

shall conduct a study of industrial insurance coverage of the horse racing industry, specifically including coverage for jockeys. The committees shall report the results of the study to the house of representatives and the senate by December 1, 1989.

*Sec. 6 was vetoed, see message at end of chapter.

NEW SECTION. Sec. 7. This act is necessary for the immediate preservation of the public peace, health, or safety, or support of the state government and its existing public institutions, and shall take effect immediately.

Passed the House April 21, 1989.

Passed the Senate April 21, 1989.

Approved by the Governor May 13, 1989, with the exception of certain items which were vetoed.

Filed in Office of Secretary of State May 13, 1989.

Note: Governor's explanation of partial veto is as follows:

"I am returning herewith, without my approval as to section 6, House Bill No. 2060 entitled:

"AN ACT Relating to the horse racing industry."

The main objective of House Bill No. 2060 is to improve the process by which industrial insurance premiums for the horse racing industry are assessed, and in so doing, to improve the industrial insurance coverage of the horse racing industry as a whole. With the exception of section 6, I fully endorse this bill.

Section 6 requires the House Commerce and Labor Committee and the Senate Economic Development and Labor Committee, in conjunction with the Horse Racing Commission and the Department of Labor and Industries, to conduct a study of industrial insurance coverage of the horse racing industry in general and coverage for jockeys specifically. Although I concur with the Legislature in the need for such a study, I feel that the practice of placing legislative studies into statute is both unnecessary and unwarranted. Although I am vetoing this section, I am directing the Horse Racing Commission and the Department of Labor and Industries to participate and cooperate fully in this study.

With the exception of section 6, House Bill No. 2060 is approved."

CHAPTER 386

[Substitute Senate Bill No. 5713]

MEDICAL TEST SITES—LICENSURE

AN ACT Relating to medical test site licensure; adding a new chapter to Title 70 RCW; prescribing penalties; providing effective dates; and declaring an emergency.

Be it enacted by the Legislature of the State of Washington:

NEW SECTION. Sec. 1. The legislature intends that medical test sites meet criteria known to promote accurate and reliable analysis, thus improving health care through uniform test site licensure and regulation including quality control, quality assurance, and proficiency testing. The legislature also intends to meet the requirements of federal laws licensing and regulating medical testing.

The legislature intends that nothing in this chapter shall be interpreted to place any liability whatsoever on the state for the action or inaction of test sites or test site personnel. The legislature further intends that nothing in this chapter shall be interpreted to expand the state's role regarding medical testing beyond the provisions of this chapter.

NEW SECTION. Sec. 2. Unless the context clearly requires otherwise, the definitions in this section apply throughout this chapter.

(1) "Department" means the department of health if enacted, otherwise the department of social and health services.

(2) "Designated test site supervisor" means the available individual who is responsible for the technical functions of the test site and who meets the department's qualifications set out in rule by the department.

(3) "Person" means any individual, or any public or private organization, agent, agency, corporation, firm, association, partnership, or business.

(4) "Proficiency testing program" means an external service approved by the department which provides samples to evaluate the accuracy, reliability and performance of the tests at each test site.

(5) "Quality assurance" means a comprehensive set of policies, procedures, and practices to assure that a test site's results are accurate and reliable. Quality assurance means a total program of internal and external quality control, equipment preventative maintenance, calibration, record-keeping, and proficiency testing evaluation, including a written quality assurance plan.

(6) "Quality control" means internal written procedures and day-to-day analysis of laboratory reference materials at each test site to insure precision and accuracy of test methodology, equipment, and results.

(7) "Test" means any examination or procedure conducted on a sample taken from the human body, including screening.

(8) "Test site" means any facility or site, public or private, which analyzes materials derived from the human body for the purposes of health care, treatment, or screening. A test site does not mean a facility or site, including a residence, where a test approved for home use by the federal food and drug administration is used by an individual to test himself or herself without direct supervision or guidance by another and where this test is not part of a commercial transaction.

NEW SECTION. Sec. 3. After July 1, 1990, no person may advertise, operate, manage, own, conduct, open, or maintain a test site without first obtaining a license for the tests to be performed, except as provided in section 4 of this act.

NEW SECTION. Sec. 4. (1) As a part of the application for licensure, a test site may request a waiver from licensure under this chapter if the test site performs only examinations which are determined to have insignificant risk of an erroneous result, including those which (a) are approved by the

federal food and drug administration for home use; (b) are so simple and accurate as to render the likelihood of erroneous results negligible; or (c) pose no reasonable risk of harm to the patient if performed incorrectly.

(2) The department shall determine by rule which tests meet the criteria in subsection (1) of this section and shall be exempt from coverage of this chapter. The standards applied in developing the list shall be consistent with federal law and regulations.

(3) The department shall grant a waiver from licensure for two years for a valid request based on subsections (1) and (2) of this section.

(4) Any test site which has received a waiver under subsection (3) of this section shall report to the department any changes in the type of tests it intends to perform thirty days in advance of the changes. In no case shall a test site with a waiver perform tests which require a license under this chapter.

NEW SECTION. Sec. 5. Test sites accredited, certified, or licensed by an organization or agency approved by the department consistent with federal law and regulations shall receive a license under section 12 of this act.

NEW SECTION. Sec. 6. A licensee that desires to perform tests for which it is not currently licensed shall notify the department. To the extent allowed by federal law and regulations, upon notification and pending the department's determination, the department shall grant the licensee temporary permission to perform the additional tests. The department shall amend the license if it determines that the licensee meets all applicable requirements.

NEW SECTION. Sec. 7. The department shall adopt standards established in rule governing test sites for quality control, quality assurance, recordkeeping, and personnel consistent with federal laws and regulations. "Recordkeeping" for purposes of this chapter means books, files, or records necessary to show compliance with the quality control and quality assurance requirements adopted by the department.

NEW SECTION. Sec. 8. (1) Except where there is no reasonable proficiency test, each licensed test site must participate in a department-approved proficiency testing program appropriate to the test or tests which it performs. The department may approve proficiency testing programs offered by private or public organizations when the program meets the standards set by the department. Testing shall be conducted quarterly except as otherwise provided for in rule.

(2) The department shall establish proficiency testing standards by rule which include a measure of acceptable performance for tests, and a system for grading proficiency testing performance for tests. The standards may include an evaluation of the personnel performing tests.

NEW SECTION. Sec. 9. A test site shall have a designated test site supervisor who shall meet the qualifications determined by the department

in rule. The designated test site supervisor shall be responsible for the testing functions of the test site.

NEW SECTION. Sec. 10. (1) The department shall establish a schedule of fees for license applications, renewals, amendments, and waivers. In fixing said fees, the department shall set the fees at a sufficient level to defray the cost of administering the licensure program. All such fees shall be fixed by rule adopted in accordance with the provisions of the administrative procedure act, chapter 34.05 RCW. In determining the fee schedule, the department shall consider the following: (a) Complexity of the license required; (b) number and type of tests performed at the test site; (c) degree of supervision required from the department staff; (d) whether the license is granted under section 5 of this act; and (e) general administrative costs of the test site licensing program established under this chapter. For each category of license, fees charged shall be related to program costs.

(2) The medical test site licensure account is created in the state treasury. The state treasurer shall transfer into the medical test site licensure account all revenue received from medical test site license fees. Funds for this account may only be appropriated for the support of the activities defined under this chapter.

(3) The department may establish separate fees for repeat inspections and repeat audits it performs under section 18 of this act.

NEW SECTION. Sec. 11. An applicant for issuance or renewal of a medical test site license shall:

(1) File a written application on a form provided by the department;

(2) Demonstrate ability to comply with this chapter and the rules adopted under this chapter;

(3) Cooperate with any on-site review which may be conducted by the department prior to licensure or renewal.

NEW SECTION. Sec. 12. Upon receipt of an application for a license and the license fee, the department shall issue a license if the applicant meets the requirements established under this chapter. All persons operating test sites before July 1, 1990, shall submit applications by July 1, 1990. A license issued under this chapter shall not be transferred or assigned without thirty days' prior notice to the department and the department's timely approval. A license, unless suspended or revoked, shall be effective for a period of two years. The department may establish penalty fees or take other appropriate action pursuant to this chapter for failure to apply for licensure or renewal as required by this chapter.

NEW SECTION. Sec. 13. Under this chapter, and chapter 34.05 RCW, the department may deny a license to any applicant who:

(1) Refuses to comply with the requirements of this chapter or the standards or rules adopted under this chapter;

(2) Was the holder of a license under this chapter which was revoked for cause and never reissued by the department;

(3) Has knowingly or with reason to know made a false statement of a material fact in the application for a license or in any data attached thereto or in any record required by the department;

(4) Refuses to allow representatives of the department to examine any book, record, or file required by this chapter to be maintained;

(5) Willfully prevented, interfered with, or attempted to impede in any way the work of a representative of the department; or

(6) Misrepresented, or was fraudulent in, any aspect of the applicant's business.

NEW SECTION. Sec. 14. Under this chapter, and chapter 34.05 RCW, the department may place conditions on a license which limit or cancel a test site's authority to conduct any of the tests or groups of tests of any licensee who:

(1) Fails or refuses to comply with the requirements of this chapter or the rules adopted under this chapter;

(2) Has knowingly or with reason to know made a false statement of a material fact in the application for a license or in any data attached thereto or in any record required by the department;

(3) Refuses to allow representatives of the department to examine any book, record, or file required by this chapter to be maintained;

(4) Willfully prevented, interfered with, or attempted to impede in any way the work of a representative of the department;

(5) Willfully prevented or interfered with preservation of evidence of a known violation of this chapter or the rules adopted under this chapter; or

(6) Misrepresented, or was fraudulent in, any aspect of the licensee's business.

NEW SECTION. Sec. 15. Under this chapter, and chapter 34.05 RCW, the department may suspend the license of any licensee who:

(1) Fails or refuses to comply with the requirements of this chapter or the rules adopted under this chapter;

(2) Has knowingly or with reason to know made a false statement of a material fact in the application for a license or in any data attached thereto or in any record required by the department;

(3) Refuses to allow representatives of the department to examine any book, record, or file required by this chapter to be maintained;

(4) Willfully prevented, interfered with, or attempted to impede in any way the work of a representative of the department;

(5) Willfully prevented or interfered with preservation of evidence of a known violation of this chapter or the rules adopted under this chapter;

(6) Misrepresented, or was fraudulent in, any aspect of the licensee's business;

(7) Used false or fraudulent advertising; or

(8) Failed to pay any civil monetary penalty assessed by the department under this chapter within twenty-eight days after the assessment becomes final.

NEW SECTION. Sec. 16. Under this chapter, and chapter 34.05 RCW, the department may revoke the license of any licensee who:

(1) Fails or refuses to comply with the requirements of this chapter or the rules adopted under this chapter;

(2) Has knowingly or with reason to know made a false statement of a material fact in the application for a license or in any data attached thereto or in any record required by the department;

(3) Refuses to allow representatives of the department to examine any book, record, or file required by this chapter to be maintained;

(4) Willfully prevented, interfered with, or attempted to impede in any way the work of a representative of the department;

(5) Willfully prevented or interfered with preservation of evidence of a known violation of this chapter or the rules adopted under this chapter;

(6) Misrepresented, or was fraudulent in, any aspect of the licensee's business;

(7) Used false or fraudulent advertising; or

(8) Failed to pay any civil monetary penalty assessed by the department pursuant to this chapter within twenty-eight days after the assessment becomes final.

The department may summarily revoke a license when it finds continued licensure of a test site immediately jeopardizes the public health, safety, or welfare.

NEW SECTION. Sec. 17. Under this chapter, and chapter 34.05 RCW, the department may assess monetary penalties of up to ten thousand dollars per violation in addition to or in lieu of conditioning, suspending, or revoking a license. A violation occurs when a licensee:

(1) Fails or refuses to comply with the requirements of this chapter or the standards or rules adopted under this chapter;

(2) Has knowingly or with reason to know made a false statement of a material fact in the application for a license or in any data attached thereto or in any record required by the department;

(3) Refuses to allow representatives of the department to examine any book, record, or file required by this chapter to be maintained;

(4) Willfully prevents, interferes with, or attempts to impede in any way the work of any representative of the department;

(5) Willfully prevents or interferes with preservation of evidence of any known violation of this chapter or the rules adopted under this chapter;

(6) Misrepresents or was fraudulent in any aspect of the applicant's business; or

(7) Uses advertising which is false or fraudulent.

Each day of a continuing violation is a separate violation.

NEW SECTION. Sec. 18. The department may at any time conduct an on-site review of a licensee or applicant in order to determine compliance with this chapter. When the department has reason to believe a waived site is conducting tests requiring a license, the department may conduct an on-site review of the waived site in order to determine compliance. The department may also examine and audit records necessary to determine compliance with this chapter. The right to conduct an on-site review and audit and examination of records shall extend to any premises and records of persons whom the department has reason to believe are opening, owning, conducting, maintaining, managing, or otherwise operating a test site without a license.

Following an on-site review, the department shall give written notice of any violation of this chapter or the rules adopted under this chapter. The notice shall describe the reasons for noncompliance and inform the licensee or applicant or test site operator that it shall comply within a specified reasonable time. If the licensee or applicant or test site operator fails to comply, the department may take disciplinary action under sections 13 through 16 of this act, or further action as authorized by this chapter.

NEW SECTION. Sec. 19. Notwithstanding the existence or use of any other remedy, the department may, in the manner provided by law and upon the advice of the attorney general, who shall represent the department in the proceedings, maintain an action in the name of the state for an injunction or other process against any person to restrain or prevent the advertising, operating, maintaining, managing, or opening of a test site without a license under this chapter. It is a misdemeanor to own, operate, or maintain a test site without a license.

NEW SECTION. Sec. 20. Any test site which has had a denial, condition, suspension, or revocation of its license, or a civil monetary penalty upheld after administrative review under chapter 34.05 RCW, may, within sixty days of the administrative determination, petition the superior court for review of the decision.

NEW SECTION. Sec. 21. No person who has owned or operated a test site that has had its license revoked may own or operate a test site within two years of the final adjudication of a license revocation.

NEW SECTION. Sec. 22. All information received by the department through filed reports, audits, or on-site reviews, as authorized under this chapter shall not be disclosed publicly in any manner that would identify persons who have specimens of material from their bodies at a test site, absent a written release from the person, or a court order.

NEW SECTION. Sec. 23. The department shall adopt rules under chapter 34.05 RCW necessary to implement the purposes of this chapter.

NEW SECTION. Sec. 24. Sections 1 through 23 of this act shall constitute a new chapter in Title 70 RCW.

NEW SECTION. Sec. 25. (1) Sections 1 through 22 of this act shall take effect July 1, 1990.

(2) Section 23 of this act is necessary for the immediate preservation of the public peace, health, or safety, or support of the state government and its existing public institutions, and shall take effect July 1, 1989.

Passed the Senate April 17, 1989.

Passed the House April 11, 1989.

Approved by the Governor May 13, 1989.

Filed in Office of Secretary of State May 13, 1989.

CHAPTER 387

[Substitute Senate Bill No. 6048]

HIV TESTING FOR INSURANCE PURPOSES

AN ACT Relating to HIV testing for coverage under Title 48 RCW; adding a new section to chapter 70.24 RCW; and declaring an emergency.

Be it enacted by the Legislature of the State of Washington:

NEW SECTION. Sec. 1. A new section is added to chapter 70.24 RCW to read as follows:

(1) This section shall apply to counseling and consent for HIV testing administered as part of an application for coverage authorized under Title 48 RCW.

(2) Persons subject to regulation under Title 48 RCW who are requesting an insured, a subscriber, or a potential insured or subscriber to furnish the results of an HIV test for underwriting purposes as a condition for obtaining or renewing coverage under an insurance contract, health care service contract, or health maintenance organization agreement shall:

(a) Provide written information to the individual prior to being tested which explains:

(i) What an HIV test is;

(ii) Behaviors that place a person at risk for HIV infection;

(iii) That the purpose of HIV testing in this setting is to determine eligibility for coverage;

(iv) The potential risks of HIV testing; and

(v) Where to obtain HIV pretest counseling.

(b) Obtain informed specific written consent for an HIV test. The written informed consent shall include:

(i) An explanation of the confidential treatment of the test results which limits access to the results to persons involved in handling or determining applications for coverage or claims of the applicant or claimant and to those persons designated under (c)(iii) of this subsection; and

(ii) Requirements under (c)(iii) of this subsection.

(c) Establish procedures to inform an applicant of the following: