

HOUSE BILL No. 2458

By Committee on Health and Human Services

2-11

9 AN ACT concerning the department of health and environment; provid-
10 ing for regulation of clinics and facilities where office-based surgeries
11 and special procedures are performed.
12

13 *Be it enacted by the Legislature of the State of Kansas:*

14 Section 1. As used in this act:

15 (a) "Local anesthesia" means the administration of an anesthetic
16 agent into a localized part of the human body by topical application or
17 local infiltration in close proximity to a nerve, which produces a transient
18 and reversible loss of sensation.

19 (b) "Minimal sedation" means the administration of oral sedative or
20 oral analgesic drugs in doses appropriate for the unsupervised treatment
21 of insomnia, anxiety or pain.

22 (c) "Minor surgery" means surgery which can be safely and comfort-
23 ably performed on a patient who has received local or topical anesthesia,
24 without more than minimal sedation and where the likelihood of com-
25 plications requiring hospitalization is remote.

26 (d) "Office-based surgery" means any surgery or other special pro-
27 cedure requiring anesthesia, analgesia or sedation which is performed by
28 a physician in a clinical location other than a medical facility licensed
29 pursuant to K.S.A. 65-425, and amendments thereto, and which results
30 in a patient stay of less than 24 hours. The term does not include minor
31 surgery.

32 (e) "Physician" means a person licensed to practice medicine and
33 surgery or osteopathic medicine and surgery in the state of Kansas.

34 (f) "Secretary" means the secretary of health and environment.

35 (g) "Special procedure" means a patient care service which requires
36 contact with the human body with or without instruments in a potentially
37 painful manner, for a diagnostic or therapeutic procedure requiring an-
38 esthesia services (i.e., diagnostic or therapeutic endoscopy, invasive ra-
39 diologic procedures, manipulation under anesthesia or endoscopic ex-
40 amination). The term does not include minor surgery.

41 (h) "Surgery" means a manual or operative procedure which involves
42 the excision or resection, partial or complete, destruction, incision or
43 other structural alteration of human tissue by any means, including the

1 use of lasers, performed upon the human body for the purpose of pre-
2 serving health, diagnosing or treating disease, repairing injury, correcting
3 deformity or defects, prolonging life or relieving suffering, or for aes-
4 thetic, reconstructive or cosmetic purposes. Surgery includes, but is not
5 limited to, incision or curettage of tissue or an organ, suture or other
6 repair of tissue or an organ, a closed or open reduction of a fracture,
7 extraction of tissue from the uterus and insertion of natural or artificial
8 implants.

9 (i) "Topical anesthesia" means an anesthetic agent applied directly or
10 by spray to the skin or mucous membranes, intended to produce a tran-
11 sient and reversible loss of sensation to a circumscribed area.

12 Sec. 2. (a) The secretary, by rules and regulations, shall establish
13 standards for clinics and other facilities where office-based surgery or
14 special procedures, or both, are performed. Such standards shall include
15 such requirements as the secretary determines necessary to promote the
16 safety of patients, including, but not limited to, standards addressing:

- 17 (1) Qualifications and supervision of nonphysician personnel;
- 18 (2) facility safety and sanitation;
- 19 (3) equipment requirements, sanitation, testing and maintenance;
- 20 (4) patient screening, assessment and monitoring;
- 21 (5) selection of procedures to be performed;
- 22 (6) anesthesia services;
- 23 (7) peri-operative care;
- 24 (8) emergencies and patient transfers; and
- 25 (9) quality assurance and peer review.

26 (b) In adopting standards pursuant to this section, the secretary shall
27 give consideration to the guidelines for office-based surgery and special
28 procedures approved by the Kansas medical society house of delegates
29 on May 5, 2002 and any subsequently approved guidelines.

30 (c) Any rules and regulations adopted by the secretary pursuant to
31 this act shall provide for protection of the identities of patients and health
32 care providers.

33 Sec. 3. (a) A correction order may be issued by the secretary or the
34 secretary's designee to a clinic or facility which performs office-based
35 surgery or special procedures, or both, whenever a duly authorized rep-
36 resentative of the secretary inspects or investigates such clinic or facility
37 and determines that the clinic or facility is not in compliance with the
38 standards adopted by the secretary by rule and regulation pursuant to
39 section 2, and amendments thereto, and that such noncompliance signif-
40 icantly and adversely affects the health and safety of such clinic's or fa-
41 cility's office-based surgery or special procedures patients. The correction
42 order shall be served upon the clinic or facility either personally or by
43 certified mail, return receipt requested. The correction order shall be in

1 writing, shall state the specific deficiency, cite the specific statutory pro-
2 vision or rule and regulation alleged to have been violated, and shall spec-
3 ify a time of 30 days for correction of the deficiency, unless the deficiency
4 is of such an extreme hazard to the health and safety of a patient that
5 immediate correction is required. In such an extreme case correction of
6 the deficiency in less than 30 days may be ordered by the secretary or
7 the secretary's designee.

8 (b) When the time period set forth in the correction order has passed,
9 the clinic or facility shall be reinspected for compliance. If the clinic or
10 facility is still in noncompliance, the secretary or the secretary's designee
11 may place a ban on the performance of any office-based surgeries and
12 special procedures at the noncompliant clinic or facility until compliance
13 is found and may level a civil penalty against such clinic or other facility
14 pursuant to section 4, and amendments thereto.

15 Sec. 4. (a) Any clinic or facility which remains noncompliant to the
16 correction order and continues to violate any provision of the rules and
17 regulations adopted under this act may incur a civil penalty in an amount
18 not more than \$5,000 for every such violation. In the case of a continuing
19 violation, every day such violation continues shall be deemed a separate
20 violation.

21 (b) The secretary, upon a finding that a clinic or facility has violated
22 any provision of rules and regulations adopted under this act may impose
23 a penalty within the limits provided in this section. In determining the
24 amount of the civil penalty, the secretary shall take into consideration all
25 relevant circumstances, including, but not limited to, the extent of harm
26 caused by the violation, the nature and persistence of the violation, the
27 length of time over which the violation occurs and any corrective actions
28 taken.

29 (c) No penalty shall be imposed under this section until written notice
30 and an opportunity for hearing have been provided to the clinic or facility
31 alleged to have committed the violation. Such notice shall state the vio-
32 lation, the penalty to be imposed and the right of the clinic or facility to
33 a hearing on the matter. Such clinic or facility, within 15 days after service
34 of the order, may make written request to the secretary for a hearing
35 thereon. The hearing shall be conducted in accordance with the provi-
36 sions of the Kansas administrative procedure act.

37 (d) Any action of the secretary pursuant to this section is subject to
38 review in accordance with the act for judicial review and civil enforcement
39 of agency actions.

40 Sec. 5. Any clinic or facility where office-based surgery or special
41 procedures, or both, are performed at the time rules and regulations
42 adopted under this act take effect shall be given reasonable time, as de-
43 termined by the secretary under the particular circumstances, but not to

1 exceed 30 days from the effective date of such rules and regulations,
2 within which to comply with such rules and regulations.

3 Sec. 6. (a) The department of health and environment shall conduct
4 unannounced inspections of any clinic or facility where office-based sur-
5 gery or special procedures are performed at least every five years on a
6 routine basis. Upon receipt of a complaint, the department of health and
7 environment shall conduct an inspection in a timely manner.

8 (b) The board of healing arts shall forward all complaints it receives
9 regarding clinics or facilities where office-based surgery or special pro-
10 cedures are performed to the department of health and environment.

11 (c) The department of health and environment shall forward the re-
12 sults of all inspections to the board of healing arts or the state board of
13 nursing, or both, as appropriate, when a clinic or facility where office-
14 based surgery or special procedures are performed are out of compliance.

15 Sec. 7. This act shall take effect and be in force from and after its
16 publication in the statute book.