DRAFT LETTER

To Senator Migden; Assembly persons Leno and Huffman

RE: SB 1096 (Calderon) – OPPOSE

Dear

The Marin County Board of Supervisors opposes SB 1096, Senator Calderon's bill regarding pharmacists' distribution of marketing information, and urges your opposition to the bill.

SB 1096 is counter to the State and federal trends aimed at protecting confidential information and in allowing consumers to proactively "opt out" of proposed uses of their personal information. The bill would encourage pharmacists to become a marketing arm of drug manufacturers and others and could lead to patient confusion over their physician's prescribed course of treatment.

The Marin County Board of Supervisors has a longstanding commitment to ensuring the privacy rights of individuals, including the ability to maintain the confidentiality of personal records. The need to protect individual privacy rights becomes more and more important, as we learn of more and more breaches and inappropriate uses of protected personal data.

We urge your opposition to SB 1096.

AMENDED IN SENATE MAY 23, 2008

AMENDED IN SENATE MAY 8, 2008

AMENDED IN SENATE APRIL 14, 2008

SENATE BILL No. 1096

Introduced by Senator Calderon

January 14, 2008

An act to amend Section 56.10 of the Civil Code, relating to medical information.

LEGISLATIVE COUNSEL'S DIGEST

SB 1096, as amended, Calderon. Medical information.

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, 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.

This bill would, under those provisions, allow a pharmacy to mail specified written communications to a patient, without the patient's authorization under specified conditions. Those conditions include, among other things, that the written communication be written in the same language as the prescription label, that it instruct the patient when to contact the health care professional, that it shall pertain only to the prescribed course of medical treatment, that it may not mention any

other pharmaceutical products, that it shall be limited to specified diseases, that further written communication may not be provided under certain circumstances, that a copy of each version shall be submitted to the federal Food and Drug Administration, ~~and~~ that it shall include specified disclosures regarding whether the pharmacy receives direct or indirect remuneration for making that written communication, *and that the patient shall receive an opportunity to opt out of the written communication*.

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

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

SECTION 1. Section 56.10 of the Civil Code is amended to read:

56.10. (a) No provider of health care, health care service plan, or contractor shall disclose medical information regarding a patient of the provider of health care or an enrollee or subscriber of a health care service plan without first obtaining an authorization, except as provided in subdivision (b), (c), or (d).

(b) A provider of health care, a health care service plan, or a contractor shall disclose medical information if the disclosure is compelled by any of the following:

(1) By a court pursuant to an order of that court.

(2) By a board, commission, or administrative agency for purposes of adjudication pursuant to its lawful authority.

(3) By a party to a proceeding before a court or administrative agency pursuant to a subpoena, subpoena duces tecum, notice to appear served pursuant to Section 1987 of the Code of Civil Procedure, or any provision authorizing discovery in a proceeding before a court or administrative agency.

(4) By a board, commission, or administrative agency pursuant to an investigative subpoena issued under Article 2 (commencing with Section 11180) of Chapter 2 of Part 1 of Division 3 of Title 2 of the Government Code.

(5) By an arbitrator or arbitration panel, when arbitration is lawfully requested by either party, pursuant to a subpoena duces tecum issued under Section 1282.6 of the Code of Civil Procedure, or any other provision authorizing discovery in a proceeding before an arbitrator or arbitration panel.

(6) By a search warrant lawfully issued to a governmental law enforcement agency.

(7) By the patient or the patient's representative pursuant to Chapter 1 (commencing with Section 123100) of Part 1 of Division 106 of the Health and Safety Code.

(8) By a coroner, when requested in the course of an investigation by the coroner's office for the purpose of identifying the decedent or locating next of kin, or when investigating deaths that may involve public health concerns, organ or tissue donation, child abuse, elder abuse, suicides, poisonings, accidents, sudden infant deaths, suspicious deaths, unknown deaths, or criminal deaths, or when otherwise authorized by the decedent's representative. Medical information requested by the coroner under this paragraph shall be limited to information regarding the patient who is the decedent and who is the subject of the investigation and shall be disclosed to the coroner without delay upon request.

(9) When otherwise specifically required by law.

(c) A provider of health care or a health care service plan may disclose medical information as follows:

(1) The information may be disclosed to providers of health care, health care service plans, contractors, or other health care professionals or facilities for purposes of diagnosis or treatment of the patient. This includes, in an emergency situation, the communication of patient information by radio transmission or other means between emergency medical personnel at the scene of an emergency, or in an emergency medical transport vehicle, and emergency medical personnel at a health facility licensed pursuant to Chapter 2 (commencing with Section 1250) of Division 2 of the Health and Safety Code.

(2) The information may be disclosed to an insurer, employer, health care service plan, hospital service plan, employee benefit plan, governmental authority, contractor, or any other person or entity responsible for paying for health care services rendered to the patient, to the extent necessary to allow responsibility for payment to be determined and payment to be made. If (A) the patient is, by reason of a comatose or other disabling medical condition, unable to consent to the disclosure of medical information and (B) no other arrangements have been made to pay for the health care services being rendered to the patient, the information may be disclosed to a governmental authority to the

extent necessary to determine the patient's eligibility for, and to obtain, payment under a governmental program for health care services provided to the patient. The information may also be disclosed to another provider of health care or health care service plan as necessary to assist the other provider or health care service plan in obtaining payment for health care services rendered by that provider of health care or health care service plan to the patient.

(3) The information may be disclosed to a person or entity that provides billing, claims management, medical data processing, or other administrative services for providers of health care or health care service plans or for any of the persons or entities specified in paragraph (2). However, no information so disclosed shall be further disclosed by the recipient in any way that would violate this part.

(4) The information may be disclosed to organized committees and agents of professional societies or of medical staffs of licensed hospitals, licensed health care service plans, professional standards review organizations, independent medical review organizations and their selected reviewers, utilization and quality control peer review organizations as established by Congress in Public Law 97-248 in 1982, contractors, or persons or organizations insuring, responsible for, or defending professional liability that a provider may incur, if the committees, agents, health care service plans, organizations, reviewers, contractors, or persons are engaged in reviewing the competence or qualifications of health care professionals or in reviewing health care services with respect to medical necessity, level of care, quality of care, or justification of charges.

(5) The information in the possession of a provider of health care or health care service plan may be reviewed by a private or public body responsible for licensing or accrediting the provider of health care or health care service plan. However, no patient-identifying medical information may be removed from the premises except as expressly permitted or required elsewhere by law, nor shall that information be further disclosed by the recipient in any way that would violate this part.

(6) The information may be disclosed to the county coroner in the course of an investigation by the coroner's office when requested for all purposes not included in paragraph (8) of subdivision (b).

(7) The information may be disclosed to public agencies, clinical investigators, including investigators conducting epidemiologic studies, health care research organizations, and accredited public or private nonprofit educational or health care institutions for bona fide research purposes. However, no information so disclosed shall be further disclosed by the recipient in any way that would disclose the identity of a patient or violate this part.

(8) A provider of health care or health care service plan that has created medical information as a result of employment-related health care services to an employee conducted at the specific prior written request and expense of the employer may disclose to the employee's employer that part of the information that:

(A) Is relevant in a lawsuit, arbitration, grievance, or other claim or challenge to which the employer and the employee are parties and in which the patient has placed in issue his or her medical history, mental or physical condition, or treatment, provided that information may only be used or disclosed in connection with that proceeding.

(B) Describes functional limitations of the patient that may entitle the patient to leave from work for medical reasons or limit the patient's fitness to perform his or her present employment, provided that no statement of medical cause is included in the information disclosed.

(9) Unless the provider of health care or health care service plan is notified in writing of an agreement by the sponsor, insurer, or administrator to the contrary, the information may be disclosed to a sponsor, insurer, or administrator of a group or individual insured or uninsured plan or policy that the patient seeks coverage by or benefits from, if the information was created by the provider of health care or health care service plan as the result of services conducted at the specific prior written request and expense of the sponsor, insurer, or administrator for the purpose of evaluating the application for coverage or benefits.

(10) The information may be disclosed to a health care service plan by providers of health care that contract with the health care service plan and may be transferred among providers of health care that contract with the health care service plan, for the purpose of administering the health care service plan. Medical information may not otherwise be disclosed by a health care service plan except in accordance with the provisions of this part.

(11) Nothing in this part shall prevent the disclosure by a provider of health care or a health care service plan to an insurance institution, agent, or support organization, subject to Article 6.6 (commencing with Section 791) of Part 2 of Division 1 of the Insurance Code, of medical information if the insurance institution, agent, or support organization has complied with all requirements for obtaining the information pursuant to Article 6.6 (commencing with Section 791) of Part 2 of Division 1 of the Insurance Code.

(12) The information relevant to the patient's condition and care and treatment provided may be disclosed to a probate court investigator in the course of any investigation required or authorized in a conservatorship proceeding under the Guardianship-Conservatorship Law as defined in Section 1400 of the Probate Code, or to a probate court investigator, probation officer, or domestic relations investigator engaged in determining the need for an initial guardianship or continuation of an existent guardianship.

(13) The information may be disclosed to an organ procurement organization or a tissue bank processing the tissue of a decedent for transplantation into the body of another person, but only with respect to the donating decedent, for the purpose of aiding the transplant. For the purpose of this paragraph, the terms "tissue bank" and "tissue" have the same meaning as defined in Section 1635 of the Health and Safety Code.

(14) The information may be disclosed when the disclosure is otherwise specifically authorized by law, including, but not limited to, the voluntary reporting, either directly or indirectly, to the federal Food and Drug Administration of adverse events related to drug products or medical device problems.

(15) Basic information, including the patient's name, city of residence, age, sex, and general condition, may be disclosed to a state or federally recognized disaster relief organization for the purpose of responding to disaster welfare inquiries.

(16) The information may be disclosed to a third party for purposes of encoding, encrypting, or otherwise anonymizing data. However, no information so disclosed shall be further disclosed by the recipient in any way that would violate this part, including the unauthorized manipulation of coded or encrypted medical information that reveals individually identifiable medical information.

(17) For purposes of disease management programs and services as defined in Section 1399.901 of the Health and Safety Code, information may be disclosed as follows: (A) to an entity contracting with a health care service plan or the health care service plan's contractors to monitor or administer care of enrollees for a covered benefit, if the disease management services and care are authorized by a treating physician, or (B) to a disease management organization, as defined in Section 1399.900 of the Health and Safety Code, that complies fully with the physician authorization requirements of Section 1399.902 of the Health and Safety Code, if the health care service plan or its contractor provides or has provided a description of the disease management services to a treating physician or to the health care service plan's or contractor's network of physicians. Nothing in this paragraph shall be construed to require physician authorization for the care or treatment of the adherents of a well-recognized church or religious denomination who depend solely upon prayer or spiritual means for healing in the practice of the religion of that church or denomination.

(18) The information may be disclosed, as permitted by state and federal law or regulation, to a local health department for the purpose of preventing or controlling disease, injury, or disability, including, but not limited to, the reporting of disease, injury, vital events, including, but not limited to, birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions, as authorized or required by state or federal law or regulation.

(19) The information may be disclosed, consistent with applicable law and standards of ethical conduct, by a psychotherapist, as defined in Section 1010 of the Evidence Code, if the psychotherapist, in good faith, believes the disclosure is necessary to prevent or lessen a serious and imminent threat to the health or safety of a reasonably foreseeable victim or victims, and the disclosure is made to a person or persons reasonably able to prevent or lessen the threat, including the target of the threat.

(20) The information may be disclosed as described in Section 56.103.

(d) Except to the extent expressly authorized by the patient or enrollee or subscriber or as provided by subdivisions (b) and (c), no provider of health care, health care service plan, contractor, or corporation and its subsidiaries and affiliates shall intentionally

share, sell, use for marketing, or otherwise use any medical information for any purpose not necessary to provide health care services to the patient. For purposes of this section, a written communication mailed to a patient by a pharmacy shall be deemed to be necessary to provide health care services to the patient and shall not require prior authorization, if all of the following conditions are met:

(1) The written communication encourages the patient to adhere to the prescribed course of medical treatment as prescribed by a licensed health care professional and may include information about that particular pharmaceutical drug as authorized in this section.

(2) The communication is written in the same language as the prescription label produced by the pharmacy when the medication was dispensed.

(3) The written communication instructs the patient to contact the prescribing or dispensing health care professional if:

(A) The patient has questions about the medication.

(B) The patient is having difficulty adhering to the medication due to adverse effects, dosing requirements, or other causes.

(4) The written communication pertains only to the prescribed course of medical treatment, and does not describe or mention any other pharmaceutical products. The written communication shall be limited to the following diseases:

(A) Diabetes.

(B) Osteoporosis.

(C) Asthma.

(D) Chronic obstructive pulmonary disease.

(E) Cancer.

(F) Gastric disorder.

(G) Hypertension.

(H) Cardiovascular disease.

(I) Thyroid disorder.

(J) Organ transplantation.

(K) Chronic eye disorder.

(L) Rheumatoid arthritis and osteoarthritis.

(M) Renal disorders.

(N) Parkinson's disease.

(O) Seizures.

(P) Multiple sclerosis.

(Q) Depression.
(R) Schizophrenia.
(S) Bipolar disorder.
(T) Anxiety disorders.
(U) Attention deficit disorder.

(5) Further written communication shall not be provided if there are no refills remaining on the prescribed course of therapy and there are no doses remaining on the final prescribed refill, or the pharmacy has been notified by a health care provider that a prescribed course of therapy has been discontinued or substituted with a different drug.

(6) All product-related information in the written communication shall be consistent with the current federal Food and Drug Administration (FDA) approved product package insert, and provide fair and balanced information regarding the product's benefits and risks in accordance with the FDA requirements and policies.

(7) A copy of each written communication version shall be submitted to the FDA Center for Drug Evaluation and Research, Division of Drug Marketing, Advertising and Communications, prior to program implementation.

(8) Evidence-based or consensus-based practice guidelines shall be the basis of any information that is provided to patients in order to improve their overall health, prevent clinical exacerbations or complications, or promote patient self-management strategies.

(9) All personally identifiable medical information collected, used, and disclosed pursuant to this subdivision shall be confidential and shall be used solely to deliver the written communication to the patient. Access to the information shall be limited to authorized persons. Any entity that receives the information pursuant to this subdivision shall comply with existing requirements, including Sections 56.101 and 1798.84, concerning confidentiality and security of information. The pharmacy must have a written agreement with any entity that receives the information. The written agreement shall require the entity to maintain the confidentiality of the information it receives from the pharmacy and prohibit the entity from disclosing or using the information for any purpose other than to deliver to the patient the written communication that is the subject of the written agreement.

(10) If the written communication is paid for, in whole or in part, by a manufacturer, distributer, or provider of a health care product or service, the written communication shall disclose whether the pharmacy receives direct or indirect remuneration, including, but not limited to, gifts, fees, payments, subsidies, or other economic benefits from a third party for making the written communication and shall disclose, in a clear and conspicuous location, the source of any sponsorship in a typeface no smaller than 14-point type.

~~(11) The communication contains instructions in a typeface no smaller than 14-point type describing how the patient may opt out of future communications by, for example, calling a toll-free number or visiting a Web site, and no further sponsored message is made to the individual after 30 calendar days from the date the individual makes the opt out request.~~

(11) A pharmacy offers the patient, at the time the patient picks up his or her initial prescription, an opportunity to opt out of receiving a written communication from a pharmacy. If the patient opts out, then no sponsored message shall be made to the patient. If, at the time the patient picks up his or her initial prescription, the patient does not opt out, then the written communication shall contain instructions in a typeface no smaller than 14-point type describing how the patient may opt out of future communications by, for example, calling a toll-free telephone number or visiting an Internet Web site, and no further sponsored message shall be made to the patient after 30 calendar days from the date the individual makes the opt out request.

(e) Except to the extent expressly authorized by the patient or enrollee or subscriber or as provided by subdivisions (b) and (c), no contractor or corporation and its subsidiaries and affiliates shall further disclose medical information regarding a patient of the provider of health care or an enrollee or subscriber of a health care service plan or insurer or self-insured employer received under this section to any person or entity that is not engaged in providing direct health care services to the patient or his or her provider of health care or health care service plan or insurer or self-insured employer.

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