

AMENDED IN ASSEMBLY APRIL 1, 1997
AMENDED IN ASSEMBLY MARCH 13, 1997

CALIFORNIA LEGISLATURE—1997–98 REGULAR SESSION

ASSEMBLY BILL

No. 221

Introduced by Assembly Member Goldsmith
(Coauthors: Assembly Members Aroner, Ashburn, Figueroa,
Floyd, House, Leach, Margett, Oller, Richter, and Wayne)
(Coauthors: Senators Leslie, Peace, and Solis)

February 5, 1997

An act to amend Sections ~~1206.5, 1241, 1241~~ and 2058 of the Business and Professions Code, and to add Section 1596.797 to the Health and Safety Code, relating to health.

LEGISLATIVE COUNSEL'S DIGEST

AB 221, as amended, Goldsmith. Health: blood glucose monitoring.

Existing law ~~governs~~ *regulates* the practice of clinical laboratory technology and ~~prohibits the performance of certain clinical laboratory tests unless specified conditions are met, including that the tests are performed by certain authorized health care personnel~~ *exempts from that regulation certain clinical laboratories, and persons performing clinical laboratory tests or examinations in these clinical laboratories.*

This bill would ~~authorize a person to administer a blood glucose monitoring test to a minor child in his or her care and control, who has been diagnosed with diabetes, without~~

~~meeting the requirements of the laws governing clinical laboratory technology if also exempt those that perform blood glucose testing for the purpose of monitoring a minor child diagnosed with diabetes when the person performing the test has been entrusted with the care and control of the child by the child's parent or legal guardian and certain requirements are satisfied.~~

Existing law, the Medical Practice Act, prohibits the unauthorized practice of medicine, but also provides that it does not prohibit service in the case of emergency, or the domestic administration of family remedies.

This bill would provide that the act shall not be construed to prohibit ~~the performance of a finger stick in~~ *obtaining a blood specimen by skin puncture for the purpose of* performing blood glucose testing for the purposes of monitoring a minor child with diabetes in accordance with specified requirements.

Existing law provides for the licensure and regulation of child day care facilities by the State Department of Social Services.

This bill would authorize ~~a child day care facility to perform~~ blood glucose testing for the purposes of monitoring a minor child with diabetes *to be performed in a child's day care facility* in accordance with specified requirements.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

1 ~~SECTION 1. Section 1206.5 of the Business and~~
 2 ~~Professions Code is amended to read:~~
 3 ~~1206.5. (a) Notwithstanding subdivision (b) of~~
 4 ~~Section 1206, no person shall perform a clinical laboratory~~
 5 ~~test or examination classified as waived under CLIA~~
 6 ~~unless the clinical laboratory test or examination is~~
 7 ~~performed under the overall operation and~~
 8 ~~administration of the laboratory director, as described in~~
 9 ~~Section 1209, including, but not limited to,~~
 10 ~~documentation by the laboratory director of the~~
 11 ~~adequacy of the qualifications and competency of the~~



1 ~~personnel, and the test is performed by any of the~~
2 ~~following persons:~~

3 ~~(1) A licensed physician and surgeon holding a M.D. or~~
4 ~~D.O. degree.~~

5 ~~(2) A licensed podiatrist or a licensed dentist when the~~
6 ~~results of the tests can be lawfully utilized within his or~~
7 ~~her practice.~~

8 ~~(3) A person licensed under this chapter to engage in~~
9 ~~clinical laboratory practice or to direct a clinical~~
10 ~~laboratory.~~

11 ~~(4) A person authorized to perform tests pursuant to~~
12 ~~a certificate issued under Chapter 7 (commencing with~~
13 ~~Section 1000) of Part 2 of Division 1 of the Health and~~
14 ~~Safety Code.~~

15 ~~(5) A licensed physician assistant when authorized by~~
16 ~~a supervising physician and surgeon in accordance with~~
17 ~~Section 3502 or Section 3535.~~

18 ~~(6) A person licensed under Chapter 6 (commencing~~
19 ~~with Section 2700).~~

20 ~~(7) A person licensed under Chapter 6.5~~
21 ~~(commencing with Section 2840).~~

22 ~~(8) A perfusionist when authorized by and performed~~
23 ~~in compliance with Section 2590.~~

24 ~~(9) A respiratory care practitioner when authorized~~
25 ~~by and performed in compliance with Chapter 8.3~~
26 ~~(commencing with Section 3700).~~

27 ~~(10) A medical assistant, as defined in Section 2069,~~
28 ~~when the waived test is performed pursuant to a specific~~
29 ~~authorization meeting the requirements of Section 2069.~~

30 ~~(11) A pharmacist, when ordering drug~~
31 ~~therapy related laboratory tests in compliance with~~
32 ~~subparagraph (B) of paragraph (4) of, or clause (ii) of~~
33 ~~subparagraph (A) of paragraph (5) of, subdivision (c) of~~
34 ~~Section 4046.~~

35 ~~(12) Other health care personnel providing direct~~
36 ~~patient care:~~

37 ~~(b) Notwithstanding subdivision (b) of Section 1206,~~
38 ~~no person shall perform clinical laboratory tests or~~
39 ~~examinations classified as of moderate complexity under~~
40 ~~CLIA unless the clinical laboratory test or examination is~~



1 performed under the overall operation and
2 administration of the laboratory director, as described in
3 Section 1209, including, but not limited to,
4 documentation by the laboratory director of the
5 adequacy of the qualifications and competency of the
6 personnel, and the test is performed by any of the
7 following persons:

8 (1) A licensed physician and surgeon holding a M.D. or
9 D.O degree.

10 (2) A licensed podiatrist or a licensed dentist when the
11 results of the tests can be lawfully utilized within his or
12 her practice.

13 (3) A person licensed under this chapter to engage in
14 clinical laboratory practice or to direct a clinical
15 laboratory.

16 (4) A person authorized to perform tests pursuant to
17 a certificate issued under Chapter 7 (commencing with
18 Section 1000) of Part 2 of Division 1 of the Health and
19 Safety Code.

20 (5) A licensed physician assistant when authorized by
21 a supervising physician and surgeon in accordance with
22 Section 3502 or Section 3535.

23 (6) A person licensed under Chapter 6 (commencing
24 with Section 2700).

25 (7) A perfusionist when authorized by and performed
26 in compliance with Section 2590.

27 (8) A respiratory care practitioner when authorized
28 by and performed in compliance with Chapter 8.3
29 (commencing with Section 3700).

30 (9) A person performing nuclear medicine technology
31 when authorized by and performed in compliance with
32 Chapter 7.2 (commencing with Section 25625) of
33 Division 20 of the Health and Safety Code.

34 (10) Any person when performing blood gas analysis
35 in compliance with Section 1245.

36 (11) (A) A person certified as an "Emergency
37 Medical Technician II" or paramedic pursuant to
38 Division 2.5 (commencing with Section 1797) of the
39 Health and Safety Code while providing prehospital
40 medical care, a person licensed as a psychiatric technician



1 under Chapter 10 (commencing with Section 4500) of
2 Division 2, as a vocational nurse pursuant to Chapter 6.5
3 (commencing with Section 2840) of Division 2, or as a
4 midwife licensed pursuant to Article 24 (commencing
5 with Section 2505) of Chapter 5 of Division 2, or certified
6 by the department pursuant to Division 5 (commencing
7 with Section 70001) of Title 22 of the California Code of
8 Regulations as a nurse assistant or a home health aide,
9 who provides direct patient care, so long as the person is
10 performing the test as an adjunct to the provision of
11 direct patient care by the person, is utilizing a
12 point-of-care laboratory testing device at a site for which
13 a laboratory license or registration has been issued, meets
14 the minimum clinical laboratory education, training, and
15 experience requirements set forth in regulations adopted
16 by the department, and has demonstrated to the
17 satisfaction of the laboratory director that he or she is
18 competent in the operation of the point-of-care
19 laboratory testing device for each analyte to be reported.

20 (B) Prior to being authorized by the laboratory
21 director to perform laboratory tests or examinations,
22 testing personnel identified in subparagraph (A) shall
23 participate in a preceptor program until they are able to
24 perform the clinical laboratory tests or examinations
25 authorized in this section with results that are deemed
26 accurate and skills that are deemed competent by the
27 preceptor. For the purposes of this section, a “preceptor
28 program” means an organized system that meets
29 regulatory requirements in which a preceptor provides
30 and documents personal observation and critical
31 evaluation, including review of accuracy, reliability, and
32 validity, of laboratory testing performed.

33 (12) Any other person within a physician office
34 laboratory when the test is performed under the
35 supervision of the patient’s physician and surgeon or
36 podiatrist who shall be accessible to the laboratory to
37 provide onsite, telephone, or electronic consultation as
38 needed, and shall: (A) ensure that the person is
39 performing test methods as required for accurate and
40 reliable tests; and (B) have personal knowledge of the



1 results of the clinical laboratory testing or examination
2 performed by that person before the test results are
3 reported from the laboratory.

4 (13) A pharmacist, when ordering drug
5 therapy-related laboratory tests in compliance with
6 subparagraph (B) of paragraph (4) of, or clause (ii) of
7 subparagraph (A) of paragraph (5) of, subdivision (c) of
8 Section 4046.

9 (c) Notwithstanding subdivision (b) of Section 1206,
10 no person shall perform clinical laboratory tests or
11 examinations classified as of high complexity under CLIA
12 unless the clinical laboratory test or examination is
13 performed under the overall operation and
14 administration of the laboratory director, as described in
15 Section 1209, including, but not limited to,
16 documentation by the laboratory director of the
17 adequacy of the qualifications and competency of the
18 personnel, and the test is performed by any of the
19 following persons:

20 (1) A licensed physician and surgeon holding a M.D. or
21 D.O. degree.

22 (2) A licensed podiatrist or a licensed dentist when the
23 results of the tests can be lawfully utilized within his or
24 her practice.

25 (3) A person licensed under this chapter to engage in
26 clinical laboratory practice or to direct a clinical
27 laboratory when the test or examination is within a
28 specialty or subspecialty authorized by the person's
29 licensure.

30 (4) A person authorized to perform tests pursuant to
31 a certificate issued under Chapter 7 (commencing with
32 Section 1000) of Part 2 of Division 1 of the Health and
33 Safety Code when the test or examination is within a
34 specialty or subspecialty authorized by the person's
35 certification.

36 (5) A licensed physician assistant when authorized by
37 a supervising physician and surgeon in accordance with
38 Section 3502 or Section 3535.

39 (6) A perfusionist when authorized by and performed
40 in compliance with Section 2590.



1 ~~(7) A respiratory care practitioner when authorized~~
2 ~~by and performed in compliance with Chapter 8.3~~
3 ~~(commencing with Section 3700).~~

4 ~~(8) A person performing nuclear medicine technology~~
5 ~~when authorized by and performed in compliance with~~
6 ~~Chapter 7.2 (commencing with Section 25625) of~~
7 ~~Division 20 of the Health and Safety Code.~~

8 ~~(9) Any person when performing blood gas analysis in~~
9 ~~compliance with Section 1245.~~

10 ~~(10) Any other person within a physician office~~
11 ~~laboratory when the test is performed under the onsite~~
12 ~~supervision of the patient's physician and surgeon or~~
13 ~~podiatrist who shall: (A) ensure that the person is~~
14 ~~performing test methods as required for accurate and~~
15 ~~reliable tests; and (B) have personal knowledge of the~~
16 ~~results of clinical laboratory testing or examination~~
17 ~~performed by that person before the test results are~~
18 ~~reported from the laboratory.~~

19 ~~(d) Clinical laboratory examinations classified as~~
20 ~~physician-performed microscopy under CLIA may be~~
21 ~~performed by a licensed physician and surgeon holding~~
22 ~~a M.D. or D.O. degree.~~

23 ~~(e) Notwithstanding any other provision of law, a~~
24 ~~person who performs blood glucose testing for the~~
25 ~~purposes of monitoring a minor child diagnosed with~~
26 ~~diabetes pursuant to subdivision (c) of Section 1241 may~~
27 ~~do so without satisfying the requirements of this chapter,~~
28 ~~unless prohibited by federal law.~~

29 ~~SEC. 2.~~

30 ~~SECTION 1.~~ Section 1241 of the Business and
31 Professions Code is amended to read:

32 1241. (a) This chapter applies to all clinical
33 laboratories in California or receiving biological
34 specimens originating in California for the purpose of
35 performing a clinical laboratory test or examination, and
36 to all persons performing clinical laboratory tests or
37 examinations or engaging in clinical laboratory practice
38 in California or on biological specimens originating in
39 California, except as provided in subdivision (b).



1 (b) This chapter shall not apply to any of the following
 2 clinical laboratories, or to persons performing clinical
 3 laboratory tests or examinations in any of the following
 4 clinical laboratories:

5 (1) Those owned and operated by the United States of
 6 America, or any department, agency, or official thereof
 7 acting in his or her official capacity to the extent that the
 8 Secretary of the federal Department of Health and
 9 Human Services has modified the application of CLIA
 10 requirements to those laboratories.

11 (2) Public health laboratories, as defined in Section
 12 1206.

13 (3) Those that perform clinical laboratory tests or
 14 examinations for forensic purposes only.

15 (4) Those that perform clinical laboratory tests or
 16 examinations for research and teaching purposes only
 17 and do not report or use patient-specific results for the
 18 diagnosis, prevention, or treatment of any disease or
 19 impairment of, or for the assessment of the health of, an
 20 individual.

21 (5) Those that perform clinical laboratory tests or
 22 examinations certified by the National Institutes on Drug
 23 Abuse only for those certified tests or examinations.
 24 However, all other clinical laboratory tests or
 25 examinations conducted by the laboratory are subject to
 26 this chapter.

27 ~~(e) This chapter shall not apply to persons who~~

28 (6) *Those that* perform blood glucose testing for the
 29 purposes of monitoring a minor child diagnosed with
 30 diabetes when the person performing the test has been
 31 entrusted with the care and control of the child by the
 32 child's parent or legal guardian and provided that all of
 33 the following occur:

34 (1)

35 (A) The blood glucose monitoring test is performed
 36 with a blood glucose monitoring instrument that has been
 37 approved by the federal Food and Drug Administration
 38 for sale over the counter to the public without a
 39 prescription.

40 (2)



1 (B) The person has been provided written
2 instructions by the child’s health care provider or an
3 agent of the child’s health care provider in accordance
4 with the manufacturer’s instructions on the proper use of
5 the monitoring instrument and the handling of associated
6 medical waste.

7 ~~(3) The person, receiving~~

8 (C) *The person, receiving written authorization from*
9 *the minor’s parent or legal guardian, complies with*
10 *written instructions from the child’s health care provider,*
11 *or an agent of the child’s health care provider, regarding*
12 *the performance of the test and the operation of the blood*
13 *glucose monitoring instrument, including how to*
14 *determine if the results are within the normal or*
15 *therapeutic range for the child.*

16 ~~(4)~~

17 (D) The person complies with specific written
18 instructions from the child’s health care provider or an
19 agent of the child’s health care provider regarding actions
20 to be taken when results are not within the normal or
21 therapeutic range for the child. *The instructions shall also*
22 *contain the telephone number of the child’s health care*
23 *provider and the telephone number of the child’s parent*
24 *or legal guardian.*

25 ~~SEC. 3.~~

26 SEC. 2. Section 2058 of the Business and Professions
27 Code is amended to read:

28 2058. (a) Nothing in this chapter prohibits service in
29 the case of emergency, or the domestic administration of
30 family remedies.

31 (b) Nothing in this chapter shall be construed to
32 ~~prohibit the performance of a finger stick in~~ *prohibit*
33 *obtaining a blood specimen by skin puncture for the*
34 *purpose of performing blood glucose testing for the*
35 *purposes of monitoring a minor child in accordance with*
36 ~~subdivision (e) paragraph (6) of subdivision (b) of~~
37 Section 1241.

38 ~~SEC. 4.~~

39 SEC. 3. Section 1596.797 is added to the Health and
40 Safety Code, to read:



1 ~~1596.797. A child day care facility may perform blood~~
2 *1596.797. Blood* glucose testing for the purposes of
3 monitoring a minor child diagnosed with diabetes *may be*
4 *performed in a child day care facility* in accordance with
5 ~~subdivision (e)~~ *paragraph (6) of subdivision (b)* of
6 Section 1241 of the Business and Professions Code.

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