Health, Department of

Health Quality

Chapter 5: Licensure of Ambulatory Surgical Centers

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RULES AND REGULATIONS FOR LICENSURE OF AMBULATORY SURGICAL CENTERS

CHAPTER 5

Section 1. <u>Authority</u>. These rules are promulgated by the Department of Health pursuant to the Health Facilities Licensure Act at W. S. 35-2-901 et seq. and the Wyoming Administrative Procedures Act at W. S. 16-3-101 et seq.

Section 2. <u>Purpose</u>. These rules have been adopted for the licensure of Ambulatory Surgical Centers. These standards are designed to protect the health and safety of patients and employees.

Section 3. <u>Severability</u>. If any portion of these rules are found invalid or unenforceable, the remainder shall continue in effect.

Section 4. <u>Definitions.</u>

- (a) "Administrator" means the person in charge of the operation of the facility; and is:
 - (i) A Physician,
 - (ii) A Registered Nurse, or
 - (iii) A person qualified with training and experience in health service management.

(b) "Acceptable plan of correction" means Wyoming Department of Health, Office of Health Quality, approved the plan to correct the deficiencies identified through an onsite survey. The plan of correction shall be a written document and must contain who is responsible for correction, what was done to correct the problem and who will monitor to ensure that the situation does not develop again and must contain a appropriate date for completion of the correction.

(c) "Ambulatory Surgical Center" means a facility which provides surgical treatment to patients not requiring hospitalization and is not part of a hospital or an office of private physicians, dentists or podiatrists.

(d) "Central Registry" means the registry operated by the Wyoming Department of Family Services pursuant to Wyoming Statute \$14-3-213, which indexes perpetrators of child abuse or neglect and abuse and neglect, exploitation or abandonment of disabled adults.

(e) "Governing body" means the individual(s), group, or agency that has ultimate authority and responsibility for establishing patient care policies, personnel policies, and providing for organizational management and planning.

(f) "Licensed Practical Nurse (LPN)" means a person who is licensed to practice as a licensed practical nurse by the Wyoming Board of Nursing pursuant to W.S. §33-21-120.

(g) "Physician" means a person licensed to practice medicine in Wyoming by the Wyoming Board of Medicine.

(h) "Registered Nurse (RN)" means a graduate of an approved school of professional nursing, who is currently licensed to practice as a registered nurse by the Wyoming Board of Nursing pursuant to W.S. §33-21-120.

Section 5. <u>Licensing.</u>

(a) Licensing requirements. The Office of Health Quality has been authorized to issue licenses to Ambulatory Surgical Centers and has established a system of licensure to comply with minimum requirements for the purpose of protecting the health, welfare and safety of patients receiving this type of service.

(b) Licensing procedure.

- (i) For an initial license to be issued the Office of Health Quality shall receive:
 - (A) A completed application form as supplied by the Office of Health Quality.

(B) The required licensure fee is outlined in Chapter 1, Rules and Regulations for Health Care Facilities Licensure Fees. The check or money order shall be made payable to the Treasurer, State of Wyoming.

(C) Demonstrated compliance with the requirements for licensure as required in paragraph (c) of this section. This documentation shall be available to the Office of Health Quality following the onsite survey.

- (D) The effective date of the initial license shall be:
 - (I) The date of the survey, if there are no

deficiencies, or

- (II) If deficiencies exist, the date that a plan of correction is approved.
- (E) The length of the license shall be from the effective date of the license until

the next June 30th.

(ii) For renewal of a full license for one year beginning July 1st, and unless suspended, or revoked, shall expire on June 30th of the following year, the Office of Health Quality shall receive:

(A) A completed application form by the date requested in the cover letter.

(B) The license fee as required in paragraph (b) of this section.

(C) Demonstrated compliance with the requirements for licensure as required in paragraph (c) of this section. This documentation is maintained on file at the Office of Health Quality following the onsite surveys.

(c) Requirements for licensure. The Office of Health Quality shall take into consideration:

(i) The ambulatory surgical center shall be in conformity with all laws and standards relating to communicable and reportable diseases as promulgated by the Department of Health, Division of Public Health.

the clients.

- (ii) The existing deficiencies that may create a hazard to the health, safety or welfare of
- (iii) The agency shall correct existing deficiencies.
- (iv) There shall be adequate policies and procedures in place to guide operations.
- (d) Transfer of license.

(i) No license granted shall be assignable or transferrable. A license shall apply only to the ambulatory surgical center described in the license application.

(A) Whenever ownership of an ambulatory surgical center is transferred from the individual or entity named in the license application to any other individual or entity, written notification of change of ownership shall be made to the Office of Health Quality. The transferree shall notify the Office of Health Quality of the transfer and apply for a new license.

(I) The transferor shall notify the Office of Health Quality at least thirty (30) days prior to the final transfer.

(1) Any license granted to the transferee shall be subject to the plan of correction submitted by the previous owner as approved by the Office of Health Quality.

(ii) If the ambulatory surgical center's name or address is changed, the Office of Health Quality shall be advised in writing and a new license shall be issued upon receipt of the licensure fee and application.

- (e) Conditions for revoking a license.
 - (i) Denial of application revocation of license.

(A) An application for license may be denied or a previously issued license may be revoked for noncompliance with minimum standards as herein set forth when noncompliance jeopardizes the health, safety or welfare of patients.

(ii) Hearings.

(A) Any ambulatory surgical center aggrieved by a decision of the Office of Health Quality may request a hearing by submitting a written request within ten (10) days of the receipt date of the notice of adverse action.

(B) Except in matters concerned with the spread of communicable disease as required in sections (c)(i), the Senior Management Consultant of the Office of Health Quality shall present the preliminary decisions and reasons to the aggrieved ambulatory surgical center and provide an opportunity for a hearing (if such is requested within the appropriate time frame).

(I) In matters concerned with the spread of communicable disease, the Wyoming State Health Officer shall present the preliminary decisions and reasons to the parties concerned and provide an opportunity for a hearing (if such is requested within the appropriate time frame).

(C) Hearings requested under the terms of these rules and regulations shall be held by the Office of Health Quality in accordance with the provisions of the Wyoming Administrative Procedures Act at W.S. §16-3-113, and with the contested case rules and regulations of the Wyoming Department of Health.

(f) Posting of license.

(i) The current license issued by the Office of Health Quality shall be displayed in a public area within the ambulatory surgical center.

(g) Survey of the ambulatory surgical center.

(i) Shall be arranged by the Office of Health Quality through its duly authorized officers, agents, or consultants. The survey shall be made unannounced and at periodic intervals dependant on the results of the previous survey and funding. All records of the ambulatory surgical center shall be made available to the surveyor.

- (h) Requirements of the Office of Health Quality.
 - (i) The Office of Health Quality shall provide each ambulatory surgical center with:
 - (A) A copy of the list of deficiencies found, if any; and
 - (B) A copy of these rules and regulations.
- (i) Voluntary closure.

(i) If an ambulatory surgical center voluntarily ceases to operate, it shall notify the Office of Health Quality in writing at least five working days prior to the closure.

(ii) The first working day after closure, the ambulatory surgical center shall return its license to the Office of Health Quality.

Section 6. <u>Organization and Administration.</u>

(a) Governing Body. The ambulatory surgical center shall have a governing body which has legal authority and responsibility to operate the ambulatory surgical center. The governing body shall:

(i) Appoint an administrator who is responsible for managing the ambulatory surgical center.

(ii) Adopt, revise, and approve personnel policies; including:

(A) Frequency of employee evaluations;

(iii) Prepare an organizational chart that reflects the administrative control and lines of authority for the delegation of responsibility from management down to the patient care level.

(iv) The governing body shall ensure that all services provided are consistent with accepted standards of practice.

(v) The governing body shall ensure that all procedures do not exceed twenty-three (23) hours of combined operating and recovery and/or convalescent time.

(vi) The governing body shall be accountable for the quality of care provided to the patient.

(vii) Personnel Records.

(A) There shall be one person designated responsible for maintaining the confidentiality.

(viii) Employee Health.

(A) Policies and procedures shall be developed to protect the employees health, and to prevent the spread of disease from employee to patient.

(B) Policies shall include but not limited to:

(I) Policies which are specific to blood borne pathogens as defined by

OSHA;

(II) Communicable disease vaccines as recommended by current CDC Prevention Guidelines for Health Care Workers and endorsed by the State Health Department, Division of Public Health.

(C) Documentation shall be maintained on the communicable disease vaccine given to the employee.

(ix) Notification.

(A) Prior to admission all perspective patients shall be notified if the ambulatory surgical center is not Medicare/Medicaid certified.

(x) Services.

(A) Furnished services, including the contracted services, shall comply with all applicable licensure standards;

(B) Medical and nursing staff shall be licensed, certified, or registered according to Wyoming laws and rules; and

(C) Staff members shall provide health services only within the scope of their license, certification or registration.

Section 7. <u>Admissions</u>.

(a) All persons admitted to the ambulatory surgical center shall be under the direct care of a member of the provider staff. The provider staff shall ensure the continuity of care for each patient including pre-operative, intra-operative, and post-operative care. Each patient shall be provided prior to admission all necessary instruction and education for pre and post-surgical care.

(b) Restrictions: Surgical care shall be limited to the following:

(i) Those that do not exceed twenty-three (23) hours of combined operating and recovery and/or convalescent time; and

(ii) Those that do not generally result in extensive blood loss,

require major or prolonged invasion of body cavities, directly involving major blood vessels, or constitute an emergency or life threatening procedure.

(c) Identification:

(i) Each patient admitted to the center shall have a visible means of identification placed and maintained on his/her person until discharge.

(ii) In cases of off-site, pre-planned transfer, such means of identification shall be maintained throughout the period of transfer and until such time as the patient becomes a patient in another licensed health care facility.

(d) Admission Requirements:

(i) All such admissions shall be in accordance with appropriate written policies and procedures which reflect the admission requirements established in this section, recommended by the provider staff and adopted by the Governing Body, specific to the ambulatory surgical center operations, that include at least the following:

(A) The patient must be in good health or have mild systemic disease which is under good control and does not require special management. Patient status shall be documented by the admitting physician.

(B) The patient or a responsible person acting on behalf of the patient must be able to strictly follow instructions related to the ingestion of fluids or solids within the specified time frame prior to the surgery.

(C) If the patient is to receive sedation or anesthetic which will result in impaired mental status following surgery, the patient must be accompanied upon discharge by a responsible adult.

(D) Patients who may require post-operative ventilation following surgery, either because of the procedure to be performed or because of a pre-existing condition, shall not be admitted for surgery.

(E) Surgery which requires the presence of special equipment, personnel, and/or facilities due to the risk of the operation involved shall not be performed in the center unless such equipment, personnel, and/or facilities are available in the ambulatory surgical center.

(F) When overnight care is provided, appropriate services shall be rendered within the defined capabilities of the organization. If overnight care is to be provided by the ambulatory surgical center, notice of such shall be provided to the Office of Health Quality.

(G) The Governing Body of the ambulatory surgical center shall have an organization wide policy on the use of smoking materials in the facility which shall be posted and disclosed to the patient upon admission.

(e) Off-Site Pre-Planned Transfers:

(i) Off-site pre-planned transfer of patients shall be limited to only those licensed health care facilities, that are physically located off-site or off-campus, when it is known in advance that further post-surgical patient care will be needed.

(A) Off-site pre-planned transfers do not include discharges to the patient's place of residence where further care will be provided by home health or home care providers.

(ii) Ambulatory surgical centers providing off-site pre-planned transfer service options shall adhere to the following requirements:

(A) Disclosure. Ambulatory surgical centers offering surgical services which include an off-site pre-planned transfer to another licensed health care facility following post-operative recovery shall disclose in written form to the patient all the details of the transfer prior to admission to the ambulatory surgical center. Disclosure includes but is not limited to the cost of the transfer, whether or not such costs shall be covered by insurance or other third party payer, and the details of the actual transfer, including but not limited to the mode of transport. Disclosure shall be made prior to the time for admission to the ambulatory surgical center. The patient shall acknowledge such disclosure in writing, and the date

thereof. Such disclosures on ambulatory surgical center policies regarding off-site pre-planned transfers shall be in addition to the requirements for informed consent.

(B) Off-site pre-planned transfers shall be made only to other licensed health care facilities that can provide the level of care necessary to meet the needs of the patient. The ambulatory surgical center shall have a written agreement with any and each licensed health care facility that admits patients for post-surgical care from an ambulatory surgical center. The ambulatory surgical center shall provide written discharge instructions, including patient progress information to the receiving health care facility.

(I) An ambulatory surgical center shall allow pre-planned transfers only with the written authorization of the attending operating surgeon or physician. The attending operating surgeon or physician shall approve such transfer if there are assurances that the continuity of care for the patient shall be maintained and contact with the patient's attending physician is continuous.

(C) All pre-planned transfers shall be by ambulance. The ambulatory surgical center shall have a written agreement with the provider(s) of ambulance services. Such transfer agreements shall include the provision for an appropriate level of care commensurate with the needs of a post-surgical recovering patient. If necessary, as determined by the attending or operating physician, licensed provider staff from the ambulatory surgical center shall accompany the patient on the ambulance to provide continuity of care that meets the post-operative needs of the patient.

(D) Ambulatory surgical centers engaging in pre-planned transfers shall provide space at the entrance to the building to facilitate patient transfers. The ambulatory surgical center shall provide close-in parking that shall be accessible at all times and shall not be obstructed by other parked vehicles or architectural barriers. The space provided shall include adequate height clearance for ambulances.

(E) Ambulatory surgical centers located above the ground level of the building that admits patients for which a pre-planned transfer is anticipated shall have at least one elevator available for the transport of such patients. The elevator shall be large enough to accommodate an ambulance cot in a horizontal position and a minimum of two attendants.

(f) On-Site Pre-Planned Transfers:

(i) On-site pre-planned transfers of patients are also authorized where it is known in advance that further post-surgical care will be needed. Such transfers are limited to:

(A) Other licensed health care facilities located on-site or on-campus and are physically connected to the ambulatory surgical center.

(B) Ambulatory surgical centers that provide extended recovery care services within the physical confines of the centers.

(ii) Extended Recovery Care Services:

(A) Extended recovery care services provided by an ambulatory surgical center shall not exceed twenty-three (23) hours combined operating and recovery and/or convalescent time.

(B) Extended recovery care services shall not be provided to more than four patients anywhere in the ambulatory surgical center, between the hours of 10:00 p.m. and 6:00 a.m.

(C) Extended recovery care area and equipment shall include as a minimum:

- (I) Direct visual observation of all patients;
- (II) Medicine administration;
- (III) Medical charting;
- (IV) Toileting;
- (V) Hand washing;
- (VI) Oxygen;
- (VII) Emergency call system;
- (VIII) Storage space for supplies and equipment; and

(IX) Bed space. There must be at least 3'0" on each side or between recovery care area beds and space at the foot of each bed for work and/or circulation.

(D) A minimum of two health care workers, one of which shall be a registered nurse with Advanced Cardiac Life Support (ACLS) certification, shall be on duty when patients are in the extended recovery care unit.

(E) Extended recovery care services shall have policies and procedures that describe the nature and extent of the extended recovery services provided, which are consistent with ambulatory surgery and anesthesia services.

(F) Extended recovery care services shall be integrated with other departments and services of the facility.

(G) In addition to the items required in a patient's medical record, the physician shall document the following:

(I) The reason(s) or need for a patient's admission to the extended

recovery care unit, and

- (II) Dietary orders to meet the nutritional needs of the patient.
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(H) The facility shall obtain a Food Service Establishment Permit, if required by the county health department.

(I) Inspection reports by the county health department shall be maintained at the facility for review by the Office of Health Quality.

(II) All personnel who prepare or serve food shall observe personal hygiene and sanitation practices which protect food from contamination.

(g) Emergency Services:

(i) Ambulatory surgical centers shall have policies and procedures which provide for adequate care of the center's patients in the event of an emergency.

(ii) There shall be a policy and procedure for obtaining ambulance services to a hospital including the notification of the next of kin or responsible party.

(iii) There shall be a written transfer agreement with a hospital or all physicians performing surgery in the ambulatory surgical center shall have admitting privileges at the hospital.

(iv) Emergency equipment and supplies shall be available on the premises.

(v) An ambulatory surgical center transferring a patient to a hospital on an emergency basis, shall submit to the receiving hospital at the time of transfer a copy of all medical records related to the patient's condition, including observations of the patient's signs and symptoms, preliminary diagnosis, treatment provided, results of any tests, and a copy of the informed written consent.

Section 8. Physical Environment.

(a) The ambulatory surgical center shall be constructed, arranged, and maintained to ensure health and safety of the patient.

(i) The building interior and exterior shall be clean, orderly, sanitary, and free of odors.

(b) Ambulatory surgical centers, certified prior to the effective date of these regulations and were lawfully constructed and in compliance with the regulations at the time of initial certification and found to be in continuing compliance during any subsequent surveys may continue to utilize existing, approved life safety systems provided that they present no hazard to life, health, or property and that there are no changes in the scope of services and utilization patterns in the ambulatory surgical center.

(i) Any renovations of the certified ambulatory surgical centers shall, after the effective date of these regulations, comply with the requirements as outlined in Section 9.

(c) All new ambulatory surgical centers shall meet the 1994 edition of the Life Safety Code of the National Fire Protection Association that is applicable to health care facilities.

(d) Medical gas and vacuum piped systems shall not be shared with non-licensed health care facilities.

(e) The critical branch of the emergency system powered by the generator shall not be shared with non-licensed health care facilities.

(f) The ventilation system shall not be share with non-licensed health care facilities.

Section 9. <u>Construction/Remodeling</u>.

This section applies to modernization, renovation, change of space use, and new construction of ambulatory surgical centers.

(a) The ambulatory surgical center shall meet all requirements established in:

(i) Guidelines for Construction and Equipment of Hospital and Medical Facilities, Chapter9. Outpatient Facilities, specifically described in Outpatient Surgical Facilities (Section 9.5).

(b) All plans and specifications for construction and/or remodeling shall be approved by the Office of Health Quality prior to construction.