HOUSE RESEARCH

Bill Summary

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1 **Definitions.** Amends § 151.01. Amends and adds various definitions to the Pharmacy Practice Act. Only amended and new definitions are described in this summary.

Subd. 2. Pharmacy. Updates the definition of "pharmacy."

Subd. 4. Drug. Adds vaccines and biologicals to the definition of "drug." Adds that the term "drug" includes any compound, substance, or derivative, not approved for human use by the FDA or permitted for use by Minnesota law, that induces effects similar to Schedule I or II controlled substances.

Subd. 7. Poison. Makes two technical changes.

Subd. 9. Board or Board of Pharmacy. Strikes the word "State" from the board's name.

Subd. 10. Director. Adds the word "executive" so that the term "director" refers to the executive director of the board.

Subd. 13. Commercial purposes. Excludes "other health care professions" from the definition of "commercial purposes." Current law already excludes the practices of medicine and pharmacy.

Subd. 14. Manufacturing. Redefines the term to mean the preparation or processing of a drug by extraction from substances of natural origin or independently by means of chemical or biological synthesis. This term includes packaging or repackaging a drug, or labeling or relabeling a container of a drug. It does not include the labeling of a container within a pharmacy or by a practitioner for dispensing to a patient pursuant to a prescription.

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Subd. 14a. Manufacturer. Adds the definition for this term and defines it as any person engaged in manufacturing.

Subd. 14b. Outsourcing facility. Adds the definition for this term. The term means a facility that meets federal requirements and registers with the FDA. These facilities compound human drugs.

Subd. 16. Prescription drug order. Adds the definition of "prescription drug order." Provides that such an order may be written, oral, or electronic, and must be for a specific patient. Requires orders for controlled substances to be prepared according to state and federal laws.

Subd. 16a. Prescription. Adds a new definition for "prescription." Lists the requirements and information that must be included on a valid prescription drug order.

Subd. 16b. Chart order. Adds this definition which means a prescription drug order for a drug that is to be administered to a patient in a hospital or long-term care facility. Lists the information that must be included in a valid chart order.

Subd. 17. Legend drug. Strikes the requirement for a specific cautionary statement to be included with legend drugs. Requires legend drugs to be dispensed by prescription only.

Subd. 18. Label. Strikes an obsolete cross-reference. Clarifies that any information required to appear on a drug or medicine label must be clearly visible on the outside of the container or wrapper.

Subd. 23. Practitioner. Requires drug manufacturers required to report payments to practitioners to include in their annual report the names of physician assistants and APRNs who are authorized to prescribe, dispense, and administer drugs, and dental therapists who are authorized to dispense and administer drugs.

Subd. 27. Practice of pharmacy. Adds that it is within a pharmacist's scope of practice to interpret results of laboratory tests to monitor drug therapy, but may modify the therapy only pursuant to a protocol or collaborative practice agreement.

Clarifies the conditions under which a pharmacist can administer influenza vaccines.

Allows pharmacists to participate in collaborative practice agreements (this term is defined in subdivision 27b).

Subd. 27a. Protocol. Defines "protocol" as a written plan describing the activities in which a pharmacist engages when initiating, modifying, managing, or discontinuing drug therapy; or a plan that authorizes the pharmacist to administer vaccines.

Subd. 27b. Collaborative practice. Defines this term as patient care activities engaged in by one or more pharmacists who work collaboratively with one or more practitioners to initiate, manage, and modify drug therapy.

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Subd. 27c. Collaborative practice agreement. Provides that this is a written, signed agreement between one or more pharmacists and one or more practitioners to engage in collaborative practice.

Subd. 28. Veterinary legend drug. Strikes the requirement for a specific cautionary statement to be included with legend drugs. Requires legend drugs to be dispensed by prescription only.

Subd. 29. Legend medical gas. Strikes the requirement for a specific cautionary statement to be included with legend medical gases. Requires these gases to be dispensed by prescription only.

Subd. 30. Dispense or dispensing. Defines these terms as the interpretation and processing of a prescription drug order in compliance with board rules.

Subd. 35. Compounding. Creates a new definition. Defines "compounding" as the preparation, mixing, assembling, packaging, and labeling of a drug for a specific patient pursuant to a prescription drug order. This term includes anticipatory compounding and preparation of drugs in which all bulk drug substances and components are nonprescription substances. Provides that the term does not include preparation of a drug for research, teaching, or chemical analysis.

Subd. 36. Anticipatory compounding. Creates a new definition which means a pharmacy's or practitioner's preparation of a supply of a compounded drug product sufficient to meet the pharmacy's short-term need for filling prescriptions or a practitioner's need for dispensing or administering the drug to patients treated by the practitioner.

Subd. 37. Extemporaneous compounding. Adds a new definition which means the compounding of a drug product pursuant to a prescription drug order that is issued in advance of the compounding.

Subd. 38. Compounded positron emission tomography drug. Creates a definition for this term. This means a drug used for PET scans images, and compounded in compliance with Minnesota Rules for a patient or research, teaching, or quality control.

2 Powers and duties. Amends § 151.06.

Subd. 1. Generally; rules. Strikes the list of conduct which may be grounds for disciplinary action. (A new statutory section on disciplinary action is created in section 3 of this bill.) Authorizes a representative of the board to enter and inspect any business licensed or registered by the board.

Subd. 1a. Cease and desist orders. Grants the board authority to issue cease and desist orders. Requires the order to include the bases for issuance of the order and a notice of hearing rights. Establishes time frames for hearings, issuance of the ALJ report, and final action by the board. Provides that if no hearing is requested with 30

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days of service of the order, the order becomes permanent. Provides that a cease and desist order remains in effect until modified or vacated by the board.

Subd. 1b. Enforcement of cease and desist orders. Provides that the allegations in the cease and desist order are considered conclusively established for purposes of enforcement of the order. Allows the person against whom an order has been issued to seek an injunction to suspend enforcement of the order.

Strikes subdivisions 3 to 5 dealing with disciplinary actions. Provisions of these subdivisions are contained in section 3 of this bill.

3 Disciplinary action. Creates § 151.071.

Subd. 1. Forms of disciplinary action. Allows the board to impose a range of disciplinary action when a licensee, registrant, or applicant has engaged in prohibited conduct under subdivision 2. These actions include denial of a license, refusal to renew, revocation or suspension, or imposition of limitations or conditions on the license.

Subd. 2. Grounds for disciplinary action. Lists prohibited conduct. Included in the list are actions such as obtaining a license by fraud, conviction of a felony related to the practice of the profession, disciplinary action by another state or licensing authority, engaging in unethical conduct, fraudulent billing practices, and termination from the Health Professional Services Program for reasons other than satisfactory completion of the program.

Subd. 3. Automatic suspension. Paragraph (a) instructs the board to automatically suspend a license if a court appoints a guardian for a licensee or the licensee is civilly committed.

Paragraph (b) allows the board to automatically suspend the license of a licensee when the board receives notice that a judgment has been entered against the licensee for, or the licensee has entered a plea of guilty to, a felony related to the practice of pharmacy.

Paragraph (c) allows the board to suspend a facility license or registration when the owner of the facility is subject to a judgment of, or a plea of guilty to, a felony related to the operation of the facility.

Paragraphs (d) and (e) allow individuals whose license or registration have been suspended under paragraphs (a) to (c) to have their license or registration reinstated by demonstrating clear and convincing evidence of rehabilitation. Allows the board to impose restrictions, conditions, or limitations upon reinstatement of the license or registration.

Paragraph (f) allows the board to suspend the license or registration of a regulated individual when the individual fails to maintain a current name and address with the board while a disciplinary investigation or action is pending.

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Paragraph (g) allows the board to suspend the license or registration of a regulated facility when the owner fails to maintain a current name and address with the board while a disciplinary investigation or action is pending.

Paragraph (h) and (j) require regulated individuals and owners of regulated facilities to maintain a current name and address with the board.

Subd. 4. Effective dates. Provides that any action taken by the board against a license or registration shall be in effect pending appeal.

Subd. 5. Conditions on reissued license. Allows the board to restore a license or registration, but as a condition the board may impose disciplinary or corrective action.

Subd. 6. Temporary suspension of license for pharmacists. Allows the board, without a hearing, to temporarily suspend a pharmacist's license if the board finds the pharmacist has violated a statute or rule the board is empowered to enforce and continued practice by the pharmacist would create a serious risk of harm to the public. Requires the board to schedule a hearing on the matter to be held no later than 30 days after the issuance of the suspension order.

Subd. 7. Temporary suspension of license for pharmacist interns, pharmacy technicians, and controlled substance researchers. Allows the board, without a hearing, to temporarily suspend the registration of a pharmacist intern, pharmacy technician, or controlled substance researcher if the board finds the registrant has violated a statute or rule the board is empowered to enforce and continued practice would create a serious risk of harm to the public. Requires the board to schedule a hearing on the matter to be held no later than 30 days after the issuance of the suspension order.

Subd. 8. Temporary suspension of license for pharmacies, drug wholesalers, drug manufacturers, medical gas manufacturers and medical gas distributors. Allows the board, without a hearing, to temporarily suspend the license or registration of a listed facility if the board finds the licensee or registrant has violated a statute or rule the board is empowered to enforce and continued operation of the facility would create a serious risk of harm to the public. Requires the board to schedule a hearing on the matter to be held no later than 30 days after the issuance of the suspension order.

Subd. 9. Evidence. Allows a copy of a judgment or proceeding under seal of the court administrator or of the administrative agency entering the judgment to be admissible as evidence in certain proceedings.

Subd. 10. Mental examination; access to medical data. Paragraph (a) allows the board to require a regulated person to undergo a mental or physical examination when the board has probable cause to believe the person is unable to practice by reason of illness, substance use, or mental illness.

Paragraph (b) allows the board access to a regulated person's medical or other health data, without the person's consent, if the board has probable cause to believe the

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person is unable to practice due to illness, substance use, or mental illness. Classifies any data obtained as private data.

Subd. 11. Tax clearance certificate. Bars the board from issuing or renewing a license or registration if the commissioner of revenue notifies the board and the regulated person that the regulated person owes the state $500 or more in delinquent taxes. Allows the board to issue or renew the license or registration when the commissioner of revenue issues a tax clearance certificate.

Allows the applicant or regulated person to request a contested case hearing.

Requires applicants and regulated persons to include their Social Security number and Minnesota business identification number on all license applications.

Subd. 12. Limitation. Requires the board to commence proceedings against a regulated person or facility within seven years of the commission of the offense, except for alleged violations of knowingly providing false or misleading information directly related to the care of a patient.

4 Reporting obligations. Creates § 151.072.

Subd. 1. Permission to report. Allows any person who has knowledge of conduct that may be grounds for disciplinary action to make a report to the board.

Subd. 2. Pharmacies. Requires pharmacies to report to the board any disciplinary action taken against a pharmacist, pharmacist intern, or pharmacy technician. Failure to report is a basis for disciplinary action against the facility.

Subd. 3. Licensees and registrants of the board. Requires regulated persons to report to the board personal knowledge of any conduct by another regulated person that may be grounds for disciplinary action. Failure to report is a basis for disciplinary action.

Subd. 4. Courts. Requires the court administrator to notify the board of any judgment or other determination by the court that a licensee or registrant is mentally ill, mentally incompetent, guilty of a felony, guilty of a violation of federal or state narcotics laws, guilty of Medicare or Medicaid fraud; or the court appoints a guardian or civilly commits the regulated person.

Subd. 5. Self-reporting. Requires regulated individuals to report any personal action that would require a report to be filed pursuant to subdivisions 2 to 4.

Subd. 6. Deadlines; forms. Requires reports to be submitted within 30 days of the reportable event. Permits the boards to provide forms for the submission of reports.

Subd. 7. Subpeonas. Allows the board to issue subpoenas for records required by subdivisions 2 to 5 or any related documents.

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5 **Immunity.** Creates § 151.073.

Subd. 1. Reporting. Provides immunity from civil or criminal liability for any person, health care facility, business, or organization that makes a good faith report to the board alleging violations of this chapter. Classifies reports as investigative data.

Subd. 2. Investigation. Provides immunity from civil and criminal liability for any board member, board employee, or person who, within the scope of their duties, is participating or testifying regarding violations of this chapter. Individuals who maintain records or make reports regarding adverse health care events are immune from criminal and civil liability.

6 **Licensee or registrant cooperation.** Creates § 151.074. Requires anyone regulated by the board who is the subject of an investigation to cooperate fully with the board's investigation.

7 **Disciplinary record on judicial review.** Creates § 151.075. Requires the reviewing court to seal the administrative record, except for the board's final decision.

8 **Records of prescriptions.** Amends § 151.211.

Subd. 1. Retention of prescription drug orders. Requires prescription drug orders to be retained at the location from which the drug was dispensed for at least two years.

Subd. 2. Refill requirements. Allows drug orders to be refilled with the consent of the prescriber and in accordance with laws and rules. Requires the date of refill to be noted and initialed by the pharmacist, intern or practitioner who refills the prescription.

9 **Compounding.** Creates § 151.251.

Subd. 1. Exemption from manufacturing licensure requirements. Provides that a pharmacist in a pharmacy or a practitioner who are engaged in extemporaneous or anticipatory compounding or compounding not done pursuant to a prescription order are exempt from manufacturing license requirements.

Subd. 2. Compounded drug. Allows a pharmacist or practitioner to compound a drug product under specified conditions:

- the drug product must be compounded from bulk drug substances that meet listed requirements;
- ingredients, other than bulk drug substance, must comply with specified standards;
- the drug products do not appear on the federal DHHS list of drug products withdrawn or removed from the market;
- the drug products are not essentially copies of commercially available drug products; and

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- the drug product has not been identified as one that presents demonstrable difficulties for compounding such that there is an adverse effect on the safety or effectiveness of the drug product.

Subd. 3. Exception. Provides that this section does not apply to compounded PET drugs or radiopharmaceuticals.

10 **Outsourcing facility.** Amends § 151.252, by adding subd. 1a. Requires any person seeking to act as an outsourcing facility to apply and obtain a license from the board and pay the applicable manufacturer licensing fee. Requires the facility to provide the board with proof that the outsourcing facility is registered with the FDA and in compliance with all laws and rules. Requires facilities physically located in other states to be licensed or registered in that state. Requires a separate license for each outsourcing facility. Requires the facility to pass an inspection conducted by a representative of the board.

11 **Exceptions.** Amends § 151.26. States that the exceptions provided in this section do not apply to any compound or substance that is not approved for human consumption by the FDA or by Minnesota law that induces an effect similar to that of a Schedule I or II controlled substance, regardless of whether the substance is marketed for human consumption.

12 **Prohibited acts.** Amends § 151.34 Adds that it is unlawful to sell any compound or substance that is not approved for human consumption by the FDA or by Minnesota law that induces an effect similar to that of a Schedule I or II controlled substance, regardless of whether the substance is marketed for human consumption.

13 **Drugs, adulteration.** Amends § 151.35. Provides that a drug shall be considered adulterated if it is produced in a facility that was not registered by the FDA or licensed by the board.

14 **After January 1, 1983.** Amends § 151.361, subd. 2. Strikes obsolete language related to drugs purchased prior to January 1, 1983, for resale.

15 **Legend drugs, who may prescribe, possess.** Amends § 151.37, as amended by Laws 2013, ch. 43, § 30; Laws 2013, ch. 55, § 2; and Laws 2013, ch. 108, art. 10, § 5. Makes technical changes to reflect updated definitions in this chapter. Modifies subdivision 4 to add that a pharmacy may compound drugs for research studies as allowed in this subdivision in compliance with specified standards. Adds the following subdivisions:

Subd. 10a. Emergency use authorizations. Adds subdivision 10a. Allows entities specifically tasked in a public health response plan to perform critical functions to purchase, possess, and use legend drugs.

Subd. 11. Exclusion for health care educational programs. Rewrites subdivision 11. Allows accredited public and private postsecondary schools to possess legend drugs that are not controlled substances when the school is preparing students for employment in the health care field and the drugs are used in the course of instruction.

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16 **Definitions.** Amends § 151.44. Strikes the definition of "manufacturer" and substitutes a cross-reference the term as it is defined in section 15.01, subd. 14b.

17 Amends § 151.58, subd. 2. Strikes "community behavioral health hospital" from the definition of a health care facility.

18 **Authorization.** Amends § 151.58, subd. 3. Clarifies that a pharmacy filling prescriptions for patients in a health care facility must have its the policies and procedures approved by the board.

19 **Operation of automated drug distribution systems.** Amends § 151.58, subd. 5. Clarifies the role of a pharmacist employed at a central services pharmacy in the operation of an automated drug distribution system.

20 **Schedule I.** Amends Minnesota Statutes 2013 Supplement § 152.02, subd. 2. Adds several synthetic drugs to the Schedule I list.

21 **Board of Pharmacy; expedited scheduling of additional substances.** Amends § 152.02, subd. 8b. This subdivision currently allows the board, using the expedited rulemaking process, to add a substance to Schedule I if specified conditions are met. It requires the board to notify the legislature of the action so that the legislature has an opportunity to ratify the action. It also provides that the scheduling of the substance expires the day after legislative adjournment unless the legislature ratifies the law.

The proposed amendment strikes language requiring notification to the legislature and would allow the board to add a substance to Schedule I through the expedited rulemaking process.