

ACT 304

S.B. NO. 1560

A Bill for an Act Relating to Electronic Prescriptions.

Be It Enacted by the Legislature of the State of Hawaii:

SECTION 1. The growing technology in the computer industry has enabled prescription information to be transmitted from a practitioner's office to a pharmacy or from pharmacy to pharmacy. The legislature finds that the use of this technology will minimize errors due to illegible prescriptions and prevent alterations of prescriptions. At the same time, this Act requires that the consumer's prescription information be kept confidential and allows the consumer a choice in which pharmacy to utilize.

The purpose of this Act is to establish minimum requirements for the receipt, transmission, filling, recordkeeping, confidentiality, and security of electronic prescription information.

SECTION 2. Chapter 328, Hawaii Revised Statutes, is amended by adding a new part to be appropriately designated and to read as follows:

**“PART . ELECTRONIC PRESCRIPTIONS: TRANSMISSION,
FILLING, SECURITY, AND RECORDKEEPING REQUIREMENTS**

§328-A Definitions. As used in this part:

“Authorized representative” means a person who acts on behalf of, and at the direction of, another individual.

“Automated data processing system” means a system utilizing computer software and hardware for the purposes of recordkeeping and prescription filling and refill information.

“Common automated data processing system” means a file or database created by an automated data processing system that enables two or more authorized

users within the same company to have common access to the file, regardless of physical location.

“Computer” means a programmable electronic device, capable of multiple functions including but not limited to storage, retrieval, and processing of information.

“Controlled substances” means substances listed and scheduled in chapter 329.

“Department” means the department of health except when otherwise provided.

“Director” means the director of health except when otherwise provided.

“Downtime” means the period of time that an automated data processing system or electronic prescription transmission system is not operable.

“Electronic prescription” means a valid prescription, other than a facsimile prescription, which is electronically transmitted from a practitioner to a pharmacy.

“Facsimile prescription” means a valid prescription transmitted by a practitioner and sent by an electronic device over telephone lines so that an exact image of the prescription is sent to a pharmacy.

“Maintained on paper of permanent quality” means that the image printed on the paper shall remain legible, and that the paper itself shall not deteriorate, for a minimum period of five years.

“Out-of-state practitioner” means a physician, surgeon, osteopathic physician and surgeon, dentist, podiatrist, or veterinarian authorized to prescribe prescription drugs to patients under the applicable laws of any state of the United States except Hawaii, or a physician, surgeon, osteopathic physician and surgeon, dentist, podiatrist, or veterinarian authorized to prescribe prescription drugs to patients under the applicable laws of Hawaii, but practicing in a state other than Hawaii.

“Pharmacist” means an individual licensed under chapter 461 to practice in a pharmacy.

“Practitioner” means an individual licensed by the State or authorized by the laws of the State to prescribe prescription drugs within the scope of the person’s practice.

“Prescription” means an order or formula issued for a legitimate medical purpose by a practitioner for the compounding or dispensing of drugs.

“Prescription drug” means any drug required by federal or Hawaii statutes, regulations, or rules to be dispensed only by a prescription, including finished dosage forms and active ingredients subject to section 328-16 or to Section 503(b) of the Federal Food, Drug, and Cosmetic Act.

“Printout” or “hard copy” means any form printed by a computer that is readable without the aid of any special device, containing all the criteria and information relating to a prescription record including refill history, if any, of that prescription or group of prescriptions.

“Reduced to writing” means the creation of a permanent paper document which contains all the information required for a written or oral prescription.

“Supply” means to sell, trade, distribute, exchange, barter, give, offer for sale, lease, rent, or provide.

§328-B Facsimile transmission of prescriptions. (a) A prescription transmitted by facsimile may be filled by a pharmacist if the following conditions are met:

- (1) The prescription is transmitted from the practitioner’s office to the pharmacy;
- (2) Facsimile prescriptions shall be in the same form as written prescriptions, as provided in section 328-16;

- (3) A prescription transmitted by facsimile shall be signed by the practitioner or, if it is not signed, the pharmacist shall orally confirm the prescription with the practitioner;
 - (4) The facsimile prescription shall include:
 - (A) The name, address, and facsimile number of the receiving pharmacy;
 - (B) The name, address, telephone number, and oral code designation of the practitioner; and
 - (C) Any other information required by federal laws or regulations and Hawaii statutes or rules;
 - (5) The receiving facsimile machine shall be physically located in a restricted area so that consumer confidentiality is ensured;
 - (6) A facsimile prescription shall be transmitted to the pharmacy of the consumer's choice. If the pharmacy of the consumer's choice is not equipped to receive a facsimile prescription, the practitioner shall provide the consumer with a nonfacsimile written prescription, an electronically transmitted prescription, or telephone an oral prescription to the pharmacy of the consumer's choice;
 - (7) Facsimile prescriptions shall be maintained on file for a period of five years from the date of original fill and shall be maintained on paper of permanent quality; and
 - (8) The pharmacist shall exercise professional judgment regarding the accuracy, validity, and authenticity of the facsimile prescription.
- (b) Facsimile prescriptions received from persons other than practitioners shall not be valid prescriptions.

§328-C Electronic transmission of prescription information. (a) A practitioner may electronically transmit a prescription to a pharmacy if the following conditions are met:

- (1) Only the practitioner shall transmit an electronic prescription, and the prescription shall be received only by a pharmacist, with no intervening person having access to view, read, manipulate, alter, store, or delete the electronic prescription prior to its receipt at the pharmacy;
- (2) The prescription shall be transmitted to the pharmacy of the consumer's choice. If the pharmacy of the consumer's choice is not equipped with the capability to accept an electronic prescription, the practitioner shall provide the patient with a written prescription or telephone an oral prescription to the pharmacy of the consumer's choice;
- (3) The electronic prescription shall contain all of the information required by this chapter to be on a prescription. The electronic prescription shall contain, at minimum, the following:
 - (A) The name and address of the practitioner;
 - (B) The telephone number of the practitioner for oral confirmation;
 - (C) The name, strength, and quantity of the drug;
 - (D) Specific directions for the drug's use;
 - (E) The name and address of the person for whom the prescription is written;
 - (F) The number of allowable refills;
 - (G) The time and date of transmission;
 - (H) The name and address or location of the receiving pharmacy; and
 - (I) An indication whether generic substitution is prohibited;
- (4) Except as provided by this part, the electronic prescription shall be reduced to writing by the pharmacist immediately upon receipt;

- (5) Hard copies of electronic prescriptions shall be maintained for a period of five years from the date of original fill and shall be maintained on paper of permanent quality;
- (6) The electronic prescription transmission system shall provide adequate safeguards against the improper manipulation or alteration of prescription records;
- (7) The computer receiving the electronic prescription shall be physically located in a restricted area so that consumer confidentiality is ensured; and
- (8) The pharmacist shall exercise professional judgment regarding the accuracy, validity, and authenticity of the electronic prescription.

(b) Electronic prescriptions received from persons other than practitioners shall not be valid prescriptions.

§328-D Notice of electronic prescription files. (a) Any pharmacy that establishes an electronic file for prescription records, which is shared with or accessible to other pharmacies, shall post in a conspicuous place a legible notice, in letters not less than one inch in height, that states:

“NOTICE TO CONSUMERS:

This pharmacy maintains its prescriptions on a computer database which is shared by or accessible to the following pharmacies:

(NAME OF PHARMACIES SHARING FILES)

Although you may refill your prescription at any pharmacy of your choice, this database makes it easier for a pharmacist at any of the above locations to refill your prescription. If for any reason you do not want your prescriptions to be maintained in this way, please notify the pharmacist.”

(b) Whenever a consumer or the consumer’s authorized representative has notified the pharmacist that the consumer does not want to have the consumer’s prescription records made accessible to other pharmacies through the use of electronic prescription files, the pharmacist shall ensure that the consumer’s records are not shared with or made accessible to another pharmacy. The pharmacist to whom the consumer or consumer’s authorized representative communicates the objection shall have the consumer or the consumer’s authorized representative sign a form which reads as follows:

“I, (consumer’s name), notify (name of pharmacy) that my prescription drug records shall not be made accessible to other pharmacies through a common or shared electronic file.

Signature of Consumer or Representative

Date

Signature of Pharmacist

Printed Last Name of Pharmacist”

The pharmacist shall date and co-sign the form and shall deliver a copy thereof to the consumer or consumer’s authorized representative. The original shall be maintained by the pharmacy for five years from the date the form is submitted by the consumer or consumer’s authorized representative.

§328-E Manual transfer of prescriptions. The transfer of original prescription information for the purpose of refill dispensing is permissible between pharmacies subject to the following requirements:

- (1) The transfer shall be directly between two licensed pharmacists, and the transferring pharmacist shall immediately:
 - (A) Write the word "VOID" on the face of the invalidated prescription;
 - (B) Record on the reverse of the invalidated prescription the name and address of the pharmacy to which the prescription was transferred, the name of the pharmacist receiving the prescription information, the date of the transfer, and the name of the pharmacist transferring the information; and
 - (C) Communicate to the pharmacist receiving the transferred prescription the original number of refills authorized and the number of valid refills remaining.
- (2) In addition to recording all of the information required by this chapter to be on a prescription, the pharmacist receiving the transferred prescription information shall immediately:
 - (A) Write the word "transfer" on the face of the transferred prescription;
 - (B) Record the date of issuance of the original prescription, the original number of refills authorized on the original prescription, the date of original dispensing, the number of valid refills remaining, the date of the last refill, and the original prescription number; and
 - (C) Record the name of the transferring pharmacy, the address or location from which the prescription information was transferred, and the name of the transferring pharmacist.
- (3) Transferred prescriptions shall be maintained on paper of permanent quality for a period of five years from the date of transfer.

§328-F Automated data processing transfer of prescription information.

(a) Two or more pharmacies located in this State and part of the same company may transfer prescription information for dispensing purposes, utilizing a common automated data processing system.

(b) Pharmacies using a common automated data processing system are not required manually to transfer prescription refill information pursuant to section 328-E.

(c) Pharmacies utilizing a common automated data processing system shall ensure that complete and accurate records are kept of each prescription and refill dispensed by their pharmacists and that the number of allowable refills has not been exceeded.

(d) The original written or oral prescription shall be verified and documented by the pharmacist when the automated data processing system is first accessed for information regarding a refill.

(e) The procedure for utilizing a common automated data processing system for the transfer of prescription information for refill purposes shall comply with all applicable Hawaii statutes and rules and federal laws and regulations.

§328-G Security; confidentiality. (a) To maintain the confidentiality of consumer prescription records, the electronic prescription transmission system or automated data processing system used to accept or transfer prescriptions shall include safeguards to prevent, detect, and ensure against unauthorized access, modification, or manipulation of consumer prescription records.

(b) Any person who transmits, maintains, or receives any prescription or prescription refill, orally or in writing or electronically, shall ensure the security,

integrity, and confidentiality of the prescription and any information contained therein.

§328-H Recordkeeping. Prescriptions that are filled or refilled using an automated data processing system, electronic prescription transmission, or facsimile transmission shall comply with the recordkeeping requirements for written and oral prescriptions as provided in sections 328-16 and 328-17.7.

§328-I Downtime of the computer. (a) Every pharmacy utilizing an automated data processing system or electronic prescription transmission system shall provide an auxiliary procedure to document prescriptions that are filled or refilled during any downtime period. The auxiliary procedure must ensure that the prescriptions that are filled or refilled are authorized by the practitioner and that the number of allowable refills has not been exceeded.

(b) When the automated data processing system or electronic prescription transmission system is restored to operation, the information regarding prescriptions that have been filled or refilled during the downtime shall be recorded in the automated data processing system or electronic prescription transmission system within forty-eight hours.

§328-J Controlled substances. This part shall not apply to prescriptions for controlled substances, except as provided in chapter 329.

§328-K Out-of-state practitioners. This part shall not apply to prescriptions from out-of-state practitioners or transferred prescriptions from an out-of-state pharmacy, except as provided in section 328-17.6.

§328-L Reduced to writing. (a) If an automated data processing system or electronic prescription transmission system is utilized, and the system is capable of printing a copy of the prescription, the printer copy may be used to satisfy the requirement that prescriptions transmitted electronically be reduced to writing. The pharmacist shall check the electronically printed prescription to ensure all required items for a valid prescription are present and that the information is accurate. The pharmacist shall initial the printed prescription upon determining that the prescription is valid and accurate.

(b) The pharmacist shall manually reduce to writing required prescription information if an automated data processing system or electronic prescription transmission system is not capable of printing a copy of the prescription.

(c) The printer copy shall be maintained on paper of permanent quality for a period of five years from the date of original filling.

§328-M Printout of prescriptions. A pharmacy utilizing an automated data processing or electronic transmission system shall have the capability to produce a daily printout of all prescriptions that were filled or refilled utilizing an automated data processing system or electronic prescription transmission system, including a prescription-by-prescription and refill-by-refill audit trail. A copy of the printout shall be made available to any authorized agent of the department, within forty-eight hours after request of the printout by the agent.

§328-N Supplying equipment prohibited. To preclude conflict of interest, drug wholesalers and manufacturers, drug salespersons, pharmacists, pharmacies, third party insurance carriers, and all related persons and their agents shall not supply electronic equipment, including computer equipment, hardware, software, facsimile machines, and related equipment, to practitioners for the transmission of

prescriptions to pharmacies. For purposes of this section, related persons shall include but not be limited to subsidiaries, partnerships, companies, trusts, and other business entities.

§328-O Misuse of technological devices. Technological devices, including facsimile machines, electronic transmission systems, and automated data processing systems, shall not be used to circumvent any provision of this chapter, or any other Hawaii statute or rule, or federal law or regulation.

§328-P Rules. The department may adopt rules pursuant to chapter 91 necessary to carry out the purposes and enforce the provisions of this part.

§328-Q Powers and duties. The department shall enforce this part, and shall have all the powers and duties conferred and imposed upon it by part I.

§328-R Criminal penalty. Any person who wilfully violates this part shall be guilty of a misdemeanor.

§328-S Administrative penalties. (a) Any person who violates this part or any rule adopted by the department pursuant to this part shall be fined not more than \$10,000 for each separate offense. Any action taken to collect the penalty provided for in this subsection shall be considered a civil action.

(b) In addition to any other administrative or judicial remedy provided by this part, or by rules adopted pursuant to this part, the director may impose by order the administrative penalty specified in this section. Factors to be considered in imposing the administrative penalty include the nature and history of the violation and of any prior violation, and the opportunity, difficulty, and history of corrective action. For any judicial proceeding to recover the administrative penalty imposed, the director need only show that notice was given, a hearing was held or the time granted for requesting a hearing has expired without such a request, the administrative penalty was imposed, and that the penalty remains unpaid.

§328-T Injunctive relief. The director may institute a civil action in any court of competent jurisdiction for injunctive relief to prevent violation of this part or any rule adopted to implement this part. The court shall have the power to grant relief in accordance with the Hawaii rules of civil procedure.”

SECTION 3. In codifying the new part added to chapter 328, Hawaii Revised Statutes, section 2 of this Act, the revisor of statutes shall substitute appropriate section numbers for the letters used in designating the new sections in that part.

SECTION 4. This Act shall take effect upon its approval and shall be repealed on June 30, 2001.

(Approved June 21, 1997.)