


REPORT OF THE CHIEF LEGISLATIVE ANALYST

DATE: July 24, 2017

TO: Honorable Members of the Rules, Elections, and Intergovernmental Relations Committee

FROM: Sharon M. Tso  Council File No.: 17-0002-S98
Chief Legislative Analyst Assignment No.: 17-07-0707

SUBJECT: Resolution to SUPPORT SB 349 (Lara) Chronic Dialysis Clinics

CLA RECOMMENDATION: Adopt Resolution (Harris-Dawson – Ryu - Buscaino) to include in the City's 2017-18 State Legislative Program SUPPORT for SB 349 (Lara) which would require chronic dialysis clinics to maintain specified staffing ratios and would authorize the California Department of Public Health to levy civil penalties against such clinics for violating these staffing ratios, among other provisions.

SUMMARY

The Resolution (Harris-Dawson – Ryu - Buscaino) states that kidney failure is a growing national health concern. Patients with this condition must undergo dialysis, which is a procedure that removes excess waste and water from the blood. Recovery from dialysis is slow, and patients are at risk of developing serious medical conditions.

Currently pending in the Legislature, is SB 349 (Lara), which would require minimum dialysis clinics to maintain specified staffing levels at all times. SB 349 would also require the State to inspect clinics annually and to levy civil penalties against clinics for violating the required staffing levels. The bill would also require health workers to be provided adequate time between patients to clean and prepare dialysis machines. According to the Resolution, SB 349 would reduce avoidable medical complications for dialysis patients.

The Resolution recommends that the City support SB 349.

BACKGROUND

According to the National Institute on Health, kidney disease is defined by the inability of an individual's kidneys to filter blood normally. This condition causes wastes to build up in the body, which leads to serious illnesses or death. Major risk factors for kidney disease include diabetes, high blood pressure, and family history of kidney failure. Complications from kidney disease include anemia, bone disease, muscle pain, decreased mental function, and a greater risk of getting infections.

According to the UCLA Health Library, dialysis is used to treat both acute and chronic kidney disease. Dialysis can be done at home, in a dialysis center, or in a hospital. Patients are able to read, write, sleep, or talk during treatment. Possible complications from treatment include muscle cramps, dizziness, and serious infections.

In Los Angeles, dialysis clinics are regulated by the Los Angeles County Department of Public Health, Health Facilities Inspection Division (LACDPH). LACDPH also inspects health care

facilities, investigates complaints, and conducts follow-up visits to ensure that complaints are resolved.

SB 349 (Lara), introduced on February 14, 2017, would require chronic dialysis clinics to meet minimum staffing ratios at all times for health workers and that the transition time between patients is at least 45 minutes to ensure medical staff properly clean and prepare dialysis machines. The bill would also require the California Department of Public Health to inspect clinics annually and to assess administrative penalties for violations of the staffing ratios. According to the bill's author, SB 349 would improve dialysis patient safety and reduce avoidable medical complications for patients receiving this treatment at outpatient clinics. The bill is sponsored by SEIU California and the United Nurses Associations of California/Union of Health Care Professionals.

SB 349 is supported by the California Labor Federation, NAACP, Latino Diabetes Association, National Association of Social Workers, and others. The bill is opposed by the California Chamber of Commerce, California Hospital Association, Los Angeles County Business Federation, California Children's Hospital Association, United Hospital Association, and other organizations. Groups in opposition to SB 349 state that additional regulations on the dialysis industry are unnecessary because current law provides adequate regulation of the industry.

DEPARTMENT NOTIFIED

Fire

Personnel

BILL STATUS

05/19/17 Set for hearing May 25.
05/25/17 From committee: Do pass as amended. (Ayes 5. Noes 2).
05/26/17 Read second time and amended. Ordered to third reading.
05/26/17 Published May 26 at 10 a.m.
05/31/17 Read third time. Passed. (Ayes 24. Noes 15.) Ordered to the Assembly.
06/01/17 In Assembly. Read first time. Held at Desk.
06/12/17 Referred to Committee on Health.
06/28/17 From committee: Do pass as amended and re-refer to Committee on Appropriations. (Ayes 10, Noes 4)
06/29/17 Read second time and amended. Re-referred to Committee on Appropriations.



Brian Randol

Analyst

Attachment: 1. Resolution
2. Text of SB 329

RESOLUTION

RULES, ELECTIONS & INTERGOVERNMENTAL RELATIONS

WHEREAS, any official position of the City of Los Angeles with respect to legislation, rules, regulations or policies proposed to or pending before a local, state or federal governmental body or agency must first have been adopted in the form of a Resolution by the City Council with the concurrence of the Mayor; and

WHEREAS, kidney failure is a growing national health concern; the number of patients in the United States diagnosed with loss of kidney function is growing by 5 percent per year; and

WHEREAS, loss of kidney function disproportionately affects low-income families, African Americans, and Latinos; and

WHEREAS, many patients with this condition must undergo dialysis, which is a medical procedure that removes excess waste and water from the blood; dialysis patients often need to visit a clinic three times per week for several hours per visit; and

WHEREAS, recovery from dialysis is slow, and patients are at risk of developing serious medical conditions, including: infections, vitamin imbalances, nausea, bleeding, and heart failure; and

WHEREAS, many health workers report being assigned to as many as twelve dialysis patients at a time despite rules that require technicians to be assigned to no more than four patients at a time; these harmful staffing practices do not allow health workers to devote adequate time to their patients, which increases the possibility that patients will develop life-threatening complications; and

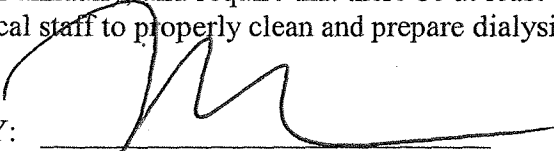
WHEREAS, currently pending in the Legislature is SB 349 (Lara), the Dialysis Patient Safety Act, which would require minimum staffing levels in dialysis clinics for registered nurses, patient care technicians, social workers, and dietitians at all times; and

WHEREAS, SB 349 would also require the California Department of Public Health to inspect clinics annually and to levy civil penalties against clinics for violating the required staffing levels; furthermore, the bill would require health workers to be provided adequate time between patients to clean and prepare dialysis machines; and

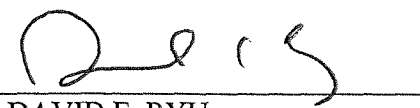
WHEREAS, SB 349 will improve dialysis patient safety and will reduce avoidable medical complications for those who need this life-saving treatment;

NOW, THEREFORE, BE IT RESOLVED, with the concurrence of the Mayor, that by the adoption of this Resolution, the City of Los Angeles hereby includes in its 2017-18 State Legislative Program SUPPORT for SB 349 (Lara), which would require chronic dialysis clinics to maintain specified minimum staffing ratios; authorize the California Department of Public Health (CDPH) to levy civil penalties for violating these staffing ratios; require CDPH to inspect clinics annually; and require that there be at least 45 minutes of transition time between dialysis patients to enable medical staff to properly clean and prepare dialysis machines.

PRESENTED BY:



MARQUEECE HARRIS-DAWSON
Councilmember, 8th District



DAVID E. RYU
Councilmember, 4th District

JUN 28 2017

SECONDED BY:



AMENDED IN ASSEMBLY JUNE 29, 2017

AMENDED IN SENATE MAY 26, 2017

AMENDED IN SENATE MAY 3, 2017

AMENDED IN SENATE APRIL 17, 2017

AMENDED IN SENATE APRIL 3, 2017

AMENDED IN SENATE MARCH 20, 2017

SENATE BILL

No. 349

**Introduced by Senator Lara
(Coauthors: Senators Bradford, Hertzberg, and Newman)**

February 14, 2017

An act to amend Sections 1226 and 1228 of, to add Sections 1226.4, 1240.1, *1240.2*, 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 amended, Lara. Chronic dialysis clinics: staffing requirements.

(1) 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 chief executive officer or administrator, 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 authorize the department to assess an administrative penalty for a violation of these provisions and would require the department to promulgate regulations to establish criteria for assessing these penalties. The bill would authorize a chronic dialysis clinic that disputes an alleged deficiency or failure to correct a deficiency, or the reasonableness of a proposed deadline for correction of a ~~violation~~, *violation* or an amount of an administrative ~~penalty~~ *penalty*, to request a hearing. Because failure to comply with the minimum staffing and minimum transition time requirements would be a crime, this bill would impose a state-mandated local program.

(2) 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 generally require the department to issue regulations necessary to implement the bill no later than ~~180 days~~ *2 years* following its effective date.

(3) 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, lifesaving treatment for Californians
4 suffering from end-stage renal disease.

5 (b) There are currently more than ~~63,000~~ 66,000 dialysis
6 patients, and ~~562~~ more than 570 licensed outpatient dialysis clinics,
7 in California.

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

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

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

22 (f) Current staffing levels in outpatient dialysis clinics in
23 California are inadequate to protect patient health and worker
24 safety, and therefore are presently causing harm to dialysis patients,
25 including unnecessary and avoidable deaths, hospitalizations,
26 infections, and medication errors.

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

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

32 1226. (a) The regulations shall prescribe the kinds of services
33 which may be provided by clinics in each category of licensure
34 and shall prescribe minimum standards of adequacy, safety, and
35 sanitation of the physical plant and equipment, and, subject to
36 Section 1226.4, minimum standards for staffing with duly qualified
37 personnel and minimum standards for providing the services
38 offered. These minimum standards shall be based on the type of

1 facility, the needs of the patients served, and the types and levels
2 of services provided.

3 (b) The Office of Statewide Health Planning and Development,
4 in consultation with the Community Clinics Advisory Committee,
5 shall prescribe minimum construction standards of adequacy and
6 safety for the physical plant of clinics as found in the California
7 Building Standards Code.

8 (c) (1) A city or county, as applicable, shall have plan review
9 and building inspection responsibilities for the construction or
10 alteration of buildings described in paragraphs (1) and (2) of
11 subdivision (b) of Section 1204 and shall apply the provisions of
12 the latest edition of the California Building Standards Code in
13 conducting these plan review responsibilities. For these buildings,
14 construction and alteration shall include conversion of a building
15 to a purpose specified in paragraphs (1) and (2) of subdivision (b)
16 of Section 1204.

17 (2) Upon the initial submittal to a city or county by the
18 governing authority or owner of these clinics for plan review and
19 building inspection services, the city or county shall reply in
20 writing to the clinic whether or not the plan review by the city or
21 county will include a certification as to whether or not the clinic
22 project submitted for plan review meets the standards as
23 propounded by the office in the California Building Standards
24 Code.

25 (3) If the city or county indicates that its review will include
26 this certification, it shall do both of the following:

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

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

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

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

4 (f) The Office of the State Fire Marshal shall prescribe minimum
5 safety standards for fire and life safety in surgical clinics.

6 (g) Notwithstanding subdivision (c), the governing authority or
7 owner of a clinic may request the office to perform plan review
8 services for buildings described in subdivision (c). If the office
9 agrees to perform these services, after consultation with the local
10 building official, the office shall charge an amount not to exceed
11 its actual costs. The construction or alteration of these buildings
12 shall conform to the applicable provisions of the latest edition of
13 the California Building Standards Code for purposes of the plan
14 review by the office pursuant to this subdivision.

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

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

21 1226.4. (a) For purposes of this section, the following terms
22 have the following meanings:

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

26 (2) "Charge nurse" means a charge nurse as described in Section
27 494.140(b)(3) of Title 42 of the Code of Federal Regulations as it
28 read on December 31, 2016.

29 (3) "Direct care" means initiating and discontinuing dialysis,
30 monitoring patients during treatment, and administering
31 medications, and physical presence in the dialysis treatment area.

32 (4) "*Full-time equivalent*" means employment by a chronic
33 dialysis clinic for 2,080 hours of work in 12 consecutive months.

34 ~~(4)~~

35 (5) "Nurse" means a registered nurse licensed pursuant to
36 Chapter 6 (commencing with Section 2700) of Division 2 of the
37 Business and Professions Code.

38 ~~(5)~~

1 (6) “Nurse manager” means a nurse manager as described in
2 Section 494.140(b)(1) of Title 42 of the Code of Federal
3 Regulations as it read on December 31, 2016.

4 ~~(6)~~

5 (7) “Registered dietitian” means a dietitian as described in
6 Section ~~494.140(e)~~ 494.140(c) of Title 42 of the Code of Federal
7 Regulations, as it read on December 31, 2016.

8 (8) “Rural county” means a county that has a population of
9 less than 250,000 and does not have a single urbanized area with
10 a population of greater than 50,000.

11 ~~(7)~~

12 (9) “Social worker” means a social worker as described in
13 Section 494.140(d) of Title 42 of the Code of Federal Regulations
14 as it read on December 31, 2016.

15 ~~(8)~~

16 (10) “Technician” means a person who holds both of the
17 following qualifications:

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

21 (B) The person is a Certified Hemodialysis Technician certified
22 pursuant to Article 3.5 (commencing with Section 1247) of Chapter
23 3 of Division 2 of the Business and Professions Code.

24 ~~(9)~~

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

30 ~~(10)~~

31 (12) “Transition time” means the period of time beginning when
32 one patient has completed treatment and has been disconnected
33 from the dialysis machine and ending when the next patient is
34 placed in the treatment station, but does not mean the period of
35 time after the last patient of the day leaves the treatment station.

36 ~~(11)~~

37 (13) “Treatment station” means a physical location within a
38 chronic dialysis clinic where an individual patient is dialyzed.

39 (b) (1) Commencing January 1, ~~2019~~, 2020, a chronic dialysis
40 clinic shall ensure that the following minimum staffing ratios are

1 met at all times that patients are receiving, or preparing to receive,
2 direct care:

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

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

12 (2) Commencing January 1, ~~2019~~, 2020, a chronic dialysis clinic
13 shall ensure that a *full-time equivalent individual* social worker is
14 not assigned more than 75 patients.

15 (3) Commencing January 1, ~~2019~~, 2020, a chronic dialysis clinic
16 shall ensure that a *full-time equivalent individual* registered dietitian
17 is not assigned more than 75 patients.

18 (4) The ratios described in paragraphs (1), (2), and (3) shall
19 constitute the minimum number of nurses, technicians, social
20 workers, and registered dietitians assigned to patients at all times.
21 Additional nurses, technicians, social workers, and registered
22 dietitians shall be assigned to the extent necessary to ensure that
23 an adequate number of qualified personnel are present whenever
24 patients are undergoing dialysis so that the patient-to-staff ratio is
25 appropriate to the level of dialysis care given and meets the needs
26 of patients.

27 (5) Commencing January 1, ~~2019~~, 2020, a chronic dialysis clinic
28 shall ensure that the transition time is at least 45 minutes.

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

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

36 (A) Actual staffing ratio and transition time data for the period
37 covered by the submission, which shall include, at a minimum,
38 daily totals of the total number and actual hours worked by nurses,
39 technicians, social workers, and registered ~~dietitians~~ dietitians, the

1 total number of patients and actual hours receiving direct care, and
2 the daily average transition time for each treatment station.

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

7 (2) The chief executive officer or administrator of the chronic
8 dialysis clinic shall personally certify that he or she is satisfied,
9 after review, that all information submitted pursuant to paragraph
10 (1) is accurate and complete.

11 (3) The chronic dialysis clinic shall periodically submit the
12 information described in paragraph (1) to the department on a
13 schedule and in a format prescribed by the department, provided
14 that the clinic shall submit that information no less frequently than
15 four times per year.

16 (e) *The department may grant a waiver of subdivisions (b), (c),
17 and (d) to a chronic dialysis clinic in a rural county if the waiver
18 does not jeopardize the health, safety, and well-being of affected
19 patients and is needed for increased operational efficiency.*

20 (e)

21 (f) The department shall inspect each chronic dialysis clinic for
22 which a license has been issued at least once per year, and shall
23 conduct such inspections as often as necessary to ensure
24 compliance with the requirements of subdivision (b), the accuracy
25 and completeness of information provided pursuant to subdivision
26 (d), and the adequacy of the quality of care being provided.

27 (f)

28 (g) Within 60 days of receiving a complaint from an employee,
29 an association of employees, a vendor, a contractor, a patient, an
30 association of patients, or a family member of a patient of a chronic
31 dialysis clinic that the chronic dialysis clinic has committed a
32 violation of the requirements of this chapter, the department shall
33 investigate the chronic dialysis clinic and, if the evidence shows
34 a violation has occurred, the department shall impose discipline
35 pursuant to Section 1240.1.

36 (g)

37 (h) (1) Any writing, record, or document received, owned, used,
38 or retained by the department in connection with subdivisions (c),
39 (d), and ~~(e)~~ (f) of this section, ~~and~~ subdivisions (b) to (g), inclusive,
40 of Section 1240.1, *and Section 1240.2*, is a public record within

1 the meaning of subdivision (e) of Section 6252 of the Government
2 Code, and, as such, is open to public inspection pursuant to the
3 California Public Records Act (Chapter 3.5 (commencing with
4 Section 6250) of Division 7 of Title 1 of the Government Code).

5 (2) The department shall redact from any writing, record, or
6 document described in this subdivision personal identifying
7 information associated with named individuals to the extent
8 required to prevent an unwarranted invasion of personal privacy,
9 as that term is used in subdivision (c) of Section 6254 of the
10 Government Code, but the department shall not withhold any such
11 writing, record, or document in its entirety under subdivision (c)
12 of Section 6254 of the Government Code.

13 (3) Information required to be submitted under subdivision (d),
14 and complaints submitted under subdivision ~~(f)~~, (g), shall not be
15 withheld on the basis of subdivision (f) of Section 6254 of the
16 Government Code.

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

19 1228. (a) Except as provided in subdivision (c), every clinic
20 for which a license or special permit has been issued shall be
21 periodically inspected. Except as provided in Section 1226.4, the
22 frequency of inspections shall depend upon the type and complexity
23 of the clinic or special service to be inspected. Inspections shall
24 be conducted no less often than once every three years and as often
25 as necessary to ensure the quality of care being provided.

26 (b) (1) During inspections, representatives of the department
27 shall offer any advice and assistance to the clinic as they deem
28 appropriate. The department may contract with local health
29 departments for the assumption of any of the department's
30 responsibilities under this chapter. In exercising this authority, the
31 local health department shall conform to the requirements of this
32 chapter and to the rules, regulations, and standards of the
33 department.

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

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

40 (1) A rural health clinic.

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

5 (3) An ambulatory surgical center.

6 (4) A comprehensive outpatient rehabilitation facility that is
7 certified to participate either in the Medicare Program under Title
8 XVIII (42 U.S.C. Sec. 1395 et seq.) of the federal Social Security
9 Act, or the Medicaid program under Title XIX (42 U.S.C. Sec.
10 1396 et seq.) of the federal Social Security Act, or both.

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

15 SEC. 5. The heading of Article 5 (commencing with Section
16 1240) of Chapter 1 of Division 2 of the Health and Safety Code
17 is repealed.

18 SEC. 6. The heading of Article 5 (commencing with Section
19 1240) is added to Chapter 1 of Division 2 of the Health and Safety
20 Code, to read:

21
22 Article 5. Suspension, Revocation, and Penalties

23
24 SEC. 7. Section 1240.1 is added to the Health and Safety Code,
25 to read:

26 1240.1. (a) The director may assess an administrative penalty
27 against a chronic dialysis clinic for a violation of this chapter. Each
28 penalty issued pursuant to this chapter shall be classified as a major
29 violation, an intermediate violation, or a minor violation according
30 to the nature of the violation and the threat of harm to patients. A
31 major violation shall be subject to an administrative penalty of up
32 to ten thousand dollars (\$10,000), and an intermediate violation
33 shall be subject to an administrative penalty of up to five thousand
34 dollars (\$5,000). The director shall not assess an administrative
35 penalty for a minor violation.

36 (b) The department shall promulgate regulations establishing
37 the criteria to assess an administrative penalty against a chronic
38 dialysis clinic, that shall include, but not be limited to, a
39 consideration of all of the following:

1 (1) The probability and severity of the risk that the violation
2 presents to the patient.

3 (2) The actual harm to patients, if any.

4 (3) The nature, scope, and severity of the violation.

5 (4) The chronic dialysis clinic's history of compliance with
6 related state and federal statutes and regulations, including, but
7 not limited to, the similarity in circumstances of the violation to
8 any previous violation by the chronic dialysis clinic within a
9 24-month period.

10 (5) Factors beyond the control of the chronic dialysis clinic that
11 restricts its ability to comply with this chapter or the rules and
12 regulations promulgated thereunder.

13 (6) The demonstrated willfulness of the violation.

14 (7) The extent to which the chronic dialysis clinic detected the
15 violation and took immediate action to correct the violation and
16 prevent that type of violation from recurring.

17 (c) If a chronic dialysis clinic disputes a determination by the
18 director regarding an alleged deficiency or failure to correct a
19 deficiency, or the reasonableness of a proposed deadline for
20 correction of a violation or an amount of an administrative penalty,
21 the chronic dialysis clinic may, within 10 working days, request
22 a hearing pursuant to Section 131071. A chronic dialysis clinic
23 shall pay all administrative penalties when all appeals have been
24 exhausted and the department's position has been upheld.

25 *SEC. 8. Section 1240.2 is added to the Health and Safety Code,*
26 *to read:*

27 *1240.2. (a) Subject to subdivision (d), prior to the effective*
28 *date of regulations adopted to implement Section 1240.1, if a*
29 *chronic dialysis clinic receives a notice of deficiency constituting*
30 *an immediate jeopardy to the health or safety of a patient or*
31 *employee and is required to submit a plan of correction, the*
32 *department may assess the licensee an administrative penalty of*
33 *up to ten thousand dollars (\$10,000).*

34 *(b) If a licensee disputes a determination by the department*
35 *regarding an alleged deficiency or the alleged failure to correct*
36 *a deficiency, or regarding the reasonableness of the proposed*
37 *deadline for correction or the amount of the penalty, the licensee*
38 *may, within 10 days, request an administrative hearing pursuant*
39 *to Section 131071. Penalties shall be paid when appeals have been*
40 *exhausted and if the department's position has been upheld.*

1 (c) For purposes of this section “immediate jeopardy” means
2 a situation in which the licensee’s noncompliance with one or
3 more requirements of licensure has caused, or is likely to cause,
4 serious injury or death to one or more patients or employees.

5 (d) This section shall only apply to incidents occurring on or
6 after January 1, 2018, except that this section shall only apply to
7 violations of subdivision (b) of Section 1226.4 occurring on or
8 after January 1, 2020.

9 (e) Notwithstanding Section 11 of the act that added this section,
10 new regulations are not required or authorized for implementation
11 of this section.

12 (f) This section shall become inoperative on the effective date
13 of regulations promulgated by the department pursuant to Section
14 1240.1.

15 ~~SEC. 8.~~

16 *SEC. 9.* Section 1266.2 is added to the Health and Safety Code,
17 to read:

18 1266.2. It is the intent of the Legislature that California
19 taxpayers not be financially responsible for implementation and
20 enforcement of minimum staffing requirements at chronic dialysis
21 clinics. In order to effectuate that intent, when calculating,
22 assessing, and collecting fees imposed on chronic dialysis clinics
23 pursuant to Section 1266, the department shall take into account
24 all costs associated with implementing and enforcing Sections
25 1226.4 and 1240.1.

26 ~~SEC. 9.~~

27 *SEC. 10.* Nothing in this act is intended to impact
28 nurse-to-patient ratios applicable to health facilities licensed
29 pursuant to subdivision (a), (b), or (f) of Section 1250 of the Health
30 and Safety Code.

31 ~~SEC. 10.~~

32 *SEC. 11.* The State Department of Public Health shall issue
33 regulations necessary to implement this act no later than ~~180 days~~
34 *two years* following its effective date.

35 ~~SEC. 11.~~

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

1 ~~SEC. 12.~~
2 *SEC. 13.* No reimbursement is required by this act pursuant to
3 Section 6 of Article XIII B of the California Constitution because
4 the only costs that may be incurred by a local agency or school
5 district will be incurred because this act creates a new crime or
6 infraction, eliminates a crime or infraction, or changes the penalty
7 for a crime or infraction, within the meaning of Section 17556 of
8 the Government Code, or changes the definition of a crime within
9 the meaning of Section 6 of Article XIII B of the California
10 Constitution.

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