

Introduced by Senator LaraFebruary 14, 2017

An act to amend Sections 1226 and 1228 of, to add Sections 1226.4, 1240.1, and 1266.2 to, and to repeal and add the heading of Article 5 (commencing with Section 1240) of Chapter 1 of Division 2 of, the Health and Safety Code, relating to clinics.

LEGISLATIVE COUNSEL'S DIGEST

SB 349, as introduced, Lara. Chronic dialysis clinics: staffing requirements.

Existing law establishes the State Department of Public Health and sets forth its powers and duties, including, but not limited to, the licensure and regulation of chronic dialysis clinics. Existing law requires the department to adopt regulations to implement these provisions, and requires those regulations to prescribe, among other things, minimum standards for staffing with duly qualified personnel. Violation of these provisions is a crime.

This bill would establish minimum staffing requirements for chronic dialysis clinics and establish a minimum transition time between patients receiving dialysis services at a treatment station. The bill would require chronic dialysis clinics to maintain certain information relating to the minimum staffing and minimum transition time requirements and provide that information, certified by the medical director and the chief executive officer or administrator under penalty of perjury, to the department on a schedule and in a format specified by the department, but no less frequently than 4 times per year. The bill would establish a schedule of penalties and actions to be taken for failing to comply with the minimum staffing and minimum transition time requirements, including, among other things, the imposition of civil fines and the

requirement that chronic dialysis clinic submit a correction action plan. The bill would also establish a private right of action to enforce the minimum staffing and minimum transition time requirements. Because failure to comply with the minimum staffing and minimum transition time requirements would be a crime, and by expanding the crime of perjury, this bill would impose a state-mandated local program.

Existing law requires every clinic for which a license or special permit has been issued to be periodically inspected, with the frequency to be determined based on the type and complexity of the clinic or special service to be inspected. Existing law makes this provision inapplicable to an end stage renal disease facility.

This bill would delete that exception and require the department to conduct an inspection of a chronic dialysis clinic at least once per year and as often as necessary to, among other things, ensure compliance with the minimum staffing and minimum transition time requirements and ensure the adequacy of care being provided.

The bill would require the department to issue regulations necessary to implement the bill no later than 180 days following its effective date.

Existing constitutional provisions require that a statute that limits the right of access to the meetings of public bodies or the writings of public officials and agencies be adopted with findings demonstrating the interest protected by the limitation and the need for protecting that interest.

This bill would make legislative findings to that effect.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

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

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

- 1 SECTION 1. The Legislature finds and declares all of the
- 2 following:
- 3 (a) Dialysis is a critical, life-saving treatment for Californians
- 4 suffering from end-stage renal disease.
- 5 (b) There are currently over 50,000 dialysis patients, and almost
- 6 500 licensed outpatient dialysis clinics, in California.

1 (c) There is broad consensus among medical professionals,
2 academics, and other experts that higher ratios of direct caregiving
3 staff to patients at outpatient dialysis clinics improve patient
4 outcomes, including by reducing the rate at which patients suffer
5 infections or must be hospitalized.

6 (d) There is also broad consensus among medical professionals,
7 academics, and other experts that adequate time to prepare a
8 treatment station for a patient to be dialyzed is necessary to ensure
9 safety and hygiene protocols are followed, and directly improve
10 patient outcomes, including by reducing the rate at which patients
11 suffer infections or must be unnecessarily hospitalized.

12 (e) Worker safety is also enhanced by higher ratios of caregiving
13 staff to patients and transition time between patients, including by
14 reducing the risk of injury on the job.

15 (f) Current staffing levels in outpatient dialysis clinics in
16 California are inadequate to protect patient health and worker
17 safety, and therefore are presently causing harm to dialysis patients,
18 including unnecessary and avoidable deaths, hospitalizations,
19 infections, and medication errors.

20 (g) Other states mandate minimum direct care staffing
21 requirements in order to enhance patient safety and health at
22 outpatient dialysis clinics.

23 SEC. 2. Section 1226 of the Health and Safety Code is amended
24 to read:

25 1226. (a) The regulations shall prescribe the kinds of services
26 which may be provided by clinics in each category of licensure
27 and shall prescribe minimum standards of adequacy, safety, and
28 sanitation of the physical plant and equipment, *and, subject to*
29 *Section 1226.4*, minimum standards for staffing with duly qualified
30 ~~personnel~~, *personnel* and minimum standards for providing the
31 services offered. These minimum standards shall be based on the
32 type of facility, the needs of the patients served, and the types and
33 levels of services provided.

34 (b) The Office of Statewide Health Planning and Development,
35 in consultation with the Community Clinics Advisory Committee,
36 shall prescribe minimum construction standards of adequacy and
37 safety for the physical plant of clinics as found in the California
38 Building Standards Code.

39 (c) (1) A city or county, as applicable, shall have plan review
40 and building inspection responsibilities for the construction or

1 alteration of buildings described in paragraph (1) and paragraph
2 (2) of subdivision (b) of Section 1204 and shall apply the
3 provisions of the latest edition of the California Building Standards
4 Code in conducting these plan review responsibilities. For these
5 buildings, construction and alteration shall include conversion of
6 a building to a purpose specified in paragraphs (1) and (2) of
7 subdivision (b) of Section 1204.

8 ~~Upon~~

9 (2) *Upon* the initial submittal to a city or county by the
10 governing authority or owner of these clinics for plan review and
11 building inspection services, the city or county shall reply in
12 writing to the clinic whether or not the plan review by the city or
13 county will include a certification as to whether or not the clinic
14 project submitted for plan review meets the standards as
15 propounded by the office in the California Building Standards
16 Code.

17 ~~If~~

18 (3) *If* the city or county indicates that its review will include
19 this certification it shall do ~~at~~ *both* of the following:

20 (1)

21 (A) Apply the applicable clinic provisions of the latest edition
22 of the California Building Standards Code.

23 (2)

24 (B) Certify in writing, to the applicant within 30 days of
25 completion of construction whether or not these standards have
26 been met.

27 (d) If upon initial submittal, the city or county indicates that
28 its plan review will not include this certification, the governing
29 authority or owner of the clinic shall submit the plans to the Office
30 of Statewide Health Planning and Development who shall review
31 the plans for certification whether or not the clinic project meets
32 the standards, as propounded by the office in California Building
33 Standards Code.

34 (e) When the office performs review for certification, the office
35 shall charge a fee in an amount that does not exceed its actual
36 costs.

37 (f) The office of the State Fire Marshal shall prescribe minimum
38 safety standards for fire and life safety in surgical clinics.

39 (g) Notwithstanding subdivision (c), the governing authority
40 or owner of a clinic may request the office to perform plan review

1 services for buildings described in subdivision (c). If the office
2 agrees to perform these services, after consultation with the local
3 building official, the office shall charge an amount not to exceed
4 its actual costs. The construction or alteration of these buildings
5 shall conform to the applicable provisions of the latest edition of
6 the California Building Standards Code for purposes of the plan
7 review by the office pursuant to this subdivision.

8 (h) Regulations adopted pursuant to this chapter establishing
9 standards for laboratory services shall not be applicable to any
10 clinic that operates a clinical laboratory licensed pursuant to
11 Section 1265 of the Business and Professions Code.

12 SEC. 3. Section 1226.4 is added to the Health and Safety Code,
13 to read:

14 1226.4. (a) For purposes of this section the following terms
15 have the following meanings:

16 (1) "At all times" includes times during which employees,
17 including, but not limited to, nurses and technicians, are provided
18 meal periods and rest or other breaks.

19 (2) "Charge nurse" means a charge nurse as described in Section
20 494.140(b)(3) of Title 42 of the Code of Federal Regulations as it
21 read on December 31, 2016.

22 (3) "Direct care" means initiating and discontinuing dialysis,
23 monitoring patients during treatment, and administering
24 medications, and physical presence in the immediate area where
25 patients are dialyzed.

26 (4) "Nurse" means a registered nurse licensed pursuant to
27 Chapter 6 (commencing with Section 2700) of Division 2 of the
28 Business and Professions Code.

29 (5) "Nurse manager" means a nurse manager as described in
30 Section 494.140(b)(1) of Title 42 of the Code of Federal
31 Regulations as it read on December 31, 2016.

32 (6) "Social worker" means a social worker as described in
33 Section 494.140(d) of Title 42 of the Code of Federal Regulations
34 as it read on December 31, 2016.

35 (7) "Technician" means a person who holds both of the
36 following qualifications:

37 (A) The person is a patient care dialysis technician, as described
38 in Section 494.140(e) of Title 42 of the Code of Federal
39 Regulations as it read on December 31, 2016.

1 (B) The person is a Certified Hemodialysis Technician certified
2 pursuant to Article 3.5 (commencing with Section 1247) of Chapter
3 3 of Division 2 of the Business and Professions Code.

4 (8) “Trainee” means a person who is undergoing training to
5 become a technician, but who has not yet been certified as a
6 Certified Hemodialysis Technician pursuant to Article 3.5
7 (commencing with Section 1247) of Chapter 3 of Division 2 of
8 the Business and Professions Code.

9 (9) “Transition time” means the period of time beginning when
10 one patient leaves a treatment station and ending when the next
11 patient is placed in the treatment station, but does not mean the
12 period of time after the last patient of the day leaves the treatment
13 station.

14 (10) “Treatment station” means a physical location within a
15 chronic dialysis clinic where an individual patient is dialyzed.

16 (b) (1) Commencing July 1, 2018, a chronic dialysis clinic shall
17 ensure that the following minimum staffing ratios are met at all
18 times that patients are receiving, or preparing to receive, direct
19 care:

20 (A) At least one nurse is providing direct care for every eight
21 patients. A nurse shall only count toward this ratio during time
22 periods the nurse has no responsibilities other than direct care. A
23 nurse manager or charge nurse shall not count toward this ratio.

24 (B) At least one technician is providing direct care for every
25 three patients. A technician shall only count toward this ratio during
26 time periods the technician has no responsibilities other than direct
27 care. Trainees shall not count toward this ratio. Nurses counted
28 toward the nurse-to-patient ratio shall not count toward this ratio.

29 (2) Commencing July 1, 2018, a chronic dialysis clinic shall
30 ensure that a social worker is not assigned more than 75 patients.

31 (3) The ratios described in paragraphs (1) and (2) shall constitute
32 the minimum number of nurses, technicians, and social workers
33 assigned to patients at all times. Additional nurses, technicians,
34 and social workers shall be assigned to the extent necessary to
35 ensure that an adequate number of qualified personnel are present
36 whenever patients are undergoing dialysis so that the
37 patient-to-staff ratio is appropriate to the level of dialysis care
38 given and meets the needs of patients.

39 (4) Commencing July 1, 2018, a chronic dialysis clinic shall
40 ensure that the transition time is at least 45 minutes.

1 (c) The department shall not issue a license to any chronic
2 dialysis clinic unless that chronic dialysis clinic demonstrates the
3 ability and intention to comply with this section.

4 (d) (1) Every chronic dialysis clinic for which a license has
5 been issued shall maintain, and provide to the department on a
6 form prescribed by the department, at a minimum, the following
7 information:

8 (A) Actual staffing ratio and transition time data for the period
9 covered by the submission, which shall include, at a minimum,
10 daily totals of the total number and actual hours worked by nurses,
11 technicians, and social workers, the total number of patients and
12 actual hours receiving direct care, and the daily average transition
13 time for each treatment station.

14 (B) Every instance, no matter how brief, during the period
15 covered by the submission when staffing ratios or transition times
16 did not meet the requirements of subdivision (b) and the reasons
17 and circumstances therefor.

18 (2) The medical director and the chief executive officer or
19 administrator of the chronic dialysis clinic shall both personally
20 certify under penalty of perjury that each of them is satisfied, after
21 review, that all information submitted pursuant to paragraph (1)
22 is accurate and complete.

23 (3) The chronic dialysis clinic shall periodically submit the
24 information described in paragraph (1) to the department on a
25 schedule and in a format prescribed by the department, provided
26 that the clinic shall submit that information no less frequently than
27 four times per year.

28 (e) The department shall inspect each chronic dialysis clinic for
29 which a license has been issued at least once per year, and shall
30 conduct such inspections as often as necessary to ensure
31 compliance with the requirements of subdivision (b), the accuracy
32 and completeness of information provided pursuant to subdivision
33 (d), compliance with corrective action plans, if any, approved
34 under subdivision (b) or (d) of Section 1240.1, and the adequacy
35 of the quality of care being provided.

36 (f) Within 60 days of receiving a complaint from an employee,
37 an association of employees, a vendor, a contractor, a patient, an
38 association of patients, or a family member of a patient of a chronic
39 dialysis clinic that the chronic dialysis clinic has engaged in a
40 staffing-related violation or gross staffing-related violation, as

1 those terms are defined in subdivision (a) of Section 1240.1, the
2 department shall investigate the chronic dialysis clinic and, if the
3 evidence shows a violation has occurred, the department shall
4 impose discipline pursuant to Section 1240.1.

5 (g) (1) Any writing, record, or document received, owned, used,
6 or retained by the department in connection with subdivisions (c),
7 (d), and (e), and subdivisions (b) to (f), inclusive, of Section
8 1240.1, is a public record within the meaning of subdivision (e)
9 of Section 6252 of the Government Code, and, as such, is open to
10 public inspection pursuant to the California Public Records Act
11 (Chapter 3.5 (commencing with Section 6250) of Division 7 of
12 Title 1 of the Government Code). However, the name and other
13 identifying or confidential information of a person that is contained
14 in those records, except the names of duly authorized officers,
15 employees, or agents of the department conducting an investigation
16 or inspection in response to a complaint filed pursuant to
17 subdivision (f), shall be redacted from copies of those records that
18 are made available for public inspection.

19 (2) The department shall redact from any writing, record, or
20 document described in this subdivision personal identifying
21 information associated with named individuals to the extent
22 required to prevent an unwarranted invasion of personal privacy,
23 as that term is used in subdivision (c) of Section 6254, but the
24 department shall not withhold any such writing, record, or
25 document in its entirety under subdivision (c) of Section 6254.

26 (3) Information required to be submitted under subdivision (d),
27 and complaints submitted under subdivision (f), shall not be
28 withheld on the basis of subdivision (f) of Section 6254 of the
29 Government Code.

30 SEC. 4. Section 1228 of the Health and Safety Code is amended
31 to read:

32 1228. (a) Except as provided in subdivision (c), every clinic
33 for which a license or special permit has been issued shall be
34 periodically inspected. ~~The~~ *Except as provided in Section 1226.4,*
35 *the* frequency of inspections shall depend upon the type and
36 complexity of the clinic or special service to be inspected.
37 Inspections shall be conducted no less often than once every three
38 years and as often as necessary to ensure the quality of care being
39 provided.

1 (b) (1) During inspections, representatives of the department
2 shall offer any advice and assistance to the clinic as they deem
3 appropriate. The department may contract with local health
4 departments for the assumption of any of the department's
5 responsibilities under this chapter. In exercising this authority, the
6 local health department shall conform to the requirements of this
7 chapter and to the rules, regulations, and standards of the
8 department.

9 (2) The department shall reimburse local health departments
10 for services performed pursuant to this section, and these payments
11 shall not exceed actual cost. Reports of each inspection shall be
12 prepared by the representative conducting it upon forms prepared
13 and furnished by the department and filed with the department.

14 (c) This section shall not apply to any of the following:

15 (1) A rural health clinic.

16 (2) A primary care clinic accredited by the Joint Commission
17 on Accreditation of Healthcare Organizations (JCAHO), the
18 Accreditation Association for Ambulatory Health Care (AAAHC),
19 or any other accrediting organization recognized by the department.

20 (3) An ambulatory surgical center.

21 ~~(4) An end-stage renal disease facility.~~

22 ~~(5)~~

23 (4) A comprehensive outpatient rehabilitation facility that is
24 certified to participate either in the Medicare program under Title
25 XVIII (42 U.S.C. Sec. 1395 et seq.) of the federal Social Security
26 Act, or the medicaid program under Title XIX (42 U.S.C. Sec.
27 1396 et seq.) of the federal Social Security Act, or both.

28 (d) Notwithstanding paragraph (2) of subdivision (c), the
29 department shall retain the authority to inspect a primary care clinic
30 pursuant to Section 1227, or as necessary to ensure the quality of
31 care being provided.

32 SEC. 5. The heading of Article 5 (commencing with Section
33 1240) of Chapter 1 of Division 2 of the Health and Safety Code
34 is repealed.

35

36 ~~Article 5. Suspension and Revocation~~

37

38 SEC. 6. The heading of Article 5 (commencing with Section
39 1240) is added to Chapter 1 of Division 2 of the Health and Safety
40 Code, to read:

1 Article 5. Suspension, Revocation, and Penalties

2
3 SEC. 7. Section 1240.1 is added to the Health and Safety Code,
4 to read:

5 1240.1. (a) For purposes of this section, the following terms
6 have the following meanings:

7 (1) “Staffing-related violation” means any of the following:

8 (A) Violation by the chronic dialysis clinic, or any of its officers,
9 employees, vendors, or contractors of Section 1226.4.

10 (B) Conduct by the chronic dialysis clinic, or any of its officers,
11 employees, vendors, or contractors intended to conceal a violation
12 of Section 1226.4.

13 (C) A misrepresentation of information provided to the
14 department pursuant to this section or subdivision (c) of Section
15 1226.4.

16 (D) Violation by the chronic dialysis clinic, or any of its officers,
17 employees, vendors, or contractors, of any part of a corrective
18 action plan described in subdivision (b) or (d).

19 (E) Other violations that the department has defined in
20 regulation.

21 (2) “Gross staffing-related violation” means any of the
22 following:

23 (A) A staffing-related violation that causes or exacerbates harm
24 to a patient, or that has a substantial possibility of causing or
25 exacerbating harm to a patient.

26 (B) A willful or intentional staffing-related violation.

27 (C) Reckless disregard of a substantial likelihood of a
28 staffing-related violation.

29 (D) A continuous period of one hour or longer in which the
30 staffing ratio is at or above one nurse providing direct care for nine
31 or more patients, or one technician providing direct care for four
32 or more patients. For purposes of this subparagraph, the terms
33 “nurse” and “technician” shall have the same meanings as in
34 Section 1226.4.

35 (E) A continuous period of one week or longer in which the
36 staffing ratio is at or above one social worker assigned to 90 or
37 more patients. For purposes of this subparagraph, “social worker”
38 has the same meaning as in Section 1226.4.

39 (F) A daily average transition time for a treatment station that
40 is 20 minutes or shorter.

1 (G) Other violations that the department has defined in
2 regulation.

3 (3) “Governing entity” means a person, firm, association,
4 partnership, corporation, or other entity that owns or operates a
5 chronic dialysis clinic for which a license has been issued, without
6 respect to whether the person or entity itself directly holds that
7 license.

8 (4) “Responsible individual” means any of the following:

9 (A) A person in a position of authority within a chronic dialysis
10 clinic who, with respect to a staffing-related violation or gross
11 staffing-related violation, knew or should have known of the
12 substantial likelihood that the violation could occur and possessed,
13 but failed to exercise, authority to prevent the violation from
14 occurring, or knew or should have known that the violation had
15 occurred and possessed, but failed to exercise, authority to
16 substantially remedy the violation.

17 (B) A member of the governing body, designated person, chief
18 executive officer, administrator, and medical director, as those
19 terms are used in Section 494.180 of Title 42 of the Code of Federal
20 Regulations as it read on December 31, 2016.

21 (C) Managerial employees, officers, or directors of the governing
22 entity, and persons who provide services under contract to that
23 governing entity.

24 (b) The department shall impose the following civil penalties
25 on a chronic dialysis clinic for a staffing-related violation and in
26 the manner provided in this chapter. Action taken under this
27 subdivision shall be in addition to the actions required or authorized
28 under subdivisions (c) and (d).

29 (1) For the first staffing-related violation in any 12-month
30 period:

31 (A) The department shall impose a civil penalty on the chronic
32 dialysis clinic of not less than five hundred dollars (\$500) and not
33 more than two thousand five hundred dollars (\$2,500).

34 (B) The department shall impose a civil penalty on each
35 responsible individual of not less than one hundred dollars (\$100)
36 and not more than one thousand dollars (\$1,000).

37 (C) The chronic dialysis clinic shall submit a corrective action
38 plan to the department describing how the chronic dialysis clinic
39 will avoid committing any further staffing-related violations. The

1 corrective action plan shall be revised and approved by the
2 department.

3 (2) For the second staffing-related violation in any 12-month
4 period:

5 (A) The department shall impose a civil penalty on the chronic
6 dialysis clinic of not less than one thousand dollars (\$1,000) and
7 not more than five thousand dollars (\$5,000).

8 (B) The department shall impose a civil penalty on each
9 responsible individual of not less than one hundred dollars (\$100)
10 and not more than two thousand dollars (\$2,000).

11 (C) The chronic dialysis clinic shall submit a corrective action
12 plan to the department describing how the chronic dialysis clinic
13 will avoid committing any further staffing-related violations. The
14 corrective action plan shall be revised and approved by the
15 department.

16 (3) For the third staffing-related violation in any 12-month
17 period:

18 (A) The department shall impose a civil penalty on the chronic
19 dialysis clinic of not less than two thousand dollars (\$2,000) and
20 not more than seven thousand five hundred dollars (\$7,500).

21 (B) The department shall impose a civil penalty on each
22 responsible individual of not less than two hundred dollars (\$200)
23 and not more than three thousand dollars (\$3,000).

24 (C) The chronic dialysis clinic shall submit a corrective action
25 plan to the department describing how the chronic dialysis clinic
26 will avoid committing any further staffing-related violations. The
27 corrective action plan shall be revised and approved by the
28 department.

29 (4) For the fourth staffing-related violation in any 12-month
30 period:

31 (A) The department shall impose a civil penalty on the chronic
32 dialysis clinic of not less than three thousand dollars (\$3,000) and
33 not more than ten thousand dollars (\$10,000).

34 (B) The department shall impose a civil penalty on each
35 responsible individual of not less than two hundred dollars (\$200)
36 and not more than four thousand dollars (\$4,000).

37 (C) The chronic dialysis clinic shall submit a corrective action
38 plan to the department describing how the chronic dialysis clinic
39 will avoid committing any further staffing-related violations. The

1 corrective action plan shall be revised and approved by the
2 department.

3 (5) For the fifth staffing-related violation in any 12-month
4 period:

5 (A) The department shall impose a civil penalty on the chronic
6 dialysis clinic of not less than four thousand dollars (\$4,000) and
7 not more than twelve thousand five hundred dollars (\$12,500).

8 (B) The department shall impose a civil penalty on each
9 responsible individual of not less than three hundred dollars (\$300)
10 and not more than five thousand dollars (\$5,000).

11 (C) The chronic dialysis clinic shall submit a corrective action
12 plan to the department describing how the chronic dialysis clinic
13 will avoid committing any further staffing-related violations. The
14 corrective action plan shall be revised and approved by the
15 department.

16 (6) For the sixth and each subsequent staffing-related violation
17 in any 12-month period:

18 (A) The department shall impose a civil penalty on the chronic
19 dialysis clinic of not less than five thousand dollars (\$5,000) and
20 not more than twenty-five thousand dollars (\$25,000).

21 (B) The department shall impose a civil penalty on each
22 responsible individual of not less than three hundred dollars (\$300)
23 and not more than six thousand dollars (\$6,000).

24 (C) The chronic dialysis clinic shall submit a corrective action
25 plan to the department describing how the chronic dialysis clinic
26 will avoid committing any further staffing-related violations. The
27 corrective action plan shall be revised and approved by the
28 department.

29 (c) Notwithstanding Section 1240, and subject to Section 1241,
30 the department shall take the following action in the manner
31 provided in this chapter. Action taken under this subdivision shall
32 be in addition to actions required or authorized under subdivisions
33 (b) and (d).

34 (1) For the first gross staffing-related violation in any 24-month
35 period, the department may suspend the license issued to the
36 chronic dialysis clinic for a period not to exceed seven days.

37 (2) For the second gross staffing-related violation in any
38 24-month period, the department shall suspend the license issued
39 to the chronic dialysis clinic for a period not to exceed seven days.

1 (3) For the third gross staffing-related violation in any 24-month
2 period, the department shall suspend the license issued to the
3 chronic dialysis clinic for a period not to exceed 30 days.

4 (4) For the fourth gross staffing-related violation in any
5 24-month period, the department shall suspend the license issued
6 to the chronic dialysis clinic for a period not to exceed 90 days.

7 (5) For the fifth gross staffing-related violation in any 24-month
8 period:

9 (A) The department may revoke the license issued to the chronic
10 dialysis clinic or, if the department does not revoke the license,
11 the department shall suspend the license for a period not to exceed
12 180 days.

13 (B) For a period not to exceed 180 days, the department may
14 refuse to issue or renew a license, and may refuse to authorize a
15 transfer of an existing license, with respect to a chronic dialysis
16 clinic owned or operated by the same, or an affiliated, governing
17 entity of the chronic dialysis clinic at which the gross
18 staffing-related violation occurred.

19 (6) For the sixth and each subsequent gross staffing-related
20 violation in any 24-month period:

21 (A) The department may revoke the license issued to the chronic
22 dialysis clinic or, if the department does not revoke the license,
23 the department shall suspend the license for a period not to exceed
24 one year.

25 (B) For a period not to exceed three years, the department may
26 refuse to issue or renew a license, and may refuse to authorize a
27 transfer of an existing license, with respect to a chronic dialysis
28 clinic owned or operated by the same, or an affiliated, governing
29 entity of the chronic dialysis clinic at which the gross
30 staffing-related violation occurred.

31 (d) Notwithstanding Section 1240, and subject to Section 1241,
32 the department shall take the following action with respect to a
33 governing entity in the manner provided in this chapter. Action
34 taken under this subdivision shall be in addition to action required
35 or authorized under subdivisions (b) and (c).

36 (1) Except as provided in paragraph (2), when chronic dialysis
37 clinics owned or operated by a governing entity or affiliated
38 governing entities commit, in the aggregate, 25 or more gross
39 staffing-related violations within any 24-month period:

1 (A) The governing entity or governing entities shall submit a
2 corrective action plan to the department describing affirmative
3 steps the governing entity or governing entities and associated
4 chronic dialysis clinics will take to prevent every chronic dialysis
5 clinic owned or operated by the governing entity or governing
6 entities from committing any further gross staffing-related
7 violations. The corrective action plan shall be revised and approved
8 by the department.

9 (B) The department shall refuse to issue or renew a license, and
10 shall refuse to authorize a transfer of an existing license, to the
11 governing entity or governing entities or a chronic dialysis clinic
12 owned or operated by the governing entity or governing entities,
13 for a period that ends on or before the later of either:

14 (i) Three years after the latest gross staffing-related violation
15 occurred.

16 (ii) The date on which the department is satisfied that the
17 governing entity or governing entities and associated chronic
18 dialysis clinics have taken all affirmative steps set forth in the
19 corrective action plan submitted under subparagraph (A).

20 (2) When chronic dialysis clinics owned or operated by a
21 governing entity or affiliated governing entities commit, in the
22 aggregate, 50 or more gross staffing-related violations within any
23 24-month period:

24 (A) The governing entity or governing entities shall submit a
25 corrective action plan to the department describing affirmative
26 steps the governing entity or governing entities and associated
27 chronic dialysis clinics will take to prevent every chronic dialysis
28 clinic owned or operated by the governing entity or governing
29 entities from committing any further gross staffing-related
30 violations of any kind. The corrective action plan shall be revised
31 and approved by the department.

32 (B) The department may revoke or suspend licenses issued to
33 the governing entity or governing entities or any chronic dialysis
34 clinic that they own or operate, and may refuse to issue, renew, or
35 authorize a transfer of, a license to the governing entity or
36 governing entities or any chronic dialysis clinic owned or operated
37 by the governing entity or governing entities.

38 (e) (1) The department shall consider the factors described in
39 paragraph (2) for all of the following:

- 1 (A) When determining the penalties to be imposed under
- 2 subdivision (b).
- 3 (B) The revisions, if any, to corrective action plans submitted
- 4 under subdivision (b) or (d).
- 5 (C) The extent to which to refuse to issue or transfer, to revoke,
- 6 or to suspend a license under subdivision (c) or (d).
- 7 (D) Whether to take any other action authorized under
- 8 subdivision (b), (c), or (d).
- 9 (2) The factors the department shall consider all of the following
- 10 factors as described in paragraph (1):
- 11 (A) The duration and severity of the violation.
- 12 (B) The willfulness of the violation.
- 13 (C) The history of the chronic dialysis clinic or governing entity
- 14 of noncompliance with Section 1226.4, including, but not limited
- 15 to, the similarity in circumstances of the violation to any previous
- 16 violation within a 24-month period.
- 17 (D) The ability and good faith effort of the chronic dialysis
- 18 clinic, and any responsible individual, to have foreseen or avoided
- 19 the violation.
- 20 (E) The good faith effort by the chronic dialysis clinic, and any
- 21 responsible individual, to remedy the violation.
- 22 (F) The harm to any patient, or exacerbation of that harm,
- 23 resulting from the violation.
- 24 (G) The extent to which the chronic dialysis clinic fully and
- 25 completely reported the violation pursuant to subdivision (c) of
- 26 Section 1226.4.
- 27 (f) Penalties collected pursuant to this section shall be used by
- 28 the department to implement and enforce Section 1226.4 and this
- 29 section.
- 30 (g) For purposes of Article 9 (commencing with Section 12650)
- 31 of Chapter 6 of Part 2 of Division 3 of Title 2 of the Government
- 32 Code, the information required to be provided under subdivision
- 33 (d) of Section 1226.4 shall be deemed material to any claim for
- 34 payment submitted by a chronic dialysis clinic within six months
- 35 of the submission of that information.
- 36 (h) (1) For purposes of this subdivision, the following terms
- 37 have the following meanings:
- 38 (A) “Enforcing plaintiff” means an employee, an association
- 39 of employees, a vendor, a contractor, a patient, an association of

1 patients, or a family member of a patient of a chronic dialysis
2 clinic.

3 (B) “Actionable violation” means a gross staffing-related
4 violation that a chronic dialysis clinic did not report to the
5 department pursuant to subdivision (d) of Section 1226.4.

6 (2) A civil action for an actionable violation may be brought
7 against a chronic dialysis clinic or a governing entity by the
8 Attorney General, or by an enforcing plaintiff, on behalf of the
9 people of the State of California, for injunctive relief, civil
10 penalties, and other appropriate equitable relief. A governing entity
11 shall be held jointly and severally liable with any chronic dialysis
12 clinic that the governing entity owns or operates.

13 (3) Before filing an action under this section, an enforcing
14 plaintiff shall give written notice of the alleged violation and his
15 or her intent to bring suit to the Attorney General. If the Attorney
16 General commences a civil action for the same alleged violation
17 within 60 days of receiving the notice, a separate action by the
18 enforcing plaintiff shall be barred.

19 (4) Civil penalties shall not exceed twenty-five thousand dollars
20 (\$25,000) for each actionable violation. The court shall determine
21 the civil penalty by reference to the factors enumerated in
22 subdivision (e).

23 (5) Seventy-five percent of civil penalties recovered in an action
24 brought by an enforcing plaintiff under this section shall be
25 distributed to the department for the purposes described in
26 subdivision (f) and the remaining 25 percent shall be distributed
27 to the enforcing plaintiff.

28 (6) An enforcing plaintiff who prevails in an action under this
29 subdivision is entitled to recover reasonable attorney’s fees and
30 costs. A chronic dialysis clinic that prevails in any action under
31 this subdivision is not entitled to recover reasonable attorney’s
32 fees and costs unless the defendant demonstrates that the action
33 was frivolous and without foundation.

34 (7) The private right of action established under this subdivision
35 shall not be construed to abridge or limit any other right, claim,
36 or cause of action of an enforcing plaintiff.

37 SEC. 8. Section 1266.2 is added to the Health and Safety Code,
38 to read:

39 1266.2. It is the intent of the Legislature that California
40 taxpayers not be financially responsible for implementation and

1 enforcement of minimum staffing requirements at chronic dialysis
2 clinics. In order to effectuate that intent, when calculating,
3 assessing, and collecting fees imposed on chronic dialysis clinics
4 pursuant to Section 1266, the department shall take into account
5 all costs associated with implementing and enforcing Sections
6 1226.4 and 1240.1.

7 SEC. 9. The State Department of Public Health shall issue
8 regulations necessary to implement this act no later than 180 days
9 following its effective date.

10 SEC. 10. The provisions of this act are severable. If any
11 provision of this act or its application is held invalid, that invalidity
12 shall not affect other provisions or applications that can be given
13 effect without the invalid provision or application.

14 SEC. 11. The Legislature finds and declares that Section 3 of
15 this act, which adds Section 1226.4 to the Health and Safety Code,
16 imposes a limitation on the public’s right of access to the meetings
17 of public bodies or the writings of public officials and agencies
18 within the meaning of Section 3 of Article I of the California
19 Constitution. Pursuant to that constitutional provision, the
20 Legislature makes the following findings to demonstrate the interest
21 protected by this limitation and the need for protecting that interest:

22 In order to protect the privacy of employees and patients of
23 chronic dialysis clinics, it is necessary that their names be redacted
24 from the writings described in subdivision (g) of Section 1226.4
25 of the Health and Safety Code when those writings are made
26 available to the public.

27 SEC. 12. No reimbursement is required by this act pursuant to
28 Section 6 of Article XIII B of the California Constitution because
29 the only costs that may be incurred by a local agency or school
30 district will be incurred because this act creates a new crime or
31 infraction, eliminates a crime or infraction, or changes the penalty
32 for a crime or infraction, within the meaning of Section 17556 of
33 the Government Code, or changes the definition of a crime within
34 the meaning of Section 6 of Article XIII B of the California
35 Constitution.

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