SENATE
STATE OF MINNESOTA
EIGHTY-NINTH SESSION

S.F. No. 567

(SENATE AUTHORS: HOFFMAN and Rosen)

DATE	D-PG	OFFICIAL STATUS
02/05/2015	212	Introduction and first reading Referred to Health, Human Services and Housing
03/26/2015		Comm report: To pass as amended and re-refer to Finance

A bill for an act

relating to health; expanding the use of automated drug distribution systems; modifying the amount of over-the-counter medications covered by medical assistance if dispensed by an automated drug distribution system; amending Minnesota Statutes 2014, sections 151.58, subdivisions 2, 5; 256B.0625, subdivision 13.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

Section 1. Minnesota Statutes 2014, section 151.58, subdivision 2, is amended to read:

Subd. 2. **Definitions.** For purposes of this section only, the terms defined in this subdivision have the meanings given.

(a) "Automated drug distribution system" or "system" means a mechanical system approved by the board that performs operations or activities, other than compounding or administration, related to the storage, packaging, or dispensing of drugs, and collects, controls, and maintains all required transaction information and records.

(b) "Health care facility" means a nursing home licensed under section 144A.02; a housing with services establishment registered under section 144D.01, subdivision 4, in which a home provider licensed under chapter 144A is providing centralized storage of medications; a board and care home licensed under section 144.56 that is providing centralized storage of medications; or a Minnesota sex offender program facility operated by the Department of Human Services.

(c) "Managing pharmacy" means a pharmacy licensed by the board that controls and is responsible for the operation of an automated drug distribution system.

Sec. 2. Minnesota Statutes 2014, section 151.58, subdivision 5, is amended to read:

Subd. 5. **Operation of automated drug distribution systems.** (a) The managing pharmacy and the pharmacist in charge are responsible for the operation of an automated drug distribution system.

(b) Access to an automated drug distribution system must be limited to pharmacy and nonpharmacy personnel authorized to procure drugs from the system, except that field service technicians may access a system located in a health care facility for the purposes of servicing and maintaining it while being monitored either by the managing pharmacy, or a licensed nurse within the health care facility. In the case of an automated drug distribution system that is not physically located within a licensed pharmacy, access for the purpose of procuring drugs shall be limited to licensed nurses. Each person authorized to access the system must be assigned an individual specific access code. Alternatively, access to the system may be controlled through the use of biometric identification procedures. A policy specifying time access parameters, including time-outs, logoffs, and lockouts, must be in place.

(c) For the purposes of this section only, the requirements of section 151.215 are met if the following clauses are met:

(1) a pharmacist employed by and working at the managing pharmacy, or at a pharmacy that is acting as a central services pharmacy for the managing pharmacy, pursuant to Minnesota Rules, part 6800.4075, must review, interpret, and approve all prescription drug orders before any drug is distributed from the system to be administered to a patient. A pharmacy technician may perform data entry of prescription drug orders provided that a pharmacist certifies the accuracy of the data entry before the drug can be released from the automated drug distribution system. A pharmacist employed by and working at the managing pharmacy, or at a pharmacy under the same ownership as the managing pharmacy, must certify the accuracy of the filling of any cassettes, canisters, or other containers that contain drugs that will be loaded into the automated drug distribution system; and

(2) when the automated drug dispensing system is located and used within the managing pharmacy, a pharmacist must personally supervise and take responsibility for all packaging and labeling associated with the use of an automated drug distribution system.

(d) Access to drugs when a pharmacist has not reviewed and approved the prescription drug order is permitted only when a formal and written decision to allow such access is issued by the pharmacy and the therapeutics committee or its equivalent. The committee must specify the patient care circumstances in which such access is allowed, the drugs that can be accessed, and the staff that are allowed to access the drugs.

(e) In the case of an automated drug distribution system that does not utilize bar coding in the loading process, the loading of a system located in a health care facility may be performed by a pharmacy technician, so long as the activity is continuously supervised, through a two-way audiovisual system by a pharmacist on duty within the managing pharmacy. In the case of an automated drug distribution system that utilizes bar coding in the loading process, the loading of a system located in a health care facility may be performed by a pharmacy technician or a licensed nurse, provided that the managing pharmacy retains an electronic record of loading activities.

(f) The automated drug distribution system must be under the supervision of a pharmacist. The pharmacist is not required to be physically present at the site of the automated drug distribution system if the system is continuously monitored electronically by the managing pharmacy. A pharmacist on duty within a pharmacy licensed by the board must be continuously available to address any problems detected by the monitoring or to answer questions from the staff of the health care facility. The licensed pharmacy may be the managing pharmacy or a pharmacy which is acting as a central services pharmacy, pursuant to Minnesota Rules, part 6800.4075, for the managing pharmacy.

Sec. 3. Minnesota Statutes 2014, section 256B.0625, subdivision 13, is amended to read:

Subd. 13. **Drugs.** (a) Medical assistance covers drugs, except for fertility drugs when specifically used to enhance fertility, if prescribed by a licensed practitioner and dispensed by a licensed pharmacist, by a physician enrolled in the medical assistance program as a dispensing physician, or by a physician, physician assistant, or a nurse practitioner employed by or under contract with a community health board as defined in section 145A.02, subdivision 5, for the purposes of communicable disease control.

(b) The dispensed quantity of a prescription drug must not exceed a 34-day supply, unless authorized by the commissioner.

(c) For the purpose of this subdivision and subdivision 13d, an "active pharmaceutical ingredient" is defined as a substance that is represented for use in a drug and when used in the manufacturing, processing, or packaging of a drug becomes an active ingredient of the drug product. An "excipient" is defined as an inert substance used as a diluent or vehicle for a drug. The commissioner shall establish a list of active pharmaceutical ingredients and excipients which are included in the medical assistance formulary. Medical assistance covers selected active pharmaceutical ingredients and excipients used in compounded prescriptions when the compounded combination is specifically approved by the commissioner or when a commercially available product:

(1) is not a therapeutic option for the patient;

(2) does not exist in the same combination of active ingredients in the same strengths as the compounded prescription; and

(3) cannot be used in place of the active pharmaceutical ingredient in the compounded prescription.

(d) Medical assistance covers the following over-the-counter drugs when prescribed by a licensed practitioner or by a licensed pharmacist who meets standards established by the commissioner, in consultation with the board of pharmacy: antacids, acetaminophen, family planning products, aspirin, insulin, products for the treatment of lice, vitamins for adults with documented vitamin deficiencies, vitamins for children under the age of seven and pregnant or nursing women, and any other over-the-counter drug identified by the commissioner, in consultation with the formulary committee, as necessary, appropriate, and cost-effective for the treatment of certain specified chronic diseases, conditions, or disorders, and this determination shall not be subject to the requirements of chapter 14. A pharmacist may prescribe over-the-counter medications as provided under this paragraph for purposes of receiving reimbursement under Medicaid. When prescribing over-the-counter drugs under this paragraph, licensed pharmacists must consult with the recipient to determine necessity, provide drug counseling, review drug therapy for potential adverse interactions, and make referrals as needed to other health care professionals. Over-the-counter medications must be dispensed in a quantity that is the ~~lower~~ lowest of: (1) the number of dosage units contained in the manufacturer's original package; ~~and~~ (2) the number of dosage units required to complete the patient's course of therapy; or (3) if applicable, the number of dosage units dispensed from a system using retrospective billing, including, but not limited to, an automated drug dispensing system as defined in section 151.58.

(e) Effective January 1, 2006, medical assistance shall not cover drugs that are coverable under Medicare Part D as defined in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108-173, section 1860D-2(e), for individuals eligible for drug coverage as defined in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108-173, section 1860D-1(a)(3)(A). For these individuals, medical assistance may cover drugs from the drug classes listed in United States Code, title 42, section 1396r-8(d)(2), subject to this subdivision and subdivisions 13a to 13g, except that drugs listed in United States Code, title 42, section 1396r-8(d)(2)(E), shall not be covered.

(f) Medical assistance covers drugs acquired through the federal 340B Drug Pricing Program and dispensed by 340B covered entities and ambulatory pharmacies under common ownership of the 340B covered entity. Medical assistance does not cover drugs

acquired through the federal 340B Drug Pricing Program and dispensed by 340B contract pharmacies.