

AMENDED IN ASSEMBLY MARCH 7, 2006

AMENDED IN ASSEMBLY JUNE 15, 2005

AMENDED IN SENATE MAY 4, 2005

AMENDED IN SENATE APRIL 12, 2005

AMENDED IN SENATE APRIL 4, 2005

SENATE BILL

No. 401

Introduced by ~~Senator Ortiz~~ *Senators Ortiz and Runner*

February 17, 2005

~~An act to amend Section 56.05 of the Civil Code, relating to medical information.~~ *An act to amend Sections 125290.30 and 125290.50 of the Health and Safety Code, relating to stem cell research.*

LEGISLATIVE COUNSEL'S DIGEST

SB 401, as amended, Ortiz. ~~Medical information: pharmacies: marketing.~~ *Stem cell research: ICOC procedures.*

The California Stem Cell Research and Cures Act, an initiative measure, establishes the California Institute for Regenerative Medicine, the purpose of which is, among other things, to make grants and loans for stem cell research, for research facilities, and for other vital research opportunities to realize therapies, protocols, and medical procedures that will result in the cure for, or substantial mitigation of, diseases and injuries. Existing law establishes the Independent Citizen's Oversight Committee (ICOC), composed of appointed members, that is required to perform various functions and duties with regard to the operation of the institute.

Existing law sets forth public meeting and conflict-of-interest procedures for the ICOC and requires the ICOC to establish standards that require that all grants and loan awards be subject to intellectual property agreements that balance the opportunity of the State of California to benefit from the patents, royalties, and licenses that result from basic research, therapy development, and clinical trials with the need to assure that essential medical research is not unreasonably hindered by the intellectual property agreements.

Existing law prohibits amendment of the initiative measure by the Legislature unless the amendment is approved by the voters, or the amendment is accomplished by a bill introduced after the first 2 full calendar years and approved by a vote of 70% of both houses.

This bill would modify the public hearing and conflict-of-interest procedures of members of the ICOC, the Citizen's Financial Accountability Oversight Committee, and the advisory and working groups established to assist these bodies, and would set forth minimum intellectual property licensing conditions applicable to ICOC standards for research and facilities grants and loans.

This bill would provide for submission of the measure to the voters at the next statewide election, and would condition the changes upon voter approval pursuant to prescribed provisions of law.

~~Existing law prohibits a provider of health care, a health care service plan, contractor, or corporation and its subsidiaries and affiliates from intentionally sharing, selling, or otherwise using any medical information, as defined, for any purpose not necessary to provide health care services to a patient, except as expressly authorized by the patient, enrollee, or subscriber, as specified, or as otherwise required or authorized by law. Violations of these provisions are subject to a civil action for compensatory and punitive damages, and, if a violation results in economic loss or personal injury to a patient, it is punishable as a misdemeanor. Existing law provides that this prohibition also applies to the marketing of medical information, as defined, excluding from that definition, for these purposes, communications for which the communicator does not receive remuneration from a 3rd party or for specified descriptive purposes, or that are tailored to the circumstances of a particular individual, as specified.~~

~~This bill would further provide that marketing includes a written communication that is provided by a pharmacy to a patient about a different drug or treatment than that being dispensed by the pharmacy and that is paid for, or sponsored by, a manufacturer, labeler, or~~

~~distributor of prescription drugs, except as specified. Because a violation thereof may be punishable as a misdemeanor, the bill would impose a state-mandated local program.~~

~~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~~*no*.

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

1 SECTION 1. Section 125290.30 of the Health and Safety
2 Code is amended to read:

3 125290.30. Public and Financial Accountability Standards

4 (a) Annual Public Report

5 The institute shall issue an annual report to the public which
6 sets forth its activities, grants awarded, grants in progress,
7 research accomplishments, and future program directions. Each
8 annual report shall include, but not be limited to, the following:
9 the number and dollar amounts of research and facilities grants;
10 the grantees for the prior year; the institute’s administrative
11 expenses; an assessment of the availability of funding for stem
12 cell research from sources other than the institute; a summary of
13 research findings, including promising new research areas; an
14 assessment of the relationship between the institute’s grants and
15 the overall strategy of its research program; and a report of the
16 institute’s strategic research and financial plans.

17 (b) Independent Financial Audit for Review by State
18 Controller

19 The institute shall annually commission an independent
20 financial audit of its activities from a certified public accounting
21 firm, which shall be provided to the State Controller, who shall
22 review the audit and annually issue a public report of that review.

23 (c) Citizen’s Financial Accountability Oversight Committee

24 There shall be a Citizen’s Financial Accountability Oversight
25 Committee chaired by the State Controller. This committee shall
26 review the annual financial audit, the State Controller’s report

1 and evaluation of that audit, and the financial practices of the
2 institute. The State Controller, the State Treasurer, the President
3 pro Tempore of the Senate, the Speaker of the Assembly, and the
4 Chairperson of the ICOC shall each appoint a public member of
5 the committee. Committee members shall have medical
6 backgrounds and knowledge of relevant financial matters. The
7 committee shall provide recommendations on the institute's
8 financial practices and performance. The State Controller shall
9 provide staff support. The committee shall hold a public meeting,
10 with appropriate notice, and with a formal public comment
11 period. The committee shall evaluate public comments and
12 include appropriate summaries in its annual report. The ICOC
13 shall provide funds for the per diem expenses of the committee
14 members and for publication of the annual report.

15 (d) Public Meeting Laws

16 (1) The ICOC shall hold at least two public meetings per year,
17 one of which will be designated as the institute's annual meeting.
18 The ICOC may hold additional meetings as it determines are
19 necessary or appropriate.

20 (2) The Bagley-Keene Open Meeting Act, Article 9
21 (commencing with Section 11120) of Chapter 1 of Part 1 of
22 Division 3 of Title 2 of the Government Code, shall apply to all
23 meetings of the ICOC, *the Citizen's Financial Accountability*
24 *Oversight Committee, and any working or advisory group*
25 *established to assist these bodies* except as otherwise provided in
26 this section. The ICOC shall award all grants, loans, and
27 contracts in public meetings and shall adopt all governance,
28 scientific, medical, and regulatory standards in public meetings.

29 (3) The ICOC, *the Citizen's Financial Accountability*
30 *Oversight Committee, and any working or advisory group*
31 *established to assist these bodies*, may conduct closed sessions as
32 permitted by the Bagley-Keene Open Meeting Act, under Section
33 11126 of the Government Code. In addition, ~~the ICOC these~~
34 ~~bodies~~ may conduct closed sessions when ~~it meets any of them~~
35 ~~meet~~ to consider or discuss:

36 (A) ~~Matters involving information relating to patients or~~
37 ~~medical subjects, the disclosure of which would constitute an~~
38 ~~unwarranted invasion of personal privacy—Individually~~
39 ~~identifiable information regarding the medical history of, mental~~
40 ~~or physical condition of, or treatment of, a patient or medical~~

1 *subject, except to the extent that the person has waived his or her*
2 *right to confidentiality regarding that information.*

3 ~~(B) Matters involving confidential~~ *Confidential* intellectual
4 property or work product, whether patentable or not, including,
5 but not limited to, any formula, plan, pattern, process, tool,
6 mechanism, compound, procedure, production data, or
7 compilation of information, which is not patented, which is
8 known only to certain individuals who are using it to fabricate,
9 produce, or compound an article of trade or a service having
10 commercial value and which gives its user an opportunity to
11 obtain a business advantage over competitors who do not know it
12 or use it.

13 ~~(C) Matters involving prepublication, confidential~~
14 *Prepublication scientific research working papers, or research*
15 *data.*

16 ~~(D) Matters concerning the~~ *The* appointment, employment,
17 performance, compensation, or dismissal of *individual* institute
18 officers and employees. Action on compensation of the institute's
19 officers and employees shall only be taken in open session.

20 *(E) (i) The scientific evaluation of any application for*
21 *research, training, or facility grants or loans submitted for*
22 *funding. However, any working or advisory group that is*
23 *charged with reviewing and recommending applications for*
24 *research, training, or facility grants or loans shall produce a*
25 *written summary that shall be a public record of the reasons for*
26 *recommending or not recommending any application for funding.*

27 *(ii) The written summaries specified in clause (i) shall be*
28 *posted on the ICOC's Web site at least 10 days prior to the*
29 *ICOC's consideration for any recommendations for funding and*
30 *shall include all of the following:*

31 *(I) In the case of any application that is recommended for*
32 *funding: the name of the applicant, the title and subject of the*
33 *application, a description of how the project proposed in the*
34 *application could benefit the state, a brief summary of the*
35 *scientific evaluation of the project, the consolidated scientific*
36 *score for the project, and the final recommendation of the full*
37 *working or advisory group on the application.*

38 *(II) In the case of any application that is not recommended for*
39 *funding: a short description of the project proposed in the*
40 *application, the disease category addressed by the proposed*

1 *project, the geographic region represented by that project, and*
2 *the general reasons for the decision not to recommend the*
3 *application for funding.*

4 (4) The meeting required by paragraph (2) of subdivision (b)
5 of Section 125290.20 shall be deemed to be a special meeting for
6 the purposes of Section 11125.4 of the Government Code.

7 (e) Public Records

8 (1) The California Public Records Act, Article 1 (commencing
9 with Section 6250) of Chapter 3.5 of Division 7 of Title 1 of the
10 Government Code, shall apply to all records of the institute,
11 except as otherwise provided in this section.

12 (2) ~~Nothing~~ *This section does not require disclosure of any*
13 *record exempt from disclosure under the California Public*
14 *Records Act. Moreover, nothing in this section shall be construed*
15 *to require disclosure of any records that are any of the following:*

16 (A) Personnel, medical, or similar files, the disclosure of
17 which would constitute an unwarranted invasion of personal
18 privacy.

19 (B) Records containing or reflecting confidential intellectual
20 property or work product, whether patentable or not, including,
21 but not limited to, any formula, plan, pattern, process, tool,
22 mechanism, compound, procedure, production data, or
23 compilation of information, which is not patented, which is
24 known only to certain individuals who are using it to fabricate,
25 produce, or compound an article of trade or a service having
26 commercial value and which gives its user an opportunity to
27 obtain a business advantage over competitors who do not know it
28 or use it.

29 (C) Prepublication scientific working papers or research data.

30 (f) Competitive Bidding

31 (1) The institute shall, except as otherwise provided in this
32 section, be governed by the competitive bidding requirements
33 applicable to the University of California, as set forth in Article 1
34 (commencing with Section 10500) of Chapter 2.1 of Part 2 of
35 Division 2 of the Public Contract Code.

36 (2) For all institute contracts, the ICOC shall follow the
37 procedures required of the Regents by Article 1 (commencing
38 with Section 10500) of Chapter 2.1 of Part 2 of Division 2 of the
39 Public Contract Code with respect to contracts let by the
40 University of California.

1 (3) The requirements of this section shall not be applicable to
2 grants or loans approved by the ICOC.

3 (4) Except as provided in this section, the Public Contract
4 Code shall not apply to contracts let by the institute.

5 (g) Conflicts of Interest

6 (1) The Political Reform Act, Title 9 (commencing with
7 Section 81000) of the Government Code, shall apply to the
8 institute and to the ICOC, except as provided in this section and
9 in subdivision (e) of Section 125290.50.

10 (A) No member of the ICOC shall make, participate in
11 making, or in any way attempt to use his or her official position
12 to influence a decision to approve or award a grant, loan, or
13 contract to his or her employer, but a member may participate in
14 a decision to approve or award a grant, loan, or contract to a
15 nonprofit entity in the same field as his or her employer.

16 (B) A member of the ICOC may participate in a decision to
17 approve or award a grant, loan, or contract to an entity for the
18 purpose of research involving a disease from which a member or
19 his or her immediate family suffers or in which the member has
20 an interest as a representative of a disease advocacy organization.

21 (C) The adoption of standards is not a decision subject to this
22 section.

23 (2) Service as a member of the ICOC by a member of the
24 faculty or administration of any system of the University of
25 California shall not, by itself, be deemed to be inconsistent,
26 incompatible, in conflict with, or inimical to the duties of the
27 ICOC member as a member of the faculty or administration of
28 any system of the University of California and shall not result in
29 the automatic vacation of either such office. Service as a member
30 of the ICOC by a representative or employee of a disease
31 advocacy organization, a nonprofit academic and research
32 institution, or a life science commercial entity shall not be
33 deemed to be inconsistent, incompatible, in conflict with, or
34 inimical to the duties of the ICOC member as a representative or
35 employee of that organization, institution, or entity.

36 (3) Section 1090 of the Government Code shall not apply to
37 any grant, loan, or contract made by the ICOC except where both
38 of the following conditions are met:

39 (A) The grant, loan, or contract directly relates to services to
40 be provided by any member of the ICOC or the entity the

1 member represents or financially benefits the member or the
2 entity he or she represents.

3 (B) The member fails to recuse himself or herself from
4 making, participating in making, or in any way attempting to use
5 his or her official position to influence a decision on the grant
6 loan or contract.

7 (4) *The chair and vice chair and any appointed member of the*
8 *ICOC, and the president of the ICOC shall divest themselves of,*
9 *or place into a blind trust, any financial or real property interest*
10 *of two thousand dollars (\$2,000) or more held by that person in*
11 *any organization that applies for funding from, or contracts with,*
12 *the ICOC or in any organization with a substantial interest in*
13 *stem cell therapy. An organization with a substantial interest in*
14 *stem cell therapy is one for which, based upon publicly available*
15 *information, more than 5 percent of the organization's current*
16 *annual research budget is allocated to stem cell therapy.*

17 (h) Patent Royalties and License Revenues Paid to the State of
18 California

19 ~~The~~

20 (1) *The ICOC shall establish standards that require that all*
21 *grants and loan awards be subject to intellectual property*
22 *agreements that balance the opportunity of the State of California*
23 *to benefit from the patents, royalties, and licenses that result from*
24 *basic research, therapy development, and clinical trials with the*
25 *need to assure that essential medical research is not unreasonably*
26 *hindered by the intellectual property agreements. The ICOC shall*
27 *establish and apply minimum licensing conditions to its grants*
28 *and loans for research and facilities consisting of the following:*

29 (A) *A requirement that every recipient of grant or loan awards*
30 *for research or facilities that is a research institution provide to*
31 *the state a portion of net licensing revenues from any invention,*
32 *research finding or tool, or technology that it develops using*
33 *funds from the grant or loan award, as follows:*

34 (i) *The grant or loan recipient shall provide 50 percent of net*
35 *licensing revenues if the state shares in the expenses of*
36 *developing and protecting any patent on the invention, research*
37 *finding or tool, or technology.*

38 (ii) *The grant or loan recipient shall provide 25 percent of the*
39 *net licensing revenues if the state does not share in the expenses*

1 of developing and protecting any patent on the invention,
2 research finding or tool, or technology.

3 (B) For any grant or loan for research or facilities that is to
4 be financed with taxable bonds, the ICOC shall require a higher
5 level of royalties than set forth in subparagraph (A), if a higher
6 level is necessary to offset the additional cost of using taxable
7 bonds.

8 (C) For any grant or loan for research or facilities that is
9 financed with nontaxable bonds, the ICOC may require that the
10 royalties required by this subdivision be paid directly to a
11 nonprofit organization that is dedicated to enhancing access to
12 clinical trials and therapies for low-income populations, rather
13 than being paid to the state, if the institute determines for tax
14 reasons that receipt of the royalties by the state would preclude
15 the use of nontaxable bonds.

16 (D) A requirement that every recipient of a grant or loan
17 award for research or facilities that is a research institution
18 require every licensee who develops a product, drug, or therapy
19 using any invention, research finding or tool, or technology
20 developed with funds from the grant or loan award to agree to
21 sell the product, drug, or therapy to state and county health
22 programs at the best price the licensee sells it to any purchaser.

23 (E) A requirement that every recipient of a grant or loan
24 award for research or facilities that is a commercial entity agree,
25 as a condition of accepting the funds, to sell any product, drug,
26 or therapy that it develops using grant or loan funds to state and
27 county health programs at the best price the recipient sells it to
28 any purchaser.

29 (F) A requirement that any recipient of a grant or loan award
30 for research or facilities that is a commercial entity provide
31 royalty payments to the state at a rate that is consistent with the
32 rates historically received by the University of California for
33 research agreements with biotechnology and pharmaceutical
34 commercial entities for that type of research.

35 (2) The ICOC shall seek licensing conditions that would
36 provide greater financial benefits to the state than those required
37 by paragraph (1) where it is possible to do so without hindering
38 research and development of promising stem cell therapies and
39 treatments.

1 (3) *The ICOC shall impose any licensing conditions in its*
2 *grants and loans for research that are necessary to ensure the*
3 *free and open dissemination of basic research tools and findings,*
4 *including research exemptions, open source and nonexclusive*
5 *licensing, compulsory licensing, development of patent pools,*
6 *and other provisions the ICOC finds are necessary to ensure*
7 *open dissemination.*

8 (4) *The ICOC shall require a grantee or licensee to grant a*
9 *nonexclusive, partially exclusive, or exclusive license to a*
10 *responsible applicant if the ICOC determines that the grantee or*
11 *licensee is violating the terms of licensing conditions, or if the*
12 *grantee or licensee is not making efforts in a reasonable period*
13 *of time to achieve practical application of an invention developed*
14 *with grant or loan funds, or if it is necessary to alleviate health*
15 *and safety needs. With the exception of actions to address health*
16 *and safety needs, prior to exercising this authority, the institute*
17 *shall give the grantee or licensee an opportunity to bring its*
18 *actions into compliance with the licensing conditions.*

19 (5) *For the purposes of this subdivision, “net licensing*
20 *revenue” shall include all forms of financial consideration from*
21 *licensing, including cash and corporate equity, and shall be*
22 *defined as gross licensing revenues, less a reasonable*
23 *administrative and licensing allowance, patent expenses, and*
24 *reasonable payments to inventors.*

25 (6) *Any proposed intellectual property agreement between the*
26 *ICOC and a grantee or loan recipient shall be reviewed by the*
27 *Attorney General prior to its approval by the ICOC, and the*
28 *ICOC shall consider any comments by the Attorney General*
29 *prior to approving the agreement.*

30 (i) **Preference for California Suppliers**

31 The ICOC shall establish standards to ensure that grantees
32 purchase goods and services from California suppliers to the
33 extent reasonably possible, in a good faith effort to achieve a
34 goal of more than 50 percent of such purchases from California
35 suppliers.

36 *SEC. 2. Section 125290.50 of the Health and Safety Code is*
37 *amended to read:*

38 125290.50. Scientific and Medical Working
39 Groups—General

1 (a) The institute shall have, and there is hereby established,
2 three separate scientific and medical working groups as follows:

3 (1) Scientific and Medical Research Funding Working Group.

4 (2) Scientific and Medical Accountability Standards Working
5 Group.

6 (3) Scientific and Medical Research Facilities Working Group.

7 (b) Working Group Members

8 Appointments of scientific and medical working group
9 members shall be made by a majority vote of a quorum of the
10 ICOC, within 30 days of the election and appointment of the
11 initial ICOC members. The working group members' terms shall
12 be six years except that, after the first six-year terms, the
13 members' terms will be staggered so that one-third of the
14 members shall be elected for a term that expires two years later,
15 one-third of the members shall be elected for a term that expires
16 four years later, and one-third of the members shall be elected for
17 a term that expires six years later. Subsequent terms are for six
18 years. Working group members may serve a maximum of two
19 consecutive terms.

20 (c) Working Group Meetings

21 Each scientific and medical working group shall hold at least
22 four meetings per year, one of which shall be designated as its
23 annual meeting.

24 (d) Working Group Recommendations to the ICOC

25 Recommendations of each of the working groups may be
26 forwarded to the ICOC only by a vote of a majority of a quorum
27 of the members of each working group. If 35 percent of the
28 members of any working group join together in a minority
29 position, a minority report may be submitted to the ICOC. The
30 ICOC shall consider the recommendations of the working groups
31 in making its decisions on applications for research and facility
32 grants and loan awards and in adopting regulatory standards.
33 Each working group shall recommend to ICOC rules, procedures,
34 and practices for that working group.

35 (e) Conflict of Interest

36 (1) The ICOC shall adopt conflict of interest rules, based on
37 standards applicable to members of scientific review committees
38 of the National Institutes of Health, to govern the participation of
39 non-ICOC working group members.

1 (2) (A) Upon his or her appointment, and each year thereafter
2 at a time specified by the ICOC, each member of a working or
3 advisory group appointed to assist the institute or its governing
4 body shall disclose to the ICOC any income, real property, and
5 investments they or a close family member has in all of the
6 following:

7 (i) A California-based academic or nonprofit research
8 institutions.

9 (ii) A biotechnology or pharmaceutical company.

10 (iii) Real property interests in California.

11 (B) In addition to the disclosures in subparagraph (A), a
12 member who is appointed to the facilities working group shall
13 disclose all construction, real estate, and development firms from
14 which they or a family member receives or has received
15 economic benefits.

16 (C) The ICOC shall provide the disclosures to the State
17 Auditor. The State Auditor, or his or her successor, shall review
18 at least annually the disclosures, in addition to the voting record
19 of each working or advisory group member regarding
20 recommendations for applications for research and facility
21 grants and loan awards and regulatory standards, and submit an
22 annual report to the Legislature containing findings on whether
23 any of the votes made by these members may constitute, or has
24 constituted, a conflict of interest that requires or required the
25 member to recuse himself or herself from consideration of an
26 application or standard if the member is otherwise required
27 under existing law to recuse himself or herself.

28 (D) A working group member shall not vote or participate in
29 the consideration of any grant, loan, or project submitted for
30 funding if he or she has a financial conflict of interest.

31 (3) For purposes of this subdivision, “financial conflict of
32 interest” means that the working or advisory group member, or a
33 close relative or professional associate of the member, has a
34 financial or other monetary interest in an application or
35 standard that is known to the member, including a direct benefit
36 of any amount deriving from an application or standard, or a
37 financial benefit of any type from an applicant institution of over
38 five thousand dollars (\$5,000) per year, including honoraria,
39 fees, stock, or other benefits. For purposes of this paragraph,
40 “close relative” and “professional associate” shall have the

1 same meaning as those terms are defined under the National
2 Institutes of Health Conflict of Interest, Confidentiality and
3 Non-Disclosure Rules.

4 (4) The ICOC shall appoint an ethics officer from among the
5 staff of the institute.

6 ~~(3)~~

7 (5) Because the working groups are purely advisory and have
8 no final decisionmaking authority, members of the working
9 groups shall not be considered public officials, employees, or
10 consultants for purposes of the Political Reform Act (Title 9
11 commencing with Section 81000) of the Government Code,
12 Sections 1090 and 19990 of the Government Code, and Sections
13 10516 and 10517 of the Public Contract Code.

14 (f) Working Group Records

15 All records of the working groups submitted as part of the
16 working groups' recommendations to the ICOC for approval
17 shall be subject to the Public Records Act. Except as provided in
18 this subdivision, the working groups shall not be subject to the
19 provisions of Article 9 (commencing with Section 11120) of
20 Chapter 1 of Part 1 of Division 3 of Title 2 of the Government
21 Code, or Article 1 (commencing with Section 6250) of Chapter
22 3.5 of Division 7 of Title 1 of the Government Code.

23 *SEC. 3. As an amendment of an initiative, Sections 1 and 2 of*
24 *this act shall become effective only upon approval by the voters*
25 *at a statewide election. The Secretary of State shall submit*
26 *Sections 1 and 2 of this act to the voters at the next statewide*
27 *election pursuant to Section 9040 of the Elections Code.*

28 ~~SECTION 1. Section 56.05 of the Civil Code is amended to~~
29 ~~read:~~

30 ~~56.05. For purposes of this part:~~

31 ~~(a) "Authorization" means permission granted in accordance~~
32 ~~with Section 56.11 or 56.21 for the disclosure of medical~~
33 ~~information.~~

34 ~~(b) "Authorized recipient" means any person who is~~
35 ~~authorized to receive medical information pursuant to Section~~
36 ~~56.10 or 56.20.~~

37 ~~(c) "Contractor" means any person or entity that is a medical~~
38 ~~group, independent practice association, pharmaceutical benefits~~
39 ~~manager, or a medical service organization and is not a health~~
40 ~~care service plan or provider of health care. "Contractor" does~~

1 not include insurance institutions as defined in subdivision (k) of
2 Section 791.02 of the Insurance Code or pharmaceutical benefits
3 managers licensed pursuant to the Knox-Keene Health Care
4 Service Plan Act of 1975 (Chapter 2.2 (commencing with
5 Section 1340) of Division 2 of the Health and Safety Code).

6 (d) “Health care service plan” means any entity regulated
7 pursuant to the Knox-Keene Health Care Service Plan Act of
8 1975 (Chapter 2.2 (commencing with Section 1340) of Division
9 2 of the Health and Safety Code).

10 (e) “Licensed health care professional” means any person
11 licensed or certified pursuant to Division 2 (commencing with
12 Section 500) of the Business and Professions Code, the
13 Osteopathic Initiative Act or the Chiropractic Initiative Act, or
14 Division 2.5 (commencing with Section 1797) of the Health and
15 Safety Code.

16 (f) (1) “Marketing” means to make a communication about a
17 product or service that encourages recipients of the
18 communication to purchase or use the product or service.

19 (2) “Marketing” does not include any of the following:

20 (A) Communications made orally or in writing for which the
21 communicator does not receive direct or indirect remuneration,
22 including, but not limited to, gifts, fees, payments, subsidies, or
23 other economic benefits, from a third party for making the
24 communication.

25 (B) Communications made to current enrollees solely for the
26 purpose of describing a provider’s participation in an existing
27 health care provider network or health plan network of a
28 Knox-Keene licensed health plan to which the enrollees already
29 subscribe; communications made to current enrollees solely for
30 the purpose of describing if, and the extent to which, a product or
31 service, or payment for a product or service, is provided by a
32 provider, contractor, or plan or included in a plan of benefits of a
33 Knox-Keene licensed health plan to which the enrollees already
34 subscribe; or communications made to plan enrollees describing
35 the availability of more cost-effective pharmaceuticals.

36 (C) Communications that are tailored to the circumstances of a
37 particular individual to educate or advise the individual about
38 treatment options, and otherwise maintain the individual’s
39 adherence to a prescribed course of medical treatment, as
40 provided in Section 1399.901 of the Health and Safety Code, for

1 a chronic and seriously debilitating or life-threatening condition
2 as defined in subdivisions (d) and (e) of Section 1367.21 of the
3 Health and Safety Code, if the health care provider, contractor, or
4 health plan receives direct or indirect remuneration, including,
5 but not limited to, gifts, fees, payments, subsidies, or other
6 economic benefits, from a third party for making the
7 communication, if all of the following apply:

8 (i) The individual receiving the communication is notified in
9 the communication in typeface no smaller than 14-point type of
10 the fact that the provider, contractor, or health plan has been
11 remunerated and the source of the remuneration.

12 (ii) The individual is provided the opportunity to opt out of
13 receiving future remunerated communications.

14 (iii) The communication contains instructions in typeface no
15 smaller than 14-point type describing how the individual can opt
16 out of receiving further communications by calling a toll-free
17 telephone number of the health care provider, contractor, or
18 health plan making the remunerated communications. No further
19 communication may be made to an individual who has opted out
20 after 30 calendar days from the date the individual makes the opt
21 out request.

22 (3) Notwithstanding any other provision of law, “marketing”
23 includes a written communication that is provided to a pharmacy
24 patient by a pharmacist or by pharmacy personnel, in conjunction
25 with the dispensing of a prescription drug or prescribed treatment
26 therapy, that includes the trade name or commercial slogan for
27 any prescription drug, prescribed treatment therapy, or
28 over-the-counter medication other than the prescription drug or
29 prescribed treatment therapy being dispensed, if the
30 communication is paid for or sponsored, directly or indirectly, by
31 a manufacturer, labeler, or distributor of prescription drugs. This
32 paragraph shall not apply when a trade name or commercial
33 slogan for a prescription drug, prescribed treatment therapy, or
34 over-the-counter medication is included in a written
35 communication for the sole purpose of providing information
36 about drug interactions, reported or potential adverse events, or
37 any other information necessary to ensure the health and safety
38 of the patient, or is part of a package insert that has been
39 approved by the federal Food and Drug Administration to be
40 distributed together with a prescription drug.

1 (g) “Medical information” means any individually identifiable
2 information, in electronic or physical form, in possession of or
3 derived from a provider of health care, health care service plan,
4 pharmaceutical company, or contractor regarding a patient’s
5 medical history, mental or physical condition, or treatment.
6 “Individually identifiable” means that the medical information
7 includes or contains any element of personal identifying
8 information sufficient to allow identification of the individual,
9 such as the patient’s name, address, electronic mail address,
10 telephone number, or social security number, or other
11 information that, alone or in combination with other publicly
12 available information, reveals the individual’s identity.

13 (h) “Patient” means any natural person, whether or not still
14 living, who received health care services from a provider of
15 health care and to whom medical information pertains.

16 (i) “Pharmaceutical company” means any company or
17 business, or an agent or representative thereof, that manufactures,
18 sells, or distributes pharmaceuticals, medications, or prescription
19 drugs. “Pharmaceutical company” does not include a
20 pharmaceutical benefits manager, as included in subdivision (c),
21 or a provider of health care.

22 (j) “Provider of health care” means any person licensed or
23 certified pursuant to Division 2 (commencing with Section 500)
24 of the Business and Professions Code; any person licensed
25 pursuant to the Osteopathic Initiative Act or the Chiropractic
26 Initiative Act; any person certified pursuant to Division 2.5
27 (commencing with Section 1797) of the Health and Safety Code;
28 any clinic, health dispensary, or health facility licensed pursuant
29 to Division 2 (commencing with Section 1200) of the Health and
30 Safety Code. “Provider of health care” does not include
31 insurance institutions as defined in subdivision (k) of Section
32 791.02 of the Insurance Code.

33 SEC. 2. No reimbursement is required by this act pursuant to
34 Section 6 of Article XIII B of the California Constitution because
35 the only costs that may be incurred by a local agency or school
36 district will be incurred because this act creates a new crime or
37 infraction, eliminates a crime or infraction, or changes the
38 penalty for a crime or infraction, within the meaning of Section
39 17556 of the Government Code, or changes the definition of a

1 ~~crime within the meaning of Section 6 of Article XIII B of the~~
2 ~~California Constitution.~~

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