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

February 17, 2005

An act to amend Section 56.05 of the Civil Code, relating to medical information.

LEGISLATIVE COUNSEL'S DIGEST

SB 401, as amended, Ortiz. Medical information: pharmacies: marketing.

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.

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

1 SECTION 1. Section 56.05 of the Civil Code is amended to
2 read:
3 56.05. For purposes of this part:
4 (a) "Authorization" means permission granted in accordance
5 with Section 56.11 or 56.21 for the disclosure of medical
6 information.
7 (b) "Authorized recipient" means any person who is
8 authorized to receive medical information pursuant to Section
9 56.10 or 56.20.
10 (c) "Contractor" means any person or entity that is a medical
11 group, independent practice association, pharmaceutical benefits
12 manager, or a medical service organization and is not a health
13 care service plan or provider of health care. "Contractor" does
14 not include insurance institutions as defined in subdivision (k) of
15 Section 791.02 of the Insurance Code or pharmaceutical benefits
16 managers licensed pursuant to the Knox-Keene Health Care
17 Service Plan Act of 1975 (Chapter 2.2 (commencing with
18 Section 1340) of Division 2 of the Health and Safety Code).
19 (d) "Health care service plan" means any entity regulated
20 pursuant to the Knox-Keene Health Care Service Plan Act of
21 1975 (Chapter 2.2 (commencing with Section 1340) of Division
22 2 of the Health and Safety Code).
23 (e) "Licensed health care professional" means any person
24 licensed or certified pursuant to Division 2 (commencing with

Section 500) of the Business and Professions Code, the Osteopathic Initiative Act or the Chiropractic Initiative Act, or Division 2.5 (commencing with Section 1797) of the Health and Safety Code.

(f) (1) "Marketing" means to make a communication about a product or service that encourages recipients of the communication to purchase or use the product or service.

(2) "Marketing" does not include any of the following:

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

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

(C) Communications that are tailored to the circumstances of a particular individual to educate or advise the individual about treatment options, and otherwise maintain the individual's adherence to a prescribed course of medical treatment, as provided in Section 1399.901 of the Health and Safety Code, for a chronic and seriously debilitating or life-threatening condition as defined in subdivisions (d) and (e) of Section 1367.21 of the Health and Safety Code, if the health care provider, contractor, or health plan 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 communication, if all of the following apply:

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

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

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

(3) "Marketing" includes a written communication that is provided to a pharmacy patient by a pharmacist or by pharmacy personnel, in conjunction with the dispensing of a prescription ~~drug, that includes the name of, or describes biochemical, pharmacological, or other scientific or health information for, any drug or treatment other than the drug or treatment~~ *drug or prescribed treatment therapy, that includes the trade name or commercial slogan for any prescription drug, prescribed treatment therapy, or over-the-counter medication other than the prescription drug or prescribed treatment therapy* being dispensed, if the communication is paid for or sponsored, directly or indirectly, by a manufacturer, labeler, or distributor of prescription drugs. *This paragraph shall not apply when a trade name or commercial slogan for a prescription drug, prescribed treatment therapy, or over-the-counter medication is included in a written communication for the sole purpose of identifying a potential adverse drug interaction with the prescription drug or prescribed treatment therapy being dispensed.*

(g) "Medical information" means any individually identifiable information, in electronic or physical form, in possession of or derived from a provider of health care, health care service plan, pharmaceutical company, or contractor regarding a patient's medical history, mental or physical condition, or treatment. "Individually identifiable" means that the medical information includes or contains any element of personal identifying information sufficient to allow identification of the individual, such as the patient's name, address, electronic mail address, telephone number, or social security number, or other information that, alone or in combination with other publicly available information, reveals the individual's identity.

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

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

(j) "Provider of health care" means any person licensed or certified pursuant to Division 2 (commencing with Section 500) of the Business and Professions Code; any person licensed pursuant to the Osteopathic Initiative Act or the Chiropractic Initiative Act; any person certified pursuant to Division 2.5 (commencing with Section 1797) of the Health and Safety Code; any clinic, health dispensary, or health facility licensed pursuant to Division 2 (commencing with Section 1200) of the Health and Safety Code. "Provider of health care" does not include insurance institutions as defined in subdivision (k) of Section 791.02 of the Insurance Code.

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

O