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HOUSE BILL 2137

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State of Washington                      53rd Legislature                      1993 Regular Session

By Representatives Veloria, Forner, Campbell and Mielke

Read first time . Referred to Committee on .

1            AN ACT Relating to clinical laboratory science practitioners;  
2 adding a new chapter to Title 18 RCW; creating a new section;  
3 prescribing penalties; providing effective dates; and declaring an  
4 emergency.

5 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF WASHINGTON:

6            NEW SECTION.    **Sec. 1.** INTENT--CONSTRUCTION. The legislature finds  
7 that it is necessary to regulate the practice of clinical laboratory  
8 science in order to protect the public health, safety, and welfare. It  
9 is the intent of the legislature that this chapter shall provide for  
10 the better protection of public health and safety by providing minimum  
11 qualifications for clinical laboratory science practitioners, thereby  
12 ensuring that clinical laboratory tests are performed with an  
13 acceptable degree of professional competency by those engaged in  
14 providing such services to the citizens of this state.

15            NEW SECTION.    **Sec. 2.** DEFINITIONS. Unless the context clearly  
16 requires otherwise, the definitions in this section apply throughout  
17 this chapter.

1 (1) "Accredited clinical laboratory program" means a program  
2 providing a predetermined amount of instruction and experience in  
3 clinical laboratory science that has been accredited by one of the  
4 accrediting agencies recognized by the United States department of  
5 education or department of health and human services.

6 (2) "Board" means the clinical laboratory board appointed by the  
7 governor.

8 (3) "Clinical laboratory" or "laboratory" means a facility, office,  
9 or site where clinical laboratory tests are performed.

10 (4) "Clinical laboratory scientist" or "medical technologist" means  
11 a person who performs tests pursuant to established and approved  
12 protocols requiring the exercise of independent judgment and  
13 responsibility, maintains equipment and records, performs quality  
14 assurance activities related to test performance, and may supervise and  
15 teach within a clinical laboratory setting.

16 (5) "Clinical laboratory science practice" means the performance of  
17 clinical laboratory tests and related activities including all phases  
18 of test performance from procurement of specimens, such as phlebotomy,  
19 to reporting of results.

20 (6) "Clinical laboratory science practitioner" means a health care  
21 professional who performs clinical laboratory tests and related  
22 activities or is engaged in management, education, consulting, or  
23 research in clinical laboratory science, and may include laboratory  
24 directors, supervisors, clinical laboratory scientists, medical  
25 technologists, specialists, technicians, and assistants working in a  
26 laboratory or testing site. Such practitioners shall be considered  
27 licensed providers under chapter 18.135 RCW and may perform, and train  
28 and authorize others to perform, phlebotomy. Persons employed by a  
29 clinical laboratory to perform supportive functions not related to  
30 direct performance of laboratory tests and clinical laboratory trainees  
31 are not included.

32 (7) "Clinical laboratory technician" or "medical laboratory  
33 technician" means a person who performs laboratory tests and related  
34 activities pursuant to established and approved protocols which require  
35 limited exercise of independent judgment and which are performed under  
36 the supervision of a clinical laboratory scientist, supervisor, or  
37 director. Such practitioners shall be considered licensed providers  
38 under chapter 18.135 RCW and may perform, and train and authorize  
39 others to perform, phlebotomy.

1 (8) "Clinical laboratory test" or "laboratory test" means a  
2 microbiological, serological, chemical, hematological, radiobioassay,  
3 cytological, biophysical, immunological, or other pathological  
4 examination that is performed on material derived from the human body,  
5 or any other such test or procedure conducted that provides information  
6 for the diagnosis, prevention, or treatment of a disease or assessment  
7 of a medical condition, including screening.

8 (9) "Clinical laboratory trainee" means a person in a structured  
9 program, approved by the board, providing instruction and experience in  
10 the clinical laboratory sciences including, but not limited to,  
11 accredited programs. Trainees must be under the direct supervision of  
12 a person qualified to perform the work being performed. Such training  
13 shall contribute to the experience requirements under this chapter.

14 (10) "Department" means the department of health.

15 (11) "Director" means the person responsible for the technical and  
16 administrative functions of laboratory testing.

17 (12) "Laboratory assistant" means a person performing testing in a  
18 limited function laboratory or performing a limited scope of testing  
19 under the direct supervision of a person qualified to perform or  
20 supervise such testing.

21 (13) "Level I practitioner" means a person certified to perform  
22 tests utilizing test methodologies and instruments such as described  
23 for the limited function laboratory.

24 (14) "Limited function laboratory" means a testing site utilizing  
25 test methodologies performed on instruments requiring little technical  
26 skill and no independent judgment due to the instruments' internal  
27 self-calibrated standards, and manual or automated test methodologies  
28 requiring little technical skill and no problem-solving or interpretive  
29 ability, or a testing site that only performs a limited scope of tests  
30 within one specialty or subspecialty.

31 (15) "Specialist" means a masters or doctorate level laboratory  
32 science practitioner or related health care professional who is  
33 qualified to practice and who is specialized in an area of the clinical  
34 laboratory sciences such as cytology, chemistry, hematology,  
35 immunology, immunohematology, or microbiology.

36 (16) "Specialty laboratory" means any site which only performs  
37 tests within one specialty or subspecialty. A person performing tests  
38 at such sites may be granted a limited license or certificate to

1 perform such testing providing the person meets appropriate  
2 qualifications set by the board.

3 (17) "Supervisor" means the person responsible for the supervision  
4 of the testing personnel, performance, or both, of tests and related  
5 activities.

6 NEW SECTION. **Sec. 3.** EXEMPTIONS. This chapter does not apply to:

7 (1) Any person licensed in this state who, under any other  
8 licensing authority, engages in the practice for which he or she is  
9 licensed.

10 (2) Clinical laboratory science practitioners employed by the  
11 United States government or any bureau, division, or agency of the  
12 United States while in the discharge of the employee's official duties.

13 (3) Clinical laboratory science practitioners engaged in teaching  
14 or research, provided that the results of an examination performed are  
15 not used in health maintenance, diagnosis or treatment of disease, or  
16 screening.

17 (4) Students or trainees enrolled in a clinical laboratory science  
18 education program, provided that these activities constitute a part of  
19 a planned course in the program, that the persons are designated by  
20 title such as intern, trainee, or student, and the persons work  
21 directly under an individual licensed by this state to practice  
22 clinical laboratory science, or an instructor exempt under subsection  
23 (3) of this section.

24 (5) Physicians licensed in this state who are certified by the  
25 American board of pathology or the American board of osteopathic  
26 pathology.

27 (6) Business managers of laboratories provided they have no direct  
28 or indirect involvement with test performance.

29 (7) A person performing tests that are waived from regulatory  
30 requirements under P.L. 100-578 (CLIA 88).

31 NEW SECTION. **Sec. 4.** LICENSE REQUIRED. (1) No person may  
32 practice clinical laboratory science or hold himself or herself out as  
33 a clinical laboratory science practitioner in this state unless  
34 licensed under this chapter.

35 (2) All persons engaged in the practice of clinical laboratory  
36 science on the effective date of this act, and who have applied to the  
37 board on or before the effective date of this act and have complied

1 with all necessary requirements for such application may continue to  
2 direct, supervise, or perform clinical laboratory tests until (a) the  
3 expiration of twelve months after the filing of the application, (b)  
4 the denial of the application by the board, or (c) the withdrawal of  
5 the application, whichever occurs first.

6 (3) The board may issue an initial license to an applicant who is  
7 an existing or prospective practitioner, who applies within twenty-four  
8 months of the effective date of this act without requiring such  
9 applicant to successfully complete an examination or obtain  
10 certification upon proof that the applicant holds the title and has  
11 been practicing at the level of the license requested.

12 (4) Effective twenty-four months after the effective date of this  
13 act, no initial license shall be issued until an applicant meets all of  
14 the requirements under this chapter and successfully meets  
15 certification or equivalent qualifications approved by the board.

16 NEW SECTION. **Sec. 5.** ADMINISTRATION. (1) There is created a  
17 clinical laboratory board within the department of health which shall  
18 consist of seven persons who are United States citizens and are actual  
19 residents of this state, and, except for the public members, who are  
20 actively engaged in their areas of practice. The governor shall make  
21 appointments to the board, and those appointments shall be confirmed by  
22 the senate.

23 (2) The board shall be composed of:

24 (a) One physician certified by the American board of pathology or  
25 American board of osteopathic pathology;

26 (b) Four clinical laboratory science practitioners, at least one of  
27 whom is a nonphysician laboratory director or manager, one of whom is  
28 a clinical laboratory scientist or medical technologist and one of whom  
29 is a clinical laboratory technician or medical laboratory technician,  
30 and who, except for the initial appointments, hold active and valid  
31 licenses as clinical laboratory science practitioners in this state;  
32 and

33 (c) Two public members, neither of whom is a member of any other  
34 licensing board, or holder of a health occupation license, or an  
35 employee of any health facility, or who has any fiduciary obligation to  
36 a health facility or agency, or who has a material financial interest  
37 in the rendering of health services.

1 (3) Board members shall serve for terms of three years and until  
2 their successors are appointed and qualified, except that the initial  
3 appointments, which shall be made within ninety days after the  
4 effective date of this act, shall be as follows:

5 (a) A pathologist, a nonphysician laboratory director or manager,  
6 and a clinical laboratory technician shall be appointed to serve for  
7 three years;

8 (b) The public representatives shall be appointed to serve for two  
9 years; and

10 (c) The remaining members shall be appointed to serve for one year.

11 (4) Whenever a vacancy occurs on the board by reason other than the  
12 expiration of a term of office, the governor shall appoint a successor  
13 of like qualifications for the remainder of the unexpired term. No  
14 person may be appointed to serve more than two successive full terms.

15 (5) The board shall hold a regular annual meeting at which it shall  
16 select from its members a chair and vice-chair. Other meetings shall  
17 be held at such times as the rules of the board may provide. Special  
18 meetings may be held at such times as may be deemed necessary or  
19 advisable by a majority of the members. Reasonable notice of all  
20 meetings shall be given in a manner prescribed by the rules of the  
21 board. A quorum of the board shall consist of a majority of its  
22 members. The secretary of the board shall be appointed by the board  
23 and shall serve at the pleasure of the board. The secretary may or may  
24 not be a member of the board. The board shall work with and through  
25 the department of health.

26 NEW SECTION. **Sec. 6.** DUTIES AND POWERS OF THE CLINICAL LABORATORY  
27 BOARD. The clinical laboratory board shall:

28 (1) Prescribe, publish, adopt, amend, and repeal rules for the  
29 implementation of this chapter including but not limited to rules that  
30 delineate qualifications for licensure of clinical laboratory science  
31 practitioners; specify requirements for the renewal of licensure or  
32 certification; and establish standards of professional conduct. The  
33 rules shall govern and control the professional conduct of every person  
34 who holds a license or certificate to perform clinical laboratory tests  
35 or otherwise engages in the profession of clinical laboratory science  
36 medical technology;

1 (2) Approve accrediting and certification bodies for purposes of  
2 licensure of clinical laboratory science practitioners as provided for  
3 in section 4 of this act;

4 (3) Adopt rules governing qualifications for licensure of  
5 specialists in such clinical laboratory science specialties as the  
6 board may determine in accordance with section 8 of this act;

7 (4) Adopt rules governing personnel performing tests in limited  
8 function laboratories, and personnel performing limited scopes of  
9 testing;

10 (5) Advise the department of health in the fixing and publication  
11 of fees for application and renewals;

12 (6) Assist the department of health in the maintenance of a roster  
13 of the names and addresses of persons currently licensed and registered  
14 under the provisions of this chapter, and of all persons whose licenses  
15 have been suspended or revoked within the previous year;

16 (7) Establish criteria and approve programs for the continuing  
17 education of clinical laboratory science practitioners as required for  
18 license renewal; and

19 (8) Adopt rules necessary to implement and further the purpose of  
20 this chapter.

21 NEW SECTION. **Sec. 7. FEES--ACCOUNT.** (1) The department shall  
22 establish a schedule of fees for license and certificate applications  
23 and renewals. In fixing the fees, the department shall set the fees at  
24 a sufficient level to defray the cost of administering the program. In  
25 determining the fee schedule, the department shall consider the  
26 following: (a) The level of license or certificate; (b) general costs  
27 of the program established under this chapter; and (c) the advice of  
28 the board.

29 (2) The clinical laboratory licensure account is created in the  
30 state treasury. All receipts from license and certificate fees shall  
31 be deposited into the account. Moneys in the account may be spent only  
32 after appropriation. Expenditures from the account may be used only  
33 for the purposes of this chapter.

34 NEW SECTION. **Sec. 8. STANDARDS FOR LICENSURE.** (1) Clinical  
35 laboratory scientist or medical technologists. The board shall issue  
36 a clinical laboratory scientist's license to an individual who is  
37 certified, or who holds equivalent credentials, in the clinical

1 laboratory sciences by an agency acceptable to the board, and who meets  
2 such other qualifications as adopted by the board, including at least  
3 one of the following qualifications. Where experience requirements are  
4 not met in the four major disciplines, the board shall issue a  
5 categorical or specialist license for those disciplines in which the  
6 person is qualified:

7 (a) A baccalaureate degree in clinical laboratory science or  
8 medical technology from an accredited college or university whose  
9 curriculum included appropriate clinical education;

10 (b) A baccalaureate degree in biological, chemical, or physical  
11 science from an accredited college or university, and at least twelve  
12 months of appropriate clinical education in an accredited clinical  
13 laboratory science program;

14 (c) A baccalaureate degree that includes a minimum of thirty-six  
15 semester or equivalent hours in the biological, chemical, and physical  
16 sciences from an accredited college or university plus two years of  
17 acceptable full-time work experience within the last five years  
18 including a minimum of four months in each of the four major  
19 disciplines of laboratory practice, clinical chemistry, clinical  
20 microbiology, hematology, or immunology or immunohematology;

21 (d) Approved certification as a clinical laboratory technician or  
22 medical laboratory technician or equivalent and an associate degree or  
23 sixty semester or equivalent hours of college course work including  
24 thirty-six semester or equivalent hours in the biological and physical  
25 sciences plus three years of acceptable full-time laboratory work  
26 experience within the last ten years that has included a minimum of  
27 four months in each of the four major disciplines of laboratory  
28 practice, chemistry, hematology, immunology or immunohematology, and  
29 microbiology. At least two years of the laboratory work experience  
30 must be under the supervision of an appropriately qualified clinical  
31 laboratory scientist;

32 (e) An associate degree or sixty semester or equivalent hours of  
33 college course work including thirty-six semester or equivalent hours  
34 in the biological and physical sciences plus five years of acceptable  
35 full-time laboratory work experience within the last ten years that has  
36 included a minimum of six months in each of the four disciplines of  
37 laboratory practice, chemistry, hematology, immunology or  
38 immunohematology, or microbiology. At least two years of the



1 laboratory work experience must be under the supervision of an  
2 appropriately qualified clinical laboratory scientist;

3 (f) A valid license, certificate, or equivalent issued in another  
4 state, city, or country, provided that the requirements under which the  
5 license, certificate, or equivalent was issued are equivalent to or  
6 exceed the standards required by this subsection (1).

7 (2) Clinical laboratory technician. The board shall issue a  
8 clinical laboratory technician's license to an individual who is  
9 certified, or who holds equivalent credentials, in the laboratory  
10 sciences by an agency acceptable to the board, and meets such other  
11 qualifications as promulgated by the board, including at least one of  
12 the following qualifications. Where experience requirements are not  
13 met in the four major disciplines, the board shall issue a categorical  
14 license for those disciplines in which the person is qualified:

15 (a) An associate degree or completion of sixty semester or  
16 equivalent hours from a clinical laboratory technician or medical  
17 laboratory technician program, or equivalent, accredited by an agency  
18 recognized by the United States department of education that included  
19 a structured curriculum in clinical laboratory techniques;

20 (b) A high school diploma, or equivalent, and (i) completion of  
21 twelve months in a technician training program in an accredited school  
22 approved by the board; or (ii) successful completion of an official  
23 military medical laboratory procedure course of at least fifty weeks  
24 duration and has held the military enlisted occupational specialty of  
25 medical laboratory specialist or laboratory technician; or

26 (c) Four years of full-time laboratory work experience that has  
27 encompassed the four major disciplines of laboratory practice, clinical  
28 chemistry, hematology, immunohematology and microbiology, plus eight  
29 continuing education units in clinical laboratory science within the  
30 last seven years. At least two years of the laboratory work experience  
31 must be under the supervision of an appropriately qualified clinical  
32 laboratory scientist, consultant, or technician;

33 (d) A valid license, certificate, or equivalent issued in another  
34 state, city, or country, provided that the requirements under which the  
35 license, certificate, or equivalent was issued are equivalent to or  
36 exceed the standards required by this subsection (2).

37 (3) The board may establish standards for such other clinical  
38 laboratory science practitioners specializing in areas such as  
39 biophysics, chemistry, cytology, hematology, histology,

1 immunoematology, microbiology, serology, nuclear medical technology,  
2 or similar recognized academic and scientific disciplines.

3 (4) The board shall issue limited function certificates to  
4 laboratory assistants who meet at least one of the following  
5 qualifications:

6 (a) Completion of an appropriate training program that is  
7 accredited by an agency recognized by the United States department of  
8 education or department of health and human services;

9 (b) Completion of a formal education program in medical assisting  
10 that is accredited by an agency recognized by the United States  
11 department of education or department of health and human services;

12 (c) Four years of full-time laboratory work experience plus twenty  
13 hours of approved education in clinical laboratory science.

14 NEW SECTION. **Sec. 9.** LICENSURE APPLICATION PROCEDURES. (1)  
15 Licensure applicants shall submit their application for licensure to  
16 the department upon the forms prescribed and furnished by the board and  
17 the department, and shall pay the designated application fee.

18 (2) Upon receipt of application and payment of a fee, the board  
19 shall issue a license for a clinical laboratory scientist or  
20 technologist, a clinical laboratory technician or an appropriate  
21 specialty or categorical license, or limited function certificate to  
22 any person who meets the qualifications specified in this chapter and  
23 the rules adopted under this chapter.

24 (3) The board may establish by rule a procedure for issuance of  
25 temporary permits to individuals otherwise qualified under this chapter  
26 who intend to engage in clinical laboratory science practice in this  
27 state for a limited period of time not to exceed eighteen months.

28 NEW SECTION. **Sec. 10.** LICENSURE RENEWAL. (1) Licenses issued  
29 under this chapter shall expire after a time specified by the board,  
30 but not less than one year or more than four years. The renewal  
31 process shall contain a grace period of not less than thirty days or  
32 more than ninety days from expiration of the license.

33 (2) Every person licensed or certified under this chapter shall be  
34 issued a renewal license or certificate upon:

35 (a) Submission of an application for renewal on a form prescribed  
36 by the board and payment of an appropriate fee determined by the  
37 department; and

1 (b) Proof of completion, in the period since the license or  
2 certificate was first issued or last renewed, of at least ten hours per  
3 year of continuing education courses, clinics, lectures, training  
4 programs, seminars, or other programs pertinent to clinical laboratory  
5 practice that are approved or accepted by the board; or proof of  
6 recertification by a board-approved national accrediting organization  
7 that mandates equivalent requirements.

8 (3) The board may require other such evidence of competency as it  
9 shall deem reasonably appropriate as a prerequisite to the renewal of  
10 a license or certificate provided for in this chapter, so long as the  
11 requirements are uniform as to application, are reasonably related to  
12 the measurement of qualification, performance, or competence, and are  
13 desirable and necessary for the protection of the public health and  
14 safety.

15 (4) The board shall develop procedures and criteria for the renewal  
16 of licenses which have expired. The board shall review such  
17 applications on a case-by-case basis to determine if the applicant's  
18 circumstances and qualifications meet the intent of this chapter. In  
19 the event such an application is denied, the board shall notify the  
20 applicant of the specific reasons for such denial, and may advise the  
21 applicant how to qualify for license renewal.

22 NEW SECTION. **Sec. 11.** DISCIPLINARY REQUIREMENTS. The board may  
23 refuse to issue, renew, or revoke a license, or may suspend, place on  
24 probation, censure, or reprimand a licensee, or may take such other  
25 disciplinary action as the board may deem appropriate, including the  
26 imposition of a civil penalty not to exceed that allowed under chapter  
27 18.130 RCW for conduct that may result from, but not necessarily be  
28 limited to:

29 (1) A material misstatement in furnishing information to the board;

30 (2) A violation or negligent or intentional disregard of this  
31 chapter, or of the rules adopted under this chapter;

32 (3) A conviction of a crime under the laws of the United States or  
33 a state or territory the United States that is a felony or a  
34 misdemeanor, an essential element of which is dishonesty, or of a crime  
35 that is directly related to the practice of the profession;

36 (4) Making a misrepresentation for the purpose of obtaining  
37 licensure or certification or violating any provision of this chapter;

1 (5) Violation of a standard of professional conduct adopted by the  
2 board;

3 (6) Engaging in dishonorable, unethical, or unprofessional conduct  
4 of a character likely to deceive, defraud, or harm the public;

5 (7) Providing professional services while mentally incompetent,  
6 under the influence of alcohol or narcotic or a dangerous, controlled  
7 substance that is in excess of therapeutic amounts or without valid  
8 medical indication;

9 (8) Directly or indirectly contracting to perform clinical  
10 laboratory tests in a manner that offers or implies an offer of rebate,  
11 fee-splitting inducements or arrangements, or other remuneration; or

12 (9) Aiding or assisting another person in violating a provision of  
13 this chapter or rule adopted under this chapter.

14 NEW SECTION. **Sec. 12.** DUE PROCESS PROCEDURES. The proceedings  
15 for the revocation, suspension, or limiting of a license or certificate  
16 may be initiated by a person, corporation, association, or public  
17 officer or by the board, by the filing of written charges with the  
18 board, but no license may be revoked, suspended, or limited without a  
19 hearing before the board within sixty days after the filing of such  
20 charges in accordance with the procedures established by the board. A  
21 license may be temporarily suspended without a hearing for a period not  
22 to exceed thirty days upon notice to the licensee, following a finding  
23 by the board that there exists a significant threat to the public  
24 health.

25 NEW SECTION. **Sec. 13.** OPERATING WITHOUT A LICENSE--INJUNCTIONS OR  
26 OTHER REMEDIES--PENALTY. Notwithstanding the existence or use of any  
27 other remedy, the board may, in the manner provided by law and upon the  
28 advice of the attorney general, who shall represent the board in the  
29 proceedings, maintain an action in the name of the state for an  
30 injunction, or other process against a person to restrain or prevent  
31 the performance of laboratory testing without a license under this  
32 chapter. It is a misdemeanor to do laboratory testing without a  
33 license.

34 NEW SECTION. **Sec. 14.** PETITION OF SUPERIOR COURT FOR REVIEW OF  
35 DISCIPLINARY ACTION. A person who has had a denial, condition,  
36 suspension, or revocation of his or her license, or a civil monetary

1 penalty upheld after administrative review under chapter 34.05 RCW,  
2 may, within sixty days of the administrative determination, petition  
3 the superior court for review of the decision.

4 NEW SECTION. **Sec. 15.** PERSONS WHO MAY NOT RECEIVE A LICENSE. No  
5 person who has had his or her license revoked may be considered for  
6 relicensure within two years of the final adjudication of a license  
7 revocation.

8 NEW SECTION. **Sec. 16.** CONFIDENTIALITY OF CERTAIN INFORMATION.  
9 All information received by the board through filed reports, audits, or  
10 on-site reviews, as authorized under this chapter, may not be disclosed  
11 publicly in any manner that would identify persons who have specimens  
12 of material from their bodies at a test site, absent a written release  
13 from the person, or a court order.

14 NEW SECTION. **Sec. 17.** SHORT TITLE. This chapter may be cited as  
15 the clinical laboratory sciences practices act.

16 NEW SECTION. **Sec. 18.** SEVERABILITY. If any provision of this act  
17 or its application to any person or circumstance is held invalid, the  
18 remainder of the act or the application of the provision to other  
19 persons or circumstances is not affected.

20 NEW SECTION. **Sec. 19.** LEGISLATIVE DIRECTIVE. Sections 1 through  
21 8 of this act constitute a new chapter in Title 18 RCW.

22 NEW SECTION. **Sec. 20.** CAPTIONS. Captions as used in this act  
23 constitute no part of the law.

24 NEW SECTION. **Sec. 21.** EFFECTIVE DATES. (1) Sections 5 through 7  
25 of this act are necessary for the immediate preservation of the public  
26 peace, health, or safety, or support of the state government and its  
27 existing public institutions, and shall take effect July 1, 1993.

28 (2) Sections 1 through 4, and 8 through 18 of this act shall take  
29 effect January 1, 1994.

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