

Board of Pharmacy

Initial Statement of Reasons

Subject Matter of Proposed Regulation: Citations and Fines for Confidentiality of Medical Information and Internet Dispensing Violations

Sections Affected: 1777, 1777.1, 1777.2, 1777.3, 1777.4, 1777.5, 1778, 1778.1, 1778.3

Problem Addressed

The rapid application of information technology to the provision of health care services has increased public concern and regulatory scrutiny of personal medical information. The advent of electronic payment systems and the emerging technologies for electronic patient records and electronic prescribing has placed large volumes of confidential patient information in electronic formats that are easier to search, duplicate and transmit without obtaining the patient's consent. Recent changes to the Confidentiality of Medical Information Act (Civil Code 56 et seq.) permit state agencies to levy administrative fines for violations of its provisions. Without such authority, state regulatory agencies are without effective enforcement tools for cases involving the unauthorized disclosure of confidential patient information.

Information technology has also created internet pharmacies. Many of these "pharmacies" are unlicensed and distribute prescription drugs without a valid prescription, and in some cases without a prescription of any kind. A recent addition to the Pharmacy Law created statutory authority for assessing an administrative fine for such internet dispensing violations. These violations are almost exclusively driven by economic gain and an economic penalty is often the only meaningful disincentive to engage in this illegal activity.

Specific Purpose of the Regulation

The proposed regulation implements the citation and fine provisions of Senate Bill 19 (Chapter 526, Statutes of 1999) regarding violations of the Confidentiality of Medical Information Act and Senate Bill 1828 (Chapter 681, Statutes of 2000) regarding internet dispensing of dangerous drugs and dangerous devices.

Sections 1777, 1777.1, 1777.2, 1777.3, 1777.4, 1777.5, 1778, 1778.1, and 1778.3 would be added.

Confidentiality of Medical Information

Section 4005 of the Business and Professions Code permits the Board of Pharmacy to adopt regulations to protect the public. Section 56.10 of the Civil Code requires that all healthcare providers or contractors obtain the consent of a patient prior to disclosing medical information regarding that patient except in specified circumstances. Section 56.36 of the Civil Code establishes penalties for violations of section 56.10 and other provisions of the Confidentiality of Medical Information Act (Act). Among the penalties provided for in Section 56.36 are administrative fines.

Section 1777, subdivision (a) specifies the authority of a committee of the board to issue citations and fines for violations of the Act. The subdivision also requires the issuance of an order of abatement requiring disgorgement of proceeds obtained for any willful violation.

Section 1777, subdivision (b) specifies the elements and requirements for a citation.

Section 1777, subdivision (c) specifies the procedural requirements for a respondent to request a hearing to dispute a finding of a violation.

Section 1777, subdivision (d) defines the procedure for a committee of the board considering alleged violations and issuing citations and fines. The procedures permit the board to issue a citation and fine in the absence of a respondent after two failures to appear before the committee. This authority is required to prevent alleged violators from delaying action by refusing to appear.

Section 1777.1, subdivision (a) specifies the penalties for a pharmacist who negligently discloses medical information in violation of the Act.

Section 1777.1, subdivision (b) specifies the penalties for a pharmacist who willfully discloses medical information in violation of the Act.

Section 1777.1, subdivision (c) specifies the penalties for a pharmacist who willfully discloses medical information for financial gain in violation of the Act.

Section 1777.1, subdivision (d) specifies that the board may not impose a fine on the same individual under section 1777.1 and 1777.2 for the same violation.

Section 1777.2, subdivision (a) specifies the penalties for a persons licensed by the board, than a pharmacist, who negligently disclose medical information in violation of the Act.

Section 1777.2, subdivision (b) specifies the penalties for persons licensed by the board, other than a pharmacist, who willfully disclose medical information in violation of the Act.

Section 1777.2, subdivision (c) specifies the penalties for persons licensed by the board, other than a pharmacist, who willfully disclose medical information for financial gain in violation of the Act.

Section 1777.2, subdivision (d) specifies that the board may not impose a fine on the same individual under section 1777.2 and 1777.1 for the same violation.

Section 1777.3 specifies the factors for a committee of the board to consider when imposing a fine.

Section 1777.4, subdivision (a) provides for the extension of an order of abatement in specified circumstances.

Section 1777.4, subdivision (b) specifies the manner of delivery for an order of abatement and the consequences for failure to comply with an order of abatement.

Section 1777.4, subdivision (c) specifies the consequences for the failure to pay a fine imposed by the board.

Section 1775.5 specifies the procedure for contesting a citation.

Internet Violations

Section 4005 of the Business and Professions Code permits the Board of Pharmacy to adopt regulations for public protection and to govern the practice of pharmacy. Section 4067 of the Business and Professions Code permits the board to issue citations and fines for dispensing or furnishing dangerous drugs or dangerous devices on the internet without a valid prescription.

Section 1778, subdivision (a) specifies the authority of a committee of the board to issue citations and fines for violations of section 4067. The subdivision also requires the issuance of an order of abatement requiring disgorgement of proceeds obtained for any willful violation.

Section 1778, subdivision (b) specifies the elements and requirements for a citation.

Section 1778, subdivision (c) specifies the procedural requirements for a respondent to request a hearing to dispute a finding of a violation.

Section 1778, subdivision (d) defines the procedure for a committee of the board considering alleged violations and issuing citations and fines. The procedures permit the board to issue a citation and fine in the absence of a respondent after two failures to appear before the committee. This authority is required to prevent alleged violators from delaying action by refusing to appear.

Section 1778.1 specifies the maximum fine and the factors for a committee of the board to consider when imposing a fine.

Section 1778.2, subdivision (a) provides for the extension of an order of abatement in specified circumstances.

Section 1778.2, subdivision (b) specifies the manner of delivery for an order of abatement and the consequences for failure to comply with an order of abatement.

Section 1778.2, subdivision (c) specifies the consequences for the failure to pay a fine imposed by the board.

Section 1778.3 specifies the procedure for contesting a citation.

Factual Basis

Board data for complaints for the unauthorized disclosure of prescription information is as follows:

Fiscal Year	Consumer Complaints	Substantiated Cases
1998-99	30	19
1999-00	36	15
2000-01	64	42

Board data for complaints for illegal dispensing on the internet is as follows:

Fiscal Year	Consumer Complaints	Substantiated Cases
1998-99	7	2
1999-00	13	1
2000-01	13	5

Underlying Data

The following survey results indicate substantial concerns on the part of the public regarding the privacy of their medical information.

California HealthCare Foundation, survey conducted by Princeton Survey Research Associates, January 1999:

One in two California residents consider the computerization of medical records as the most serious threat to medical privacy.

One in five American adults believes that a health care provider, insurance plan, government agency or employer has improperly disclosed personal medical information. Half of these people believe that it resulted in personal embarrassment or harm.

One in seven Americans has done something out of the ordinary to keep personal medical information confidential. To protect their privacy and avoid embarrassment, stigma, and discrimination, people withhold information from their health care providers, provide inaccurate information, doctor-hop to avoid a consolidated medical record, pay out-of-pocket for care that is covered by insurance, and – in the most extreme cases – avoid care altogether.

Two out of three U.S. adults say they don't trust health plans and government programs, such as Medicare, to maintain confidentiality all or most of the time.

Gallup survey commissioned by MedicAlert Foundation, November 2000:

Seventy-seven percent of the respondents said the privacy of their personal health information is very important;

sixty-one percent are very concerned that their personal health information might be made available to others without their consent;

fifty-five percent would not trust an insurance company or a managed care company to keep their personal health information private and secure.

Business Impact

Businesses will be affected by this regulation to the extent they fail to comply with existing provisions of the Pharmacy Law and are fined for those violations. This regulation imposes no new requirements.

Specific Technologies or Equipment

This regulation does not mandate the use of specific technologies or equipment.

Consideration of Alternatives

The board has not identified any equally effective alternatives that would lessen any adverse impact on small business.