House Study Bill 48 - Introduced

HOUSE FILE

BY (PROPOSED COMMITTEE ON HUMAN RESOURCES BILL BY CHAIRPERSON MILLER)

A BILL FOR

- 1 An Act relating to the licensure of ambulatory surgical
- 2 centers, providing fees and penalties, and including
- 3 effective date provisions.
- 4 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

1 Section 1. NEW SECTION. 135P.1 Definitions.

2 As used in this chapter, unless the context otherwise 3 requires:

1. "Ambulatory surgical center" means a distinct facility 5 that operates exclusively for the purpose of providing surgical 6 services to patients not requiring hospitalization and in which 7 the expected duration of services does not exceed twenty-four 8 hours following an admission. "Ambulatory surgical center" does 9 not include individual or group practice offices of private 10 physicians, podiatrists, or dentists that do not contain a 11 distinct area used for outpatient surgical treatment on a 12 regular basis, or that only provide surgery routinely provided 13 in a physician's, podiatrist's, or dentist's office using local 14 anesthesia or conscious sedation; or a portion of a licensed 15 hospital designated for outpatient surgical treatment.

16 2. "Department" means the department of inspections and 17 appeals.

18 Sec. 2. NEW SECTION. 135P.2 Purpose.

19 The purpose of this chapter is to protect the public 20 health, safety, and welfare by providing for the licensing and 21 regulation of ambulatory surgical centers.

22 Sec. 3. NEW SECTION. 135P.3 Licensure.

23 A person, acting severally or jointly with any other person, 24 shall not establish, operate, or maintain an ambulatory 25 surgical center in this state without obtaining a license as 26 provided under this chapter.

Sec. 4. <u>NEW SECTION</u>. 135P.4 Application for license — fee. 1. An applicant for an ambulatory surgical center license shall submit an application to the department. Applications shall be upon such forms and shall include such information as the department may reasonably require, which may include affirmative evidence of ability to comply with reasonable rules and standards prescribed under this chapter.

34 2. a. An application for an initial license for35 an ambulatory surgical center that is in existence and

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1 Medicare-certified prior to July 1, 2014, shall be accompanied 2 by a fee of fifty dollars.

3 b. An application for an initial license for an ambulatory 4 surgical center established on or after July 1, 2014, shall 5 be accompanied by a fee sufficient to cover the costs of 6 performing the inspection required in section 135P.8 in an 7 amount as provided in rules adopted by the department.

8 Sec. 5. <u>NEW SECTION</u>. 135P.5 Issuance and renewal of 9 license.

10 1. Upon receipt of an application for license and the 11 license fee, the department shall issue a license if the 12 applicant and the ambulatory surgical center meet the 13 requirements of this chapter and the rules adopted by the 14 department.

15 2. A license shall be issued only for the premises and 16 persons named in the application.

17 3. A license is not transferable or assignable except with18 the written approval of the department.

A license shall be posted in a conspicuous place on the
 licensed premises as prescribed by rule of the department.

5. Separate licenses are not required for ambulatory surgical center facilities that are maintained on the same physical site and that have the same ownership or control. Multiple buildings located on the same physical site under the same ownership or control shall be considered one ambulatory surgical center facility for purposes of this chapter and rection 135.61, subsection 21, and may operate under one license.

6. A license, unless sooner suspended or revoked, shall expire on December 31 of each year and shall be renewed annually. The department shall renew a license upon payment of a five hundred dollar annual license renewal fee and filing of an application for renewal at least thirty days prior to the expiration of the existing license. The annual licensure fee shall be dedicated to support the staffing necessary to conduct

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1 the inspections and investigations provided in section 135P.8.

2 Sec. 6. <u>NEW SECTION</u>. 135P.6 Denial, suspension, or 3 revocation of license — hearings and review.

The department may deny, suspend, or revoke a license in
 any case where it finds there has been a substantial failure
 to comply with this chapter or the rules and standards adopted
 under this chapter.

8 2. The denial, suspension, or revocation of a license by 9 the department and appeal from that action are governed by the 10 procedures for a contested case hearing under chapter 17A. 11 3. *a*. If the department finds, after providing notice of 12 noncompliance and a reasonable time for corrective action, that 13 an ambulatory surgical center is in repeated noncompliance with 14 this chapter or the department's rules but that noncompliance 15 does not endanger public health or safety, the department may 16 issue a conditional license to the ambulatory surgical center 17 as an alternative to suspending or revoking the ambulatory 18 surgical center's license.

19 b. The department shall provide notice of its intent to 20 issue a conditional license to the ambulatory surgical center 21 and of the items of noncompliance not less than ten days before 22 the date the conditional license is issued.

c. The department shall designate a period of not more
than one year during which the ambulatory surgical center may
operate under a conditional license.

26 d. During the period an ambulatory surgical center is 27 operating under a conditional license, the ambulatory surgical 28 center shall correct the items that are in noncompliance and 29 report the corrections to the department for approval.

30 4. The department may suspend or revoke the license of an 31 ambulatory surgical center that does not correct items that 32 are in noncompliance or that does not comply with this chapter 33 or the rules adopted under this chapter within the applicable 34 period.

35 5. The department may issue an emergency order to suspend

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1 a license issued under this chapter if the department has 2 reasonable cause to believe that the conduct of the ambulatory 3 surgical center creates an immediate danger to the public 4 health and safety. An emergency suspension is effective 5 immediately without a hearing or notice to the licensee. On 6 written request of the licensee, the department shall conduct 7 a hearing not earlier than the tenth day or later than the 8 thirtieth day after the date the hearing request is received 9 to determine if the emergency suspension is to be continued, 10 modified, or rescinded. The hearing and any appeal are 11 governed by the department's rules for a contested case hearing 12 and chapter 17A.

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Sec. 7. NEW SECTION. 135P.7 Rules.

14 1. The department, with the advice and approval of the state 15 board of health, shall adopt rules specifying the standards for 16 ambulatory surgical centers to be licensed under this chapter. 17 The rules shall be consistent with and shall not exceed the 18 requirements of this chapter and the conditions for coverage in 19 the federal Medicare program for ambulatory surgical centers 20 under 42 C.F.R. pt. 416.

21 2. The department shall adopt rules as the department deems 22 necessary to implement the provisions of this chapter relating 23 to the issuance, renewal, denial, suspension, and revocation 24 of a license to establish, operate, and maintain an ambulatory 25 surgical center.

3. An ambulatory surgical center which is in operation at the time of adoption of any applicable rules or standards under this chapter shall be given a reasonable time, not to exceed one year from the date of adoption, within which to comply with such rules and standards.

31 4. The department shall enforce the rules.

32 Sec. 8. NEW SECTION. 135P.8 Inspections.

33 1. The department shall make or cause to be made inspections 34 or investigations of ambulatory surgical centers to determine 35 compliance with this chapter and applicable rules and

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standards. The department shall perform inspections on a
 schedule that is of the same frequency required for inspections
 of Medicare-certified ambulatory surgical centers.

4 2. The department shall recognize, in lieu of its own
5 licensure inspection, the comparable inspection and inspection
6 findings of a Medicare conditions for coverage survey.

7 3. A department inspector shall not participate in an 8 inspection or investigation of an ambulatory surgical center in 9 which the inspector or a member of the inspector's immediate 10 family works or has worked within the last two years or in 11 which the inspector or the inspector's immediate family has 12 a financial ownership interest. For the purposes of this 13 section, *"immediate family member"* means a spouse, natural or 14 adoptive parent or grandparent, child, grandchild, sibling, 15 stepparent, stepchild, or stepsibling.

16 Sec. 9. <u>NEW SECTION</u>. 135P.9 Employee background checks. 17 1. An ambulatory surgical center shall comply with child and 18 dependent adult abuse information and criminal record checks 19 and evaluations in the same manner as provided in section 20 135B.34, except that the authorization of an exemption under 21 section 135B.34, subsection 4, paragraph "b", from requirements 22 for reevaluation of the latest record checks by the department 23 of human services relative to a person being considered for 24 employment in an ambulatory surgical center is subject to all 25 of the following provisions:

a. The position with the ambulatory surgical center is
substantially the same or has the same job responsibilities as
the position for which the previous evaluation was performed. *b.* Any restrictions placed on the person's employment in the
previous evaluation by the department of human services shall
remain applicable in the person's employment in the ambulatory
surgical center.

33 c. The person subject to the record checks has maintained 34 a copy of the previous evaluation and provides the evaluation 35 to the ambulatory surgical center or the previous employer

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1 provides the previous evaluation from the person's personnel 2 file pursuant to the person's authorization. If a physical 3 copy of the previous evaluation is not provided to the 4 ambulatory surgical center, the record checks shall be 5 reevaluated.

d. Although an exemption may be authorized, the ambulatory
7 surgical center may instead request a reevaluation of the
8 record checks and may employ the person while the reevaluation
9 is being performed.

10 2. An ambulatory surgical center licensed in this state 11 may access the single contact repository established by the 12 department pursuant to section 135C.33 as necessary for the 13 ambulatory surgical center to perform record checks of persons 14 employed or being considered for employment by the ambulatory 15 surgical center.

16 Sec. 10. NEW SECTION. 135P.10 Confidentiality.

The department's final findings or the final survey findings 17 18 of an accrediting body with respect to compliance by an 19 ambulatory surgical center with requirements for licensing 20 or accreditation shall be made available to the public in a 21 readily available form and place. Other information relating 22 to an ambulatory surgical center obtained by the department 23 which does not constitute the department's findings from an 24 inspection of the ambulatory surgical center or the final 25 survey findings of the accrediting body shall not be made 26 available to the public, except in proceedings involving the 27 denial, suspension, or revocation of a license under this 28 chapter. The name of a person who files a complaint with the 29 department shall remain confidential and shall not be subject 30 to discovery, subpoena, or other means of legal compulsion for 31 its release to a person other than department employees or 32 agents involved in the investigation of the complaint.

33 Sec. 11. <u>NEW SECTION</u>. 135P.11 Injunction.
 34 Notwithstanding the existence or pursuit of any

Notwithstanding the existence or pursuit of any other remedy, the department may, in the manner provided by law,

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maintain an action in the name of the state for injunction
 or other process against any person to restrain or prevent
 the establishment, operation, or maintenance of an ambulatory
 surgical center without a license.

5 Sec. 12. NEW SECTION. 135P.12 Judicial review.

6 Judicial review of an action of the department may be sought 7 in accordance with chapter 17A. Notwithstanding the provisions 8 of chapter 17A, petitions for judicial review may be filed 9 in the district court of the county in which the ambulatory 10 surgical center is located or is to be located and the status 11 quo of the petitioner or licensee shall be preserved pending 12 final disposition of the judicial review matter.

13 Sec. 13. NEW SECTION. 135P.13 Penalties.

14 Any person establishing, operating, or maintaining any 15 ambulatory surgical center without a license commits a serious 16 misdemeanor, and each day of continuing violation after 17 conviction shall be considered a separate offense.

18 Sec. 14. Section 135.11, Code 2013, is amended by adding the 19 following new subsection:

20 NEW SUBSECTION. 32. Adopt rules requiring ambulatory 21 surgical centers to report quality data to the department of 22 public health that is consistent with the data required to be 23 reported to the centers for Medicare and Medicaid services 24 of the United States department of health and human services 25 as authorized by the Medicare Improvements and Extension Act 26 of 2006 under Title I of the Tax Relief and Health Care Act 27 of 2006, Pub. L. No. 109-432, and the regulations adopted 28 under such Acts. Notwithstanding any provision of law to 29 the contrary, nothing in this subsection shall require an 30 ambulatory surgical center to provide health data to the 31 department of public health or any other public or private 32 entity that is in addition to, different than, or exceeds 33 the quality data required to be reported to the centers for 34 Medicare and Medicaid services of the United States department 35 of health and human services.

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Sec. 15. EFFECTIVE DATE. This Act takes effect July 1,
 2 2014.

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EXPLANATION

4 This bill creates a new Code chapter to provide for the 5 licensing and regulation of ambulatory surgical centers.

6 The bill defines "ambulatory surgical center" as a distinct 7 facility that operates exclusively for the purpose of providing 8 surgical services to patients not requiring hospitalization 9 and in which the expected duration of services does not 10 exceed 24 hours following an admission. "Ambulatory surgical 11 center" does not include individual or group practice offices 12 of private physicians, podiatrists, or dentists that do not 13 contain a distinct area used for outpatient surgical treatment 14 on a regular basis, or that only provide surgery routinely 15 provided in a physician's, podiatrist's, or dentist's office 16 using local anesthesia or conscious sedation; or a portion of a 17 licensed hospital designated for outpatient surgical treatment. 18 The department of inspections and appeals is designated to 19 enforce the regulations.

The bill provides that the purpose of the new Code chapter is to protect the public health, safety, and welfare by providing for the licensing and regulation of ambulatory surgical centers. The bill prohibits the establishment, operation, and or maintenance of an ambulatory surgical center in the state swithout obtaining a license.

The bill provides the process for application for licensure. An application for an initial license for an ambulatory surgical center that is in existence and Medicare-certified prior to July 1, 2014, is required to be accompanied by a fee of \$50. An application for an initial license for an ambulatory surgical center established on or after July 1, 2014, is required to be accompanied by a fee sufficient to cover the costs of performing the required inspection in an amount provided in rules adopted by the department.

35 The bill provides for the issuance and renewal of licenses.

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1 A license is to be issued only for the premises and persons 2 named in the application; is not transferable or assignable 3 except with the written approval of the department; and is 4 required to be posted in a conspicuous place on the licensed 5 premises as prescribed by rule of the department. The bill 6 provides that separate licenses are not required for ambulatory 7 surgical center facilities that are maintained on the same 8 physical site and that have the same ownership or control. 9 Multiple buildings located on the same physical site under the 10 same ownership or control shall be considered one ambulatory 11 surgical center facility for purposes of the new Code chapter 12 and Code chapter 135, division VI, relating to the health 13 facilities council and certificate of need provisions, and are 14 to be permitted to operate under one license. Licenses expire 15 on December 31 of each year and are required to be renewed 16 annually. The bill directs the department to renew a license 17 upon payment of a \$500 annual license renewal fee and filing 18 of an application for renewal at least 30 days prior to the 19 expiration of the existing license. The annual licensure fee 20 is to be dedicated to support the staffing necessary to conduct 21 the inspections and investigations under the Code chapter. The bill provides for denial, suspension, or revocation of 22 23 licenses. A license may be denied, suspended, or revoked if 24 the department finds there has been a substantial failure to 25 comply with the Code chapter or the rules and standards adopted 26 under the Code chapter. The denial, suspension, or revocation 27 of a license by the department and appeal from that action are 28 governed by the procedures for a contested case hearing under 29 Code chapter 17A. The bill authorizes the department, after 30 providing notice of noncompliance and a reasonable time for 31 corrective action, and if the noncompliance does not endanger 32 public health or safety, to issue a conditional license to the 33 ambulatory surgical center as an alternative to suspending or 34 revoking its license.

35 The bill also authorizes the department to issue an

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1 emergency order to suspend a license if the department has 2 reasonable cause to believe that the conduct of the ambulatory 3 surgical center creates an immediate danger to the public 4 health or safety. On written request of the licensee, the 5 department is required to conduct a hearing to determine if 6 the emergency suspension is to be continued, modified, or 7 rescinded. The hearing and any appeal are governed by the 8 department's rules for a contested case hearing and Code 9 chapter 17A.

10 The bill directs the department to adopt rules with the 11 advice and approval of the state board of health to specify 12 the standards for ambulatory surgical centers. The rules are 13 required to be consistent with and not exceed the requirements 14 of the Code chapter and the conditions for coverage in the 15 federal Medicare program for ambulatory surgical centers. 16 The department is also directed to adopt rules relating to 17 provisions of the Code chapter relating to the issuance, 18 renewal, denial, suspension, and revocation of a license to 19 establish, operate, and maintain an ambulatory surgical center. 20 If an ambulatory surgical center is in operation at the time of 21 adoption of any applicable rules or standards, the center is 22 to be given a reasonable time, not to exceed one year from the 23 date of adoption, within which to comply with such rules and 24 standards.

The bill provides for inspections or investigations of ambulatory surgical centers, and directs that the department shall perform inspections on a schedule that is of the same requency required for inspections of Medicare-certified ambulatory surgical centers. The bill also requires the department to recognize, in lieu of its own licensure inspection, the comparable inspection and inspection findings of a Medicare conditions for coverage survey.

33 The bill prohibits a department inspector from participating 34 in an inspection or investigation of an ambulatory surgical 35 center in which the inspector or a member of the inspector's

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1 immediate family works or has worked within the last two years
2 or in which the inspector or the inspector's immediate family
3 has a financial ownership interest.

The bill requires an ambulatory surgical center to comply 5 with child and dependent adult abuse information and criminal 6 record checks and evaluations in the same manner as provided 7 for hospitals, but specifically provides that the authorization 8 of an exemption from a reevaluation of the person's criminal 9 or abuse record prior to commencing employment is subject to 10 specific provisions. The bill also authorizes an ambulatory 11 surgical center to access the single contact repository 12 established by the department as necessary for the ambulatory 13 surgical center to perform record checks of persons employed 14 or being considered for employment by the ambulatory surgical 15 center.

16 The bill provides confidentiality provisions relating to 17 ambulatory surgical center information. The final findings or 18 the final survey findings of an accrediting body with respect 19 to compliance by an ambulatory surgical center are to be 20 made available to the public in a readily available form and 21 place. Other information relating to an ambulatory surgical 22 center shall not be made available to the public, except in 23 proceedings involving the denial, suspension, or revocation of 24 a license. The name of a person who files a complaint with 25 the department is required to remain confidential and not 26 be subject to discovery, subpoena, or other means of legal 27 compulsion.

The bill provides for injunctive relief and judicial review. The bill provides that any person establishing, operating, or maintaining an ambulatory surgical center without a license commits a serious misdemeanor, and each day of continuing violation after conviction shall be considered a separate a offense. A serious misdemeanor is punishable by confinement for no more than one year and a fine of at least \$315 but not more than \$1,875.

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1 The bill also directs the department of public health 2 to adopt rules requiring ambulatory surgical centers to 3 report quality data to the department of public health that 4 is consistent with the data required to be reported to the 5 centers for Medicare and Medicaid services of the United States 6 department of health and human services. However, the rules 7 are not to require an ambulatory surgical center to provide 8 health data to the department of public health or any other 9 public or private entity that is in addition to, different 10 than, or exceeds the quality data required to be reported to 11 the centers for Medicare and Medicaid services of the United 12 States department of health and human services.

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13 The bill takes effect July 1, 2014.