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	1387a	Comm report: To pass as amended and re-refer to Finance See SF1458, Art. 9, Sec. 11-12, 14-15

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, subdivisions 13, 13e.

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 boarding care home licensed under sections 144.50 to 144.58 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 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, unless the filled cassettes, canisters, or containers have been provided by a repackager registered with the U.S. Food and Drug Administration and licensed by the board as a manufacturer; 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, as provided under subdivision 13e, paragraph (b).

(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.

EFFECTIVE DATE. This section is effective January 1, 2016, or upon federal approval, whichever is later.

Sec. 4. Minnesota Statutes 2014, section 256B.0625, subdivision 13e, is amended to read:

Subd. 13e. **Payment rates.** (a) The basis for determining the amount of payment shall be the lower of the actual acquisition costs of the drugs or the maximum allowable cost by the commissioner plus the fixed dispensing fee; or the usual and customary price charged to the public. The amount of payment basis must be reduced to reflect all discount amounts applied to the charge by any provider/insurer agreement or contract for submitted charges to medical assistance programs. The net submitted charge may not be greater than the patient liability for the service. The pharmacy dispensing fee shall be $3.65 for legend prescription drugs, except that the dispensing fee for intravenous solutions which must be compounded by the pharmacist shall be $8 per bag, $14 per bag for cancer chemotherapy products, and $30 per bag for total parenteral nutritional products dispensed in one liter quantities, or $44 per bag for total parenteral nutritional products dispensed in quantities greater than one liter. The pharmacy dispensing fee for over the counter drugs shall be $3.65, except that the fee shall be $1.31 for retrospectively billing pharmacies when billing for quantities less than the number of units contained in the manufacturer's original package. Actual acquisition cost includes quantity and other special discounts except time and cash discounts. The actual acquisition cost of a drug shall be estimated by the commissioner at wholesale acquisition cost plus four percent for independently owned pharmacies located in a designated rural area within Minnesota, and at wholesale acquisition cost plus two percent for all other pharmacies. A pharmacy is "independently owned" if it is one of four or fewer pharmacies under the same ownership nationally. A "designated rural area" means an area defined as a small rural area or isolated rural area according to the four-category classification of the Rural Urban Commuting Area system developed for the United States Health Resources and Services Administration. Effective January 1, 2014, the actual acquisition cost of a drug acquired through the federal 340B Drug Pricing Program shall be estimated by the commissioner at wholesale acquisition cost minus 40 percent. Wholesale acquisition cost is defined as the manufacturer's list price for a drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates, or reductions in price, for the most recent month for which information is available, as reported in wholesale price guides or

other publications of drug or biological pricing data. The maximum allowable cost of a multisource drug may be set by the commissioner and it shall be comparable to, but no higher than, the maximum amount paid by other third-party payors in this state who have maximum allowable cost programs. Establishment of the amount of payment for drugs shall not be subject to the requirements of the Administrative Procedure Act.

(b) Pharmacies dispensing prescriptions to residents of long-term care facilities using an automated drug distribution system meeting the requirements of section 151.58, or a packaging system meeting the packaging standards set forth in Minnesota Rules, part 6800.2700, that govern the return of unused drugs to the pharmacy for reuse, may employ retrospective billing for prescription drugs dispensed to long-term-care facility residents. A retrospectively billing pharmacy must submit a claim only for the quantity of medication used by the enrolled recipient during the defined billing period. A retrospectively billing pharmacy must use a billing period not less than one calendar month or 30 days.

(c) An additional dispensing fee of $.30 may be added to the dispensing fee paid to pharmacists for legend drug prescriptions dispensed to residents of long-term care facilities when a unit dose blister card system, approved by the department, is used. Under this type of dispensing system, the pharmacist must dispense a 30-day supply of drug. The National Drug Code (NDC) from the drug container used to fill the blister card must be identified on the claim to the department. The unit dose blister card containing the drug must meet the packaging standards set forth in Minnesota Rules, part 6800.2700, that govern the return of unused drugs to the pharmacy for reuse. ~~The~~ A pharmacy provider ~~will be~~ using packaging that meets the standards set forth in Minnesota Rules, part 6800.2700, is required to credit the department for the actual acquisition cost of all unused drugs that are eligible for reuse, unless the pharmacy is using retrospective billing. The commissioner may permit the drug clozapine to be dispensed in a quantity that is less than a 30-day supply.

~~(c)~~ (d) Whenever a maximum allowable cost has been set for a multisource drug, payment shall be the lower of the usual and customary price charged to the public or the maximum allowable cost established by the commissioner unless prior authorization for the brand name product has been granted according to the criteria established by the Drug Formulary Committee as required by subdivision 13f, paragraph (a), and the prescriber has indicated "dispense as written" on the prescription in a manner consistent with section 151.21, subdivision 2.

~~(d)~~ (e) The basis for determining the amount of payment for drugs administered in an outpatient setting shall be the lower of the usual and customary cost submitted by the provider, 106 percent of the average sales price as determined by the United States Department of Health and Human Services pursuant to title XVIII, section 1847a of the

federal Social Security Act, the specialty pharmacy rate, or the maximum allowable cost set by the commissioner. If average sales price is unavailable, the amount of payment must be lower of the usual and customary cost submitted by the provider, the wholesale acquisition cost, the specialty pharmacy rate, or the maximum allowable cost set by the commissioner. Effective January 1, 2014, the commissioner shall discount the payment rate for drugs obtained through the federal 340B Drug Pricing Program by 20 percent. The payment for drugs administered in an outpatient setting shall be made to the administering facility or practitioner. A retail or specialty pharmacy dispensing a drug for administration in an outpatient setting is not eligible for direct reimbursement.

~~(e)~~ (f) The commissioner may negotiate lower reimbursement rates for specialty pharmacy products than the rates specified in paragraph (a). The commissioner may require individuals enrolled in the health care programs administered by the department to obtain specialty pharmacy products from providers with whom the commissioner has negotiated lower reimbursement rates. Specialty pharmacy products are defined as those used by a small number of recipients or recipients with complex and chronic diseases that require expensive and challenging drug regimens. Examples of these conditions include, but are not limited to: multiple sclerosis, HIV/AIDS, transplantation, hepatitis C, growth hormone deficiency, Crohn's Disease, rheumatoid arthritis, and certain forms of cancer. Specialty pharmaceutical products include injectable and infusion therapies, biotechnology drugs, antihemophilic factor products, high-cost therapies, and therapies that require complex care. The commissioner shall consult with the formulary committee to develop a list of specialty pharmacy products subject to this paragraph. In consulting with the formulary committee in developing this list, the commissioner shall take into consideration the population served by specialty pharmacy products, the current delivery system and standard of care in the state, and access to care issues. The commissioner shall have the discretion to adjust the reimbursement rate to prevent access to care issues.

~~(f)~~ (g) Home infusion therapy services provided by home infusion therapy pharmacies must be paid at rates according to subdivision 8d.

EFFECTIVE DATE. This section is effective January 1, 2016, or upon federal approval, whichever is later.