SECOND REGULAR SESSION

HOUSE BILL NO. 2808

102ND GENERAL ASSEMBLY

INTRODUCED BY REPRESENTATIVE HADEN.

5781H.01I

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DANA RADEMAN MILLER, Chief Clerk

AN ACT

To repeal sections 197.200, 197.205, 197.215, 197.220, 197.221, 197.225, 197.230, 197.235, and 197.240, RSMo, and to enact in lieu thereof nine new sections relating to health care facilities, with penalty provisions.

Be it enacted by the General Assembly of the state of Missouri, as follows:

Section A. Sections 197.200, 197.205, 197.215, 197.220, 197.221, 197.225, 197.230,

- 2 197.235, and 197.240, RSMo, are repealed and nine new sections enacted in lieu thereof, to
- 3 be known as sections 197.200, 197.205, 197.215, 197.220, 197.221, 197.225, 197.230,
- 4 197.235, and 197.240, to read as follows:

197.200. As used in sections 197.200 to 197.240, unless the context clearly indicates otherwise, the following terms mean:

- 3 (1) "Abortion facility", as such term is defined in section 188.015;
- 4 (2) "Ambulatory surgical center"[-]:
- (a) Any [public or private establishment operated primarily] distinct establishment that operates exclusively for the purpose of [performing] providing surgical procedures [or primarily for the purpose of performing childbirths, and which does not provide services or other accommodations for] to patients [to stay more than twenty three hours within the establishment,] not requiring hospitalization and in which the duration of services for each patient is not expected to exceed twenty-four hours following the patient's admission; provided, however, that nothing in this definition shall be construed to include the
- 12 offices of dentists currently licensed pursuant to chapter 332; or
 - (b) Any distinct establishment that:

EXPLANATION — Matter enclosed in bold-faced brackets [thus] in the above bill is not enacted and is intended to be omitted from the law. Matter in **bold-face** type in the above bill is proposed language.

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a. Operates, in part, for the purpose of providing surgical procedures to patients not requiring hospitalization and in which the duration of services for each patient is not expected to exceed twenty-four hours following the patient's admission;

- b. Meets the requirements of paragraph (a) of this subdivision except for the requirement of operating exclusively for the purpose of providing surgical procedures to patients; and
- c. Applies to the department to be designated and regulated as an ambulatory surgical center;
- (3) "Birthing center", any facility that is not licensed as part of a hospital, that provides maternity care away from the mother's usual residence, and in which low-risk births are planned to occur following normal, uncomplicated pregnancies;
- 25 (4) "Certified registered nurse anesthetist", the same meaning given to the term 26 in section 335.016;
 - (5) "Deep sedation and analgesia", a drug-induced depression of consciousness during which:
- 29 (a) The patient cannot be easily aroused but responds purposefully following 30 repeated or painful stimulation;
 - (b) The patient's ability to independently maintain ventilatory function may be impaired;
 - (c) The patient may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate;
 - (d) Cardiovascular function is usually maintained; and
 - (e) Any physician or certified registered nurse anesthetist operating under a collaborative practice arrangement administering such drug-induced depression of consciousness shall have the skills and equipment to rescue any patient who enters a state of general anesthesia;
- 40 **(6)** "Dentist", any person currently licensed to practice dentistry pursuant to chapter 41 332;
 - [(4)] (7) "Department", the department of health and senior services;
- 43 [(5)] (8) "General anesthesia", a drug-induced loss of consciousness during 44 which:
 - (a) The patient is not arousable, even by painful stimulation;
- 46 **(b)** The patient's ability to independently maintain ventilatory function is often 47 impaired;
- 48 (c) The patient often requires assistance in maintaining a patent airway, and 49 positive pressure ventilation may be required because of depressed spontaneous 50 ventilation or drug-induced depression of neuromuscular function; and

- 51 (d) Cardiovascular function may be impaired;
 - (9) "Governmental unit", any city, county or other political subdivision of this state, or any department, division, board or other agency of any political subdivision of this state;
 - [(6)] (10) "Major conduction anesthesia", the administration of a drug or combination of drugs to interrupt nerve impulses without loss of consciousness, such as epidural, caudal, or spinal anesthesia; lumbar or brachial plexus blocks; and intravenous regional anesthesia. The term "major conduction anesthesia" shall not include isolated blockade of small peripheral nerves, such as digital nerves;
 - (11) "Minimal procedural sedation":
 - (a) A drug-induced state of sedation during which:
 - a. The patient responds normally to verbal commands; and
 - b. Cognitive function and physical coordination may be impaired, but airway reflexes and ventilatory and cardiovascular functions are unaffected; and
 - (b) The term "minimal procedural sedation" shall not include the administration of a mild pre-procedural oral anxiolytic during a surgical procedure;
 - (12) "Moderate procedural sedation", a drug-induced depression of consciousness during which:
 - (a) The patient responds purposefully to verbal commands, either alone or accompanied by light tactile stimulation;
 - (b) No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate;
 - (c) Cardiovascular function is usually maintained; and
 - (d) Any physician or certified registered nurse anesthetist administering such drug-induced depression of consciousness shall have the skills and equipment to rescue any patient who enters a state of deep sedation and analgesia;
 - (13) "Office-based surgery facility", any distinct establishment that is operated, in whole or in part, for the purpose of performing surgical procedures under procedural sedation or anesthesia not expected to require hospitalization, or for the purpose of performing any surgical procedure the department determines is of such risk to the patient that it requires additional safety procedures but that is not expected to require hospitalization, and in which the duration of services for each patient is not expected to exceed twenty-four hours following the patient's admission. The term "surgical procedure" as used in this subdivision shall not include any dental procedure performed by a dentist currently licensed under chapter 332;
- 85 (14) "Person", any individual, firm, partnership, corporation, company, or association and the legal successors thereof;

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87 [(7)] (15) "Physician", any person currently licensed to practice medicine pursuant to 88 chapter 334;

- 89 [(8)] (16) "Podiatrist", any person currently licensed to practice podiatry pursuant to 90 chapter 330;
 - (17) "Procedural sedation", the use of short-acting medications prior to and during a surgical procedure in order to provide analgesia and light to moderate sedation that enables physicians to perform surgical procedures effectively while monitoring the patient closely for potential adverse effects;
 - "Surgical procedure", an act that is performed for the purpose of structurally altering the human body by incision or destruction of tissues and that is part of the practice of medicine. The term "surgical procedure" shall also include the diagnostic evaluation or therapeutic treatment of conditions or disease processes by any instruments causing localized alteration or transposition of live human tissue, which include lasers, ultrasound, ionizing radiation, scalpels, probes, and needles. Such tissue alteration includes cutting, burning, vaporizing, freezing, suturing, probing, or manipulating by closed reduction for major dislocations and fractures or otherwise altering the tissue by any mechanical, thermal, light-based, electromagnetic, or chemical means. The term "surgical procedure" shall also include the injection of diagnostic or therapeutic substances into body cavities, internal organs, joints, sensory organs, and the central nervous system. The term "surgical procedure" shall not include administration by nursing personnel of injections, such as subcutaneous, intramuscular, and intravenous injections, when ordered by a physician.
- 197.205. 1. No person or governmental unit acting severally or jointly with any other 2 person or governmental unit shall establish, conduct or maintain an ambulatory surgical 3 center, office-based surgery facility, birthing center, or abortion facility in this state without a license under sections 197.200 to 197.240 issued by the department of health and senior services.
- 6 2. Nothing in sections 197.200 to 197.240 shall be construed to impair or abridge the authority of a governmental unit to license ambulatory surgical centers, office-based surgery facilities, birthing centers, or abortion facilities, provided that any ordinance of a governmental unit shall require compliance with all rules, regulations, and standards adopted by the department to implement the provisions of sections 197.200 to 197.240.
- 197.215. 1. Upon receipt of an application for a license, the department of health and 2 senior services shall issue a license if the applicant [and] is an ambulatory surgical center [facilities], office-based surgery facility, birthing center, or abortion [facilities meet] 4 facility, the applicant meets the requirements established under sections 197.200 to 197.240, and [have] the applicant has provided affirmative evidence that:

6 (1) Each member of the surgical staff is a physician, dentist or podiatrist currently 7 licensed to practice in Missouri, and each person authorized to perform or induce abortions is 8 a physician currently licensed to practice in Missouri;

- (2) Surgical procedures are performed as follows:
- (a) If performed in ambulatory surgical centers, surgical procedures shall be performed only by physicians[, dentists] or podiatrists[,] who are authorized to administer such treatment within the scope of practice of their license and who at the time are privileged to admit patients to, and to perform surgical procedures in, at least one licensed hospital in the community in which the ambulatory surgical center is located, thus providing assurance to the public that patients treated in the center shall receive continuity of care should the services of a hospital be required; alternatively, the applicant shall submit a copy of a current working agreement with at least one licensed hospital in the community in which the ambulatory surgical center is located, guaranteeing the transfer and admittance of patients for emergency treatment whenever necessary; or
- (b) If performed in an office-based surgery facility, surgical procedures shall be performed only by physicians or podiatrists authorized to administer such treatment within the scope of practice of their license or by other health care professionals through a lawful collaborative practice arrangement with a physician;
- (3) Continuous physician services or registered professional nursing services are provided [whenever a] for the patient [is] in the center or facility from admission through discharge; and
 - (4) Adequate medical records for each patient are to be maintained.
- 2. Upon receipt of an application for a license, or the renewal thereof, the department shall issue or renew the license if the applicant and program meet the requirements established under sections 197.200 to 197.240. Each license shall be issued only for the persons and premises named in the application. A license, unless sooner suspended or revoked, shall be issued for a period of one year.
- 3. Each license shall be issued only for the premises and persons or governmental units named in the application, and shall not be transferable or assignable except with the written consent of the department. Licenses shall be posted in a conspicuous place on the licensed premises.
- 4. If, during the period in which an ambulatory surgical center license, an office-based surgery facility license, a birthing center license, or an abortion facility license is in effect, the license holder or operator legally transfers operational responsibilities by any process to another person as defined in section 197.200, an application shall be made for the issuance of a new license to become effective on the transfer date.

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197.220. **1.** The department of health and senior services may deny, suspend or revoke a license in any case in which the department finds that there has been a substantial failure to comply with the requirements of sections 197.200 to 197.240, or in any case in which the director of the department **or the director's designee** makes a finding that:

- (1) The applicant, or if the applicant is a firm, partnership or association, any of its members, or if a corporation, any of its officers or directors, or the person designated to manage or supervise the facility, has been finally adjudicated and found guilty, or entered a plea of guilty or nolo contendere, in a criminal prosecution under the laws of any state or of the United States, for any offense reasonably related to the qualifications, functions, or duties of an ambulatory surgical center, of an office-based surgery facility, of a birthing center, or of an abortion facility, or for any offense an essential element of which is fraud, dishonesty, or an act of violence, or for any offense involving moral turpitude, whether or not sentence is imposed;
- (2) The licensure status or record of the applicant, or if the applicant is a firm, partnership or association, of any of its members, or if a corporation, of any of its officers or directors, or of the person designated to manage or supervise the facility, from any other state, federal district or land, territory or commonwealth of the United States, or of any foreign country where the applicant has done business in a similar capacity indicates that granting a license to the applicant would be detrimental to the interests of the public.
- 2. As used in this section, "substantial failure to comply with the requirements of sections 197.200 to 197.240" shall include, but is not limited to:
- (1) The refusal to grant a department representative immediate access to any regulated center or facility;
- (2) The refusal to grant a department representative immediate access to records of a regulated center or facility; or
- (3) The refusal of officers, employees, or contractual staff to submit to reasonable interviews by the department in furtherance of the department's obligations under the law.
- 197.221. **1.** Any person aggrieved by an official action of the department of health and senior services affecting the licensed status of a person under the provisions of sections 197.200 to 197.240, including the refusal to grant, the grant, the revocation, the suspension, or the failure to renew a license, may seek a determination thereon by the administrative hearing commission pursuant to the provisions of section 621.045 and it shall not be a condition to such determination that the person aggrieved seek a reconsideration, a rehearing, or exhaust any other procedure within the department of health and senior services.
 - 2. Any petition for a determination described in subsection 1 of this section shall be filed with the administrative hearing commission by the aggreed party no later

than sixty days from the mailing date of the notice of an official action of the department affecting the licensed status of a person or governmental unit under the provisions of sections 197.200 to 197.240.

- 197.225. 1. The department of health and senior services may adopt such reasonable rules, regulations, and standards for the types of services provided as are necessary to carry out the provisions of sections 197.200 to 197.240, and to assure quality patient care and patient safety, which shall include, but not be limited to:
- (1) Construction of the facility including, but not limited to, plumbing, heating, lighting, and ventilation which should [insure] ensure the health, safety, comfort, and privacy of patients and protection from fire hazard;
- 8 (2) Number, qualifications, and organization of all personnel, having responsibility 9 for any part of the care provided to the patients;
 - (3) Equipment essential to the health, welfare, and safety of the patients;
 - (4) Facilities, programs, and services to be provided in connection with the care of patients in ambulatory surgical centers, office-based surgery facilities, birthing centers, and abortion facilities; [and]
 - (5) Procedures for peer review and for receiving and investigating complaints regarding any ambulatory surgical center, office-based surgery facility, birthing center, or abortion facility or any physician, dentist, podiatrist, nurse, assistant, manager, supervisor, or employee practicing or working in any such center or facility; and
 - (6) A tiered level of regulation of office-based surgery facilities that imposes only those regulations necessary to ensure the safety of patients at each tier. The tier designation of an office-based surgery facility shall be based on the surgical procedure with the highest type of designation to be performed at such facility. Such tiers shall include:
 - (a) Type I: Surgical procedures where only minimal procedural sedation is required and the chances of complications requiring hospitalization are remote, and any surgical procedure the department determines is of such risk to the patient that it requires additional safety procedures;
 - (b) Type II: Surgical procedures that require moderate procedural sedation or deep sedation and analgesia and that require close perioperative monitoring, and any surgical procedure the department determines is of such risk to the patient that it requires additional safety procedures; and
 - (c) Type III: Surgical procedures that require either the use of general anesthesia or major conduction anesthesia combined with procedural sedation, and any surgical procedure the department determines is of such risk to the patient that it requires additional safety procedures.

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2. Consistent with this section, the department of health and senior services may adopt separate rules, regulations, or standards to apply to ambulatory surgical centers, to apply to each type of office-based surgery facility, to apply to birthing centers, and to apply to abortion facilities.

- 3. Ambulatory surgical centers, office-based surgery facilities, birthing centers, and abortion facilities shall be required to maintain a written protocol for managing medical emergencies and the transfer of patients requiring further emergency care to a hospital within a reasonable distance from the [abortion] originating center or facility.
- 197.230. 1. The department of health and senior services shall make, or cause to be made, such inspections and investigations as it deems necessary. The department may delegate its powers and duties to investigate and inspect ambulatory surgical centers, office-based surgery facilities, birthing centers, or abortion facilities to an official of a political subdivision having a population of at least four hundred fifty thousand if such political subdivision is deemed qualified by the department to inspect and investigate ambulatory surgical centers, office-based surgery facilities, birthing centers, or abortion facilities. The official so designated shall submit a written report of his or her findings to the department and the department may accept the recommendations of such official if it determines that the facility [inspected] inspection meets minimum standards established pursuant to sections 197.200 to 197.240.
 - 2. In the case of any abortion facility, the department shall make or cause to be made an unannounced on-site inspection and investigation at least annually. Such on-site inspection and investigation shall include, but not be limited to, the following areas:
 - (1) Compliance with all statutory and regulatory requirements for an abortion facility, including requirements that the facility maintain adequate staffing and equipment to respond to medical emergencies;
 - (2) Compliance with the provisions of chapter 188; and
 - (3) Compliance with the requirement in section 197.215 that continuous physician services or registered professional nursing services be provided [whenever a] for the patient [is] in the center or facility from admission through discharge.
- 3. Inspection, investigation, and quality assurance reports shall be made available to the public. Any portion of a report may be redacted when made publicly available if such portion would disclose information that is not subject to disclosure under the law.
- 197.235. 1. Any person operating, conducting, managing, or establishing an ambulatory surgical center, **office-based surgery facility, birthing center,** or abortion facility without a license required by sections 197.200 to 197.240 is guilty of a class A misdemeanor and, upon conviction, shall be subject to a fine of not more than five hundred dollars. Each day of continuing violation shall constitute a separate offense.

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2. The attorney general shall represent the department of health and senior services and shall institute an action in the name of the state for injunctive or other relief against any person or governmental unit to restrain or prevent the establishment, conduct, management, or operation of an ambulatory surgical center, office-based surgery facility, birthing center, or abortion facility without a license issued pursuant to the provisions of sections 197.200 to 197.240.

3. Any person operating, conducting, managing, or establishing an ambulatory surgical center, office-based surgery facility, birthing center, or abortion facility who, in the course of advertising, promoting, or otherwise publicizing the activities, business, location, or any other matter concerning the operations of said ambulatory surgical center, office-based surgery facility, birthing center, or abortion facility, uses or employs in any manner the words "State, Missouri, State of Missouri, Department of Health and Senior Services, the initials 'Mo.'," or any emblem of the state of Missouri or the department of health and senior services, for the purpose of conveying or in any manner reasonably calculated to convey the false impression that the state of Missouri or any department, agency, bureau, or instrumentality thereof is involved in the business of said ambulatory surgical center, office-based surgery facility, birthing center, or abortion facility, or took part in said advertisement, promotion, publicity, or other statement, shall be subject to a fine of one hundred dollars per day for each day during the period beginning with the day said advertisement, promotion, publication, or statement first appears and ending on the day on which it is withdrawn.

197.240. [After September 28, 1975,] No individual or group health insurance policy of insurance providing coverage on an expense incurred basis, nor individual or group service or indemnity type contract issued by a nonprofit corporation, nor any self-insured group health benefit plan or trust, of any kind or description, shall be issued or payment accepted therefor in renewal or continuation thereof unless coverage for any service performed in an 5 ambulatory surgical center, office-based surgery facility, birthing center, or abortion facility is provided for therein if such service would have been covered under the terms of the policy or contract as an eligible inpatient service, except as provided in section 376.805. Nothing in this section shall apply to a group contract, plan or trust which provides health care and surgical [eare] procedures directly to its members and their dependents. Nothing in 10 this section shall be construed to mandate coverage under an individual or group health 12 insurance policy of insurance providing coverage on an expense-incurred basis, or an individual or group service or indemnity type contract issued by a nonprofit corporation, or 13

14 any self-insured group health benefit plan or trust, of any kind or description, to provide

15 health insurance for services which are usually performed in a physician's office.

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