

MAR 2 2005
HUMAN RESOURCES

HOUSE FILE 508
BY MASCHER

Passed House, Date _____ Passed Senate, Date _____
Vote: Ayes _____ Nays _____ Vote: Ayes _____ Nays _____
Approved _____

A BILL FOR

1 An Act relating to the licensure of clinical laboratories and
2 imposing penalties.

3 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

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HF 508

1 Section 1. NEW SECTION. 135M.1 TITLE.

2 This chapter shall be known and may be cited as the "Iowa
3 Clinical Laboratory Law".

4 Sec. 2. NEW SECTION. 135M.2 APPLICATION OF CHAPTER --
5 EXEMPTIONS.

6 This chapter applies to all clinical laboratories within
7 this state, except all of the following:

8 1. A clinical laboratory operated by the United States
9 government.

10 2. A clinical laboratory that performs only waived tests
11 and has received a certificate of exemption from the
12 department under section 135M.11.

13 3. A clinical laboratory operated and maintained
14 exclusively for research and teaching purposes that do not
15 involve patient or public health service.

16 Sec. 3. NEW SECTION. 135M.3 CLINICAL LABORATORIES
17 OPERATED BY PRACTITIONERS FOR EXCLUSIVE USE -- LICENSURE AND
18 REGULATION.

19 1. A clinical laboratory operated by one or more
20 practitioners licensed under chapter 148, 149, 150, 150A, 151,
21 152, or 153, exclusively in connection with the diagnosis and
22 treatment of their own patients, shall be licensed under this
23 chapter and shall comply with the provisions of this chapter,
24 except that the department shall adopt rules for staffing;
25 personnel, including education and training of personnel;
26 proficiency testing; and construction standards relating to
27 the licensure and operation of the laboratory based upon and
28 not exceeding the standards contained in the Act as defined in
29 section 135M.4.

30 2. Subsection 1 does not apply to a clinical laboratory
31 operated by one or more practitioners who hold the facilities
32 of the laboratory out as available for the performance of
33 diagnostic tests for other practitioners or their patients.

34 3. This chapter applies to any clinical laboratory that
35 receives any referred work or performs any work for patients

1 referred by another practitioner.

2 Sec. 4. NEW SECTION. 135M.4 DEFINITIONS.

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

5 1. "Act" means the federal Clinical Laboratory Improvement
6 Amendments of 1988, Pub. L. No. 100-578. "Act" includes the
7 federal regulations adopted pursuant to the Act.

8 2. "Clinical laboratory" means the physical location in
9 which one or more of the following services are performed to
10 provide information or materials for use in the diagnosis,
11 prevention, or treatment of a disease or the identification or
12 assessment of a medical or physical condition:

13 a. Anatomic laboratory services.

14 b. Clinical laboratory services.

15 c. Cytology laboratory services.

16 3. "Clinical laboratory examination" means a procedure
17 performed to deliver the services defined in subsection 2,
18 including the oversight or interpretation of such procedures.

19 4. "Clinical laboratory proficiency testing program" means
20 a program approved by the department for evaluating the
21 performance of clinical laboratories.

22 5. "Collection station" or "branch office" means a
23 facility operated by a clinical laboratory where materials or
24 specimens are withdrawn or collected from patients or
25 assembled after being withdrawn or collected from patients
26 elsewhere, for subsequent delivery to another location for
27 examination.

28 6. "Department" means the Iowa department of public
29 health.

30 7. "Hospital laboratory" means a laboratory located in a
31 hospital that provides services solely to that hospital and
32 that is owned by the hospital and governed by the hospital
33 medical staff or governing board.

34 8. "Licensed practitioner" means a physician licensed
35 under chapter 148, 148D, 150, or 150A; a podiatrist licensed

1 under chapter 149; a dentist licensed under chapter 153; a
2 chiropractor licensed under chapter 151; or an advanced
3 registered nurse practitioner licensed under chapter 152.

4 9. "Waived test" means a test that the federal health care
5 financing administration has determined qualifies for a
6 certificate of waiver under the federal Act.

7 Sec. 5. NEW SECTION. 135M.5 POWERS AND DUTIES OF
8 DEPARTMENT.

9 The department shall adopt rules as necessary to implement
10 this chapter. The rules shall include, but not be limited to,
11 all of the following:

12 1. LICENSING AND QUALIFICATIONS. The department shall
13 provide for biennial licensure of all clinical laboratories
14 meeting the requirements of this chapter and shall prescribe
15 the qualifications necessary for such licensure. A license
16 issued for operating a clinical laboratory, unless sooner
17 suspended or revoked, expires on the date set forth by the
18 department on the face of the license.

19 2. STANDARDS OF PERFORMANCE IN THE EXAMINATION OF
20 SPECIMENS. The department shall prescribe all of the
21 following:

22 a. Overall standards of performance that comply with the
23 Act, for a comprehensive quality assurance program.

24 b. Standards of performance in the examination of
25 specimens for clinical laboratory proficiency testing programs
26 using external quality control procedures.

27 3. SHIPMENT OF SPECIMENS. The department shall adopt
28 requirements for collecting, transporting, handling, and
29 storing specimens shipped by common carrier from clinical
30 laboratories or collection stations.

31 4. CONSTRUCTION OF CLINICAL LABORATORIES. A clinical
32 laboratory shall comply with all applicable local, county,
33 state, and federal standards for the construction, renovation,
34 maintenance, and repair of clinical laboratories, including
35 standards for plumbing, heating, lighting, ventilation, and

1 electrical services, and similar services.

2 5. SAFETY AND SANITARY CONDITIONS. The department shall
3 establish standards relating to safety and sanitary conditions
4 within a clinical laboratory and its surroundings, including
5 standards for water supply; sewage; handling of specimens;
6 identification, segregation, and separation of biohazardous
7 wastes; storage of chemicals; workspace; fire safety; and
8 general measures that will protect the public health.

9 6. EQUIPMENT. The department shall establish minimum
10 standards for clinical laboratory equipment essential to its
11 proper operation, its calibration, and its adequacy for
12 testing procedures.

13 7. POLICY AND PROCEDURE MANUAL. The department shall
14 require that each clinical laboratory adopt and maintain a
15 written policy and procedure manual. The manual shall be
16 readily available to laboratory personnel and shall be
17 followed by laboratory personnel. The manual shall address,
18 but not be limited to, the following topics:

19 a. The performance of all analytical methods used by the
20 clinical laboratory, including specimen collection and
21 preservation.

22 b. Instrument calibration.

23 c. Quality control systems, measures, and remedial
24 actions.

25 d. Equipment performance evaluations.

26 e. Test performance.

27 f. Maintenance and filing of required records and reports.

28 g. Channels of communication.

29 h. Space, equipment, and supply requirements.

30 8. STANDARDS FOR PATIENT TEST MANAGEMENT. The department
31 shall adopt rules that prescribe standards for patient test
32 management, including requirements for record retention and
33 patient test reporting.

34 9. ALTERNATE-SITE TESTING. The department shall adopt
35 rules for alternate-site testing to be performed under the

1 supervision of a clinical laboratory director.

2 Sec. 6. NEW SECTION. 135M.6 INSPECTION OF CLINICAL
3 LABORATORIES.

4 1. The department shall ensure that each clinical
5 laboratory subject to this chapter is inspected either onsite
6 or offsite as deemed necessary by the department. However,
7 each clinical laboratory shall be inspected at least every two
8 years, for the purpose of evaluating the operation,
9 supervision, and procedures of the facility to ensure
10 compliance with this chapter. Collection stations and branch
11 offices may be inspected either onsite or offsite, as deemed
12 necessary by the department. The department may conduct
13 announced or unannounced inspections at any reasonable time,
14 however, to the extent practicable inspections shall be
15 scheduled so as to cause the least disruption to the
16 practitioner's scheduled patients.

17 2. The department may accept, in lieu of its own periodic
18 inspections for licensure, the survey of or inspection by a
19 private accrediting organization which is approved by the
20 department, which performs inspections of clinical
21 laboratories accredited by such organization, including
22 postinspection requirements imposed by the department.

23 a. The department shall accept inspections performed by
24 such an organization if the accreditation is not provisional,
25 if such organization performs postinspection activities
26 required by the department and provides the department with
27 all necessary inspection and postinspection reports and
28 information necessary for enforcement, if such organization
29 applies standards equal to or exceeding standards established
30 and approved by the department, and if such accrediting
31 organization is approved by the federal centers for Medicare
32 and Medicaid services to perform such inspections.

33 b. The department may conduct complaint investigations
34 made against laboratories inspected by an accrediting
35 organization.

1 c. The department may conduct sample validation
2 inspections of laboratories inspected by an accrediting
3 organization to evaluate the accreditation process used by an
4 accrediting organization.

5 d. The department may conduct a full inspection of a
6 clinical laboratory if an accrediting survey has not been
7 conducted within the previous twenty-four months.

8 e. The department shall adopt criteria by rule for
9 accepting inspection and postinspection reports of an
10 accrediting organization in lieu of conducting a state
11 licensure inspection.

12 Sec. 7. NEW SECTION. 135M.7 CLINICAL LABORATORY LICENSE.

13 A person shall not conduct, maintain, or operate a clinical
14 laboratory in this state, except a laboratory that is exempt
15 under section 135M.2, unless the clinical laboratory has
16 obtained a license from the department. A clinical laboratory
17 shall not send a specimen drawn within this state to a
18 clinical laboratory located outside the state for examination
19 unless the out-of-state laboratory has obtained a license from
20 the department. A license is valid only for the person or
21 persons to whom it is issued and may not be sold, assigned, or
22 transferred, voluntarily or involuntarily, and is not valid
23 for any premises other than those for which the license is
24 issued. However, a new license may be secured for a new
25 location before the actual change in location if the
26 contemplated change complies with this chapter and the rules
27 adopted under this chapter. Application for a new clinical
28 laboratory license must be made sixty days before a change in
29 the ownership of the clinical laboratory.

30 Sec. 8. NEW SECTION. 135M.8 APPLICATION FOR LICENSE.

31 1. An application for a clinical laboratory license shall
32 be made by the owner or director of the clinical laboratory or
33 by the public official responsible for operating a state,
34 municipal, or county clinical laboratory or institution that
35 contains a clinical laboratory, upon forms provided by the

1 department.

2 2. An applicant for licensure shall comply with the
3 following requirements:

4 a. Upon receipt of a completed, signed, and dated
5 application, the department shall require a background check
6 of the managing director or other similarly titled individual
7 who is responsible for the daily operation of the laboratory
8 and of the financial officer, or other similarly titled
9 individual who is responsible for the financial operation of
10 the laboratory, including billings for patient services. The
11 department may require background screening of any other
12 individual who is an applicant if the department believes the
13 person has been convicted of a crime that relates to the
14 person's ability to work in a clinical laboratory.

15 b. An applicant shall submit to the department, with its
16 application, a description and explanation of any exclusions,
17 permanent suspensions, or terminations of the applicant from
18 the Medicare or Medicaid programs. Proof of compliance with
19 the requirements for disclosure of ownership and control
20 interests under the Medicare or Medicaid programs may be
21 accepted in lieu of this submission.

22 c. The department shall not grant a license to an
23 applicant if the applicant has been found guilty of any crime
24 which would relate to that applicant's ability to work in a
25 clinical laboratory.

26 Sec. 9. NEW SECTION. 135M.9 ISSUANCE AND DISPLAY OF
27 LICENSE.

28 1. A license is valid for a period of two years and shall
29 be issued to a clinical laboratory to perform only those
30 clinical laboratory procedures and tests that are within the
31 specialties or subspecialties in which the clinical laboratory
32 personnel are qualified. A license shall not be issued unless
33 the department determines that the clinical laboratory is
34 adequately staffed and equipped to operate in conformity with
35 the requirements of this chapter and the rules adopted under

1 this chapter.

2 2. A license shall be issued authorizing the performance
3 of one or more clinical laboratory procedures or one or more
4 tests in each specialty or subspecialty. A separate license
5 is required of all laboratories maintained on separate
6 premises even if the laboratories are operated under the same
7 management. Upon receipt of a request for an application for
8 a clinical laboratory license, the department shall provide to
9 the applicant a copy of the rules relating to licensure and
10 operations applicable to the laboratory for which licensure is
11 sought.

12 3. A license shall specify, on its face, the names of the
13 owner or operator and directors of the laboratory; the
14 procedures, specialties, or subspecialties authorized; the
15 period for which it is valid; and the location at which such
16 procedures may be performed. The clinical laboratory license
17 and the licenses of all personnel in the laboratory shall be
18 displayed at all times in a prominent place in the clinical
19 laboratory where the licenses may be viewed by the public.

20 Sec. 10. NEW SECTION. 135M.10 ADMINISTRATIVE PENALTIES
21 -- LICENSE SANCTIONS -- CONTESTED CASE HEARING.

22 1. The department may deny, suspend, revoke, limit, or
23 deny renewal of a license or impose an administrative fine,
24 not to exceed one thousand dollars per violation, for the
25 violation of any provision of this chapter or rules adopted
26 pursuant to this chapter. In determining the penalty to be
27 imposed, the following factors shall be considered:

28 a. The severity of the violation, including the
29 probability that death or serious harm to the health or safety
30 of any person will result or has resulted, the severity of the
31 actual or potential harm, and the extent to which the
32 provisions of this chapter were violated.

33 b. Actions taken by the licensee to correct the violation
34 or to remedy complaints.

35 c. Any previous violation by the licensee.

- 1 d. The financial benefit to the licensee of committing or
2 continuing the violation.
- 3 2. The department may take any action described in
4 subsection 1, based on grounds which have been adopted by
5 rule. Such grounds shall include, but not be limited to:
- 6 a. Making a fraudulent statement on an application for a
7 clinical laboratory license or any other document required by
8 the department.
- 9 b. Permitting unauthorized persons to perform technical
10 procedures or to issue reports.
- 11 c. Demonstrating incompetence or making consistent errors
12 in the performance of clinical laboratory examinations and
13 procedures or erroneous reporting.
- 14 d. Performing a test and rendering a report thereon to a
15 person not authorized by law to receive such services.
- 16 e. Knowingly having professional connection with or
17 knowingly lending the use of the name of the licensed clinical
18 laboratory or its director to an unlicensed clinical
19 laboratory.
- 20 f. Violating or aiding and abetting in the violation of
21 any provision of this chapter or the rules adopted under this
22 chapter.
- 23 g. Failing to file any report required by the provisions
24 of this chapter or the rules adopted under this chapter.
- 25 h. Reporting a test result for a clinical specimen if the
26 test was not performed on the clinical specimen.
- 27 i. Performing and reporting tests in a specialty or
28 subspecialty in which the laboratory is not licensed.
- 29 j. Knowingly advertising false services or credentials.
- 30 k. Failing to correct deficiencies within the time
31 required by the department.
- 32 3. Except as provided in section 17A.18A any action or
33 sanction imposed by the department shall be preceded by notice
34 and the opportunity for an evidentiary hearing as set out in
35 chapter 17A.

1 Sec. 11. NEW SECTION. 135M.11 APPLICATION FOR A
2 CERTIFICATE OF EXEMPTION.

3 An application for a certificate of exemption shall be made
4 by the owner or director of a clinical laboratory that
5 performs only waived tests. A certificate of exemption
6 authorizes a clinical laboratory to perform waived tests. A
7 laboratory maintained on a separate premises and operated
8 under the same management may apply for a single certificate
9 of exemption or multiple certificates of exemption. The
10 department shall, by rule, specify the process for biennially
11 issuing certificates of exemption.

12 Sec. 12. NEW SECTION. 135M.12 LICENSE FEES.

13 1. Each application for a license shall be accompanied by
14 the annual license fee prescribed by this section, subject to
15 refund to the applicant if the license is denied, which fee
16 shall be deposited in the general fund of the state.

17 2. The department shall establish a biennial license fee
18 schedule by rule. The fee schedule shall base the fee for
19 licensure on the number of tests annually performed by the
20 applicant and the fees shall be calculated to approximate the
21 actual cost of administering this chapter.

22 3. The department shall assess a biennial fee of one
23 hundred dollars for a certificate of exemption and a one
24 hundred dollar license fee for a facility inspected by an
25 approved accrediting organization.

26 Sec. 13. NEW SECTION. 135M.13 BRANCH OFFICES --
27 REPRESENTATION OF OTHER LABORATORIES.

28 A person may not represent or maintain an office or
29 collection station or other facility for the representation of
30 any clinical laboratory situated in this state or any other
31 state which makes examinations in connection with the
32 diagnosis and control of diseases unless the clinical
33 laboratory meets or exceeds the minimum standards of the
34 department and the rules adopted under this chapter.

35 Sec. 14. NEW SECTION. 135M.14 CRIMINAL PENALTIES.

1 A person who violates a provision of this chapter is guilty
2 of a simple misdemeanor.

3 Sec. 15. NEW SECTION. 135M.15 REBATES PROHIBITED --
4 PENALTIES.

5 1. A person shall not pay or receive any commission,
6 bonus, kickback, or rebate or engage in any split-fee
7 arrangement in any form whatsoever with any dialysis facility,
8 physician, surgeon, organization, department, or person,
9 either directly or indirectly, for patients referred to a
10 clinical laboratory licensed under this chapter.

11 2. The department shall adopt rules that assess
12 administrative penalties for acts prohibited by subsection 1.
13 In the case of a clinical laboratory, other entity, or
14 licensed practitioner licensed by the department, such
15 penalties may include any disciplinary action available to the
16 department under the appropriate licensing laws. In the case
17 of a person not licensed by the department, such penalties may
18 include any of the following:

19 a. A fine not to exceed one thousand dollars.

20 b. If applicable, a recommendation by the department to
21 the appropriate licensing board that disciplinary action be
22 taken.

23 Sec. 16. NEW SECTION. 135M.16 INJUNCTION.

24 The operation or maintenance of an unlicensed clinical
25 laboratory or the performance of any clinical laboratory
26 procedure or operation in violation of this chapter is
27 unlawful. The department, or the county attorney may, in
28 addition to other remedies provided in this chapter, bring an
29 action for an injunction to restrain such violation, or to
30 enjoin the future operation or maintenance of any such
31 clinical laboratory or the performance of any laboratory
32 procedure or operation in violation of this chapter, until
33 compliance with this chapter or the rules adopted pursuant to
34 this chapter has been demonstrated to the satisfaction of the
35 department.

