardiac catheterization laboratory shall be available to perform these procedures on an emergency basis.

(e) The hospital shall have an open heart surgery program and shall meet all of the regulatory requirements for this service.

(f) The hospital shall meet the following conditions:

(1) Possess expertise in other relevant areas including cardiology, cardiovascular surgery and pulmonary diseases.

(2) Identify individuals in these areas to achieve a stable transplant team.

§ 158.33. Liver transplantation program.

(a) The general standards in §§ 158.1—158.19 apply to liver transplantation programs. Additionally, the criteria contained in this section apply only to liver transplantation programs.

(b) A liver transplantation program shall have overall plans and resources to assure a reasonable concentration of experience.

(c) A hospital shall have on staff and available a gastroenterologist who is either certified by or who has attained preboard certification status with the American Board of Gastroenterology or an equivalent Board. The gastroenterologist shall have at least 2 years experience in hepatology. The gastroenterologist may also serve as the transplant physician.

(d) The pathologist shall be specifically trained in liver pathology.

§ 158.34. Lung and heart/lung transplantation programs.

(a) The general standards in §§ 158.11—158.19 apply to lung and heart/lung transplantation programs. Additionally, the criteria contained in this section apply only to lung and heart/lung transplantation programs.

(b) A lung or heart/lung transplantation program shall have overall plans and resources to assure a reasonable concentration of experience.

(c) A lung or heart/lung transplantation program shall have on staff and available a cardiologist and a pulmonologist who are either certified by or who have attained preboard certification status with the respective appropriate American Board or equivalent Board. Either of these specialists may also serve as the transplant physician.

(d) The hospital shall have a cardiac catheterization service which meets all of the regulatory requirements for this service. The cardiac catheterization laboratory shall be available to perform these procedures on an emergency basis.

(e) The hospital shall have an open heart surgery program and shall meet all of the regulatory requirements for this service.

§ 158.35. Pancreas transplantation programs.

(a) The general standards in §§ 158.1—158.19 apply to pancreas transplantation programs. Additionally, the criteria contained in this section applies only to pancreas transplantation programs.

(b) A pancreas transplantation program shall have overall plans and resources to assure a reasonable concentration of experience.

(c) A hospital in which a pancreas transplantation program performs combined kidney/pancreas transplants or sequential kidney and pancreas or sequential pancreas and kidney transplants shall have an active kidney transplantation program.

(d) A hospital which has a pancreas transplantation program shall have a division of endocrinology comprised of at least one endocrinologist currently certified by the American Board of Endocrinology or an equivalent Board. If the endocrinologist serves as the transplant physician,

then the endocrinologist shall have at least 1 year of training or 2 years experience in the care of transplant patients.

§ 158.36. Other organs.

A facility proposing to establish a program for transplant of an organ other than kidney, heart, liver, lung, heart/lung or pancreas shall:

(1) Comply with the general criteria contained in this chapter.

(2) Comply with Organ Procurement Transplant Network criteria applicable to the specific organ.

§ 158.37. Pediatric transplantation programs.

(a) A transplantation center that provides a transplantation program to pediatric patients shall do the following:

(1) Follow the general criteria for transplantation centers and programs in §§ 158.1—158.19.

(2) Follow the supplementary criteria for the applicable organ transplantation program in §§ 158.31—158.36.

(3) Follow the criteria in this section in the treatment of pediatric patients.

(b) In those instances where criteria for pediatric transplantation programs differs from supplementary criteria for organ specific transplants, transplantation centers providing services to both adult and to pediatric patients are required to fulfill both the supplementary criteria for the specific organ and the following pediatric transplant criteria. Transplantation centers providing programs exclusively to pediatric patients need only meet the criteria for pediatric transplantation programs.

(c) Those transplantation centers which are exclusively pediatric shall have overall plans and resources to assure a reasonable concentration of experience.

(d) Transplantation centers providing services to pediatric patients shall have on staff and available the following specialists who shall be either certified by or have attained preboard certification status with the appropriate subspecialty board of the American Board of Pediatrics or an equivalent Board:

(1) Pediatric transplantation programs shall have on staff: a pediatric nephrologist, a pediatric infectious disease specialist and a pediatric internist.

(2) Pediatric liver transplantation programs shall have on staff: a pediatric gastroenterologist and a pediatric pulmonologist.

(3) Pediatric heart, lung and combined heart/lung transplantation programs shall have on staff: a pediatric pulmonologist, a pediatric cardiologist and a pediatric cardiac surgeon.

(4) Pediatric pancreas transplantation programs shall have on staff a pediatric endocrinologist.

(e) Transplantation centers providing services to pediatric patients shall have on staff and available the following personnel who are certified or qualified, or both, as follows:

(1) An anesthesiologist who is either certified by or who has attained preboard certification status with the American Board of Anesthesiology or an equivalent Board and has 2 years of experience providing anesthesiology services to pediatric patients.

(2) A dietitian who is registered by the American Dietetic Association or who is a feeding specialist and who has 2 years of experience providing dietetic services to pediatric patients.

(3) A radiologist who is either certified by or who has attained preboard certification status with the American Board of Radiology or an equivalent Board and who has 2 years of experience providing radiology services to pediatric patients.

(4) A physical therapist who has 2 years experience providing services to pediatric patients.

(5) A psychiatrist who is either certified by or who has attained preboard certification status with the American Board of Child Psychiatry or an equivalent Board.

(6) A social worker who has 1 year of experience providing social services to pediatric patients.

(7) A nursing staff that is experienced in providing nursing services to pediatric patients and is of a sufficient complement to meet nursing care goals, standards of nursing practice and nursing care needs of pediatric patients.

(8) An occupational therapist who is registered with the American Occupational Therapy Association and who has 1 year of experience in treating pediatric patients.

(f) A pediatric heart transplantation center shall have cardiac catheterization and open heart surgical services which meet all of the regulatory requirements for pediatric patients.

(g) A pediatric program which provides kidney transplantation services to pediatric patients shall have on staff and available a urologist who is either certified by or who has attained preboard certification status with the American Board of Urology or an equivalent Board and who has 2 years experience providing urology services to pediatric patients.

(h) Transplantation centers that provide transplantation programs to pediatric patients shall have appropriate equipment available to provide the following services to pediatric patients:

(1) Dialysis.

(2) Anesthesia.

(3) Intensive care.

(4) Operating room.

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