

AMENDED IN ASSEMBLY APRIL 7, 2010
AMENDED IN ASSEMBLY MARCH 24, 2010
CALIFORNIA LEGISLATURE—2009—10 REGULAR SESSION

ASSEMBLY BILL

No. 2112

Introduced by Assembly Member Monning

February 18, 2010

An act to add Part 2.7 (commencing with Section 60) to Division 1 of the Civil Code, and to amend Section 130202 of the Health and Safety Code, relating to privacy.

LEGISLATIVE COUNSEL'S DIGEST

AB 2112, as amended, Monning. Prescription Record Privacy Act.

The Confidentiality of Medical Information Act prohibits a provider of health care, a health care service plan, contractor, or corporation and its subsidiaries and affiliates from intentionally sharing, selling, using for marketing, or otherwise using any medical information, as defined, for any purpose not necessary to provide health care services to a patient, unless a specified exception applies.

This bill would enact the Prescription Record Privacy Act, prohibiting a person *or entity, including a pharmacist*, from ~~knowingly disclosing or using regulated records that include prescription information containing individual identifying information for marketing a prescribed product, as provided, except when information may be transferred to another entity, as provided, and in accordance with other state and federal laws. The act would not prohibit conduct involving the collection, use, transfer, or sale of regulated records for marketing purposes if the data is aggregated, does not contain individual identifying information, and cannot reasonably be used to obtain individual~~

~~identifying information~~ *selling or releasing to a 3rd party any physician prescribing data for marketing purposes, as defined, except when the data is necessary for any local, state, or federal governmental or oversight activity, as provided, or is necessary for the processing of a health care claim. The bill also would permit the release of physician prescribing data to a licensed health care professional, service plan, contractor, or facility, as provided, a health insurer or disability insurer, or an authorized operator of a program related to the treatment of chronic and seriously debilitating or life-threatening conditions. The bill would also permit the release of data for clinical trials or established research projects, as provided.* This bill would also require that any person that knowingly fails to comply with these provisions be subject to an administrative penalty of at least \$10,000 and not more than \$50,000 per violation.

This bill would authorize the Secretary of California Health and Human Services to adopt regulations to implement these provisions. This bill would require the office of the Attorney General to enforce payment of penalties for violations of these provisions, as provided. This bill would also authorize the Office of Health Information Integrity, upon receipt of a complaint of a violation of these provisions, to conduct an administrative hearing, in accordance with the administrative adjudication provisions set forth in the Administrative Procedure Act, and to assess an administrative fine against a person or entity found to have committed a violation of these provisions.

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. Part 2.7 (commencing with Section 60) is added
- 2 to Division 1 of the Civil Code, to read:
- 3
- 4 PART 2.7. PRESCRIPTION RECORD PRIVACY ACT
- 5
- 6 60. This part may be cited as the Prescription Record Privacy
- 7 Act.
- 8 60.5. It is the intent of the Legislature to *further the state's*
- 9 *interest in improving the quality and lowering the cost of health*
- 10 *care, restrain undue influence exerted by pharmaceutical industry*
- 11 *marketing representatives over prescribing decisions, combat*

1 *vexatious and harassing sales practices*, safeguard the
2 confidentiality of ~~prescribing information~~ *physician prescribing*
3 *data*, protect the integrity of the doctor-patient relationship, and
4 maintain the integrity and public trust of the medical profession;
5 ~~combat vexatious and harassing sales practices, restrain undue~~
6 ~~influence exerted by pharmaceutical industry marketing~~
7 ~~representatives over prescribing decisions, and further the state's~~
8 ~~interest in improving the quality and lowering the cost of health~~
9 ~~care. The Legislature intends to regulate the monitoring of~~
10 ~~prescribing practices~~ *physician prescribing data* only for
11 commercial marketing purposes by companies selling prescribed
12 products. The intent is not to regulate ~~monitoring~~ for other uses,
13 such as quality control, research unrelated to marketing, or use by
14 governments or other entities not in the business of selling health
15 care products.

16 61. For purposes of this part:

17 (a) ~~“Bona fide clinical trial” means any research project that~~
18 ~~prospectively assigns human subjects to intervention and~~
19 ~~comparison groups to study the cause and effect relationship~~
20 ~~between a medical intervention and a health outcome, has received~~
21 ~~approval from an appropriate institutional review board, and has~~
22 ~~been registered at <http://ClinicalTrials.gov> prior to commencement.~~

23 (b) ~~“Individual identifying information” means information that~~
24 ~~directly or indirectly identifies a prescriber or a patient in this state,~~
25 ~~indicates where the information is derived from, or relates to a~~
26 ~~prescription for any prescribed product.~~

27 (a) *“Licensee” means a person described in Section 4036 or*
28 *4037 of the Business and Professions Code.*

29 (e)

30 (b) *“Marketing” means any activity by a company making or*
31 *selling prescribed products, or by that company’s agent, intended*
32 *to influence prescribing or purchasing choices of its products,*
33 *including, but not limited to:*

34 (1) *Advertising, publicizing, promoting, or sharing information*
35 *about a product.*

36 (2) *Identifying individuals to receive a message promoting use*
37 *of a particular product, including, but not limited to, an*
38 *advertisement, brochure, or contact by a sales representative.*

1 (3) Planning the substance of a sales representative visit or
2 communication or the substance of an advertisement or other
3 promotional message or document.

4 (4) Evaluating or compensating sales representatives.

5 (5) Identifying individuals to receive any form of gift, product
6 sample, consultancy, or any other item, service, compensation, or
7 employment of value.

8 (6) Advertising or promoting prescribed products directly to
9 patients.

10 ~~(d) "Person" means a business, individual, corporation, union,~~
11 ~~association, firm, partnership, committee, or other organization or~~
12 ~~group of persons.~~

13 ~~(e) "Pharmacy" means any individual or entity licensed under~~
14 ~~state law to dispense prescribed products.~~

15 ~~(c) "Physician" means a person described in Section 2041 of~~
16 ~~the Business and Professions Code.~~

17 ~~(d) "Physician prescribing data" means information that sets~~
18 ~~forth a prescription written on or after the operative date of this~~
19 ~~part by a physician in combination with any data that individually~~
20 ~~identifies the physician, including a unique number identifier~~
21 ~~assigned for tracking purposes, telephone number, e-mail address,~~
22 ~~medical identification number, business or home address, or any~~
23 ~~other information that can reasonably be used to identify the~~
24 ~~physician or track the prescribing habits of the physician.~~

25 ~~(f)~~

26 ~~(e) "Prescribed product" includes a biological product as defined~~
27 ~~in Section 262 of Title 42 of the United States Code and a device~~
28 ~~or a drug as defined in Section 321 of Title 21 of the United States~~
29 ~~Code.~~

30 ~~(g) "Regulated record" means information or documentation~~
31 ~~from a prescription written by a prescriber doing business in this~~
32 ~~state or a prescription dispensed in this state.~~

33 ~~62. (a) No person shall knowingly disclose or use regulated~~
34 ~~records that include prescription information containing individual~~
35 ~~identifying information for marketing a prescribed product.~~

36 ~~(b) A regulated record containing individual identifying~~
37 ~~information may be transferred to another entity, including to~~
38 ~~another branch or subsidiary of the same firm, only if it carries~~
39 ~~satisfactory assurance that the recipient will safeguard the records~~
40 ~~from being disclosed or used for a marketing purpose prohibited~~

1 under this section and only if the transfer is in accordance with
2 other state and federal laws.

3 ~~(e) Regulated records containing individual identifying
4 information may be disclosed, sold, transferred, exchanged, or
5 used for nonmarketing purposes only in accordance with other
6 state and federal laws.~~

7 ~~(d) This section does not prohibit conduct involving the
8 collection, use, transfer, or sale of regulated records for marketing
9 purposes if:~~

10 ~~(1) The data is aggregated.~~

11 ~~(2) The data does not contain individual identifying information.~~

12 ~~(3) There is no reasonable basis to believe that the data can be
13 used to obtain individual identifying information.~~

14 ~~(e) This section shall not prevent any person from disclosing
15 regulated records to the identified individual as long as the
16 information does not include protected information pertaining to
17 any other person.~~

18 ~~(f) “Release to a third party” or “release” does not include
19 communication or use of physician prescribing data among covered
20 entities that participate in an organized health care arrangement,
21 as defined in Section 160.103 of Title 45 of the Code of Federal
22 Regulations.~~

23 *62. A person or entity, including a licensee, shall not sell or
24 release to a third party, or exchange for remuneration, any
25 physician prescribing data for marketing purposes.*

26 *63. Nothing in this part may be construed to limit or restrict
27 the release of physician prescribing data that is necessary for any
28 local, state, or federal governmental oversight or regulatory
29 activity, including, but not limited to, the release of physician
30 prescribing data to a local, state, or federal law enforcement or
31 public health authority in furtherance of its regulatory activity.*

32 *64. Nothing in this part may be construed to limit or restrict
33 the release of physician prescribing data that is necessary for the
34 processing of a health care claim.*

35 *65. Nothing in this part is intended to limit or restrict the
36 otherwise lawful activities of a licensee.*

37 *66. Nothing in this part is intended to prohibit or limit an
38 individual patient of a physician from releasing any identifiable
39 information relating to a prescription that the patient received, or*

1 *that the physician wrote, that is not otherwise restricted or*
2 *prohibited by law.*

3 *67. Nothing in this part may be construed to limit or restrict*
4 *the release of physician prescribing data to any of the following:*

5 *(a) A licensed health care professional, if the release is directly*
6 *related to providing health care to a patient.*

7 *(b) A health insurer or disability insurer, health care service*
8 *plan, pharmacy benefit manager, employee-sponsored health*
9 *benefit plan, or their contractors, if the data is directly related to*
10 *administering or monitoring the use of a health care benefit.*

11 *(c) An authorized operator of a program related to the treatment*
12 *of chronic and seriously debilitating or life-threatening conditions,*
13 *as defined in subdivisions (d) and (e) of Section 1367.21 of the*
14 *Health and Safety Code.*

15 *(d) An employee benefit plan or any other person or private*
16 *entity responsible for paying for health care services rendered to*
17 *the patient, if the physician prescribing data is reasonably*
18 *necessary to complete or verify a health care transaction related*
19 *to the prescription information sought to be disclosed.*

20 *(e) Any health care service plan, contractor, or other health*
21 *care professional or facility exclusively for purposes of diagnosis*
22 *or treatment of a patient.*

23 *(f) Use by a health care service plan or health insurer or*
24 *disability insurer as permitted or required by Sections 1367.01 or*
25 *1370 of the Health and Safety Code or Sections 10123.135 or*
26 *subdivision (d) of Section 10133 of the Insurance Code.*

27 *68. Nothing in this part may be construed to prohibit the release*
28 *of aggregate prescription data to any individual or entity, provided*
29 *that data does not include identifiable physician prescribing data*
30 *as described in this part.*

31 *69. (a) Nothing in this part may be construed to prohibit the*
32 *release of physician prescribing data if it is solely intended to be*
33 *used for clinical trials or established research projects conducted*
34 *in accordance with protocols, guidelines, or standards recognized*
35 *by the federal Health and Human Services Agency, the federal*
36 *Food and Drug Administration, the National Institutes of Health,*
37 *the National Cancer Institute, or the Centers for Disease Control*
38 *and Prevention.*

39 *(b) Any entity receiving physician prescribing data pursuant to*
40 *this section may not use the data for any other purpose.*

1 70. *Nothing in this part may be construed to limit or restrict*
2 *the release of physician prescribing data for the purposes of*
3 *providing the physician with information regarding action by the*
4 *state or by the federal Food and Drug Administration limiting or*
5 *disallowing the sale or use of a specific drug, or to provide the*
6 *physician with information regarding adverse events related to a*
7 *specific drug or medical device.*

8 71. *Nothing in this part shall prohibit the otherwise lawful use*
9 *or release of physician prescribing data for litigation purposes.*

10 ~~63.~~

11 72. The Secretary of California Health and Human Services
12 may adopt regulations as necessary to implement this part.

13 ~~64.~~

14 73. Any person that knowingly fails to comply with the
15 requirements of this part or regulations adopted pursuant to this
16 part by using or disclosing regulated records in a manner not
17 authorized by this part or its regulations, shall be subject to an
18 administrative penalty of at least ten thousand dollars (\$10,000)
19 per violation and not more than fifty thousand dollars (\$50,000)
20 per violation, as assessed by the California Health and Human
21 Services Agency. Each disclosure of a regulated record shall
22 constitute a violation. The office of the Attorney General shall
23 take necessary action to enforce payment of penalties assessed
24 under this section. Minimum statutory penalties shall be set at ten
25 thousand dollars (\$10,000) per violation, notwithstanding Section
26 125.9 of the Business and Professions Code.

27 ~~64.5.~~

28 74. In addition to any other remedy provided by law, a violation
29 of this chapter shall be an unfair or deceptive act in trade or
30 commerce and an unfair method of competition and may be
31 enforced as an unfair business practice pursuant to Chapter 5 of
32 Part 2 of Division 7 of the Business and Professions Code.

33 ~~65. (a) The intent of this section is to ensure the confidentiality~~
34 ~~of data held by a state agency or its agent, which could be used to~~
35 ~~directly or indirectly identify a patient or a health care professional~~
36 ~~licensed to prescribe drugs, biological products, or medical devices.~~

37 ~~(b) For the purposes of this section:~~

38 ~~(1) "Individual identifying information" shall have the same~~
39 ~~meaning as in Section 61.~~

1 (2) “Prescribed product” includes a biological product as defined
2 in Section 262 of Title 42 of the United States Code and a device
3 or a drug as defined in Section 321 of Title 21 of the United States
4 Code.

5 (3) “State health care program” means a program for which the
6 state purchases prescribed products, including, but not limited to,
7 a state pharmaceutical assistance program, or a program for state
8 employees and their dependents, individuals under the supervision
9 of corrections, or state retirees and their dependents with the
10 exception of the state medical assistance program (Medi-Cal).

11 (e) Records held by an agency administering a state health care
12 program that include prescription information containing individual
13 identifying information shall only be disclosed for the purposes
14 allowed in Section 62.

15 (d) Any person who knowingly fails to comply with the
16 requirements of this chapter or rules adopted pursuant to this part
17 by using or disclosing regulated records in a manner not authorized
18 by this part or its rules shall be subject to an administrative penalty
19 of at least ten thousand dollars (\$10,000) per violation and not
20 more than fifty thousand dollars (\$50,000) per violation, as
21 assessed by the California Health and Human Services Agency.
22 Each disclosure of a regulated record shall constitute a violation.
23 The office of the Attorney General shall take necessary action to
24 enforce payment of penalties assessed under this section.

25 65.5. (a) The intent of this part is to ensure compliance with
26 federal Medicaid law and regulations prohibiting the disclosure
27 and use of Medicaid data, except to administer the Medicaid
28 program, and to ensure that data held by the state agency or its
29 agents that could directly or indirectly identify patients or health
30 care professionals licensed to prescribe products be kept
31 confidential.

32 (b) The State Department of Health Care Services, which
33 administers the state medical assistance program (Medi-Cal) under
34 subchapter C of Chapter 4 of Title 42 of the Code of Federal
35 Regulations (Medicaid) or a Medicaid waiver approved by the
36 Centers for Medicare and Medicaid Services, shall disclose records
37 that include prescription information only as provided for under
38 Section 431 of Title 42 of the Code of Federal Regulations and
39 the federal Privacy Act of 1974. The department shall ensure that
40 any agent or contractors with the department are informed of the

1 ~~limitations on redisclosure or use of the data provided for under~~
2 ~~applicable federal regulations and shall have policies and~~
3 ~~procedures for ensuring compliance with this statute and federal~~
4 ~~regulations.~~

5 ~~(e) Any person that knowingly fails to comply with the~~
6 ~~requirements of this part or rules adopted pursuant to this part by~~
7 ~~using or disclosing regulated records in a manner not authorized~~
8 ~~by this part or its rules shall be subject to an administrative penalty~~
9 ~~of at least ten thousand dollars (\$10,000) per violation and not~~
10 ~~more than fifty thousand dollars (\$50,000) per violation, as~~
11 ~~assessed by the California Health and Human Services Agency.~~
12 ~~Each disclosure of a regulated record shall constitute a violation.~~
13 ~~The office of the Attorney General shall take necessary action to~~
14 ~~enforce payment of penalties assessed under this section.~~

15 ~~66.~~

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

20 ~~67.~~

21 76. Nothing in this act shall be interpreted to regulate conduct
22 that takes place entirely outside of the state.

23 ~~67.5.~~

24 77. Nothing in this act shall be interpreted to regulate the
25 content, time, place, or manner of any discussion between a
26 prescriber and his or her patient, or a prescriber and any person
27 representing a prescription drug manufacturer.

28 SEC. 2. Section 130202 of the Health and Safety Code is
29 amended to read:

30 130202. (a) (1) Upon receipt of a referral from the State
31 Department of Public Health, the office may assess an
32 administrative fine against any person or any provider of health
33 care, whether licensed or unlicensed, for any violation of this
34 division in an amount as provided in Section 56.36 of the Civil
35 Code. Proceedings against any person or entity for a violation of
36 this section shall be held in accordance with the administrative
37 adjudication provisions of Chapter 4.5 (commencing with Section
38 11400) and Chapter 5 (commencing with Section 11500) of Part
39 1 of Division 3 of Title 2 of the Government Code.

1 (2) Paragraph (1) shall not apply to a clinic, health facility,
2 agency, or hospice licensed pursuant to Section 1204, 1250, 1725,
3 or 1745 if Senate Bill 541 of the 2007–08 Regular Session is
4 enacted and becomes effective on or before January 1, 2009.

5 (3) Nothing in paragraph (1) shall be construed as authorizing
6 the office to assess the administrative penalties described in Section
7 1280.15 of the Health and Safety Code.

8 (b) Upon receipt of a complaint under Part 2.7 (commencing
9 with Section 60) of Division 1 of the Civil Code, the office may
10 assess an administrative fine against any person or any provider
11 of health care, whether licensed or unlicensed, for any violation
12 of that part. Proceedings against any person or entity for a violation
13 of Part 2.7 (commencing with Section 60) of Division 1 of the
14 Civil Code shall be held in accordance with the administrative
15 adjudication provisions of Chapter 4.5 (commencing with Section
16 11400) and Chapter 5 (commencing with Section 11500) of Part
17 1 of Division 3 of Title 2 of the Government Code.

18 (c) The office shall adopt, amend, or repeal, in accordance with
19 the provisions of Chapter 3.5 (commencing with Section 11340)
20 of Part 1 of Division 3 of Title 2 of the Government Code, such
21 rules and regulations as may be reasonable and proper to carry out
22 the purposes and intent of this division, and to enable the authority
23 to exercise the powers and perform the duties conferred upon it
24 by this division not inconsistent with any other provision of law.

25 (d) Paragraph (3) of subdivision (a) shall only become operative
26 if Senate Bill 541 of the 2007–08 Regular Session is enacted and
27 becomes effective on or before January 1, 2009.