



Communication and Public Education Committee

Medication Information Technology Task Force Meeting Minutes February 23, 2000

Present: M. Standifer Shreve, Chairperson, Member, California State Board of Pharmacy
Ellen Bull (representing Jeff Herzfeld), McKesson Pharmaceutical Services and
International Group
George Pennebaker, EDS, representing the California Pharmacists Association
Adrian Wong, RPh, e-Physician, technology specialist
Daniel Dong, UCSF School of Pharmacy
William Marcus, Deputy Attorney General, California Department of Justice
Steve Gray, Kaiser Permanente
Virginia Herold, Assistant Executive Officer, California State Board of Pharmacy

1. Introduction and Welcome

Chairperson Marilyn Shreve called the meeting to order at 9:25 a.m.

Chairperson Shreve stated that during this meeting, discussion will focus on the privacy of medical records and changes in California law that took effect January 1, 2000, via enactment of SB 19 (Figueroa, Chapter 526, Statutes of 1999).

Deputy Attorney General William Marcus gave a presentation on SB 19. Mr. Marcus pointed out that California has a strong right of privacy, including in the state constitution, and a Confidentiality of Medical Information Act (Civil Code sections 56 and following) that bars unauthorized disclosures of medical information, including that maintained by pharmacies. The new provisions enacted by SB 19 are intended to heighten privacy protections, including by expanding the law to include health care plans and contractors and by broadening the definition of "individually identifiable" information.

The federal government is also currently grappling with patient privacy issues to implement its privacy regulations. The concern of some interested parties is that unless the federal government acts, there will be at least 50 different standards for patient privacy. However, there is no certainty about when the federal government will issue regulations in the area; it is currently reviewing the more than 40,000 comments it received in response to proposed rules.

Mr. Marcus noted that the use of technology does not affect the applicability of the provisions of the act. In addition, health care plans and providers must have policies and procedures to protect the security of medical information, and a health care plan or provider cannot require a waiver or

release which would allow disclosures otherwise prohibited by the act as a condition of receiving health care services. Health plans must advise enrollees of how medical information collected by the plan will be used. Also included are requirements for confidential storage and destruction of records and prohibitions against the intentional sharing or use, or sale, of health care information.

Mr. Marcus stated that under SB 19, there are strong penalties for violations. The new law broadens the ability of patients to sue for misuse of information, and also authorizes action for administrative fines or civil penalties by governmental agencies or by local or state prosecutors. Depending on the intent behind the violation and the commercial misuse of information, the fine or penalty can reach \$250,000 per violation. He added that in all likelihood, court cases will establish the parameters and meaning of the law, and, because of the broad manner in which the law is written, class actions cases are likely to be a vehicle used since large penalties can be assessed.

Mr. Marcus stated that compliance programs may not violate the law if the sole purpose of the program is to assure patients are complying with directions for medication use established by the prescriber. However, if financial incentives or benefits are involved on the part of the entity making the contacts, the practice could be a violation of law.

If a pharmacist is making calls to patients, in order not to violate current law, the pharmacist may need to be acting under the protocol of a prescriber (for example, to make smoking cessation calls to patients). But the parameters of the program may still violate the act if the program is operated by an entity that benefits from the sale of the products being discussed by the pharmacist.

The committee discussed the circumstances under which a pharmacist can make calls from a location outside a pharmacy under current law. Additionally, since “ask a nurse” telephone advice lines must now be licensed by the Department of Consumer Affairs; if pharmacists operate similar services, they may need to be similarly licensed if the calls are made from outside a pharmacy.

The committee discussed the need for legislative and regulation changes in several areas.

The ability of pharmacists to enter into protocols with physicians to manage patients’ drug therapy has expanded since the last amendment to section 4051. As such, the committee recommends the following amendment:

- 4051(a) Except as otherwise provided in this chapter, it is unlawful for any person to manufacture, compound, furnish, sell, or dispense any dangerous drug or dangerous device, or to dispense or compound any prescription pursuant to Section 4040 of a prescriber unless he or she is a pharmacist under this chapter.
- (b) Notwithstanding any other law, a pharmacist may authorize the initiation of a prescription and otherwise provide clinical advice or

information or patient consultation from outside a pharmacy premises, if all of the following conditions are met:

- ~~(1) The clinical advice or information or patient consultation is provided either to a health care professional or to a patient of or resident in a licensed acute care hospital, health care facility, home health agency, or hospice.~~
- ~~(2) The pharmacist has access to prescription, patient profile, or other relevant medical information for purposes of patient and clinical consultation and advice.~~
- ~~(3) Access to the information described in paragraph (2) is secure from unauthorized access and use.~~

Additionally, pharmacists provide patient information as part of the scope of practice. As such, section 4050 needs to be amended to include this function.

4050. (a) In recognition of and consistent with the decisions of the appellate courts of this state, the Legislature hereby declares the practice of pharmacy to be a profession.
- (b) Pharmacy practice is a dynamic patient-oriented health service that applies a scientific body of knowledge to improve and promote patient health by means of appropriate drug use, and drug-related therapy and communication for clinical and consultative purposes.

Patients can currently prevent the sharing of information in the electronic records of the pharmacy. However, CURES requires the transmission of this information for Schedule II drugs even if the patient objects and electronic maintenance and sharing of prescription and other medical information is much more pervasive than when the board's regulation on shared electronic files was drafted. For that reason, the task force proposed that section 1717.2 be modified:

1717.2 Common Electronic Files

- ~~(a) Any pharmacy which establishes an electronic file for prescription records, which is shared with or accessible to other pharmacies, shall post in a place conspicuous to and readily readable by prescription drug consumers a notice in substantially the following form:
NOTICE TO CONUSMERS:
This pharmacy maintains its prescription information in an electronic file which is shared by or accessible to the following pharmacies: By offering this service, your prescriptions may also be refilled at the above locations. ~~If for any reason you do not want your prescriptions to be maintained in the way, please notify the pharmacist in charge.~~~~
- ~~(b) Whenever a consumer objects to his or her prescription records being made accessible to other pharmacies through use of electronic prescription files, it is the duty of the pharmacy to assure that the consumer's records are not shared~~

~~with or made accessible to another pharmacy, except as provided in Section 1764. The pharmacist to whom the consumer communicated the objections shall ask the consumer to sign a form which reads substantially as follows: I hereby notify (name of pharmacy) that my prescription drug records may not be made accessible to other pharmacies through a common or shared electronic file.~~

~~(date)~~

~~(signature of patient)~~

~~(acknowledgment of pharmacist)~~

~~The pharmacist shall date and cosign the form, and shall deliver a copy thereof to the patient. The original shall be maintained by the pharmacy for three years from the date of the last filling or refilling of any prescription in the name of the consumer.~~

The committee voted to refer these proposed amendments to the board for consideration as legislative or regulation changes for 2000. The proposals will be advanced to the board under the Communication and Public Education Committee report.

Discussion occurred on what activities the committee may need to undertake next. Ms. Herold stated that the board will be publishing an article on the implementation of SB 19. Since legislative action in this area has established parameters for patient privacy, the work of the task force is completed, and no future meeting is planned at this time, pending additional, relevant developments.

Meeting Closure

There being no additional discussion, Chairperson Shreve adjourned the meeting at 11:30.