



**PARKVIEW KOSCIUSKO SURGERY
ONE, LLC**

**MEDICAL STAFF
RULES & REGULATIONS**

RECOMMENDATION / APPROVAL
Medical Staff Executive Committee:

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Parkview Kosciusko Surgery ONE, LLC
MEDICAL STAFF RULES & REGULATIONS

ARTICLE I
DEFINITIONS AND GENERAL CONSIDERATIONS

1.01. As used herein:

- (a) The term “ASC” shall mean the Parkview Kosciusko Surgery ONE, LLC.
- (b) The term “Medical Staff” shall mean all licensed physicians who are privileged by the ASC to attend to patients in the ASC.
- (c) The term “Advanced Practice Professional” or “APP” shall mean any individually licensed or certified health care provider (excluding a Physician or Podiatrist) who: (a) has an independent or dependent scope of practice, (b) is authorized by the Governing Board to exercise specified Clinical Privileges within the ASC in a manner that is consistent with the provider’s scope practice, and (c) is therefore credentialed through the Medical Staff credentialing process.
- (d) The term “Allied Health Practitioner” or “AHP” means any individually licensed or certified health care provider (excluding a Physicians, Podiatrists, or APPs) who: (a) has a strictly dependent scope of practice, (b) is credentialed through the ASC's Human Resources Department or other designated ASC office, and (c) is not eligible to receive or exercise specified Clinical Privileges within the ASC. Dependent Practitioners include, by way of example, registered nurses, counselors, non-physician surgical assistants, and other such dependent practitioners.
- (e) The term “Clinical Privileges” means the permission granted to a Practitioner by the Governing Board to render specific patient care services within the Practitioner's lawful scope of practice to patients at the ASC, and permission to efficiently use ASC resources necessary to exercise granted Clinical Privileges.
- (f) The term “Governing Board” shall mean the Board of Managers of the ASC. The Governing Board's authority and responsibilities are delineated in Parkview Kosciusko Surgery ONE, LLC’s Operating Agreement.
- (g) The term “Chief Operating Officer” or “COO” of the ASC means the individual appointed by the Governing Board to act on its behalf in the overall management of the ASC.
- (h) The term “Medical Director” means the individual appointed by the Governing Board of the ASC to serve as the liaison between the Medical Staff and the Governing Board and who, in so doing, provides oversight over the Medical Staff’s compliance with the Bylaws, Policies, and Procedures, and overall direction to the Medical Staff in the continuing performance of its services.
- (i) The term “Medical Staff Bylaws” or “Bylaws” means the Medical Staff Bylaws

of the ASC's Medical Staff, which include both the Governance and Credentialing Manual and the Corrective Action and Fair Hearing Manual.

(j) The term “Medical Staff President” (or “President of the Medical Staff”) means the principal elected officer of the organized Medical Staff.

(k) The term “Member” shall mean any Physician or Podiatrist who has been granted Membership on the Medical Staff by the Governing Board.

(l) The term “Physician” means a duly licensed allopathic or osteopathic Physician.

(m) The term “Podiatrist” means a duly licensed Podiatrist.

(n) The term “Practitioner” means any Physician, Podiatrist, or APP who has been granted Medical Staff Membership and/or Clinical Privileges at the ASC, as applicable.

1.02. All Practitioners privileged at the shall abide by the Medical Staff Bylaws of the ASC, the Medical Staff Rules and Regulations, the ASC Policies and Procedures, and the Operating Agreement of Parkview Kosciusko Surgery ONE, LLC.

1.03. No practitioner, except a Practitioner who is a Member of Medical Staff and/or has Clinical Privileges at the ASC, shall be permitted to assume care of any patient in the ASC.

1.04. In the case of an emergency, any Medical Staff member or other practitioner, to the degree permitted by his/her license, shall be permitted and assisted to do everything possible to save life or prevent serious harm utilizing all his/her facilities, consultations available, and good judgment.

1.05. An emergency is defined as a condition in which serious permanent harm would result to a patient or in which the life of a patient is in immediate danger and any delay in administering treatment would add to that danger.

1.06. Standing orders of Medical Staff members may be formulated by conference between the Medical Staff member and the ASC's Director of Operations. They can be changed only by mutual consent of the Medical Staff member and the Director of Operations. Such orders or their changes shall be posted for all personnel. These orders shall be signed by the attending Medical Staff member and updated annually.

1.06. All orders for treatment shall be in writing. An order shall be considered to be in writing if dictated to a registered nurse and signed by the attending Medical Staff member within 24 hours. Orders taken over the telephone must be dictated to a registered nurse. All verbal and telephone orders shall be written, dated, and signed by the person to whom dictated.

1.07. General policies of the ASC as adopted by the Governing Board shall be a part of these ASC/Medical Staff Rules and Regulations.

1.08. No patients will be treated who, in advance, are known to require more than a 24 hour stay at the ASC.

1.09. No patients will be treated who, in advance, are known to require blood or blood products as part of their procedure.

1.10. The use of tobacco or tobacco products is not permitted in any location within the ASC.

1.11. The rights, duties, and responsibilities granted to and/or imposed upon Members of Medical Staff as set forth in these Rules and Regulations shall also apply to APPs who have been granted Clinical Privileges at the ASC. Such APPs shall be governed by and subject to the Medical Staff Bylaws and these Rules and Regulations.

ARTICLE II ADMISSIONS AND DISCHARGES

2.01. All admissions for surgery shall be arranged through the ASC's business office by a Member of the Medical Staff and will be in accordance with the ASC Admitting Policy.

2.02. When arranging for admission for surgery, the attending Medical Staff member will be expected to furnish the ASC with a provisional diagnosis. Further, not more than 30 days before the date of the scheduled surgery, each patient must have a comprehensive medical history and physical assessment completed by a physician or other qualified practitioner, and a copy shall be placed in the patient's medical record prior to the surgical procedure.

2.03. Upon admission of a patient, the attending Medical Staff member shall be expected to state any unusual or known dangers his/her patient may present to other patients or nursing staff. Also, upon admission, each patient must have a pre-surgical assessment completed by a Practitioner with the Clinical Privileges to do so that includes, at a minimum, an updated medical record entry documenting an examination for any changes in the patient's condition since the completion of the most recently documented medical history and physical assessment, including any allergies to drugs or biologicals. A copy shall be placed in the patient's medical record prior to the surgical procedure.

2.04. Patients shall be discharged only on a written order of the attending Medical Staff member and/or anesthesiologist. Should a patient leave the ASC against the advice of the attending Medical Staff member or without proper discharge, a notation of the incident shall be made in the patient's medical record.

2.05. The ASC shall provide each patient with written discharge instructions and overnight supplies. When appropriate, the ASC shall make follow up appointments with the Practitioner for the patient and ensure that all patients are informed, either in advance of their surgical procedure or prior to their leaving the ASC, of their prescriptions, post-operative instructions, and physician contact information for follow-up care.

2.06. Patients shall be discharged in the company of a responsible adult, excepting

those patients who are exempted by the attending Medical Staff member.

2.07. In the event of an emergency transfer from the ASC to an acute care hospital, the attending Medical Staff member and anesthesiologist shall be responsible for providing adequate documentation in the patient's medical record so that the receiving hospital and/or physician can continue providing appropriate care to the patient and the ASC's committee can evaluate the reason for transfer. A copy of the appropriate sections of the medical record shall accompany the patient.

2.08. In the event of a death at the ASC, the deceased shall be pronounced dead by the attending Medical Staff member. The body shall not be released until an entry has been made and signed in the medical record of the deceased by the attending Medical Staff member. Policies with respect to release of dead bodies shall conform to local law.

ARTICLE III MEDICAL RECORDS

3.01. The attending Medical Staff member shall be responsible for the completion of the medical record for his/her patient. This record may be in paper format or in an electronic/computerized form and shall include as appropriate: identification; provisional diagnosis; complaint; appropriate history; physical and special reports; x-ray, lab test, and pathology findings; surgical treatment; final diagnosis; and conditions upon discharge. The pre-surgical assessments shall also be included in the medical record.

3.02. The Pre-Operative Nurse will ensure the attending Medical Staff member is aware of all reports and test results upon their receipt or prior to surgery.

3.03. An informed consent for surgery will be signed by the patient and by a witness and made part of the medical record.

3.04. The following items -- identification, provisional diagnosis, complaint, appropriate history and physical, and signed informed consent must be recorded in the patient's medical record before any operation or potentially hazardous diagnostic procedure is performed, unless the attending Medical Staff member states in writing that such delay would be detrimental to the patient.

3.05. Operative reports shall include a detailed account of the findings of surgery as well as detail of the surgical technique. Operative reports shall be written (or dictated) within twenty-four (24) hours following surgery and the report promptly signed or authenticated (as applicable) by the Medical Staff member and made a part of the patient's medical report.

3.06. The patient's post-surgical condition must be assessed and documented in the medical record by a physician or other qualified practitioner. Post-surgical needs must be addressed and included in the discharge notes.

3.07. Post-Surgical Surgical Specimens. All surgical specimens removed shall be sent

to the laboratory except those granted exemption and approved by the State Licensure Board (see Pathology Waiver Policy). A gross description of tissues removed shall become a part of the patient's medical record. Whenever a microscopic examination is done, a description of the findings shall become a part of the patient's medical record. Microscopic examination is to be carried out by the pathologist when, in his/her opinion, such examination is necessary for proper diagnosis of the disease state in the tissue submitted, or when requested by the attending Medical Staff member.

3.08. The final diagnosis shall be recorded in full, dated, and signed (electronically or legibly, as applicable) by the responsible Medical Staff member at the time of discharge of the patient.

3.09. All treatment and procedures shall be documented in the patient's medical record.

3.10. Signatures. The attending Medical Staff member shall electronically or legibly sign or initial all entries, including verbal orders, which he/she makes in the patient's medical record.

3.11. Completion of patient's medical record:

(a) A medical record shall be considered complete when required reports have been dictated and/or written and electronically or legibly signed, and all progress notes and orders have been electronically or legibly signed.

(b) If a Medical Staff member has not completed one or more records of a patient fourteen (14) days after the day of surgery, the Medical Staff member shall be considered as having delinquent medical records.

3.12. Legal Status of Medical Record. The medical record is the property of the ASC, and shall not be removed, except under subpoena duces tecum or court order, or pursuant to applicable federal and state laws.

3.13. Accessibility of the Medical Record. Access to medical records of patients shall be afforded to the patient or properly authorized representative and to Practitioners who are Members of the Medical Staff and/or who have been granted Clinical Privileges at the ASC for bona fide study and investigational research, consistent with preserving the confidentiality of personal information concerning individual patients. The medical record shall also be available to licensing and/or accrediting personnel for purposes of their reviews.

3.14. A medical record shall not be permanently filed until it is completed by the responsible Medical Staff member or is ordered filed by the Medical Records Committee.

3.15. The ASC shall have an organized "medical record service" with the administrative responsibility for the medical records that must be maintained for every patient of the ASC. The organization of the medical record service shall be appropriate to the scope and complexity of the services provided at the ASC. The ASC shall utilize the services of a registered

record administrator (RRA) or an accredited record technician (ART). If a full-time and/or part-time RRA or ART is not employed, then a consultant RRA or ART shall assist the qualified person in charge. Documentation of the findings and recommendations of the consultant shall be maintained. The ASC's organized medical record service shall be responsible for ensuring the timely processing, coding/indexing, and retrieval of records; protecting the confidentiality of medical information; and compiling and retrieving data for quality assessment and improvement activities of the ASC.

3.16. Overall, the ASC shall maintain an adequate medical record with documentation of services rendered for each patient of the ASC as follows:

(a) Medical records are to be documented accurately and in a timely manner, readily accessible, and permit prompt retrieval of information.

(b) A unit record system of filing should be utilized. When this is not practicable, the ASC shall establish a system to retrieve, when necessary, all divergently located record components.

(c) The ASC shall use a system of author identification and record maintenance that ensures the integrity of the authentication and protects the security of all record entries. Each entry must be authenticated in accordance with the Medical Staff policies.

(d) Medical records shall be retained in their original or legally reproduced form as required by federal or state law.

(e) Plain paper facsimile orders, reports, and documents shall be acceptable for inclusion in the medical record, as addressed by and consistent with ASC policies.

(f) The ASC's "IS" System is organized by unique patient identifiers; this system of indexing medical records allows for the timely retrieval of records in order to support continuous quality assessment and improvement activities.

(g) The ASC shall ensure the confidentiality of patient records. The ASC shall develop, implement, and maintain the following:

1. A procedure for releasing information or copies of records only to authorized individuals, in accordance with federal and state laws.
2. A procedure that ensures that unauthorized individuals cannot gain access to patient records.

3.17. The medical record must contain sufficient information to (a) identify the patient; (b) support the diagnosis; (c) justify the treatment; and (d) document accurately the course of the patient's stay in the ASC and the results.

3.18. All entries in the medical record must be as follows:

- (a) Legible and complete.
- (b) Made only by authorized individuals as specified in ASC policies.

(c) Authenticated and dated within the time frame approved by the Medical Staff and ASC policy, not to exceed thirty (30) days from the date of the procedure.

3.19. All patient records must document and contain, at a minimum, the following:

(a) Patient identification.

(b) Appropriate medical history and results of a physical examination completed within the time frame approved by the Medical Staff and ASC policy, not to exceed thirty (30) days from the date of the procedure.

(c) Preoperative diagnostic studies recorded in the record before surgery, if performed.

(d) Pre-surgical assessment performed upon admission of the patient, including any allergies or sensitivities.

(e) Entries related to anesthesia administration.

(f) Evidence of appropriate informed consent for procedures and treatments for which it is required, as specified by the informed consent policy developed by the Medical Staff and Governing Board of the ASC and consistent with federal and state law.

(g) Post-surgical assessment.

(h) Discharge diagnosis.

(i) Medical history, chief complaint, and physical examination, including copies of laboratory and x-ray consultations and other special reports or summaries of those same findings by the admitting physician.

(j) A written or dictated report describing techniques, findings, and tissue removed or altered.

(k) Signatures of Medical Staff members and health care workers who treated or cared for the patient.

(l) Condition on discharge, disposition of the patient, and time of dismissal, as well as post-surgical needs.

(m) Final progress note, including instructions to the patient and family, with dismissal diagnosis.

(n) A copy of the transfer form if the patient is referred to a hospital or other facility.

(o) Documentation in a prominent part of the medical record of whether or not the patient has executed an advance directive.

(p) Notices of patient rights, financial interests or ownership held by physicians, and other notices required by applicable laws, rules, and regulations.

(q) All original medical records or legally reproduced medical records shall be maintained by the ASC for a minimum period of seven (7) years, shall be readily accessible, and shall be kept in a fire resistive structure.

ARTICLE IV SURGERY

4.01. Surgical operations are to be performed only with the written, signed, and informed surgery consent placed in the medical record.

4.02. All patients undergoing general anesthesia shall have such lab work as determined to be appropriate in the discretion of the attending Medical Staff member/anesthesiologist.

4.03. All cases for surgery shall have the appropriate pre-op ordered by the attending Medical Staff member and/or anesthesiologist.

4.04. No one shall be permitted to observe or work in the surgical suite unless properly garbed with cap, mask, shoe covers or dedicated shoes, and proper surgical clothing, provided by the ASC.

4.05. In all surgical cases, the Medical Staff member shall state his/her pre-operative diagnosis immediately before surgery.

4.06. In all surgical cases, the Medical Staff member shall examine the patient immediately before surgery to evaluate the risk of the procedure to be performed.

4.07. Operative reports shall be dictated or written within 24 hours following surgery and shall contain a full description of the procedure performed. Operative reports shall include date of surgery, pre-operative and post-operative diagnosis, procedure(s) performed, and description of those procedure(s).

4.08. In any surgical procedure with unusual hazard to life, there must be a qualified assistant present and scrubbed.

4.09. Surgical Services shall be organized in accordance with the scope of services offered at the ASC to meet the needs of the patient and in accordance with acceptable standards of practice and safety. These ASC/Medical Staff Rules and Regulations and the ASC policies governing surgical care shall be designed and implemented to assure the achievement and maintenance of standards of medical and patient care as follows:

(a) The ASC shall maintain a roster of Medical Staff members, specifying the surgical privileges of each Medical Staff member.

(b) An appropriate history and physical workup must be in the medical record of every patient before surgery.

(c) The following equipment and supplies shall be available to the surgical and recovery areas:

1. Emergency call system.
2. Oxygen.
3. Resuscitation equipment.
4. Defibrillator.
5. Cardiac monitors.
6. Tracheostomy set.
7. Oximeter.
8. Suction equipment.
9. Other supplies and equipment specified by Medical Staff.

(d) Adequate provision of immediate postoperative care is required as set forth pursuant to ASC policy and/or procedure.

(e) Consistent with ASC policy, the patient register shall be complete and up to date.

(f) An operative report describing techniques, findings, and tissue removed or altered shall be written or dictated immediately following surgery and authenticated by the Medical Staff member, in accordance with ASC policy and Governing Board approval.

(g) A list of tissues excluded from microscopic examination, if applicable, shall be maintained by the ASC's surgery department.

ARTICLE V ANESTHESIA

5.01. Only qualified anesthesiologists or supervised Certified Registered Nurse Anesthetists ("CRNAs") will be allowed to administer, or be supervised in the administration of, anesthesia at the ASC.

5.02. The anesthesiologist/CRNA shall include in the medical record a complete report of each anesthetic agent administered.

5.03. Only Medical Staff-approved anesthetic agents shall be used in the ASC.

5.04. The patient's medical record shall contain pre-operative and post-operative patient evaluation anesthesia notes written by the anesthesiologist/CRNA.

5.05. The anesthesiologist/CRNA shall accompany all patients to the post-operative anesthesia recovery room following surgery.

5.06. An anesthesiologist/CRNA shall be required to remain at the ASC until an anesthetized patient has been deemed medically stable by the Aldrete criteria.

5.07. Pre-anesthesia, intra-operative, and post-anesthesia responsibilities are as follows:

(a) The completion, within forty-eight (48) hours before surgery, of a pre-anesthesia evaluation for each patient by an individual qualified to administer anesthesia, for all types of anesthetics other than local. Such evaluations shall be updated according to ASC policy when completed more than forty-eight (48) hours before surgery.

(b) The completion, immediately before surgery, of an examination or evaluation of the risk of anesthesia by a Medical Staff member.

(c) The completion by the Medical Staff member administering anesthesia of intra-operative anesthesia monitoring and notations, to include vital signs, for each patient, in accordance with ASC policy.

(d) The completion of a postanesthetic evaluation for proper anesthesia recovery of each patient prior to discharge, in accordance with written policies and procedures approved by the Medical Staff.

(e) The requirement that all postoperative patients shall be discharged from the postanesthetic care unit only by personnel permitted to administer anesthesia and are responsible for the patient's care in accordance with ASC policy and following an evaluation of the patient for proper anesthesia recovery.

5.08. Pursuant to ASC policy, all anesthetic agents will be stored or used in the ASC in accordance with current standards of practice and as required by the National Fire Protection Association ("NFPA").

ARTICLE VI PATIENT CARE SERVICES

6.01. All patient care services must meet the needs of the patient, within the scope of the service offered, in accordance with acceptable standards of practice. Patient care services at the ASC must be under the direction of a qualified person or persons. The ASC requires the following:

(a) That, in accordance with Parkview Ortho Center, LLC's quality assessment and improvement program, the ASC patient care services rendered are reviewed and

analyzed at regular meetings of patient care personnel and used as a basis for evaluating the quality of services provided.

(b) That personnel with appropriate training are available at all times to handle possible emergencies involving patients of the ASC.

(c) That a registered nurse serves as head nurse supervising patient care services personnel.

(d) That all registered nurses and licensed practical nurses be currently licensed in Indiana or through the Nurse Licensure Compact (NLC) multistate license with the authority to practice in both their home state and other NLC states.

(e) That an experienced registered nurse supervises all nursing personnel, including, but not limited to, registered nurses, licensed practical nurses, and surgical technologists, in surgical areas and recovery unit(s) as follows:

1. Licensed practical nurses and surgical technologists may serve as scrub personnel under the supervision of a qualified registered nurse.
2. Circulating duties in the operating room shall be performed by a qualified registered nurse. Licensed practical nurses and surgical technologists may assist in circulating duties under the supervision of a qualified registered nurse who is immediately available to respond to emergencies, in accordance with applicable state law and approved Medical Staff policies and procedures.
3. A registered nurse must be in attendance in the post-anesthesia recovery room during its operational period when patients are present.

6.02. Written ASC patient care policies and procedures shall be available to personnel and shall include, but not be limited to, the following:

(a) A provision that a reliable method of patient identification must be used. Particular attention must be given to identification of infants, young children, and others unable to identify themselves.

(b) A requirement that side rails be provided on recovery carts and kept in the upright position when occupied by sedated patients.

(c) A provision for instruction(s) to be given to the patient, responsible adult, and/or family regarding follow-up care and transportation needed by the patient on discharge.

(d) A provision that facilities, reusable equipment, and supplies shall be thoroughly cleaned and/or sterilized following use, according to ASC policies and procedures.

(e) A provision that all nursing personnel must meet annual in-service requirements as established by ASC and federal and state requirements.

(f) A provision that a registered nurse must assign the care of each patient-to-patient care personnel in accordance with the patient's need and the specialized qualifications and competence of the patient care personnel available.

ARTICLE VII PHARMACEUTICAL SERVICES

7.01. The ASC shall provide drugs and biologicals in a safe and effective manner, in accordance with accepted professional practice, and under the direction of an individual(s) designated responsible for pharmaceutical services as pursuant to ASC policy.

7.02. Consistent with ASC policies and procedures, pharmaceutical services shall have the following:

(a) A designated professional person with prescriptive authority or a pharmacist, who is responsible for the control of drug stocks in the ASC.

(b) Records of stock supplies of all scheduled substances, including an accounting for all items purchased and dispensed.

(c) Written policies and procedures developed, implemented, maintained, and made available to personnel, including, but not limited to, the following:

1. Drug handling, storing, labeling, and dispensing.
2. Drug administration according to established ASC policies and acceptable standards of practice.
3. Intravenous medications administration as it relates to sedation.
4. Reporting of adverse reactions and medication errors to the Medical Staff member responsible for the patient and to the appropriate committee; such reactions and errors must be documented in the patient's medical record.
5. Drugs must be accurately and clearly labeled and stored in specially-designated, well-illuminated cabinets, closets, or storerooms. Furthermore:
 - a. Drug cabinets must be accessible only to authorized personnel.
 - b. Should the ASC store controlled drugs, drug cabinets for storage of controlled drugs listed in Schedule II of the Comprehensive Drug Abuse Prevention and Control Act of 1976 and other drugs subject to abuse must be permanently stored in compartments that are separately locked.
 - c. Drug carts with controlled drugs as designated in item 5b. above must be securely affixed when not in use.
6. To the extent the ASC provides patients with take home medication, instructions to the patient on the use of take-home medication is the responsibility of the prescribing Medical Staff member.

(d) A formulary.

(e) A list of available emergency drugs.

ARTICLE VIII QUALITY ASSESSMENT AND IMPROVEMENT

8.01. Parkview Ortho Center, LLC's quality assessment and improvement program incorporates and addresses ASC-wide quality assessment and improvement matters. The Quality Improvement Committee ("QIC") shall address the ASC's opportunities for improvement and shall therefore document any action taken regarding ASC quality assessment and improvement matters; the QIC shall also document the outcome of such action taken, to include effectiveness, follow-up, and/or impact on patient care.

8.02. The QIC shall be responsible for developing, implementing, and maintaining an ongoing, data-driven quality assessment and performance improvement ("QAPI") program.

(a) The QAPI program will include an ongoing program that demonstrates measureable improvements in patient health outcomes and improves patient safety by using quality indicators or performance measures associated with improved health outcomes and by identifying and reducing medical errors.

(b) The QAPI program will require the QIC to measure, analyze, and track quality indicators, adverse patient events, infection control, and other aspects of performance that include care and services furnished in the ASC.

(c) The QAPI program will incorporate quality indicator data, including patient care and other relevant data regarding services furnished in the ASC. The QIC will use this data to monitor the effectiveness and safety of the ASC's services and the quality of its care, and to identify opportunities that could lead to improvements and changes in its patient care.

8.03. Other duties of the QIC regarding the ASC shall include the evaluation of:

(a) All services, including services furnished by a contractor.

(b) All functions, including, but not limited to, the following:

1. Discharge and transfer.
2. Infection control.
3. Medication errors.
4. Response to patient emergencies.

(c) All services performed in the ASC with regard to appropriateness of diagnoses and treatments related to a standard of care and anticipated or expected outcomes.

8.04. The QIC shall set priorities for its performance improvement activities that affect health outcomes, patient safety, and quality of care. In setting priorities, the QIC shall focus on high risk, high volume, and problem-prone areas after considering incidence, prevalence, and severity of problems in those areas.

8.05. The QIC shall conduct performance improvement activities that track adverse patient events, examine their causes, implement improvements, and ensure that improvements are sustained over time. The QIC shall also implement preventative strategies throughout the

ASC targeting adverse patient events and ensuring that all staff members are familiar with these strategies.

8.06. The QIC shall determine the number and scope of distinct improvement projects to be conducted annually based upon the scope and complexity of the services and operations of the ASC. The QIC shall document the projects that are being conducted and said documentation shall include the reasons for implementing the project as well as a description of the project's results.

8.07. The QIC shall be responsible for implementing a process for determining the occurrence of and reporting "reportable events" within the ASC.

(a) The term "reportable events" shall include all surgical events, product or device events, patient protection events, care management events, environmental events, and criminal events described and listed as "reportable events" in 410 Indiana Administrative Code 15-2.4-2.2.

(b) The QIC shall ensure that upon an occurrence of a "reportable event," a report (with all requisite information included in the report) is made with the Indiana State Department of Health in accordance with 410 IAC 15-2.4-2.2.

8.08. The QIC shall be responsible for implementing policies and procedures designed to prevent or minimize the occurrence of "reportable events" within the ASC. Said policies and procedures shall include, without implied limitation, surgical "time outs" and anesthesia "time outs" pursuant to which all staff in the operating room or procured room shall, prior to commencing anesthesia and/or surgery, take a "time out" to review the patient name, procedure, orientation, etc., associated with the particular surgical or anesthesia case prior to commencing anesthesia and surgery.

ARTICLE IX INFECTION CONTROL PROGRAM

9.01. The ASC shall provide a safe and healthful environment that minimizes infection exposure and risk to patients, health care workers, and visitors. Further, the ASC shall provide a functional and sanitary environment for the provision of surgical services by adhering to professionally acceptable standards of practice.

9.02. The ASC shall maintain a written, active, and effective ASC-wide infection control program. This program shall be designed to prevent, control, and investigate infections and communicable diseases. Included in this program is a system designed for the identification, surveillance, investigation, control, and prevention of infections and communicable diseases in patients and health care workers. The program will include documentation that the ASC has considered, selected, and implemented nationally recognized infection control guidelines. In particular, the ASC shall adopt the Center for Disease Control's standards for infection control.

9.03. The infection control program shall identify and evaluate trends or clusters of ASC-generated infections or communicable diseases.

9.04. The Infection Control Committee (formed by appointment pursuant to the Medical Staff Bylaws) shall monitor and guide the infection control program in the ASC. The ASC shall designate as the "Infection Preventionist" the person, qualified by training or experience, responsible for ongoing infection control activities and the development and implementation of policies governing control of infections and communicable diseases.

9.05. The Infection Control Committee, along with the ASC's Chief Operating Officer, Medical Staff, and nursing manager shall:

(a) be responsible for the implementation of successful corrective action plans in affected problem areas and ensure that infection control policies are followed;

(b) provide for appropriate infection control input into plans for renovation and new construction to ensure awareness of federal, state, and local rules that affect infection control practices, as well as plan for appropriate protection of patients and employees during construction or renovation; and

(c) be responsible for immediately implementing corrective and preventative measures that result in improvements.

9.06. The Infection Control Committee responsibilities must include, but are not limited to, the following:

(a) Establishing techniques and systems for identifying, reviewing, and reporting infections in the ASC.

(b) Recommending corrective action plans, reviewing outcomes, and assuring resolution of identified problems.

(c) Reviewing employee exposure incidents and making appropriate recommendations to minimize risk.

(d) Completing written reports of quarterly meetings.

(e) Reviewing and recommending changes in procedures, policies, and programs that are pertinent to infection control. These include, but are not limited to, the following:

1. Sanitation.
2. Universal precautions, including infectious waste management.
3. Cleaning, disinfection, and sterilization.
4. Aseptic technique, invasive procedures, and equipment usage.
5. Reuse of disposables.
6. A patient isolation system.
7. A system, which complies with state and federal law, to monitor the immune status of health care workers exposed to communicable diseases.
8. An employee health program to determine the communicable disease history of new personnel as well as an ongoing program for current personnel as required by state and federal agencies.

9. Requirements for personal hygiene and attire that meet acceptable standards of practice.
10. A program of linen management.

9.07. Sterilization of equipment and supplies shall be provided, within the scope of the service offered, in accordance with acceptable standards of practice, or manufacturer's recommendations, and applicable state laws and rules, including 410 IAC 1-4. Sterilization services must be directed by a qualified person or persons and must provide for the following:

(a) Biological indicators shall be used to check sterilization processes at least monthly. Chemical sterilizing indicators must be used to check the sterilizing process of individual packs.

(b) Written ASC policies and procedures shall be available and followed by personnel responsible for sterilizing equipment and supplies, including, but not limited to, the following:

1. Minimum time and temperature for processing various size bundles and packs.
2. Instructions for loading, operating, cleaning, and maintaining sterilizers.
3. Instructions for cleaning, packaging, storing, labeling, and dispensing of sterile supplies.
4. Procedure for maintaining and recording the particular sterilizing cycle.
5. Sterilization of heat labile reusable equipment.

(c) Records of results must be maintained and evaluated periodically in accordance with 410 IAC 15-2.4-2, to include, but not be limited to, the following:

1. Records of recording thermometers or a daily record of the sterilizing cycle (date, time, temperature, pressure, and contents) for each sterilizer load.
2. Results of biological indicators used in testing the sterilizing processes.

9.08. Environmental surfaces and equipment not requiring sterilization that have been contaminated by blood or other potentially infectious materials shall be cleaned then decontaminated in accordance with acceptable standards of practice and applicable state laws and rules, including 410 IAC 1-4.

9.09. The ASC, whether it operates its own laundry or uses an outside laundry service, shall ensure that the laundry process complies with a recognized laundry standard as follows:

- (a) Clean linen must be separated from soiled linen at all times as follows:
 1. Contaminated linens must be clearly identified and bagged.
 2. Clean linens must be covered during transit, and separate containers or carts must be provided for transporting thereof.
- (b) Central clean linen storage space must be provided as follows:
 1. If commercial laundry services are utilized:
 - a. A soiled linen collection room must be provided; and

- b. A hand washing station is required in each area where unbagged soiled linen is handled.
- 2. If laundry is processed in the ASC:
 - a. A laundry processing room must be provided;
 - b. Clean linen storage and mending must be separated from soiled linen handling and storage; and
 - c. Employee hand washing facilities shall be available in each room where clean or soiled linen is processed and handled.

ARTICLE X LABORATORY SERVICES

10.01. With the exception of EKGs performed at the ASC from time to time (such EKGs are not provided for pre-operative admission criteria or diagnosis) and blood glucose scans, hemoglobin and hematocrit, and INR and urine pregnancy testing performed at the ASC, the ASC sends all laboratory specimens to a reference lab for testing; the ASC shall make available those pathology and medical laboratory services and consultation necessary to meet the needs of patients as determined by the Medical Staff of the ASC.

10.02. Any laboratory that performs tests, examines specimens, and reports the evaluation, shall do so only upon the written request of individuals and practitioners authorized by law.

10.03. If applicable, based on services provided at the ASC, the Medical Staff shall determine what tissue specimen examination will be utilized on each specimen as follows:

- (a) Microscopic examination only.
- (b) Macroscopic examination only.
- (c) Both microscopic and macroscopic examinations.

The ASC maintains an exempt list, to include toenail and miniscal shaving.

10.04. The ASC shall assure that all laboratory services provided to its patients are performed in a facility possessing a valid certificate, in accordance with 42 CFR 493 (excluding Subparts F, R, Q, and T), authorizing the performance of testing in the specialty or subspecialty of service for level of complexity in which the test is categorized. The ASC shall maintain a copy of the CLIA certificate of any laboratories with which the ASC contracts.

10.05. All nursing and other ASC personnel performing laboratory tests at the ASC shall have competency assessed annually, with documentation of assessment maintained in the employee file for the procedures performed. The ASC shall maintain a CLIA waiver certificate identifying that the ASC shall be limited to performing certain tests.

10.06. Pursuant to ASC policy, the ASC shall not store blood, test blood, or provide transfusion services.

ARTICLE XI RADIOLOGY SERVICES

11.01. The ASC shall provide or make available diagnostic radiology services and reports required in connection with any surgery to be performed and necessary to meet the needs of the patients, as determined by the Medical Staff.

11.02. Radiology services solely under arrangement must meet the needs of the patient and meet all state and federal requirements.

11.03. Radiology services provided at the ASC shall meet the hospital conditions of participation for radiological services specified in 42 CFR 482.26. In addition, the ASC shall comply with all regulations set forth in 410 IAC 15-2.5-8 and 410 IAC 5 when/if radiology services are provided on-site by the ASC, including, but not limited to, the following:

(a) Diagnostic radiologic and therapeutic services must meet professionally approved standards for safety and personnel qualifications.

(b) All radiation therapy treatments, including all aspects of radium treatments, must be under the direct supervision of a radiation oncologist. A qualified full-time, part-time, or consulting radiologist must supervise the ionizing radiology services and must interpret only those radiologic tests that are determined by the medical staff to require a radiologist's specialized knowledge. A radiologist is a doctor of medicine or osteopathy who is qualified by education and experience in radiology.

(c) If therapeutic or diagnostic nuclear medicine services are provided, they must comply with the applicable requirements of this section and with 410 IAC 15-1.6- 3.

(d) All diagnostic radiographic procedures must be conducted by an individual meeting the requirements of 410 IAC 5-11.

(e) Written policies and procedures must be developed, implemented, and maintained and made available to personnel.

11.04. Safeguards for patients, personnel, and public must be specified, including, but not limited to, the following:

(a) Proper safety precautions must be maintained against radiation hazards in accordance with the ASC's radiation and safety program(s).

(b) Hazards and faulty equipment identified must be promptly corrected in accordance with current standards of practice and applicable federal and state rules, including, but not limited to, collimation and filtration and evaluations of equipment performance.

11.05. Procedures and treatments are to be performed on the written request of individuals and practitioners allowed to order such procedures and treatments and receive the

results of the evaluations, to the extent permitted by law and as authorized by the Governing Board.

11.06. All radiologic equipment must be registered and inspected prior to use and then periodically, according to 410 IAC 5 and all other applicable state and federal statutes and rules.

11.07. Although the ASC utilizes no radioactive materials, the ASC recognizes that all radioactive materials must be registered and/or licensed under all applicable state and federal statutes and rules.

11.08. The use of fluoroscopes must be limited to physicians or others authorized to operate them in accordance with 410 IAC 5.

11.09. Records of the results of all radiological procedures must be kept on file and recorded on the patient's medical record. The ASC shall maintain the following for at least five (5) years:

- (a) Copies of reports and printouts.
- (b) Films, scans, and other image records.
- (c) If Section 11.09 (a) and (b) are maintained in the medical record, these items shall be maintained in accordance with state and federal law.

ARTICLE XII PHYSICAL PLANT, EQUIPMENT MAINTENANCE, AND ENVIRONMENTAL SERVICES

12.01. The ASC shall be constructed, arranged, and maintained to ensure the safety of the patient and to provide facilities for services authorized under the ASC license, as follows:

- (a) The plant operations and maintenance service, equipment maintenance, and environmental services must be as follows:
 - 1. Staffed to meet the scope of the services provided.
 - 2. Under the direction of a person or persons qualified by education, training, or experience, as according to ASC policy and approved by the Governing Board.
- (b) The ASC shall provide a physical plant and equipment that meets the statutory requirements and regulatory provisions of the state department of fire and building services, 675 IAC 22, Indiana fire prevention codes, and 675 IAC 13, Indiana building codes.
- (c) The ASC shall have emergency power and lighting in accordance with National Fire Protection Association (NFPA) 99.
- (d) The ASC acknowledges that in new construction, renovations, and additions, the ASC site and facilities, or nonlicensed facilities acquired for the purpose of providing ASC services, shall meet the following:

1. The 1996-1997 and any supplemental editions of the national "Guidelines for Design and Construction of Hospitals and Health Care Facilities" ("Guidelines").
2. All building, fire safety, and handicapped accessibility codes and rules adopted and administered by the state building commission shall apply to all facilities covered by this rule and take precedence over any building, fire safety, or handicapped accessibility requirements of the Guidelines.
3. When renovation or replacement work is done within an existing ASC, all new work or additions, or both, shall comply, insofar as practical, with applicable sections of the Guidelines and, for certification, with appropriate parts of NFPA 101.
4. Water supply and sewage disposal services shall be obtained from municipal or community services.
5. As early in the construction, addition, and/or renovation project as possible, the functional and operational description shall be submitted to the division. This submission shall consist of, but not be limited to, the following:
 - a. Functional program narrative as established in the Guidelines.
 - b. Schematics, based upon the functional program, consisting of drawings (as single-line plans), outline specifications, and other documents illustrating the scale and relationship of project components.
6. Prior to the start of construction, addition, and/or renovation projects, detailed architectural and operational plans for construction shall be submitted to the plan review division and the division of sanitary engineering of the department of fire and building services as follows:
 - a. Working drawings, project manuals, and specifications shall be included.
 - b. Prior to submission of final plans and specifications, recognized standards and codes, including infection control standards, shall be reviewed as required in section 1(e)(2) of this rule.
 - c. All required approvals shall be obtained from the department of fire and building services, and final approval shall be obtained from the division of sanitary engineering of the department prior to issuance of the occupancy letter by the division.
7. Upon receipt of a plan release from the fire and building commissioner and documentation of a completed plan review by the division of sanitary engineering of the department of fire and building services, a licensure application shall be submitted to the division of sanitary engineering on the form approved and provided by the department.
8. Documentation from the state building commissioner that the ASC is in compliance with the fire safety rules of the fire prevention and building safety commission shall be furnished to the division of sanitary engineering with the licensure application.

12.02. The condition of the physical plant and the overall ASC environment shall be developed and maintained in such a manner that the safety and well-being of patients are assured as follows:

(a) No condition in the ASC or on the grounds may be maintained which may be conducive to the harboring or breeding of insects, rodents, or other vermin.

(b) No condition may be created or maintained which may result in a hazard to patients, the public, or employees.

(c) Provision must be made for the periodic inspection, preventive maintenance, and repair of the physical plant and equipment by qualified personnel as follows:

1. Operation, maintenance, and spare parts manuals must be available, along with training and/or instruction of the appropriate ASC personnel in the maintenance and operation of fixed and movable equipment.
2. All mechanical equipment (pneumatic, electric, sterilizing, or other) must be on a documented maintenance schedule of appropriate frequency in accordance with acceptable standards of practice or the manufacturer's recommended maintenance schedule.
3. Operational and maintenance control records must be established and analyzed at least triennially. These records must be readily available on the premises.
4. Maintenance and repairs must be carried out in accordance with applicable codes, rules, standards, and requirements of local jurisdictions, the administrative building council, the state fire marshal, and the department.

(d) The patient care equipment requirements are as follows:

1. There must be sufficient patient care equipment and space to assure the safe, effective, and timely provision of the available services to patients.
2. All patient care equipment must be in good working order and regularly serviced and maintained as follows:
 - a. All patient care equipment must be on a documented maintenance schedule of appropriate frequency in accordance with acceptable standards of practice or the manufacturer's recommended maintenance schedule.
 - b. There must be evidence of preventive maintenance on all patient care equipment.
 - c. Appropriate records must be kept pertaining to equipment maintenance, repairs, and electrical current leakage checks, and such records must be analyzed at least triennially.
 - d. Defibrillators must be discharged at least in accordance with manufacturers' recommendations, and a discharge log with initialed entries must be maintained.

(e) The building(s), including fixtures, walls, floors, ceiling, and furnishings throughout, must be kept clean and orderly in accordance with current standards of practice, including the following:

1. Environmental services must be provided in such a way as to guard against transmission of disease to patients, health care workers, the public, and visitors by using the current principles of the following:
 - a. Asepsis.
 - b. Cross-contamination prevention.
 - c. Safe practice.
2. Refuse, biohazards, infectious waste, and garbage must be collected, transported, sorted, and disposed of by methods that will minimize nuisances or hazards according to federal, state, and local laws and rules.

12.03. The ASC's written safety management/disaster preparedness program shall include, but not be limited to, the following:

(a) A review of safety functions by a committee appointed by the Executive Officer which includes representatives from administration and patient care services.

(b) An ongoing ASC-wide process to evaluate and collect information about hazards and safety practices to be reviewed by the committee.

(c) The ASC safety program includes the following:

1. Patient safety.
2. Health care worker safety.
3. Public and visitor safety.
4. The provision of emergency care of patients, staff, and others in the facility in the event of a disaster.

(d) The ASC written fire control plan contains provisions for the following:

1. Prompt reporting of fires.
2. Extinguishing of fires.
3. Protection of patients, personnel, and guests.
4. Evacuation.
5. Cooperation with firefighting authorities.
6. Fire drills.

(e) Maintenance of written evidence of regular inspection and approval by state or local fire control agencies, in accordance with ASC policy and state and local regulations.

(f) Emergency and disaster preparedness coordinated with appropriate community, state, and federal agencies.

(g) Drills conducted at least annually to test the disaster/safety plan's effectiveness. The ASC will complete a written evaluation of each drill and promptly implement any corrections to the plan.

ARTICLE XIII DIETARY SERVICES

13.01. If nourishments are provided to patients in the ASC, refrigeration and a hand washing lavatory must be provided in the area where the nourishment is prepared.

13.02. If prepackaged single service nourishments are provided, refrigeration storage must be provided in the clean area.

ARTICLE XIV OTHER SERVICES

14.01. The ASC acknowledges that services must meet the needs of the patients served, within the scope of the service offered, and in accordance with acceptable standards of practice.

14.02. The services shall be under the direction of a qualified person or persons.

14.03. The services shall be staffed in accordance with written ASC policies and comply with the applicable state and federal rules.

ARTICLE XV PATIENT RIGHTS

15.01. The ASC will provide the patient with verbal and written notice of the patient's rights in advance of the date of the procedure. The notice will be provided in a language and manner that the patient understands. In addition, the ASC will post written notice of patient rights in a place within the ASC likely to be noticed by patients waiting for treatment. The notice of rights will include the name, address, and telephone number of a representative in the State agency to whom patients may report complaints, as well as the website for the Office of the Medicare Beneficiary Ombudsman.

15.02. The ASC will disclose to patients in waiting in advance of the date of the procedure any physician financial interests or ownership in the ASC in compliance with applicable requirements. In particular, physicians having a financial or ownership interest in the ASC are required to disclose in writing to the individual, before referring the individual to the ASC, that the physician has such a financial or ownership interest in the ASC. In addition, the physician must inform the individual that the individual may choose to be referred to another health care facility. The physician is required to obtain the individual's acknowledgement of receipt of the notice. And the physician is required to keep a copy of the signed notice. Further, the ASC is required to disclose to patients in writing, in advance of the date of the procedure, information regarding physicians having an ownership or financial interest in the ASC.

15.03. The ASC shall provide to the patient, in advance of the date of the procedure, information concerning the ASC's policies on advance directives. The information provided to the patient shall include a description of applicable health and safety laws and, if requested, shall

include a copy of the official State advance directives forms. Further, the ASC shall inform the patient of the patient's right to make informed decisions regarding the patient's care. The ASC shall document in a prominent part of the patient's current medical record whether or not the patient has executed an advance directive.

15.04. The ASC shall establish and maintain a grievance procedure for documenting the existence, submission, investigation, and disposition of a patient's written or verbal grievance to the ASC. As part of this grievance procedure, all alleged violations/grievances relating to, but not limited to, treatment or care that is (or is not) given, mistreatment, neglect, and/or verbal, mental, sexual, or physical abuse must be fully documented.

(a) The grievance process shall require that all allegations be immediately reported to a person in authority in the ASC.

(b) The grievance process shall specify the time frames for review of the grievance and the provisions of a response.

(c) The grievance process will require that the ASC document how the grievance was addressed, as well as provide the patient with written notice of its decision. The decision must include the name of an ASC contact person, the steps taken to investigate the grievance, the results of the grievance process, and the date the grievance process was completed.

(d) Upon completion of the investigation, substantiated allegations shall be reported to the State or local authority, as applicable.

15.05. All patients at the ASC have the right to confidentiality with regards to their medical records and protected health information. The ASC shall comply with all applicable privacy and security laws, rules, and regulations (including, without implied limitation, those specified in 45 CFR parts 160 and 164).

15.06. The ASC shall ensure that the patient's rights to personal privacy, receive care in a safe setting, and be free from all forms of abuse and harassment are protected. All patients shall have the right to exercise his or her rights without being subjected to discrimination or reprisal. If the patient is adjudged incompetent under applicable State laws or by a court of proper jurisdiction, the rights of the patient may be exercised by the person appointed to act on the patient's behalf.

Approved by the Governing Board of the ASC:

Chair, Board of Managers

Date

Adopted by the Medical Staff:

President of the Medical Staff

Date