Senate Amendments Section-by-Section Analysis

### **HOUSE VERSION**

SECTION 1. Subchapter C, Chapter 562, Occupations Code, is amended by adding Section 562.1011 to read as follows:

Sec. 562.1011. OPERATION OF CLASS C PHARMACY IN CERTAIN RURAL HOSPITALS. (a) In this section:

- (1) "Nurse" has the meaning assigned by Section 301.002. The term includes a nurse who is also registered as a pharmacy technician.
- (2) "Rural hospital" means a licensed hospital with 100 beds or fewer that:
- (A) is located in a county with a population of 50,000 or less; or
- (B) has been designated by the Centers for Medicare and Medicaid Services as a critical access hospital, rural referral center, or sole community hospital.
- (b) If a practitioner orders a prescription drug or device for a patient in a rural hospital when the hospital pharmacist is not on duty or when the institutional pharmacy is closed, a nurse or practitioner may withdraw the drug or device from the pharmacy in sufficient quantity to fill the order.
- (c) At the time the nurse or practitioner withdraws a drug or device from an institutional pharmacy under Subsection (b), the nurse or practitioner shall make a record of the withdrawal that contains:
- (1) the name of the patient;
- (2) the name of the device or drug;
- (3) the dosage of the drug, strength of the drug, and dosage form;

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SECTION 1. Subchapter C, Chapter 562, Occupations Code, is amended by adding Section 562.1011 to read as follows:

Sec. 562.1011. OPERATION OF CLASS C PHARMACY IN CERTAIN RURAL HOSPITALS. (a) In this section:

- (1) "Nurse" has the meaning assigned by Section 301.002. The term includes a nurse who is also registered as a pharmacy technician.
- (2) "Rural hospital" means a licensed hospital with 75 beds or fewer that:
- (A) is located in a county with a population of 50,000 or less; or
- (B) has been designated by the Centers for Medicare and Medicaid Services as a critical access hospital, rural referral center, or sole community hospital.
- (b) If a practitioner orders a prescription drug or device for a patient in a rural hospital when the hospital pharmacist is not on duty or when the institutional pharmacy is closed, a nurse or practitioner may withdraw the drug or device from the pharmacy in sufficient quantity to fill the order.

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- (4) the quantity withdrawn;
- (5) the time and date of the withdrawal; and
- (6) the signature of the person making the withdrawal.
- (d) The original medication order or a copy of the order may substitute for the record of withdrawal if the medication order contains all of the information required by Subsection (c).
- (e) The hospital pharmacist shall verify the withdrawal of a drug or device under Subsection (b) and perform a drug regimen review not later than the seventh day after the date of the withdrawal.
- (f) In a rural hospital that uses a floor stock method of drug distribution, a nurse or practitioner may withdraw a prescription drug or device from the institutional pharmacy in the original manufacturer's container or a prepackaged container.
- (g) At the time a nurse or practitioner withdraws a drug or device from an institutional pharmacy under Subsection (f), the nurse or practitioner shall make a record of the withdrawal that contains:
- (1) the name of the drug or device;
- (2) the strength of the drug and dosage form;
- (3) the quantity of the drug or device withdrawn;
- (4) the location of the floor stock;
- (5) the time and date of the withdrawal; and
- (6) the signature of the person making the withdrawal.
- (h) The hospital pharmacist shall verify the withdrawal of a drug or device under Subsection (f) and perform a drug regimen review not later than the seventh day after the date of the withdrawal.

- (c) The hospital pharmacist shall verify the withdrawal of a drug or device under Subsection (b) and perform a drug regimen review not later than the seventh day after the date of the withdrawal.
- (d) In a rural hospital that uses a floor stock method of drug distribution, a nurse or practitioner may withdraw a prescription drug or device from the institutional pharmacy in the original manufacturer's container or a prepackaged container.

(e) The hospital pharmacist shall verify the withdrawal of a drug or device under Subsection (d) and perform a drug regimen review not later than the seventh day after the date of the withdrawal.

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- (f) A rural hospital may allow a pharmacy technician to perform the duties specified in Subsection (g) if:
- (1) the pharmacy technician is registered and meets the training requirements specified by the board;
- (2) a pharmacist is accessible at all times to respond to any questions and needs of the pharmacy technician or other hospital employees, by telephone, answering or paging service, e-mail, or any other system that makes a pharmacist accessible; and
- (3) a nurse or practitioner or a pharmacist by remote access verifies the accuracy of the actions of the pharmacy technician.
- (g) If the requirements of Subsection (f) are met, the pharmacy technician may, during the hours that the institutional pharmacy in the hospital is open, perform the following duties in the pharmacy without the direct supervision of a pharmacist:
- (1) enter medication order and drug distribution information into a data processing system;
- (2) prepare, package, or label a prescription drug according to a medication order if a licensed nurse or practitioner verifies the accuracy of the order before administration of the drug to the patient;
- (3) fill a medication cart used in the rural hospital;
- (4) distribute routine orders for stock supplies to patient care areas:
- (5) access and restock automated medication supply cabinets; and
- (6) perform any other duty specified by the board by rule.

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(i) This section does not restrict or prohibit the board

from adopting a rule governing the withdrawal of a drug

or device by a nurse or practitioner from an institutional

pharmacy not located in a rural hospital.

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(h) The pharmacist-in-charge of an institutional pharmacy in a rural hospital shall develop and implement policies and procedures for the operation of the

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- pharmacy when a pharmacist is not on-site.

  (i) On or after September 1, 2011, the board may establish, by rule, a requirement for prospective and retrospective drug use review by a pharmacist for each new drug order. A drug use review is not required when a delay in administration of the drug would harm the patient in an urgent or emergency situation, including sudden changes in a patient's clinical status.
- (j) Rural hospitals may establish standing orders and protocols, to be developed jointly by the pharmacist and medical staff, that may include additional exceptions to instances in which prospective drug use review is required.
- (k) This section does not restrict or prohibit the board from adopting a rule related to authorizing the withdrawal of a drug or device by a nurse or practitioner from, or the supervision of a pharmacy technician in, an institutional pharmacy not located in a rural hospital. As part of the rulemaking process, the board shall consider the effect that a proposed rule, if adopted, would have on access to pharmacy services in hospitals that are not rural hospitals.
- (1) The board shall adopt rules to implement this section, including rules specifying:
- (1) the records that must be maintained under this section;
- (2) the requirements for policies and procedures for

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(j) This section expires January 1, 2012.

No equivalent provision.

operation of a pharmacy when a pharmacist is not onsite; and

(3) the training requirements for pharmacy technicians.

- SECTION 2. Chapter 568, Occupations Code, is amended by adding Section 568.008 to read as follows: Sec. 568.008. TECHNICIANS IN HOSPITALS WITH CLINICAL PHARMACY PROGRAM. (a) In this section, "clinical pharmacy program" means a program that provides pharmaceutical care services as specified by board rule.
- (b) A Class C pharmacy that has an ongoing clinical pharmacy program may allow a pharmacy technician to verify the accuracy of work performed by another pharmacy technician relating to the filling of floor stock and unit dose distribution systems for a patient admitted to the hospital if the patient's orders have previously been reviewed and approved by a pharmacist.
- (c) The pharmacist-in-charge of the clinical pharmacy program shall adopt policies and procedures for the verification process authorized by this section.
- (d) A hospital must notify the board before implementing the verification process authorized by this section.
- (e) The board shall adopt rules to implement this section, including rules specifying:
- (1) the duties that may be verified by another pharmacy technician;
- (2) the records that must be maintained for the

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verification process; and

(3) the training requirements for pharmacy technicians who verify the accuracy of the work of other pharmacy technicians.

The following rows were presented as the engrossed version of Senate Bill 1127 relating to the confidentiality of test results of samples of compounded products.

No equivalent provision.

SECTION \_\_. Section 556.053, Occupations Code, is amended to read as follows:

Sec. 556.053. EXTENT OF INSPECTION; CONFIDENTIALITY. (a) Except as otherwise provided in an inspection warrant, the person authorized to represent the board may:

- (1) inspect and copy documents, including records or reports, required to be kept or made under this subtitle, Chapter 481 or 483, Health and Safety Code, or the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. Section 801 et seq.) or rules adopted under one of those laws;
- (2) inspect, within reasonable limits and in a reasonable manner, a facility's storage, equipment, security, prescription drugs or devices, components used in

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compounding, finished and unfinished products, or records; or

- (3) perform an inventory of any stock of prescription drugs or devices, components used in compounding, or finished and unfinished products in a facility and obtain samples of those substances.
- (b) Reports, records, formulas, and test results of samples of products compounded by pharmacies obtained by the board may be provided to the pharmacy that compounded the product but otherwise are confidential and do not constitute public information for purposes of Chapter 552, Government Code. The board may create, use, or disclose statistical information from the test results of samples of compounded products.
- (c) The board may disclose information confidential under Subsection (b):
- (1) in a disciplinary hearing before the board or in a subsequent trial or appeal of a board action or order;
- (2) to a pharmacist licensing or disciplinary authority of another jurisdiction; or
- (3) under a court order.
- (d) The board shall require a pharmacy to recall a compounded product and may release the results of the tests of the samples of the compounded product if the board determines that:
- (1) the test results indicate a patient safety problem that may involve potential harm to a patient; and
- (2) the release of the test results is necessary to protect the public.
- (e) The board shall release the test results described by

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	Subsection (d) if a pharmacy is unable to or does not recall the compounded product within 48 hours after the board's request under that subsection.	
	The following rows were presented as the engrossed version of Senate Bill 1853 relating to disciplinary actions regarding a pharmacy technician or pharmacy technician trainee.	
No equivalent provision.	SECTION Section 568.003, Occupations Code, is amended to read as follows:  Sec. 568.003. GROUNDS FOR DISCIPLINARY ACTION. (a) The board may take disciplinary action under Section 568.0035 if the board determines that the applicant or registrant has:  (1) violated this subtitle or a rule adopted under this subtitle;  (2) engaged in gross immorality, as that term is defined by the rules of the board;  (3) engaged in any fraud, deceit, or misrepresentation, as those terms are defined by the rules of the board, in seeking a registration to act as a pharmacy technician;  (4) been convicted of or placed on deferred adjudication	

community supervision or deferred disposition or the

(ii) under Chapter 481 or 483, Health and Safety Code, or the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. Section 801 et seq.); or

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applicable federal equivalent for:

(i) involving moral turpitude; or

(A) a misdemeanor:

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- (B) a felony;
- (5) <u>developed an incapacity that prevents the applicant or registrant from practicing as a pharmacy technician or pharmacy technician trainee with reasonable skill, competence, and safety to the public [a drug or alcohol dependency];</u>
- (6) violated:
- (A) Chapter 481 or 483, Health and Safety Code, or rules relating to those chapters;
- (B) Sections 485.031-485.035, Health and Safety Code; or
- (C) a rule adopted under Section 485.011, Health and Safety Code;
- (7) violated the pharmacy or drug laws or rules of this state, another state, or the United States; [or]
- (8) <u>performed duties in a pharmacy that only a pharmacist may perform, as defined by the rules of the board;</u>
- (9) used alcohol or drugs in an intemperate manner that, in the board's opinion, could endanger a patient's life;
- (10) engaged in negligent, unreasonable, or inappropriate conduct when working in a pharmacy;
- (11) violated a disciplinary order;
- (12) been convicted or adjudicated of a criminal offense that requires registration as a sex offender under Chapter 62, Code of Criminal Procedure; or
- (13) been disciplined by a pharmacy or other health regulatory board of this state or another state [had a registration as a pharmacy technician issued by another state revoked, surrendered, or suspended] for conduct

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substantially equivalent to conduct described by <u>this</u> <u>subsection</u> [Subdivisions (1) (6)].

(b) A certified copy of the record of a state taking action described by Subsection (a)(13) [(a)(8)] is conclusive evidence of the action taken by the state.

SECTION \_\_. Section 568.0035, Occupations Code, is amended to read as follows:

Sec. 568.0035. DISCIPLINE AUTHORIZED: <u>EFFECT ON TRAINEE</u>. (a) On a determination that a ground for discipline exists under Section 568.003, the board may:

- (1) suspend the person's registration;
- (2) revoke the person's registration;
- (3) restrict the person's registration to prohibit the person from performing certain acts or from practicing as a pharmacy technician in a particular manner for a term and under conditions determined by the board;
- (4) impose an administrative penalty under Chapter 566;
- (5) refuse to issue or renew the person's registration;
- (6) place the offender's registration on probation and supervision by the board for a period determined by the board and impose a requirement that the registrant:
- (A) report regularly to the board on matters that are the basis of the probation;
- (B) limit practice to the areas prescribed by the board;
- (C) continue or review professional education until the registrant attains a degree of skill satisfactory to the board in each area that is the basis of the probation; or
- (D) pay the board a probation fee to defray the costs of monitoring the registrant during the period of probation;

9.147.492

No equivalent provision.

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No equivalent provision.

- (7) reprimand the person;
- (8) retire the person's registration as provided by board rule; or
- (9) impose more than one of the sanctions listed in this section.
- (b) A disciplinary action affecting the registration of a pharmacy technician trainee remains in effect if the trainee obtains registration as a pharmacy technician.

SECTION \_\_. Chapter 568, Occupations Code, is amended by adding Section 568.0036 to read as follows: Sec. 568.0036. SUBMISSION TO MENTAL OR PHYSICAL EXAMINATION. (a) This section applies to a pharmacy technician, pharmacy technician applicant, pharmacy technician trainee, or pharmacy technician trainee applicant.

- (b) In enforcing Section 568.003(a)(5), the board, on probable cause, may request a person subject to this section to submit to a mental or physical examination by a physician or other health care professional designated by the board.
- (c) If the person refuses to submit to the examination, the board shall:
- (1) issue an order requiring the person to show cause why the person will not submit to the examination; and
- (2) schedule a hearing on the order not later than the 30th day after the date notice of the order is served on the person under Subsection (d).
- (d) The person shall be notified by either personal service or certified mail, return receipt requested.

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(e) At the hearing, the person and the person's counsel may present testimony or other evidence to show why the person should not be required to submit to the examination.

- (f) After the hearing, the board shall, by order:
- (1) require the person to submit to the examination; or
- (2) withdraw the request for examination.

No equivalent provision.

SECTION \_\_. The changes in law made by this Act apply only to conduct occurring on or after the effective date of this Act. Conduct occurring before the effective date of this Act is governed by the law in effect immediately before the effective date of this Act, and the former law is continued in effect for that purpose.

SECTION 2. This Act takes effect immediately if it receives a vote of two-thirds of all the members elected to each house, as provided by Section 39, Article III, Texas Constitution. If this Act does not receive the vote necessary for immediate effect, this Act takes effect September 1, 2009.

SECTION 3. Same as House version.