PROPOSED RULEMAKING

DEPARTMENT OF HEALTH

[28 PA. CODE CHS. 51, 136, 138, 139 AND 158]]

Health Facility Licensure

The Department of Health (Department) proposes to amend Part IV (relating to health facilities) by adding Chapters 51, 136, 138, 158 and amending Chapter 139 to read as set forth in Annex A.

Purpose and Procedure

This proposed 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 would prohibit open heart surgery, cardiac catheterizations and organ transplantation surgery from being performed at nonhospital locations. Finally, the Department proposes to add a general information chapter which would set forth regulations which are applicable to all health care facilities.

On December 18, 1996, those provisions of the Health Care Facilities Act (act) (35 P. S. §§ 448.101—448.904b), relevant to the Certificate of Need (CON) Program terminated. See section 904(a) of the act (35 P. S. § 448.904(a)). On December 14, 1996, the Department published notice that it would undertake a review of those clinically related health services covered under the CON Program. See 26 Pa.B. 6029 (December 14, 1996).

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

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

The Department determined that the work groups on open heart surgical services, organ transplantation surgical services, cardiac catheterization services and neonatal services should begin to meet immediately. This was due to the need to address as quickly as possible any quality assurance gaps which could be present for these high risk health services.

The work groups met during the months of January and February, 1997. Their assigned task was to examine the criteria contained in the State Health Services Plan (SHSP) and determine if any of the criteria contained therein discussing quality assurance and patient safety should be added to existing regulations of the Department regarding licensure of health care facilities. The act provides that, in order to be issued a license, a health care provider must show that: (1) it is a responsible person; (2) the place to be used as a health care facility is adequately constructed, equipped and maintained and safely and efficiently operated; (3) it will provide safe and efficient services adequate for the care and treatment of patients or residents; and (4) it is in substantial compliance with the rules and regulations of the Department. See section 808(a) of the act (35 P. S. § 448.808(a)). Therefore, with the termination of the CON Program, the Department's focus is on the quality of care provided at the health care facilities which it licenses in this Commonwealth.

The open heart surgery, cardiac catheterization, vital organ transplantation surgery and neonatal services work groups were comprised of representatives from the Department, the Pennsylvania Medical Society (PMS), the Pennsylvania Nurses Association (PNA), the Hospital Association of Pennsylvania (HAP), Legislative staff and other persons with expertise regarding these services. The following specialists were active members of their respective work groups: cardiac surgeon (open heart surgical services), cardiologist (cardiac catheterization), transplant surgeon (organ transplant work group) and neonatologist (neonatal). These four work groups were chaired by a Deputy Secretary of the Department. The four work groups submitted to the Secretary of Health (Secretary) a report and draft regulations. Those materials were then made available to the general public and public hearings were conducted. Before the amendments in Annex A were decided upon, the written and verbal comments received during the hearing process were considered by the Secretary and Department staff. Additional input regarding the merits of recommendations contained in the comments was also solicited from persons with relevant expertise.

At the conclusion of their review and discussion of relevant material regarding these various health care services, the work groups drafted proposed recommendations to the Secretary. The recommendations of the work groups differed depending on the service being reviewed. The work groups on open heart surgery, cardiac catheterization and vital organ transplantation surgery recommended that the Department draft new regulations to address quality assurance aspects of these services. The work group on neonatal care recommended that the Department amend its current regulations so as to assure compliance with the Nationally recognized standards of neonatal care. The work groups agreed that the Department should address, in a general information chapter, the notification requirements for health care facilities that intend to offer these services.

On February 1, 1997, the Department published notice that six work group recommendations were available and that a public meeting would be held on February 11, 1997. See 27 Pa.B. 621 (February 1, 1997). These six work groups reviewed the following services: cardiac catheterization, intermediate or skilled nursing care inpatient services, ambulatory surgical care, neonatal care, open heart surgery and vital organ transplantation services. Approximately seven individuals presented testi-

mony at the public meeting on February 11. In addition, written comments were received from various individuals and institutions.

The existing hospital licensure regulations do not address or include any specific requirements that focus upon the provision of open heart surgical, cardiac catheterization services and organ transplantation surgery. The Department has concluded that the current regulations do not impose quality standards necessary to protect the health, safety and welfare of potential candidates for these services and that the regulatory deficiency requires remedy through the addition of regulations addressing these specific services and the relevant quality assurance requirements. Under CON, hospitals which planned to offer these services needed to meet quality standards in the SHSP. In the absence of quality standards, the health, safety and welfare of the patients who need these services are at risk.

Following the sunset of CON, hospitals that had not received a CON to provide open heart surgery, cardiac catheterization services, organ transplantation services and neonatal services have been able to provide those services without first demonstrating to the Department satisfaction of important quality standards. To date, the Department is aware of six hospitals that have started or intend to start to provide open heart surgery since the termination of CON. The Department has also been notified that six new cardiac catheterization laboratories are commencing to provide services and that one hospital is starting to provide transplantation surgery. Each of these services constitutes a surgical procedure involving invasion of a vital organ, and life threatening circumstances.

Similarly, while Chapter 139 (relating to newborn services) of the Department's present regulations discuss newborn services, the Department believes that the chapter is not consistent with the current standards and technology for the treatment of newborns and infants and needs to be updated. The Department is aware of at least one hospital that has opened a neonatal intensive care unit (NICU) since the termination of CON. These units provide intensive care to newborns and infants who suffer from low birth weight, respiratory distress, congenital anomalies, seizures, infections or serious feeding difficulties which pose an immediate threat to neonatal survival. The Department is concerned that NICU units meet all of the current quality assurance standards. The proposed amendments will address these issues, by adopting the current Guidelines for Perinatal Care issued by the American Academy of Pediatrics and the American College of Obstetrics and Gynecology and by setting forth other updated standards relating to quality assurance matters.

Finally, the Department agrees with the work groups that a general information chapter should be added to the regulations to address notification requirements for the addition of services at health care facilities. The Department also proposes to address other issues in this chapter which are common to all health care facilities.

Summary

Subpart A. General Provisions.

Chapter 51. General Information

Subpart A and Chapter 51 are proposed new additions to the licensure regulations. This subpart will contain those provisions which are applicable to all health care facilities. Chapter 51 contains general information which must be followed by all health care facilities.

Section 51.1 (relating to legal base and scope) would provide that this chapter is applicable to all health care facilities.

Section 51.2 (relating to licensed facilities) would identify the types of health care facilities which are licensed by the Department.

Section 51.3(a) (relating to notification) would provide that when health care facilities wish to add new health care services, they must first notify the Department of their intent to do so and cannot add these services until the Department has informed them of their compliance with all licensure requirements. With the termination of CON, the licensure process becomes the chief mechanism by which the Department can assess compliance with quality assurance and patient safety criteria. Section 51.3(b) provides a similar notification requirement for the addition of beds to a health care facility. This language already appeared in the regulations for general and special hospitals and long term care facilities, but now will be applicable to all health care facilities. Under § 51.3(h), a health care facility may not provide a new health care service or add beds until it has been informed by the Department that it is in compliance with the licensure regulations.

Section 51.3(c) would provide that a health care facility must provide written notice to the Department at least 30 days before the date it intends to cease the provision of an existing health care service or to decrease its bed complement. Unlike § 51.3(a) and (b), the health care facility may cease these services or decrease the number of beds after the passage of 30 days from the date of notification to the Department, even if the Department has not responded to the health care facility.

Section 51.3(d) would provide that a health care facility must provide written notice to the Department at least 30 days prior to the initiation of any design phase for new construction, alteration or renovation of the facility. By requiring this notice, the Department will be apprised as soon as possible of a health care facility's construction plans and will be able to provide advice and assistance to the health care facility at an early juncture, which could lead to a cost savings for the facility if it finds at this beginning phase that its construction plans need to be modified in order to comply with the Department's regulations.

Section 51.3(e) and (f) would provide that if a health care facility becomes aware that it is in noncompliance with the Department's regulations or is aware of the occurrence of an event at the facility or a situation at the facility which could compromise the quality of care or patient safety, the facility must immediately notify the Department of this fact and the steps which it will take to bring the facility into compliance with the regulations or rectify the situation. These sections reflect the Department's concern that it be aware of any situations at licensed health care facilities which could pose a threat to the quality of care being provided and the safety of the patients or residents in that facility. By requiring immediate notification, the Department can assure that it will learn of these matters as soon as possible and can take steps, including working with the facility in question, to ensure that the matter is corrected before any further problems occur.

Section 51.4 (relating to change in ownership; change in management) would require that health care facilities inform the Department when a change of ownership or a transfer of more than 5% of the stock or equity occurs.

Section 51.5 (relating to building occupancy) would require that all health care facilities must undergo occupancy surveys at least 2 weeks prior to the expected commencement of the occupancy of new or remodeled facilities.

Sections 51.11—51.13 (relating to civil rights) would provide the civil rights compliance expected from all health care facilities.

Under §§ 51.21—51.24 (relating to restriction of provision of health care services) restrictions would be placed on the location of the provision of certain health care services. These restrictions grew out of the recommendations of the work groups that certain services should only be performed in hospitals or in appropriately equipped ambulatory surgical facilities. Under § 51.21, surgery may only be performed in an acute care hospital or in a licensed ambulatory surgical facility. Section 51.22 would limit the performance of cardiac catheterization services to acute care hospitals. Section 51.23 provides that PET may be provided only in a hospital which complies with the Department's regulations governing nuclear medicine and radiology. Section 51.24 provides that lithotripsy services may only be provided in a hospital or in an ambulatory surgical facility which is authorized to provide anesthesia. These restrictions were believed to be appropriate to assure quality of care and patient safety.

Sections 51.31—51.34 (relating to exceptions) provide for an exceptions process, wherein any health care facility may request that the Department waive the applicability of certain regulations.

The proposed addition of Chapter 51 will necessitate the future deletion of duplicative requirements elsewhere in the regulations, particularly in the general hospital, long term care facility and ambulatory surgical facility regulations.

Subpart B. General and Special Hospitals

Chapter 136. Open Heart Surgical Services

The work group that considered the provisions of the SHSP on open heart surgical services included all of the representatives of the various entities set forth previously.

After an exhaustive review of the criteria contained in the SHSP, the current regulations, National standards and the approaches taken by other states, the work group recommended that the Department promulgate new regulations addressing this service. Existing regulations do not address qualitative criteria for an open heart surgery program. Due to the complexity and life threatening aspects of this surgery, the Department agrees that specific regulations are necessary to ensure quality of care and patient safety.

Section 136.1 (relating to principle) would require that all adult open heart surgical services and all pediatric open and closed heart surgical services must be performed in hospitals and at no other location. This continues the requirement previously contained in Chapter 6 of the SHSP and is in accordance with current medical practice.

Section 136.2 (relating to definitions) would contain definitions for the various terminology associated with this service. Most of these definitions appeared in the SHSP. The terms "board certified" and "board eligible" have been defined precisely so as to indicate that a physician must maintain board certification and that board eligibility does not last indefinitely. The inclusion of both open and closed heart procedures in the definition of "pediatric heart surgery" is in accordance with current medical practice. The age requirement contained therein was arrived at after consultation with several cardiologists.

Section 136.11 (relating to director) would require that the director of the open heart surgery program shall be a board certified surgeon whose training emphasized cardiac surgery. This requirement was contained in the SHSP.

Section 136.12 (relating to medical staff) would specify minimum qualifications for the physicians staffing the service and includes standards to ensure adequate physician staffing of the service at all times. These requirements were also contained in the SHSP.

Section 136.13 (relating to nursing staff) would address the minimum qualifications of nurses staffing the service, including the nurse who directs and supervises the nursing staff, and specifies nursing practice and procedure issues that are to be addressed and the mechanisms for doing so. These requirements reflect those contained in the SHSP.

Section 136.14 (relating to support team in the operating room) would address requirements for the operating room support team, with particular focus on requirements for perfusionists and extracorporeal pump oxygenators to enable operation of the service at all times. These requirements are consistent with those found in the SHSP.

Section 136.15 (relating to other support services) would identify supportive services which are to be available at all times, and specifies which of those services are to be available on site. As set forth in the definition section (§ 136.2), "onsite" means that the service is located in the physical structure in which the open heart surgical services are being offered or in an adjoining structure. While these proposed requirements are consistent with those contained in the SHSP, the work group carefully evaluated the need for each of them and whether the particular support service needed to be on site or simply available. This section also addresses size and equipment requirements for operating rooms. The standards for operating room size and equipment are to be consistent with the requirements of the Inter-Society Commission on Heart Disease (ICD) and the *Guidelines and Indications for Coronary Artery Bypass Graft Surgery* issued in 1991 by the American College of Cardiology/American Heart Association (ACC/AHA Guidelines).

Section 136.16 (relating to rapid mobilization) would require rapid mobilization capability and support team availability for emergency procedures at all times, and require physician on-call schedules to be posted. These requirements were contained in the SHSP. The on-call schedule must be posted at each area where cardiac surgical patients are present so that the physicians can be contacted immediately.

Section 136.17 (relating to observation of patients) would require that a cardiac surgical care service have the ability to maintain visual observation of all patients. The cardiac surgical care service is referenced instead of the open heart surgical service because the former incorporates the latter and patient observation capabilities need not be separately addressed at the open heart surgical service level. This requirement is consistent with that contained in the SHSP. The work group strongly felt that capability of the medical and nursing staff to have direct visual observation of the cardiac patients was necessary so that immediate response could occur if the patient developed problems.

Section 136.18 (relating to post-operative care) would require that an intensive surgical care service be available to the open heart surgery patient immediately following surgery, and specifies that the cardiac surgical service shall be responsible for the postoperative care of the patient and be involved in discharge planning. These requirements are consistent with those suggested in the ACC/AHA Guidelines.

Section 136.19 would address the training and education the staff of the open heart surgical program are to secure and provide. These requirements are consistent with those found in the SHSP.

Section 136.20 (relating to pediatric open heart surgery—supplementary criteria) would specify standards a hospital needs to satisfy, in addition to other standards contained in the chapter, to offer a pediatric open heart surgical program. These requirements are consistent with those found in the SHSP.

Section 136.21 (relating to quality management and improvement) would require a hospital that performs open heart surgery to maintain statistics on outcomes of its open heart surgery program, including morbidity and mortality data; to integrate that data in its quality assurance program; and to participate in the Department's collection and review of outcome data.

The quality of all open heart surgery programs will be monitored on an ongoing basis through a quality assessment process. Quality indicators such as morbidity, mortality and infection data will be used to select hospitals for a vigorous assessment of whether they are meeting quality standards. Based upon the findings, the Department will determine whether any remedial or corrective action is necessary.

The use of a quality assessment process will enable the Department to determine whether acceptable quality standards are being met based upon evolving technology and changing standards in clinical practice as embraced by the medical community. Review of services in this manner enables the Department to consider practice changes embraced in the current medical literature and avoid adopting regulations detailing precise standards of practice which may become rapidly outdated.

The work group spent a considerable amount of time on this issue and looked at the approaches taken by other states, including New York and New Jersey. The proposal will assure that the Department is able to monitor the quality assurance of each open heart surgery program without placing an undue burden on the hospitals, as most of the data requested is readily available and may already be included in reports sent to other entities. The Department intends to adopt a mechanism to implement this requirement through a statement of policy. This will allow the Department to alter the policy if other, less burdensome mechanisms can be used in the reporting of this data.

Chapter 138. Cardiac Catheterization Services

The work group that considered the provisions of the SHSP on cardiac catheterization services included all of the representatives of the various entities set forth under Purpose and Procedure. In addition to a cardiologist who attended the meetings, several additional cardiologists were also contacted and their suggestions and input were considered by the work group and the Department.

After an exhaustive review of the criteria contained in Chapter 7 of the SHSP, the current regulations, National standards and the approaches taken by other states, the work group recommended that the Department promulgate new regulations addressing this service. Existing regulations do not address qualitative criteria for cardiac catheterization services. Due to the complexity and life threatening aspects of this service, the Department agrees that specific regulations are necessary to ensure quality of care and patient safety.

Section 138.1 (relating to principle) would require that all cardiac catheterizations be performed in hospitals in accordance with accepted and prevailing standards of medical practice. Although there has been discussion about freestanding and mobile cardiac catheterization labs, these laboratories were not permitted under the SHSP. In reviewing this area, the work group agreed that the current standard of practice is that cardiac catheterizations are performed in hospitals, due to the availability of the support services. The procedure involves the insertion of a catheter in a blood vessel of the arm or leg and manipulating that catheter into the veins and arteries of the heart. This procedure can only be performed where immediate treatment is available if a problem should occur. The potentiality of life-threatening complications necessitates that the staff, equipment and services of a hospital be immediately available.

Section 138.2 (relating to definitions) contains definitions for the various terminology associated with this service. Most of these definitions appeared in the SHSP. The term "board certified" has been defined precisely so as to indicate that a physician must maintain board certification. The distinction between "high-risk" and "low risk" cardiac catheterizations is important as only hospitals that also perform open heart surgery may also perform high-risk cardiac catheterizations. The definition of high-risk cardiac catheterization contains those type of catheterizations which present a significant risk of cardiac complication. These include certain diagnostic catheterizations, all percutaneous transluminal coronary angioplasties (PTCA) and pediatric catheterizations, and most therapeutic electrophysiology procedures. The current standards of medical practice indicate that these procedures are, or have the potential to be, in the high-risk category. The cardiologists consulted by the Department agreed that these types of catheterizations were appropriately classified as high-risk. The definition of "pediatric cardiac catheterization" was arrived at after consultation with several cardiologists. Although there is no universally agreed upon definition of when a pediatric patient becomes an adult patient, reference to the patient's physical development appears to be an appropriate measure.

Section 138.11 (relating to director) would prescribe the qualifications for the director of a cardiac catheterization program. The requirement that the director be Board certified in cardiology or pediatric cardiology is consistent with the standards established in the *Guidelines for Cardiac Catheterization and Cardiac Catheterization Laboratories* issued by the American College of Cardiology/American Heart Association (ACC/AHA Guidelines) in 1991.

Section 138.12 (relating to medical staff) would specify minimum qualifications for the physicians staffing the service. The requirement that two physicians must staff the cardiac catheterization laboratory does not mean that two physicians must be present when catheterizations are performed. The laboratory must utilize the services of at least two physicians but only one physician has to be present for the actual catheterization. These requirements are consistent with those contained in the SHSP.

Section 138.13 (relating to nursing staff) would specify the minimum qualifications for the nurses staffing the service, and identifies nursing practice and procedure issues that are to be addressed and the mechanisms for doing so. Although not explicitly set forth in the SHSP, this section is consistent with general nursing staff requirements.

Section 138.14 (relating to programs and services) would specify the services that are to be onsite or available for a hospital to perform cardiac catheterization services. "Onsite" is defined as being in the same physical structure in which the cardiac catheterization services are being offered or in an adjoining structure. It also addresses requirements for performing outpatient diagnostic cardiac catheterization and the circumstances under which a mobile cardiac catheterization laboratory may be utilized on site on a temporary basis. Outpatient cardiac catheterizations are only permitted on low risk patients if a physician determines that treatment on an outpatient basis is appropriate. As stated previously, freestanding or mobile cardiac catheterization laboratories are not permitted. However, the work group recognized that a hospital may be undergoing renovation of its fixed catheterization laboratory and may need to utilize a mobile facility while the renovation is occurring. As long as all other quality standards are adhered to, this usage would be permitted.

Section 138.15 (relating to high-risk cardiac catheterizations) would require that high-risk cardiac catheterizations be performed only at a hospital that has an open heart surgical program onsite. As previously discussed, this reflects the requirements in the SHSP and the standards of current medical practice, as set forth in the ACC/AHA Guidelines.

Section 138.16 (relating to transfer agreements for low-risk cardiac catheterization hospital) would permit a hospital that does not have an open heart surgical program onsite to perform low-risk cardiac catheterizations if it has protocols for distinguishing between low and high-risk cardiac catheterization patients and an agreement which addresses designated items with at least one hospital that does have an open heart surgical program. The section also requires that an agreement be in effect at all times and reviewed at least annually. This is consistent with the requirements in the SHSP.

Section 138.17 (relating to PTCA) would establish specific physician and peer review requirements for hospitals in which elective PTCAs are performed. It also makes an exception for emergent PTCAs from the requirement that high-risk cardiac catheterizations be performed only at a hospital with an open heart surgical program onsite. It treats an emergent PTCA as an extraordinary occurrence and requires the hospital to report the circumstances to the Department within 72 hours. The Department's assessment of the propriety of performing each PTCA performed at a hospital that does not have an open heart surgical program onsite will be made by assessing the appropriateness of the hospital's protocols and its adherence to those protocols. These requirements are consistent with those found in the SHSP.

Section 138.18 (relating to EPS) would prescribe the standards that need to be met by a physician who performs EPS. It also addresses where certain types of therapeutic electrophysiology may be conducted. These standards were reviewed with several cardiologists and are consistent with current medical practice.

Section 138.19 (relating to pediatric cardiac catheterizations) would prescribe requirements in addition or alternative to other requirements contained in the chapter that need to be satisfied for a hospital to perform pediatric cardiac catheterizations. These requirements are consistent with the standards contained in the ACC/AHA Guidelines.

Section 138.20 (relating to quality management and improvement) would require a hospital that performs cardiac catheterizations to maintain statistics on outcomes of its cardiac catheterization patients, including morbidity and mortality data; to integrate that data in its quality assurance program; and to participate in the Department's collection and review of outcome data.

The quality of all cardiac catheterization programs would be monitored on an ongoing basis through a quality assessment process in a manner similar to the manner in which the quality of open heart surgical programs will be monitored. (See previous discussion at § 136.21.)

Chapter 139. Newborn Services

The work group assigned to review the quality criteria for neonatal care and for neonatal intensive care units which appears in the SHSP found that the existing regulations basically addressed those issues. However, the work group did recommend that the regulations be amended to incorporate the Guidelines for Perinatal Care issued by the American Academy of Pediatrics and the American College of Obstetrics and Gynecology (Guidelines). Additionally, the work group recommended that, throughout the regulations, the term "newborn" be replaced with "neonatal," as this reflects current usage and terminology.

Under the proposed amendments, the regulations distinguish between the levels and types of care provided in "neonatal care units" and "neonatal intensive care units." Under § 139.12 (relating to neonatal care units), all hospitals that provide maternity services must also have a neonatal care unit with areas for newborn recovery, observation and isolation. Hospitals must follow the Guidelines in determination of the appropriate standards applicable for staffing, equipment and other areas for neonatal care units.

The term "neonatal intensive care unit" replaces the former designation of "special care nursery" to describe those areas in hospitals which are specifically equipped and staffed for the care and treatment of high-risk infants and those neonatals otherwise in need of intensive care. Under present § 139.12(d) (proposed as new subsection (c)), neonatal intensive care units must meet the standards established in the Guidelines for these types of units. Those hospitals which provide maternity services but do not have a neonatal intensive care unit, must have arrangements for referrals with a hospital which does possess a unit.

Section 139.3 (relating to director) provides that all neonatal care units must have a medical director who is either board eligible or board certified. Section 139.22 (relating to physicians' services) requires that a board eligible or board certified physician must be available at all times. Under § 139.2a (relating to definitions), "Board certified" is defined as a licensed physician who has passed an examination and maintained certification in the relevant medical specialty area and/or subspecialty area offered by a medical specialty board recognized by either the American Board of Medical Specialties, the American Osteopathic Association or a foreign equivalent. "Board eligible" is defined as a licensed physician who has completed the necessary requirements to take the examination recognized by one of the aforementioned organiza-

tions and who is within 3 years of attaining eligibility. The work group added these definitions to ensure that the medical director and physicians on call possessed the appropriate skills necessary for the treatment of neonatals.

Chapter 158. Vital Organ Transplantation Services

The work group which reviewed the quality criteria contained in the SHSP found that there was a gap between those criteria and those in the present licensure regulations. Although organ transplantation surgical services are subject to the general hospital regulations, there are no regulations which discuss the specific quality criteria which must be followed by such a program. The work group believed that it was necessary to address these specific quality criteria in the regulations.

The work group noted that organ transplantation is unique in the surgical field in that any program that wishes to obtain organs must participate in the procurement system established by the Organ Procurement and Transplantation Network (OPTN). This network was created for the express purpose of procuring and allocating organs for transplantation. See 42 U.S.C.A. § 274. In addition to this function, the OPTN also establishes membership and medical criteria which must be met by every transplantation program in the United States. The Work Group reviewed the present membership/medical criteria of the OPTN and found it to be detailed and geared to quality assurance and patient safety. The work group recommended that the OPTN standards be incorporated into the Department's regulations.

The work group concluded that a chapter addressing specific quality criteria should be added to the licensure regulations. As current standards of medical practice establish that organ transplantation can be performed safely only in a hospital setting, the work group proposed to add a chapter to the regulations pertaining to general and special hospitals.

The work group also noted that this chapter would only apply to certain organs defined as "vital organs," that is, heart, lung, liver, kidney, pancreas, small bowel. Transplantation issues regarding bone, bone marrow, tissue and eye are not covered by this proposed chapter. The work group recommended that the Department review these types of transplantations and determine if any additional regulations are necessary.

Section 158.1 (relating to principle) would set forth the requirement that all transplantation services shall be provided in hospitals. The work group found that the services, staff and programs immediately available in a hospital are crucial to a transplantation program and that performance of transplantations in hospitals is the prevailing medical practice.

Section 158.2 (relating to definitions) would set forth definitions of terminology used in the proposed amendments. Of primary importance is the distinction between "transplantation center" and "transplantation program." A transplantation center is the entire unit of a hospital which is devoted to the performance of organ transplantations. A transplantation program is the actual surgical program established for the operation of organ transplantation. Each type of organ transplanted constitutes a separate transplantation program.

Section 158.3(b) (relating to scope) would require that each transplantation program shall be a participating member of the OPTN and shall comply with its standards, guidelines and bylaws. This section also requires hospitals that provide transplantation services to make a commitment of resources and planning. Section 158.3(a)(1)—(9) lists a variety of areas in which this commitment must be shown including an identifiable and stable transplant team, adequate support staff and appropriate mechanisms for selection of the patients who will receive transplantations.

Section 158.11 (relating to medical director) would require that the hospital appoint a medical director of transplantation who shall be either a transplantation surgeon or a transplantation physician and who is either certified or eligible for certification by the American Board of Surgery, the American Board of Internal Medicine or an equivalent board. Board eligibility must have been attained within the 3 years previous to appointment to the position of medical director. These requirements will assure that an individual with appropriate knowledge, skills and experience is in charge of the various transplantation programs at a hospital.

Section 158.12 (relating to transplantation) would require that each hospital also employ a transplantation coordinator who shall be certified by the American Board of Transplant Coordinators. This individual will assure that all of the transplantation programs are operating appropriately and will work with the OPTN and other health care facilities in the organ procurement process.

Section 158.13 (relating to medical staff) would establish the requirements for the medical staff. Section 158.13(a) requires that each transplantation program have at least one transplantation surgeon and one transplantation physician on staff. These physicians must meet OPTN standards also. Section 158.13(b) requires that certain supporting medical staff at the transplantation center be available at all times. These include nephrologists, pathologists, anesthesiologists, radiologists, internists and psychiatrists. After some discussion as to whether all of these specialists were needed for every type of transplantation program, the work group agreed that any transplantation program involving a vital organ could require the services of any one or more of these specialties.

Section 158.14 (relating to laboratories) would require that laboratory services shall be on site or immediately accessible. The requirements set forth in this section reflect those present in the current OPTN standards.

Section 158.15 (relating to support services) would require that the hospital maintain or have access to certain support services, including rehabilitation services, social services and counseling. The hospital must also maintain adequately equipped operating rooms, adequate equipment and supplies, intensive care facilities capable of maintaining transplant patients and facilities for acute hemodialysis. Many of these criteria were contained in the SHSP. The work group believed that all of these support services were necessary regardless of the type of organ being transplanted.

Section 158.16 (relating to selection criteria) would require that each transplantation program establish written procedures for selecting transplantation candidates and distributing organs in a fair and equitable manner. The section requires the program to comply with the OPTN criteria. The criteria established by OPTN are detailed and set forth specific qualifications for patient eligibility and selection. This section reinforces the necessity of establishing written patient selection criteria which must take into account the relevant ethical and medical considerations.

Section 158.17 (relating to referrals, hours of operation) would require a transplantation center to accept referrals from all physicians, ensuring that all individuals have an opportunity to be evaluated as a transplantation candidate. This section further provides that all transplantation services must be available at all times. This is of particular importance as an organ which can be transplanted may become available at any time and the organ must be transplanted within a limited period of time to retain its viability.

Section 158.18 (relating to volume of procedures) would address the number of procedures which must be performed by each program. The SHSP set a minimum number of procedures for each type of transplantation program. The standards currently adopted by the OPTN do not require a minimum number of procedures for any transplantation program. Rather, the OPTN looks at the "survivability rate" of each program. By use of a formula accounting for patient mix, severity of medical condition upon occurrence of transplantation and other relevant factors, the OPTN reviews each program to determine if it deviates significantly from the expected survival rate. If a program does deviate in this manner and it cannot be explained through some unique clinical aspect, it will be considered for probation by the OPTN. The Health Care Finance Administration (HCFA), which provides reimbursement for some types of transplantation surgery, does require a minimum number of transplant surgeries for certain types of organs (heart:12 transplants per year; liver: 12 transplants per year; lung: 10 transplants per year) for each transplantation program which attempts to obtain reimbursement from the Medicare program.

After extensive discussion of this issue, the work group believed that the review conducted by the OPTN was probably the best method of analyzing the success of a transplantation program. However, the work group also felt that the minimum procedures established by HCFA were not unreasonable. Therefore, § 158.18(a) provides that each transplantation program must perform an adequate number of procedures to maximize quality. Section 158.18(b) provides that a program must perform the number of procedures required by either HCFA or OPTN where those standards exist. Thus, a HCFA participant is expected to perform the minimum number of transplantations established by that agency. Finally, § 158.18(c) provides that failure to meet the standards set forth in subsection (c) shall cause the Department to review the transplantation program and determine its compliance with other quality assurance criteria. These provisions will provide the Department with the flexibility of reviewing a program: (1) at any time if there are concerns that the low number of transplantations performed is negatively affecting quality outcomes; and (2) if the program fails to meet the HCFA minimums or the OPTN survivability rate.

Section 158.19 (relating to post-transplantation care) would require that the hospital maintain an extensive post-transplantation care program which shall last throughout the recipient's life. This standard is adopted from the OPTN and is a recognition that transplantation recipients require constant and extensive follow-up monitoring and treatment. It is the responsibility of the program that performed the transplantation to assure that this treatment is provided.

Sections 158.31—158.35 would set forth supplementary criteria for the various transplantation programs. Each of these sections addresses a transplantation program for a specific vital organ (§ 158.31=kidney, § 158.32=heart, § 158.33=liver, § 158.34=lung, heart/lung, § 158.35=pancreas). Each of these sections contains criteria relating to specific staffing or support services which must be present on site in order for the hospital to maintain one of these transplantation programs.

Section 158.36 (relating to other organs) states that any transplantation program involving organs not covered in §§ 158.31—158.35, must comply with specific criteria of the OPTN applicable to these organs.

Finally, § 158.37 (relating to pediatric transplantation programs) would set forth supplementary criteria which apply to any pediatric transplantation program. Section 158.37(b) provides that where the pediatric transplantation criteria differ from the general transplantation criteria, any hospital which provides pediatric transplantation must follow the pediatric criteria when transplants are performed on infants and children. The remainder of Section 158.37 details the specific staff and support services necessary for a pediatric transplantation program. The common element of these criteria is that certification or training is required in treating pediatric patients. This reflects the concern of the Work Group that children be considered as a group requiring individualized and specialized treatment, and not simply as "little adults."

Fiscal Impact

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

The proposed amendments to the Department's licensure regulations will impose additional costs on health care providers to some degree. Most of the proposed regulations 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 that 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 proposed amendments will not eliminate

all of the costs which health care facilities experienced under CON, the overall effect should be a reduced fiscal impact.

Paperwork Requirements

The Department will experience some increase in paperwork related to reviews in processing licensure requests and additional regulatory requirements. 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, in order 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 proposed amendments will become effective upon final publication in the *Pennsylvania Bulletin*.

Statutory Authority

Section 803(2) of the act (35 P. S. § 448.803(2)) authorizes the Department to promulgate, after consultation with the Health Policy Board, regulations necessary to carry out the purposes and provisions of the act. Section 801.1 of the act (35 P. S. § 448.801a) provides that a purpose of the act is to promote the public health and welfare through the establishment of regulations setting minimum standards for the operation of health care facilities. The same section provides that the minimum standards are to assure safe, adequate and efficient facilities and services, and are also to promote the health, safety and adequate care of patients or residents of these facilities.

These provisions, in combination with the Department's express authority under the definition of "health care facility" in section 802.1 of the act 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.

Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on May 21, 1997, a copy of the proposed amendments was submitted to the Independent Regulatory Review Commission (IRRC) and to the Chairpersons of the House Committee on Health and Human Services and the Senate Committee on Public Health and Welfare. In addition to submitting the proposed amendments, the Department has provided IRRC and the Committees with a copy of a detailed Regulatory Analysis Form prepared by the Department in compliance with Executive Order 1996-1, "Regulatory Review and Promulgation." A copy of this material is available to the public upon request.

If IRRC has objections to any portion of the proposed amendments, it will notify the Department within 30 days of the close of the public comment period. The notification shall specify the regulatory review criteria which have not been met by that portion. The Regulatory Review Act specifies detailed procedures for review prior to final publication of the regulation, by the Department, the General Assembly and the Governor, of objections raised.

Contact Person

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

DANIEL F. HOFFMAN,
Secretary

Fiscal Note: 10-148. (1) General Fund;

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

(4) Fiscal Year 1995-96 $1.9 million; Fiscal Year 1994-95 $1.5 million; Fiscal Year 1993-94 $1.2 million; (7) General Government Operations; (8) recommends adoption.

(*Editor's Note*: Chapters 51, 136, 138 and 159 are new. They have printed in regular type to enhance readability. Chapter 139 exists and appears with brackets and bold face to show changes.)

Annex A

TITLE 28. HEALTH AND SAFETY

PART IV. HEALTH FACILITIES

Subpart A. GENERAL PROVISIONS

CHAPTER 51. GENERAL INFORMATION

GENERAL PROVISIONS

Sec.

CIVIL RIGHTS

GENERAL PROVISIONS

§ 51.1. Legal base, scope and definitions.

(a) This subpart implements the act (35 P. S. §§ 448.101—448.904b).

(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 closely 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 30 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 30 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 30 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 notify the Department in writing at least 30 days prior to the initiation of the design phase of any proposed new construction, alteration or renovation to the facility.

(e) If a health care facility is in possession 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, 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 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) 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.

(h) 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 any 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 90 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 persons responsible for the day to day operation of the health care facility change.

§ 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) The Department will conduct an onsite survey of the new or remodeled part of a health care facility prior to granting approval for occupancy.

(c) A health care facility shall request a preoccupancy survey at least 2 weeks 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 orally. If oral authorization for occupancy is given, the Department will provide the health care facility with written confirmation of the oral authorization within 30 days.

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) Copies of signed and dated annual notification to physicians, social workers and others who normally refer patients or residents of the health care facility's nondiscrimination policy.

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

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

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

(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 in this part 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.

§ 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 any 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) If the Department proposes to approve an exception, it may request public comment on the exception by notice in the *Pennsylvania Bulletin*.

(d) 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 good 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.

Subpart [A] B. GENERAL AND SPECIAL HOSPITALS

CHAPTER 136. OPEN HEART SURGICAL SERVICES

GENERAL PROVISIONS

PROGRAM, SERVICE AND PERSONNEL REQUIREMENTS

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).

Board eligible—A physician licensed to practice medicine in this Commonwealth who has completed the preliminary 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 is presently eligible to take the examination and is within 3 years of attaining eligibility.

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.

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 whose physical development precludes them from being handled as an adult when receiving these procedures.

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.

The Director of the open heart surgery program shall be a Board certified surgeon whose training emphasized cardiac surgery.

§ 136.12. Medical staff.

Supporting medical staff of the service shall include:

(1) Board certified or Board eligible surgeons whose training emphasized cardiac surgery. There shall be a sufficient number of surgeons within the service to allow for 24-hour-per-day continuous coverage. In a pediatric service, these surgeons shall have expertise in the special problems of pediatric patients.

(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.

(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, where 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.

§ 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 have training, experience, and, preferably, certification in the techniques of cardiopulmonary bypass. The perfusionist's duties shall include the operation of the extracorporeal pump oxygenator (heart-lung machine) in accordance with the requirements of the operating surgeon. 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 shall be 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, available.

(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) Emergency department, staffed onsite with an advanced cardiac life support certified physician.

(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 should 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 open heart surgery—supplementary criteria.

(a) A hospital which provides pediatric open 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 open 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) Staff, including nurses and technicians, responsible for care of the pediatric patient shall have experience and training in pediatrics. Specialty staff shall include cardiac surgeons, anesthesiologists and cardiologists who have special training and experience in the care of the pediatric patient and shall be available 24 hours per day.

§ 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 (stroke, deep sternal wound, bleeding requiring reoperation, length of stay, and the like).

(3) Patient risk factors (age, medical history, and the like).

(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) 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. The Department will publish, by statement of policy, the values or standards, or both, for each of the factors reported to the Department.

(d) 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.

PROGRAM, SERVICE, PERSONNEL AND AGREEMENT REQUIREMENTS

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.

EPS—Electrophysiology study—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.

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 reopen collapsed, blocked or partially blocked arteries.

Pediatric cardiac catheterization—The performance of cardiac catheterization on a person who is younger than 18 years of age and whose physical development precludes that person from being handled as an adult when receiving the procedure.

Therapeutic electrophysiology—EPS used as or in combination with a therapeutic procedure, which includes procedures designed to induce ventricular or supraventricular tachycardia; activation sequence mapping of cardiac tachyarrhythmias; electrode catheter ablative procedures; and implantation of antitachyarrhytmia devices and implantable cardiovertor defibrillators.

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.

The director of the cardiac catheterization service shall be Board certified in cardiology or pediatric cardiology.

§ 138.12. Medical staff.

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

(b) These physicians shall have graduated from an accredited training program in cardiac catheterization or have demonstrated training and experience acceptable to the credentialling committee of the hospital.

§ 138.13. Nursing staff.

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

(b) Other nursing personnel shall include nurses with specialized education which includes theory, advanced technical skills and supervised experience in a cardiac catheterization service before assuming primary responsibility for the nursing care of cardiac catheterization patients.

(c) There shall be nursing service goals and objectives, standards of nursing practice, procedure manuals and written job descriptions for each level of personnel which includes 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.

§ 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 hospital's party to the agreement, and between their sending and receiving physicians.

(5) A provision prohibiting the hospital receiving the transferred patient from duplicating the diagnostic cardiac catheterization unless clinically appropriate.

(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 have graduated from an accredited training program in PTCA or have demonstrated training and experience acceptable to the credentialling committee of the hospital.

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

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

§ 138.18. EPS.

(a) In a hospital in which EPS is performed, each physician performing EPS shall have graduated from an accredited training program in electrophysiology or have demonstrated training and experience acceptable to the credentialling committee of the hospital.

(b) Therapeutic electrophysiology, including ablation and the implantation of automatic implantable cardiover-

tor defibrillators shall be performed in a hospital with an open heart surgery program, and not in any other 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 (stroke rate, rate of myocardial infarction, vascular complications, length of stay, rate of emergency bypass surgery for PTCA, and the like).

(3) Patient risk factors (age, medical history, and the like).

(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 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) 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. The Department will publish, by statement of policy, the values or standards, or both, for each of the factors reported to the Department.

(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. **[NEWBORN] NEONATAL** SERVICES

GENERAL PROVISIONS

§ 139.1. Principle.

When a hospital provides **[newborn] neonatal** services, they shall be provided in **[such]** a manner **[as to meet] that meets** the medical needs of the newborns.

§ 139.2. Scope.

This chapter applies to hospitals which provide obstetrical or **[newborn] 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, offered by one of the following groups:**

(i) The American Board of Medical Specialists.

(ii) The American Osteopathic Association.

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

***Board eligibility* or *board eligible*—A physician licensed to practice medicine in this Commonwealth who has completed the preliminary requirements necessary to take an examination by the American Board of Medical Specialists, the American Osteopathic Association or the foreign equivalent of either group and who is presently eligibile to take the examination and is within 3 years of attaining eligibility.**

***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.**

§ 139.3. Director.

A member of the medical staff shall be appointed director of **[newborn] neonatal** services. **[He] The director** shall be certified by the American Board of Pediatrics or an equivalent board, eligible for Board certification or have successfully completed an approved residency in pediatrics.

§ 139.4. Nursing services.

(a) **[Newborn] Neonatal** nursing services shall be provided in accordance with Chapter 109 (relating to nursing services) and **[the provisions of]** this section.

(b) A registered professional nurse, especially trained and experienced in the care of normal and high-risk infants,**[shall be designated as the nursing supervisor of the nurseries. At least one registered professional nurse shall be on duty in at least one nursery at all times when any nursery is occupied] shall be responsible for the neonatal care unit at all times when the unit is occupied.** No **[occupied nursery] newborn** shall be left unattended.

(c) **[All nursery personnel shall have education and nursing skills which are appropriate to their duties and assignments] 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) **[A sufficient number of nursing personnel shall be on duty at all times to provide adequate infant care in all nurseries.] 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 **[newborn] neonatal** service and shall be **[based on current recommendations of the American Academy of Pediatrics] consistent with the Guidelines**.

FACILITIES

§ 139.11. Facilities and equipment.

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

§ 139.12. **[Nursery] Neonatal care** units.

(a) **[All hospitals] Hospitals** with maternity services shall provide **[well infant nurseries] neonatal care units** with areas for newborn recovery, observation**[,]** and isolation and provisions or arrangements for the care of high-risk infants in a **["special care nursery,"] neonatal intensive care unit** either at the facility of birth or at a transfer site. Space allocation and total number of bassinets **[should conform to the current recommendation of the American Academy of Pediatrics] shall be consistent with the Guidelines.**

[(b) Well newborn infants delivered within the hospital may be admitted directly to the infant nursery. The term "well infant nursery" shall mean a nursery for the care of well newborn infants.

(c)] (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 any 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 **[nursery]** nursing personnel **and shall meet the standards established in the Guidelines for this type of care.**

[(d)] (c) A **[special care nursery] 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 **[must] shall** be made with **[a "transfer nursery"] 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 newborn period, manifests or is likely to manifest persistent and significant signs of distress. This **[includes but is not limited to the following] may include**:

* * * * *

[(e) A "transfer nursery," as used in subsection (d), is a special care nursery staffed and equipped to receive and provide appropriate care to infants transferred from the facility of birth for specialized diagnostic and treatment services. All requirements in this chapter for special care nurseries also apply to transfer nurseries.]

§ 139.13. **[Nursery equipment] 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 **[newborn] neonatal** service which shall be **[based upon current recommendations of the American Academy of Pediatrics] 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 **[nursery] neonatal care unit** shall have its own wash basin 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) **[Special care nurseries] Neonatal intensive care units** shall be equipped with all equipment and supplies required for other **[nurseries] 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 **[American Academy of Pediatrics] Guidelines.**

§ 139.15. Temperature control.

A stable year-round temperature and humidity shall be maintained in all **[nurseries] neonatal care units** in accordance with written newborn service policies consistent with **[current recommendations of the American Academy of Pediatrics] the Guidelines.**

§ 139.16. Housekeeping and maintenance.

The **[nursery service] 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. **[Special care nurseries] Neonatal intensive care units (Levels II and III).**

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

(1) The construction and arrangement of the **[special care nursery] neonatal intensive care unit** shall permit personnel to observe the infants and have immediate access to them. Total **[nursery] neonatal care unit** space, exclusive of anteroom, shall provide adequate floor space consistent with the **[current recommendations of the American Academy of Pediatrics] the Guidelines.**

(2) Each infant requiring heat or air control, or both, shall have **[his own] a separate** incubator or other warming device and **[his own] 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.

* * * * *

(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**[nursery] unit** shall be on the emergency electrical circuit of the hospital and shall be so marked.

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

(6) Air within **[special care nurseries shall] 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 **[newborn] neonatal** services shall be responsible for developing written policies and procedures for **[nursery] 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 **[the requirements of]** §§ 139.22—139.29 **[of this title (relating to policies)]**.

§ 139.22. Physicians' services.

(a) **[A physician on-call schedule shall be posted in the nursery to ensure that] There shall be** a physician **[is]** available at all times. **This physician shall be certified by the American Board of Pediatrics or an equivalent board, eligible for Board certification, or have successfully completed an approved residency in pediatrics.**

(b) **[All newborn] Newborn** infants shall have a complete physical examination **[by a physician or his authorized delegate in the delivery room and also within 24 hours after admission to the nursery], 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.

* * * * *

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

§ 139.23. Delivery suite services.

* * * * *

(b) The director of obstetrics and the director of **[newborn] neonatal** services shall formulate policies and procedures for delivery room care of infants **[which are consistent with the recommendations of the nursery committee]**. 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 **[in charge of the nursery] responsible for the provision of nursing services in the neonatal care unit** when the delivery of a potentially high-risk infant is expected.

* * * * *

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

(9) The record of the newborn infant to accompany **[him] the infant** from the place of delivery to the **[nursery] neonatal care unit** and be immediately available to **[nursery] 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. **[Special care nurseries] Neonatal intensive care units (Levels II and III).**

(a) In hospitals with **[special care nurseries] neonatal intensive care units,** the director of the **[newborn] neonatal** services **[and the nursery committee]** shall develop written policies and procedures regarding admission of infants to **[special care nurseries] neonatal intensive care units.**

(b) Policies for **[special care nurseries shall] neonatal intensive care units** include:

(1) **[requirements] Requirements**, in accordance with the **[current recommendations of the Academy of Pediatrics] Guidelines,** for staffing of **[special**

care nurseries] neonatal intensive care units. In addition, **[transfer and special care nurseries] 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] A** requirement that a pediatrician designated by the director of the **[newborn] neonatal** services shall be on call 24 hours a day.

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

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

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

(6) **[a] A** definite written policy, developed by the **[nursery committee] director of neonatal services**, which provides for the unique problems involved in the total care of infants in **[special care nurseries] 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 **[newborn] neonatal** services **[and the nursery committee] through the hospital's infection control program** shall establish procedures for the control of infection, governing **[such]** matters **such** as **[nursery] appropriate** attire, isolation, and cleaning of equipment **in the neonatal care unit.** Infection control procedures for **[newborn] neonatal** services may be included among the responsibilities of the committee established **[pursuant to § 147.21 (relating to infection control)] 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] Prohibit** common or group carriers for transporting infants to their mothers**[; and]**.

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

(c) **[Consideration shall be given to the current recommendations of the American Academy of Pediatrics] The infection control standards shall be consistent with the current Guidelines.**

§ 139.26. Care given by parents.

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

* * * * *

§ 139.27. Laboratory services and radiological services.

* * * * *

(d) A hospital in which a **[special care nursery] neonatal intensive care unit** is located shall have a licensed blood bank, available or on call to the **[nursery] unit** on a 24-hour-a-day, **[seven] 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 **[newborn] neonatal** record if the entire maternal records are not maintained as the **[newborn] neonatal** records **[as set forth]** in § 115.23(b) (relating to preservation of medical records):

* * * * *

(9) Condition of infant at birth, including the **[one] 1**-and **[five] 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 **[nursery] neonatal care unit.**

* * * * *

§ 139.29. Infant nursing records.

Upon admission to a **[nursery] 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.

[FORMULA] NUTRITIONAL SERVICES

§ 139.31. Policies and procedures.

Written policies and procedures for infant feeding **[and formula preparation, if appropriate,]** shall be established and shall be available to the medical and nursing staffs.

§ 139.32. Commercial formula.

Precautions **[must] shall** be taken to prevent the contamination and expiration of commercial formulas.

§ 139.33. Formula preparation.

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

* * * * *

§ 139.34. Breastfeeding.

Management of breastfeeding mothers and infants shall be **[in accordance with current recommendations of the American Academy of Pediatrics] consistent with the Guidelines.**

CHAPTER 158. VITAL ORGAN TRANSPLANTATION SERVICES

GENERAL PROVISIONS

Sec.

PROGRAM, SERVICE AND PERSONNEL REQUIREMENTS

SUPPLEMENTARY CRITERIA

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).

Board eligible—A physician licensed to practice medicine in this Commonwealth who has completed the preliminary 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 is within 3 years of attaining eligibility to take the examination.

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.

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 teams 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.

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 or who has become Board eligible within the previous 3 years.

§ 158.12. Transplantation coordinator.

Each transplantation center shall have onsite on a full time basis a transplantation coordinator. The transplantation coordinator shall be certified by the American Board of Transplant Coordinators.

§ 158.13. Medical staff.

(a) Each transplantation program shall have at least one transplantation surgeon and one transplantation physician who are 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 certified or eligible for certification in nephrology by 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 certified or eligible for certification by 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 certified or eligible for certification by 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 currently certified or eligible for certification in psychiatry by 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. 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.

§ 158.15. 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 all of 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.

§ 158.16. 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.

§ 158.17. 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.

§ 158.18. Volume of procedures.

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

(b) Where standards exist, the transplantation program shall perform the number of procedures required by either the Health Care Finance Administration or the Organ Procurement Transplantation Network.

(c) Failure to meet the standards in subsection (b) shall cause the Department to review the transplantation program and to determine its compliance with other quality assurance criteria.

§ 158.19. 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 and.

(4) An obligation to follow the patient at appropriate intervals to assess the outcome of the transplant and to provide any 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 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 certified or eligible for certification by 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 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 certified or are eligible for certification by 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 in order 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 certified or eligible for certification by 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 §§ 158.1—158.19 apply to lung and heart/lung transplantation programs. Additionally, the criteria contained in this section shall 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 certified or eligible for certification by 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 shall apply 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 when 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 certified or are eligible for certification by 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 certified or eligible for certification by 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 certified or eligible for certification by 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 certified or eligible to be certified by 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 certified or eligible to be certified by 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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