

RULES AND REGULATIONS
FOR THE LICENSURE OF
PHYSICIAN OFFICE SETTINGS
PROVIDING SURGICAL TREATMENTS
(R23-17-POSPST)

STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS

DEPARTMENT OF HEALTH

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the provisions of section 42-35-4.1 of the
Rhode Island General Laws, as amended)**

INTRODUCTION

These *Rules and Regulations for the Licensure of Physician Office Settings Providing Surgical Treatments (R23-17-POSPST)* are promulgated pursuant to the authority conferred under section 23-17-10 of the General Laws of Rhode Island, as amended, and are established for the purpose of adopting minimal standards for the licensure of physician office settings providing surgical treatments in this state.

Pursuant to the provisions of section 42-35-3(c) of the General Laws of Rhode Island, as amended, the following were given consideration in arriving at the regulations: (1) alternative approaches to the regulations; (2) duplication or overlap with other state regulations; and (3) significant economic impact placed on facilities through these regulations. No alternative approach was identified. Furthermore, the protection of the health, safety and welfare of the public necessitates the adoption of these regulations, despite the economic impact that may be incurred as a result of the regulations.

These rules and regulations shall supersede any previous rules and regulations pertaining to the licensure of physician office settings providing surgical treatments promulgated by the Department of Health and filed with the Secretary of State.

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PART I **DEFINITIONS AND LICENSURE PROCEDURES**

Section 1.0 **Definitions**

Wherever used in these rules and regulations the following terms shall be construed as follows:

- 1.1 **"Accreditation agency"** means an entity, approved by the Director, which grants accreditation to physician office settings providing surgical treatment. Accreditation agencies approved by the Director include: the Joint Commission on Accreditation of Healthcare Organizations, the American Association for Accreditation of Ambulatory Surgery Facilities, Inc., and the Accreditation Association for Ambulatory Health Care, Inc.
- 1.2 **"Anesthesiologist"** means a physician licensed in Rhode Island who is board certified, or becoming so, in anesthesia and has privileges to administer anesthesia in a Rhode Island licensed health care facility.
- 1.3 **"Certified registered nurse anesthetist"** means a registered nurse who has successfully met the requirements for licensure which are set forth in the *Rules and Regulations for the Licensing of Professional (Registered), Certified Registered Nurse Practitioners, Certified Registered Nurse Anesthetists, and Practical Nurses and Standards for the Approval of Basic Nursing Education Programs* of reference 17 herein.
- 1.4 **"The practice of certified registered nurse anesthesia"** means providing certain health care services under the supervision of anesthesiologists, licensed physicians, or licensed dentists, in accordance with section 5-31.1-1(g) of the Rhode Island General Laws, as amended, which requires substantial specialized knowledge, judgement and skill related to the administration of anesthesia, including pre-operative and post-operative assessment of patients; administration of anesthetics; monitoring patients during anesthesia; management of fluid in intravenous therapy and respiratory care.
- 1.5 **"Conscious sedation"** means a drug-induced depression of consciousness during which patients respond purposefully (reflex withdrawal from a painful stimulus is *not* considered a purposeful response) to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.
- 1.6 **"Director"** means the Director of the Rhode Island Department of Health.
- 1.7 **"Employee"**, as used in section 2.3 herein, means an individual who is required to comply with instructions about when, where, and how to work, both as to the final results and as to the details of when, where, and how the work is to be done. The employer need not actually exercise this control; it is sufficient that he has the right to do so. When the employer does not possess this control, the individual involved is not an employee, but an independent contractor.

1.8 **"Exempt procedures"** means:

- a) Minor surgical procedures such as excision of skin lesions, moles, warts, lipomas and repair of lacerations, incision and drainage of superficial abscesses, or surgery limited to the skin and subcutaneous tissue performed under topical or local anesthesia not involving drug induced alteration of consciousness other than minimal pre-operative tranquilization of the patient;
- b) Procedures not requiring or using conscious sedation techniques or pre-operative medications other than minimal pre-operative tranquilization of the patient;
- c) Procedures requiring or using only local, topical, or no anesthesia.

1.9 **"General anesthesia"** means a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

1.10 **"The licensed capacity"** of the office operatory means the number of operating/procedure rooms that the office operatory is licensed to operate.

1.11 **"Licensing agency"** or **"state agency"** means the Rhode Island Department of Health.

1.12 **"Local anesthesia"** means the injection of a local anesthetic agent (e.g., Lidocaine) into and around the operative site to achieve numbness in the area where a painful procedure is to be performed. This type of anesthesia does not involve any systemic sedation.

1.13 **"Operating room** or **procedure room"** means the area of the office operatory wherein a surgical treatment is performed.

1.14 **"Person"** means any individual, trust or estate, partnership, corporation (including associations, joint stock companies), limited liability company, state, or political subdivisions or instrumentality of a state.

1.15 **"Physician"** means a person licensed to practice allopathic or osteopathic medicine in this state, pursuant to the provisions of Chapter 5-37 of the General Laws of Rhode Island, as amended.

1.16 **"Physician office setting providing surgical treatment"**, hereinafter referred to as "office operatory", means an office or portion thereof owned and/or operated by a physician-controlled professional services corporation as defined in Chapter 5.1 of Title 7, as amended (the "Professional Service Corporation Law"), or a private physician's office or group of physicians' offices (whether owned and/or operated by an individual practitioner, alone or as a member of a partnership, professional service corporation, organization, or association) which is utilized for the purpose of furnishing surgical services to said owner and/or operator's own patients on an ambulatory basis.

- 1.17 **"Regional anesthesia"** means the use of local anesthetic agents to block nerves leading to the area where a painful procedure is to be done. There are many examples of regional anesthesia, including, but not limited to, spinal, interscalene, ankle, etc. Generally, regional anesthesia involves more of a physiological reaction because of the larger area blocked and/or the dose of local anesthesia. This type of anesthesia may or may not involve sedation.
- 1.18 **"Registered nurse"** means a person licensed under the provisions of Chapter 5-34 of the Rhode Island General Laws, as amended, and the regulations adopted thereunder.
- 1.19 **"Surgery"** means the excision or resection partial/complete, destruction, incision or other structural alteration of human tissue by any means. Surgery shall have the same meaning as **"operate."**

Section 2.0 ***General Requirements for Licensure***

- 2.1 On or after January 1, 2001, no person acting severally or jointly with any other person, shall establish, conduct or maintain an office operatory in this state without a license in accordance with the requirements of section 23-17-4 of reference 1. Office operatory licensure shall not be required for the performance of exempt procedures as defined in section 1.8 herein.
- 2.2 In accordance with reference 10, a certificate of need is not required as a precondition to the establishment of an office operatory. Initial licensure and/or changes in owner, operator or lessee of an office operatory are subject to approval of the licensing agency.
- 2.3 Surgery provided within the office operatory shall be provided solely by physicians who are or who comprise, or are employees of, the person to whom the license is issued.

Section 3.0 ***Application for License***

- 3.1 Application for a license to conduct, maintain or operate an office operatory shall be made to the licensing agency upon forms provided by it one (1) month prior to expiration date of license and shall contain such information as the licensing agency reasonably requires which may include affirmative evidence of ability to comply with the provisions of reference 1 and the rules and regulations herein.
- 3.1.1 Each application shall be accompanied by a non-refundable application fee of five hundred dollars (\$500), made payable by check or money order to the Rhode Island General Treasurer.
- 3.2 A notarized listing of names and addresses of direct and indirect owners whether individual, partnership or corporation with percentages of ownership designated shall be provided with the application for licensure and shall be updated upon any change to such ownership information.
- 3.2.1 The licensing agency shall be informed forthwith of any change in owner of a licensed office operatory.

Section 4.0 ***Issuance and Renewal of License***

4.1 Upon receipt of an application for a license, the licensing agency shall issue a license or renewal thereof for a period of no more than one (1) year if the applicant meets the requirements of reference 1 and the rules and regulations herein. Said license, unless sooner suspended or revoked, shall expire by limitation on the 31st day of December beginning in the year 2001 and may be renewed from year to year after inspection and approval by the licensing agency.

4.1.1 All renewal applications shall be accompanied by a non-refundable application fee of five hundred dollars (\$500) made payable by check or money order to the Rhode Island General Treasurer.

4.2 A license shall be issued to a specific licensee for a specific location and shall not be transferable.

4.3 A license issued hereunder shall be the property of the state loaned to such licensee and it shall be kept posted in a conspicuous place on the licensed premises.

Section 5.0 ***Capacity***

5.1 The license for an office operator shall be issued for a specified number of operating/procedure rooms.

5.2 The post-surgical recovery area of a office operator shall be adequate to meet patients' needs.

Section 6.0 ***Inspections***

6.1 The licensing agency shall make or cause to be made such inspections and investigations as it deems necessary and in accordance with section 23-17-10 of reference 1 and the rules and regulations herein.

6.1.1 Within nine (9) months of initial licensure, the office operator shall file an acceptable application with an accreditation agency, as defined in section 1.1 herein.

6.1.2 Within twenty four (24) months of initial licensure, the office operator shall attain appropriate certification from an accreditation agency, as defined in section 1.1 herein.

6.1.3 Each office operator, having obtained accreditation pursuant to subsection 6.1.2, shall maintain such certification as a condition of licensure.

6.1.4 The office operator shall provide the state agency with complete copies of all correspondence received from or mailed to any accreditation agency related to certification from the accreditation agency. Said copies shall be supplied to the state agency within three (3) days of receipt or mailing of the correspondence.

- 6.2 Every office operator shall be given prompt notice by the licensing agency of any deficiencies reported as a result of an inspection or investigation.
- 6.3 Written reports and recommendations of inspections, including such materials from the state agency and the accreditation agency, shall be maintained on file in each office operator for a period of no less than three (3) years. Office operator plans for the correction of identified deficiencies shall also be maintained on file for a period of no less than three (3) years.
- 6.4 All materials required pursuant to section 6.0 shall be deemed to be public records and shall be made available by the office operator to members of the public on request.

Section 7.0 ***Denial, Suspension, Revocation of License or Curtailment of Activities***

- 7.1 The licensing agency is authorized to deny, suspend or revoke the license or curtail activities of any office operator which: (1) has failed to comply with the rules and regulations pertaining to the licensing of office operator; and (2) has failed to comply with the provisions of reference 1.
 - a) Lists of deficiencies noted in inspections conducted in accordance with section 6.0 herein shall be maintained on file in the licensing agency, and shall be considered by the licensing agency in rendering determinations to deny, suspend or revoke the license or to curtail activities of an office operator.
- 7.2 Where the licensing agency deems that operation of an office operator results in undue hardship to patients as a result of deficiencies, the licensing agency is authorized to deny licensure to an office operator not previously licensed, or to suspend for a stipulated period of time or revoke the license of an office operator already licensed or curtail activities of the office operator.
- 7.3 Whenever an action shall be proposed to deny, suspend or revoke an office operator license, or curtail its activities, the licensing agency shall notify the office operator by certified mail, setting forth reasons for the proposed action, and the applicant or licensee shall be given an opportunity for a prompt and fair hearing in accordance with section 23-17-8 of reference 1 and section 42-35-9 of reference 2.
- 7.4 However, if the licensing agency finds that public health, safety or welfare imperatively requires emergency action and incorporates a finding to that effect in its order, the licensing agency may order summary suspension of license or curtailment of activities pending proceedings for revocation or other action in accordance with section 23-1-21 of reference 5 and section 42-35-14(c) of reference 2.
- 7.5 The appropriate state and federal placement and reimbursement agencies and the relevant accreditation agency(ies) shall be notified of any action taken by the licensing agency pertaining to denial, suspension or revocation of license, or curtailment of activities.

PART II ***ORGANIZATION AND MANAGEMENT***

Section 8.0 ***Control and Management***

- 8.1 Each office operatory shall be responsible for: (1) the management and control of the operation; (2) the assurance of the quality of care and services; (3) the conformity of the office operatory with all federal, state and local laws and regulations relating to fire, safety, sanitation, infection control; and (4) other relevant health and safety requirements and with all the rules and regulations herein.
- 8.2 The office operatory shall provide appropriate personnel, physical resources, and equipment based on the scope of services provided.
- 8.3 The office operatory shall designate: (a) an administrator who shall be responsible for the management and operation of the office operatory; and (b) a medical director to assure achievement and maintenance of quality standards of professional practice. The administrator and the medical director may be the same individual.
- 8.4 The office operatory shall adopt and maintain policies/procedures defining responsibilities for the operation and performance of the office operatory, identifying purposes and means of fulfilling such, and in addition the policies/procedures shall include but not be limited to:
- a) a statement of qualifications and responsibilities of the medical director and administrator;
 - b) a statement of the office operatory's responsibility for the quality of care and services;
 - c) a statement of office operatory's policy establishing the criteria for the selection and admission of patients;
 - d) such other matters as may be relevant to the organization of the office operatory.
- 8.5 All policies and procedures adopted by the office operatory shall be reviewed annually.

Section 9.0 ***Personnel Requirements***

- 9.1 The appointment of all personnel shall be documented in writing. The job description of each member of the office operatory shall be documented in writing and shall include directives related to responsibilities and discipline.
- 9.2 A timely written performance evaluation shall be required for all employees.
- 9.3 The number and type of registered nurses and ancillary personnel shall be based on the scope of services provided and staff capabilities, to ensure direct patient care as needed throughout the period

of the patient's stay. All personnel, such as nurses, shall be licensed as required by the Rhode Island General Laws, as amended.

- 9.4 The office operator shall make initial appointments, and assignment or curtailment of surgical privileges, based on the education, training, experience and evidence of competence of the licensed professional staff person providing surgical services, consistent with state law. (See also section 19.2).
- 9.5 The office operator shall clearly define in writing the responsibilities and supervision of any student personnel utilized in the office operator.
- 9.6 The office operator shall adhere to a written procedure for granting and renewing privileges for anesthesiologists or certified registered nurse anesthetists that specifies the required training, experience, board certification, and/or other factors that indicate acceptable proficiency.
- 9.7 An office operator shall require all persons, including students, who examine, observe, or treat a patient of such office operator to wear photo identification badge which states, in a reasonably legible manner, the first name, licensure/registration status, if any, and staff position of such person.
- 9.8 All surgical personnel, pre-operative, and recovery personnel shall be trained in basic life support (CPR) at least every two (2) years.
- 9.9 All surgical personnel shall be trained in basic aseptic techniques.
- 9.10 All surgical personnel shall wear suitable attire.

Administrator

- 9.11 The office operator shall appoint a qualified administrator who may be the medical director, who shall be responsible for: (1) the management and operation of the office operator; (2) the enforcement of policies, rules and regulations and statutory provisions pertaining to the health and safety of patients; (3) serving as liaison between the office operator and the staff; and (4) the planning, organizing and directing of such other activities as may be delegated by the office operator.

Medical Director

- 9.12 The surgical services of the office operator shall be under the direction of a physician licensed under the provisions of Chapter 5-37 of the Rhode Island General Laws, as amended, who meets the qualifications set forth by the office operator in accordance with section 8.0 herein, and who shall be responsible for no less than the following.
 - a) the coordination, supervision and functioning of services;
 - b) the establishment of provisions for infection control;

- c) the achievement and maintenance of quality assurance of professional practices through a mechanism of peer review acceptable to the Director; and
- d) the establishment of policies and procedures for surgical and anesthesia services and other related health care services.

Health Requirements

- 9.13 The office operator shall establish written policies or protocols that require appropriate employee health examinations, screenings or testing to control communicable diseases. The necessity of these employee health screenings shall be determined by the office operator to document that employees are physically able to perform their duties and show no evidence of communicable disease.

Blood Borne pathogens:

- 9.14 The office operator shall abide by the OSHA *Blood borne Pathogens Standard* (29 CFR 1910-1030), including the offering of hepatitis B vaccination along with all recommendations for infection control training and provision of protective equipment to those employees at risk.

- 9.14.1 An exposure control plan shall be in place in all health care facilities licensed by the Department of Health, pursuant to the provisions of Chapter 23-17 of the General Laws.

Section 10.0 *Quality Assurance*

- 10.1 The office operator shall establish a formal mechanism for quality assurance for all surgical services provided by all physicians performing surgical procedures in the office operator. The quality assurance mechanism shall be in accordance with the requirements established by the accreditation agency.

Section 11.0 *Peer Review*

- 11.1 An organized process of peer review shall be conducted in accordance with the requirements of the accreditation agency. At a minimum, peer review shall provide for:
- a) regular review of reportable events (see section 17.5 herein) with formal determination of strategies to improve outcomes and assessment of change accomplished; and
 - b) formal review of credentials and privileges of all surgeons, certified registered nurse anesthetists, and anesthesiologists.
- 11.2 Medical peer review shall be conducted in accordance with sections 5-37-1 (10)(a) and (b) of the Rhode Island General Laws, as amended, and subject to the confidentiality provisions of section 5-37.3-7 of the Rhode Island General Laws, as amended.

Section 12.0 ***Administrative Records***

12.1 Each office operator shall maintain such administrative records as may be deemed necessary for the business operation of the office operator, in addition to the following;

- a) monthly statistical summary of numbers of surgical procedures performed, appropriately classified;
- b) controlled substances register if such are maintained at the office operator;
- c) an operating/procedure room log book maintained in chronological sequence of admissions which shall include pertinent information such as patient's name, pre-op and post-op diagnosis, name of operating physician and person administering anesthesia, circulating nurse, surgical procedures performed, specimen sent for pathological examination, type of anesthesia and complications (if any); and
- d) a record of all transfers to a hospital for post-surgical care.

Section 13.0 ***Disaster Preparedness***

13.1 Each office operator shall develop and maintain a written disaster preparedness plan that shall include specific provisions and procedures for the emergency care of patients in the event of fire, loss of utilities, bomb threat, natural disaster or functional failure of equipment.

- a) Such a plan shall be developed and coordinated with appropriate state and local agencies and representatives concerned with emergency safety and rescue;
- b) A copy of the plan shall be submitted to the licensing agency;
- c) Simulated drills testing the effectiveness of the plan shall be conducted at least semi-annually. Written reports and evaluation of all drills shall be maintained by the office operator and available for review by the licensing agency.

13.2 Emergency action steps shall be clearly outlined and posted in conspicuous locations throughout the office operator.

Section 14.0 ***Uniform Reporting System***

14.1 Each office operator shall establish and maintain records and data in such a manner as to make uniform the system of periodic reporting. The manner in which the requirements of this regulation may be met shall be prescribed from time to time in directives promulgated by the Director.

PART III ***PATIENT CARE SERVICES***

Section 15.0 ***Rights of Patients***

- 15.1 Each office operator shall observe the standards enumerated in section 23-17-19.1 of reference 1 with respect to each patient admitted to its office operator.
- 15.2 Each office operator shall display in a conspicuous place in the licensed office operator a copy of the "Rights of Patients."

Section 16.0 ***Admission, Transfer and Discharge***

- 16.1 Each office operator shall have and implement written admission, transfer and discharge policies and procedures pertaining to at least the following:
- a) types of surgical procedures and conditions acceptable for admission;
 - b) requirements for pre-admission history;
 - c) transfer of patients for continuity of care or emergency care accompanied by the "Rhode Island Department of Health Continuity of Care Short Form" available on-line: **www.health.state.ri.us**;
 - d) Emergency instructions shall be posted at each telephone. The names and telephone numbers to be called in an emergency shall be posted and easily accessible (including, but not limited to, "911", physicians to be called in an emergency, nearest hospital emergency department).
 - e) emergency transfer of patients to the nearest full-service emergency department of an acute care hospital. When indicated, a physician or nurse shall accompany the patient.
 - f) discharge of patient with responsible adult, as indicated;
 - g) constraints imposed by limitations of services, physical facilities; and
 - h) instruction of patients on self-care upon discharge.

Section 17.0 ***Patient Care Management***

- 17.1 Each patient shall be under the continuing supervision of a physician on-site throughout the period of a patient's stay in the office operator.
- 17.2 A physician, registered nurse, physician assistant, advanced practice nurse, or midwife shall care for the patient at all times while in the recovery area.

- 17.3 Each office operatory shall have and implement written patient care management policies and procedures pertaining to at least the following:
- a) scope of services provided either directly or per contractual arrangements;
 - b) criteria for admission, transfer and discharge;
 - c) management of patients with known or suspected infectious diseases, including the exclusion of patients who are known or suspected of having airborne infectious diseases;
 - d) physician services and consultation services;
 - e) staffing plan that delineates the personnel required to be present in the office operatory in order to provide effective safe patient care and all other related services;
 - f) radiology and laboratory services, including the facility's required minimum specific testing; and
 - g) counseling services, if indicated.
- 17.4 All orders for medications or treatments must be in writing. An order is considered to be in writing if: (1) it is written and signed by a lawfully authorized person; or (2) it is dictated to and transcribed by a registered nurse or other appropriately licensed person onto the order form. Additionally, the registered nurse or other appropriately licensed person must: (1) date the order and identify the verbal order by the name and title of the authorized individual who gave the order; and (2) sign the order entry with his/her own name and title. All verbal orders must be appropriately signed within twenty-four (24) hours.
- 17.5 The office operatory shall, within seventy-two (72) hours of receipt of such information, notify the licensing agency of any reportable event as follows:
- a) transfer of the patient from the office operatory to a hospital emergency department;
 - b) unscheduled hospital admission of the patient within seventy-two (72) hours of discharge from the office operatory;
 - c) extension of the surgical procedure beyond four (4) hours;
 - d) unplanned readmission to the office operatory within seventy-two (72) hours;
 - e) death of the patient within thirty (30) days;

- f) subjecting a patient to a procedure not ordered or intended by the patient's physician, *excluding*: procedures not requiring a physician's order, medication errors, and collection of specimens, for laboratory study, obtained by non-invasive means or routine phlebotomy;
- g) or any other incident reported to the malpractice insurance carrier.

Section 18.0 **Anesthesia Service**

18.1 Each office operatory shall have and implement written anesthesia service policies and procedures pertaining to at least the following:

- a) staff privileges for anesthesia services established in accordance with sections 9.4 and 9.6 herein;
- b) emergency coverage;
- c) administration of anesthetics;
- d) the maintenance of safety controls, including, but not limited to, inspection, maintenance, and calibration of equipment;
- e) qualifications and supervision of non-physician anesthetists;
- f) qualifications of the supervising physician;
- g) anesthesia monitoring standards of reference 19 herein.

18.2 In addition, the policies shall include provisions for at least the following:

- a) pre-anesthesia evaluation by a physician;
- b) safety of the patient during the anesthesia period;
- c) review of patient's condition prior to induction of anesthesia and post-anesthetic evaluation in accordance with the standards cited in reference 19 herein; and
- d) recording of all events related to each phase of anesthesia care.

18.3 A board-certified anesthesiologist or a board-certified anesthesiologist, in conjunction with a certified registered nurse anesthetist, if the facility utilizes certified registered nurse anesthetists to administer anesthesia shall be responsible for developing the policies and procedures cited in sections 18.1 and 18.2 herein.

- 18.4 General anesthesia shall be permitted only in those licensed office operatories that meet the requirements of sections 18.5, 18.7, and 21.4 herein. If any type of anesthesia is administered that may fail mid-procedure necessitating the use of general anesthesia, the office operatory shall be in compliance with sections 18.5, 18.7, and 21.4 herein at all times.
- 18.5 No explosive anesthetics shall be utilized in any office operatory.
- 18.6 The administration of anesthesia, with or without sedation or a dissociative drug, shall be under the direct supervision of a qualified physician.
- 18.7 In a licensed facility administering general anesthesia, an anesthesiologist or a certified registered nurse anesthetist shall administer the anesthesia.
- 18.8 In a licensed facility administering all types of anesthesia, other than general anesthesia, an anesthesiologist, a certified registered nurse anesthetist, or a physician shall administer anesthesia.
- 18.9 The person administering anesthesia shall not function in any other capacity during the surgical procedure.

Section 19.0 ***Surgical Service***

- 19.1 Written staff rules and regulations and policies shall be established and implemented to govern surgical services that shall include surgical staff privileges, supporting services of professional and paramedical personnel, provisions for emergency coverage and operating suite procedures.
- 19.2 Surgical procedures shall be performed only by physicians who have current surgical privileges for the same or a similar class of procedures at a nearby hospital.
- 19.3 Each office operatory shall schedule elective surgery only.
- 19.4 Discharge of the patient shall be the responsibility of the operating physician and shall take place only after direct evaluation by the physician, determining the patient is adequately recovered to function independently (i.e., vital signs stable, full responsiveness and orientation, ability to move voluntarily). If sedation, regional block, or general anesthesia has been utilized, a responsible adult shall accompany the patient and be instructed about the patient's care.
- 19.5 Surgical procedures performed in the office operatory shall:
 - a) be performed only on patients determined in writing by the operating physician prior to surgery to be classified as ASA Class 1, ASA Class 2, or ASA Class 3 under the American Society of Anesthesiology "Physical Status Classification" (see Appendix "A").

For ASA Class 3 patients, surgical procedures utilizing planned general anesthesia, or planned epidurals, spinals, or brachial plexus blocks, may be performed only when the operating physician and a board-certified anesthesiologist concur (in writing prior to the surgery) that the patient is an acceptable candidate for a surgical procedure in the office operatory setting;

- b) not exceed an expected duration of two (2) hours, as documented in writing prior to the initiation of the procedure by the operating physician; Surgical procedures exceeding two (2) hours in duration shall be peer-reviewed and documented in accordance with the requirements set forth in section 11.1 herein.
 - c) be permitted only when at least one (1) physician or a certified registered nurse_anesthetist currently trained in Advanced Cardiac Life Support (ACLS) is available and will continue to be available in the recovery area until the patient is discharged from the office operatory.
- 19.6 No overnight stays shall be permitted in the office operatory under any circumstances.
- 19.7 If termination of pregnancy procedures are performed in an office operatory, the requirements of the rules and regulations of reference 7 shall also apply.
- 19.8 Each operating/procedure room suite shall have policies and procedures pertaining to safety controls prominently posted.
- 19.9 All tissues/specimens removed at surgery shall be submitted for pathological examination except those exempted in writing by the operating physician.
- 19.10 The patient's medical record shall be available in the operating/procedure room at the time of surgery.
- 19.11 An accurate and complete description of operative procedure shall be recorded by the operating physician within a timely fashion following completion of surgery.
- 19.12 Areas for the processing of clean and dirty supplies and equipment shall be separated by physical barriers.
- 19.13 Written procedures shall be adhered to for all sterilization and for the appropriate disposal of wastes and contaminated supplies.
- 19.14 Reports of bacteriological tests and inspection records shall be maintained on the premises.

Section 20.0 ***Infection Control***

- 20.1 A mechanism shall be established by the medical director for the development of infection control policies that shall pertain to no less than:

- a) infection surveillance activities;
- b) sanitation and asepsis;
- c) handling and disposal of waste and contaminants;
- d) sterilization, disinfection, and laundry;
- e) reporting, recording and evaluation of occurrences of infections; and
- f) documentation of infection rate.

20.2 The office operator shall report promptly to the licensing agency infectious diseases that may present a potential hazard to patients, personnel, and the public. Included are the reportable diseases cited in reference 13 herein and the occurrences of other diseases in outbreak form.

Section 21.0 ***Supplies and Equipment***

- 21.1 Supplies of appropriate sterile linens, gloves, dressings and so forth, shall be maintained in sufficient quantities for routine and emergency use.
- 21.2 Such surgical instruments, accessory and operating/procedure room lights, and resuscitation equipment as are appropriate for the types of surgery and surgical risks that may be encountered in an office operator shall be provided and maintained in clean, safe, and sterile condition.
 - 21.2.1 An adequately-stocked cardiopulmonary resuscitative cart shall be available for emergencies and shall include, at a minimum, an Ambu Bag, a laryngoscope, airway management equipment, and a medication kit. The medication kit shall include appropriate medications for the treatment of anaphylaxis, cardiac arrhythmias, cardiac arrest, and malignant hyperthermia.
- 21.3 When anesthesia is utilized, appropriate monitoring equipment shall be available, shall be maintained in proper working condition, shall meet the requirements of the guidelines of reference 20 herein, and shall include monitors for pulse oximeter, non-invasive blood pressure, and EKG.
- 21.4 In those office operatories administering general anesthesia, the following monitoring equipment shall be present in the facility: blood pressure apparatus, EKG oscilloscope, defibrillator, pulse oximeter with alarm, oxygen analyzer with alarm, and CO₂ monitor.
- 21.5 Defibrillating equipment shall be available.
- 21.6 Supplies of appropriate drugs, medications, fluids, electrolyte solutions, etc. shall be maintained in sufficient quantities for routine and emergency use.

Section 22.0 ***Laboratory, Radiology, and Pharmaceutical Services***

- 22.1 Each office operator may perform on the premises limited procedures such as urinalysis and CBC, provided that personnel are qualified by training and are under the supervision of a physician.
- 22.2 The requirements of reference 9 pertaining to radiology shall apply to those office operator providing such services.
- 22.3 Each office operator performing laboratory testing shall be in compliance with the requirements of 42 *Code of Federal Regulations*, Part 493 of reference 16 herein.
- 22.4 Pharmaceutical services, if provided by the office operator, shall be provided in accordance with prevailing standards of professional practice and shall be supervised by a pharmacist licensed in Rhode Island or by an operating physician who is qualified to assume professional, organization, and administrative responsibility for the quality of services rendered.
- 22.5 Record-keeping and security measures shall be maintained to assure the control and safe dispensing of drugs in compliance with all state and federal laws.
- 22.6 Provisions for secure storage and proper record-keeping of all controlled substances shall be in accordance with Chapter 21-28 of the Rhode Island General Laws, as amended (the "Uniform Controlled Substances Act").
- 22.7 Dispensing and labeling of all pharmaceuticals shall be in accordance with Chapter 21-31 of the Rhode Island General Laws, as amended (the "Rhode Island Food, Drugs, and Cosmetic Act").
- 22.8 The quality and appropriateness of medication usage shall be monitored and evaluated as part of the quality assurance program required herein.

Section 23.0 ***Medical Records***

- 23.1 An individual shall be designated to supervise the medical records and to ensure proper documentation, completion, indexing, filing, retrieval, and safe storage.
- 23.2 A medical record shall be established and maintained for every patient cared for in the office operator. Said medical record may be the same patient record maintained in the physician's office, provided that the information stipulated in section 23.3 (below) is included.
- 23.3 Each medical record shall contain sufficient information and data to support the diagnosis, plan of treatment, and shall contain no less than the following:

- a) patient identification, (name, address, birth date, etc.);
- b) medical history and physical examination;
- c) pre-operative and final diagnosis;
- d) results of all appropriate, minimum specific tests for the procedure(s) to be performed;
- e) a signed consent form for surgical procedure;
- f) a signed consent form for anesthesia;
- g) the expected duration of the surgical procedure(s);
- h) the type(s) of anesthesia to be used and the expected duration of each;
- i) the patient's pre-operative ASA classification(s) as determined by both 1) the operating physician; 2) any consulting physician(s); and 3) the anesthesiologist or certified registered nurse anesthetist; (For ASA Class 3 patients who are undergoing surgical procedures utilizing planned general anesthesia, or planned epidurals, spinals, or brachial plexus blocks, a written statement from a board-certified anesthesiologist concurring that the patient is an acceptable candidate for a surgical procedure in the office operatory setting shall also be required. See section 19.5(a) herein).
- j) nurses' notes;
- k) anesthesiologist's and/or certified registered nurse anesthetist's reports, including pre-anesthesia evaluation, intra-operative anesthesia record, and post-anesthesia evaluation;
- l) medical consultation, and counseling (if any);
- m) operating physician's operative notes, progress reports, and discharge notes;
- n) instructions given patient upon discharge; and
- n) other related reports.

Section 24.0 ***Medical Consultation***

- 24.1 Consultation and assistance in specialty fields shall be readily available and used as indicated prior to and/or following a surgical procedure. An office operatory shall maintain a current list of consultants available.

PART IV ***ENVIRONMENTAL MAINTENANCE***

Section 25.0 ***Environment***

- 25.1 The office operatory shall be maintained and equipped to provide a functional sanitary, safe and comfortable environment, with all furnishings in good repair. The premises shall be kept free of hazards.
- 25.2 Written policies and procedures shall be established pertaining to environmental controls to assure comfortable, safe and sanitary environment with well-lighted space for the services provided.
- 25.3 Equipment and supplies shall be provided for cleaning of all surfaces. Such equipment shall be maintained in a safe, sanitary condition.
- 25.4 Hazardous cleaning solutions, compounds and substances shall be labeled, stored in a safe place and kept in an enclosed section separate from other cleaning materials.
- 25.5 Cleaning shall be performed in a manner that minimizes the spread of pathogenic organisms in the atmosphere.
- 25.6 Operating/procedure rooms shall be thoroughly cleaned after each operation.
- 25.7 Smoking shall not be permitted.

PART V ***PHYSICAL PLANT AND EQUIPMENT***

Section 26.0 ***New Construction***

- 26.1 All new construction shall be subject to the provisions of references 3, 4, and 6.
- 26.2 In addition, any other applicable state and local laws, codes and regulations shall apply. Where there is a difference between codes, the code having the more stringent standard shall apply.

Section 27.0 ***Physical Facility***

- 27.1 Each office operatory shall meet the fire and safety provisions of reference 3 and shall conform to all state and local building codes.
- 27.2 A building entrance shall be located at grade level and able to accommodate wheelchairs.
- 27.3 An elevator shall be provided where patient care is provided at other than street level. The cab size shall be large enough to accommodate a stretcher and an attendant.
- 27.4 Administrative and public areas shall include at least the following:
- a) a lobby area including a waiting area, conveniently accessible wheelchair storage, a reception/information desk, accessible public toilets, public telephone(s) and drinking fountain(s).
 - b) interview space for private interviews relating to admission, credit, etc.
 - c) general and individual office space for business transactions, records and administrative and professional staff. These shall be separate from public and patient areas with provisions for confidentiality of records. Enclosed office spaces for administration and consultation shall be provided.
 - d) general storage facilities.
- 27.5 A system for sterilizing equipment and supplies shall be provided. When sterilization is provided off-site, adequate sterile supplies shall be provided. If on-site processing facilities are provided, they shall include the following:
- a) ***Soiled workroom:*** This room shall be physically separated from all other areas of the facility. Work space shall be provided to handle the cleaning and terminal sterilization/disinfection of all medical/surgical instruments and equipment. The soiled workroom shall contain work table(s), sink(s), flush-type device(s) and washer/sterilizer decontaminator(s) or other decontamination equipment. Pass-through doors and washer/sterilizer decontaminators should deliver into clean processing areas/workrooms.

- b) **Clean Assembly/Workroom and Sterilization Area:** Clean and soiled work areas should be physically separated. This room is exclusively for the inspection, assembly and packaging and sterilization of medical/surgical supplies and equipment. The room shall contain handwashing facilities, work space and equipment for terminal sterilizing of medical and surgical equipment and supplies. The assembly work area should contain work tables, counter, storage facilities for back-up supplies and a drying cabinet or equipment. Access to the sterilization room should be restricted.
- c) Alternatively, based on the scope of the practice, a single utility room may be adequate for clean and soiled activities, provided the room includes a sink for cleaning instruments/equipment, a hand wash sink, adequate work counter space, and allow for instrument/equipment processing to flow from soiled area, to clean area, to sterilization, and finally to storage, without crossing paths.

27.5.1 **Clean/Sterile Supplies – Storage:** Storage for packs, etc., shall include provisions for ventilation, humidity, and temperature control.

- 27.6 Provisions shall be made to separate pediatric from adult patients. This shall include pre- and post-operative care areas and should allow for parental presence.
- 27.7 At least one room shall be provided for examination and testing of patients prior to surgery, assuring both visual and audible privacy. Exam rooms shall have a minimum floor area of 80 square feet, excluding vestibules, toilets and closets. Room arrangement should permit at least 2 feet 8 inches clearance at each side and the foot of the examination table. A handwashing fixture and a counter or shelf space for writing shall be provided.
- 27.8 Each operating room shall have a minimum clear area of 250 square feet, exclusive of cabinets and shelves. Additional clear area may be required to accommodate the functional plan, which may require additional staff or equipment. There shall be at least one x-ray film illuminator in each room.
- 27.9 A room for post-anesthesia recovery shall be provided as required by volumes and procedure type. At least 3 feet shall be provided at each side and at the foot of each bed. If pediatric surgery is part of the program, separation from the adult section and space for parents shall be provided. Bedpans and bedpan-cleaning facilities shall be provided in this area.
- 27.10 A designated supervised recovery lounge shall be required for patients who do not require post-anesthesia recovery but need additional time for their vital signs to stabilize before safely leaving the facility. This lounge shall contain space for staff and family members and provisions for privacy. It shall have convenient access to toilets. Hand washing and nourishment facilities must be provided.
- 27.11 The surgical service area must include a drug distribution station. Provisions shall be made for storage and preparation of medications administered to patients. Locked storage, including a refrigerator and double-locked storage for controlled substances shall be provided. Convenient access to handwashing facilities shall be provided.

- 27.12 Scrub facilities shall be provided near the entrance to each operating room and may service two operating rooms if needed. Scrub facilities shall be arranged to minimize incidental splatter on nearby personnel or supplies.
- 27.13 The surgical service area must include a soiled work area, containing a clinical sink or equivalent flushing-type fixture, a work counter sink for handwashing and waste receptacle(s).
- 27.14 Fluid waste disposal facilities shall be provided, convenient to operating rooms. A clinical sink or equivalent equipment in a soiled workroom shall meet this standard.
- 27.15 Provisions shall be made for cleaning, testing, and storing anesthesia equipment. If a separate workroom, it shall contain a work counter, sink and racks for cylinders. Provisions shall be made for the separate storage of clean and soiled items. Provisions shall be made for the separate storage of reserve gas cylinders.
- 27.15.1 If flammable agents are present in an operating/procedure room, the room shall be constructed and equipped in accordance with the standards of publication number 56A, (1975) of reference 8.
- 27.15.2 If only non-flammable agents are present in the operating/procedure room, the room shall be constructed and equipped in accordance with the standards of publication number 56G, (1975) of reference 8
- 27.16 Equipment storage area(s) for equipment and supplies used in the surgical service shall be provided.
- 27.17 Appropriate change areas shall be provided for staff working within the surgical area. Change area(s) shall contain toilets, lavatories for handwashing, and space for donning scrub attire.
- 27.18 Provisions shall be made for patients to change from street clothing into hospital gowns, if required by the functional program, and prepare for surgery. This should include waiting areas, toilets, changing areas, and space for administration of medication. Provisions shall be made for securing patients' clothing and personal effects.
- 27.19 Stretcher storage shall be provided, convenient for use and out of the way of normal traffic.
- 27.20 Facilities having three (3) or more operating rooms shall provide a lounge area for surgical staff and a staff toilet room shall be provided near the recovery area.
- 27.21 Space containing a floor receptacle or service sink and storage space for housekeeping supplies and equipment shall be provided
- 27.22 Provisions shall be made for convenient access to and use of emergency equipment at both surgical and recovery areas.

27.23 If laboratory services are provided, at least the following minimal facilities shall be provided:

- a) Laboratory work counter with sink, vacuum, gas and electrical services.
- b) Lavatory or counter sink equipped for handwashing.
- c) Storage cabinet(s) or closet(s).
- d) Specimen collection facilities.

27.24 If radiology services are provided, at least the following minimal facilities shall be provided:

- a) Radiographic room(s)
- b) Film processing facilities
- c) Viewing areas
- d) Storage facilities for exposed film
- e) Dressing rooms, as required by services provided, with convenient toilet access.

27.25 Heating and ventilation systems shall be capable of maintaining adequate ventilation and temperature for the comfort and safety of patients and staff.

27.26 If the office operatory includes an endoscopy suite, the following minimal facilities must be provided:

- 27.26.1 Each procedure room shall have a minimum clear area of 200 square feet, exclusive of fixed cabinets and built-in shelves, and be designed for visual and acoustical privacy. Oxygen, vacuum and medical air shall be provided.
- 27.26.2 Dedicated processing room(s) for cleaning and disinfecting instrumentation must be provided. Cleaning rooms should allow for the flow of instrumentation from the contaminated area to the clean area, and, finally, to storage.
- 27.26.3 The decontamination room shall be equipped with the following: two utility sinks remote from each other; freestanding handwashing fixture; work counter space: space and plumbing for automatic endoscope cleaners, sonic processor and flash sterilizer (where required); and outlets for vacuum and compressed air. Negative pressure shall be maintained in the decontamination room and all air should be vented to the outside to avoid recirculation within the facility.

Section 28.0 ***Emergency Power***

- 28.1 Each office operatory shall be equipped with an alternate emergency energy power source with a minimum two (2) hour capability.
- 28.2 The emergency electrical power system shall have a sufficient capacity to supply power to maintain the operation of the operating/procedure room and other life-support systems, and lighting of egress, fire detection equipment, alarm and extinguishing systems.
- 28.3 Monthly testing of emergency power shall be documented and reports retained for at least three (3) years.

Section 29.0 ***Lighting and Electrical Services***

- 29.1 All electrical and other equipment used in the office operatory shall be maintained free of defects that could be a potential hazard to patients or personnel. Periodic calibration and/or preventive maintenance of equipment shall be provided and documentation of all testing shall be maintained for at least three (3) years.

Section 30.0 ***Plumbing***

- 30.1 All plumbing material and plumbing systems or parts thereof installed shall meet the minimum requirements of reference 4.
- 30.2 All plumbing shall be installed in such a manner as to prevent back siphonage or cross-connections between potable and non-potable water supplies.

Section 31.0 ***Water Supply***

- 31.1 Water shall be obtained from a community water system and shall be distributed to conveniently located taps and fixtures throughout the office operatory and shall be adequate in volume and pressure for all purposes including fire fighting.

Section 32.0 ***Medical Waste Disposal***

- 32.1 Medical waste as defined in the *Rules and Regulations Governing the Generation, Transportation, Storage, Treatment, Management and Disposal of Regulated Medical Waste (DEM-DAH-MW-01-92)*, promulgated by the Rhode Island Department of Environmental Management, shall be managed in accordance with the provisions of the aforementioned regulations.

Section 33.0 ***Waste Water Disposal***

- 33.1 If a municipal sanitary sewer system is available, the office operatory shall be connected to the system, if feasible. If a municipal sanitary sewer system is not available, the office operatory shall meet the standards set forth by the Department of Environmental Management.

PART VI ***DEFICIENCIES, VARIANCE, AND SEVERABILITY***

Section 34.0 ***Deficiencies and Plans of Correction***

- 34.1 The licensing agency shall notify the office operator of violations of individual standards through a notice of deficiencies which shall be forwarded to the office operator within fifteen (15) days of inspection of the office operator unless the Director determines that immediate action is necessary to protect the health, welfare, or safety of the public or any member thereof through the issuance of an immediate compliance order in accordance with section 23-1-21 of the General Laws of Rhode Island, as amended.
- 34.2 An office operator that received a notice of deficiencies must submit a plan of correction to the licensing agency within fifteen (15) days of the date of the notice of deficiencies. The plan of correction shall detail any requests for variances as well as document the reasons therefor.
- 34.3 The licensing agency will be required to approve or reject the plan of correction submitted by an office operator within fifteen (15) days of receipt of the plan of correction.
- 34.4 If the licensing agency rejects the plan of correction, or if the office operator does not provide a plan of correction or if an office operator whose plan of correction has been approved by the licensing agency fails to execute its plan within a reasonable time, the licensing agency may invoke the sanctions enumerated in section 7.0 herein. If the office operator is aggrieved by the action of the licensing agency, the office operator may appeal the decision and request a hearing in accordance with Chapter 42-35.

Section 35.0 ***Variance Procedure***

- 35.1 The licensing agency may grant a variance upon request of the applicant from the provisions herein, if it finds in specific cases, that a literal enforcement of such provision will result in unnecessary hardship to the applicant and that such a variance will not be contrary to the public interest.
- 35.2 A request for a variance shall be filed by an applicant in writing, setting forth in detail the basis upon which the request is made.
 - 35.2.1 Upon filing of each request for variance with the licensing agency and within a reasonable time thereafter, the licensing agency shall notify the applicant by certified mail of its approval or in the case of a denial, a hearing date, time and place may be scheduled if the facility appeals the denial. Such hearing must be held in accordance with the provisions of section 36.0 herein.

Section 36.0 ***Rules Governing Practices and Procedures***

- 36.1 All hearings and reviews required under the provisions of Chapter 23-17 of the General Laws of Rhode Island, as amended, shall be held in accordance with the provisions of the *Rules and*

Regulations of the Rhode Island Department of Health Regarding Practices and Procedures Before the Department of Health and Access to Public Records of the Department of Health (R42-35-PP).

Section 37.0 ***Severability***

- 37.1 If any provision of these regulations or the application thereof to any office operator or circumstances shall be held invalid, such invalidity shall not affect the provisions or application of the regulations which can be given effect, and to this end the provisions of the regulations are declared to be severable.

October 19, 2001

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PART VII **REFERENCES**

1. "Health Care Facility Licensing Act of Rhode Island," Chapter 23-17 of the General Laws of Rhode Island, as amended.
2. "Administrative Procedures Act," Chapter 42-35 of the General Laws of Rhode Island, as amended.
3. "Rhode Island State Fire Safety Code," Chapter 23-28.1 of the General Laws of Rhode Island, as amended.
4. "Rhode Island State Building Code," Chapter 23-27.3 of the General Laws of Rhode Island, as amended.
5. "Department of Health," Chapter 23-1 of the General Laws of Rhode Island, as amended.
6. The American National Standard - Specifications for Making Buildings and Facilities Accessible to and Usable by, The Physically Handicapped," American National Standards Institute, Inc., 1430 Broadway, New York, New York 10018.
7. *Rules and Regulations for the Termination of Pregnancy*, Rhode Island Department of Health, March 2000 and subsequent amendments thereto.
8. "National Fire Protection Association," One Battery March Park, Quincy, MA 02269-9101.
9. *Rules and Regulations for the Control of Radiation*, Radiation Control Agency, Rhode Island Department of Health, June 1999 and subsequent amendments thereto.
10. "Health Care Certificate of Need Act of Rhode Island", Chapter 23-15 of the Rhode Island General Laws, as amended.
11. *Rules and Regulations Governing the Generation, Transportation, Storage, Treatment, Management and Disposal of Regulated Medical Waste in Rhode Island (DEM-DAH-MW-01-92)*, Rhode Island Department of Environmental Management, April 1994 and subsequent amendments thereto.
12. *Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis in Health-Care Facilities*, 1994, U.S. Department of Health & Human Services, Public Health Service, Centers for Disease Control & Prevention, October 28, 1994, vol. 43, no. RR-13.
13. *Rules and Regulations Pertaining to the Reporting of Communicable, Environmental and Occupational Diseases (R23-5-6, 10, 11, 23-24.6-CD/ERD and R23-24.5 ASB)*, Rhode Island Department of Health, April, 1996 and subsequent amendments thereto.

14. *Rules and Regulations Relating to Quality Assurance Standards for Mammograms (R23-1-MAM)*, Rhode Island Department of Health, December 1998 and subsequent amendments thereto.
15. *The ASA Physical Status Classification System*, available on: www.asahq.org., American Society of Anesthesiologists, 1999.
16. "Clinical Laboratory Improvement Act--1988." Department of Health and Human Services, Public Health Service: 42 *Code of Federal Regulations*, Part 493 (February 1992), pp. 7146--end.
17. *Rules and Regulations for the Licensing of Professional (Registered), Certified Registered Nurse Practitioners, Certified Registered Nurse Anesthetists & Practical Nurses & Standards for the Approval of Basic Nursing Education Programs (R5-34-NUR/ED)*, Rhode Island Department of Health, December 1998 and subsequent amendments thereto.
18. *Rules and Regulations Pertaining to Pharmacists, Pharmacies & Manufacturers, Wholesalers & Distributors (R5-19-PHAR)*), Rhode Island Department of Health, April 2001 and subsequent amendments thereto.
19. American Society of Anesthesiologists, *Basic Standards for Preanesthesia Care, Standards for Basic Anesthetic Monitoring, and Standards for Postanesthesia Care*, available online at: **www.asahq.org/standards/homepage.html**.
20. American Society of Anesthesiologists, *Guidelines for Office-Based Anesthesia*, available online at: **www.asahq.org/Standards/12.HTM**.

APPENDIX “A”

The ASA Physical Status Classification System

- P1 A normal healthy patient
- P2 A patient with mild systemic disease
- P3 A patient with severe systemic disease
- P4 A patient with severe systemic disease that is a constant threat to life
- P5 A moribund patient who is not expected to survive without the operation
- P6 A declared brain-dead patient whose organs are being removed for donor purposes

Taken from: *The ASA Physical Status Classification System*, available on: www.asahq.org., American Society of Anesthesiologists, 1999.