SENATE
STATE OF MINNESOTA
EIGHTY-NINTH SESSION

S.F. No. 934

(SENATE AUTHORS: FRANZEN, Sheran, Rosen, Metzen and Marty)

DATE	D-PG	OFFICIAL STATUS
02/19/2015	358	Introduction and first reading Referred to Health, Human Services and Housing
03/16/2015	793a	Comm report: To pass as amended and re-refer to Commerce
03/19/2015	991a	Comm report: To pass as amended and re-refer to State and Local Government
03/23/2015	1093a	Comm report: To pass as amended and re-refer to Finance

A bill for an act

relating to health care coverage; modifying utilization review and prior authorization requirements for prescription drug coverage; requiring prescription drug benefit transparency and disclosure; establishing a prescription drug advisory council; requiring an annual report; amending Minnesota Statutes 2014, sections 62J.497, subdivisions 1, 3, 4; 62M.02, subdivisions 12, 14, 15, 17, by adding subdivisions; 62M.05, subdivisions 3a, 3b, 4; 62M.06, subdivisions 2, 3; 62M.07; 62M.09, subdivisions 3, 6; 62M.10, subdivision 7; 62M.11; 256B.0625, subdivision 13f; 256B.69, subdivision 6; proposing coding for new law in Minnesota Statutes, chapters 62M; 62Q.

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

Section 1. Minnesota Statutes 2014, section 62J.497, subdivision 1, is amended to read:

Subdivision 1. **Definitions.** For the purposes of this section, the following terms have the meanings given.

(a) "Backward compatible" means that the newer version of a data transmission standard would retain, at a minimum, the full functionality of the versions previously adopted, and would permit the successful completion of the applicable transactions with entities that continue to use the older versions.

(b) "Dispense" or "dispensing" has the meaning given in section 151.01, subdivision 30. Dispensing does not include the direct administering of a controlled substance to a patient by a licensed health care professional.

(c) "Dispenser" means a person authorized by law to dispense a controlled substance, pursuant to a valid prescription.

(d) "Electronic media" has the meaning given under Code of Federal Regulations, title 45, part 160.103.

(e) "E-prescribing" means the transmission using electronic media of prescription or prescription-related information between a prescriber, dispenser, pharmacy benefit

manager, or group purchaser, either directly or through an intermediary, including an e-prescribing network. E-prescribing includes, but is not limited to, two-way transmissions between the point of care and the dispenser and two-way transmissions related to eligibility, formulary, and medication history information.

(f) "Electronic prescription drug program" means a program that provides for e-prescribing.

(g) "Group purchaser" has the meaning given in section 62J.03, subdivision 6, but does not include workers' compensation plans or the medical component of automobile insurance coverage.

(h) "HL7 messages" means a standard approved by the standards development organization known as Health Level Seven.

(i) "National Provider Identifier" or "NPI" means the identifier described under Code of Federal Regulations, title 45, part 162.406.

(j) "NCPDP" means the National Council for Prescription Drug Programs, Inc.

(k) "NCPDP Formulary and Benefits Standard" means the National Council for Prescription Drug Programs Formulary and Benefits Standard, Implementation Guide, Version 1, Release 0, October 2005.

(l) "NCPDP SCRIPT Standard" means the National Council for Prescription Drug Programs Prescriber/Pharmacist Interface SCRIPT Standard, Implementation Guide Version 8, Release 1 (Version 8.1), October 2005, or the most recent standard adopted by the Centers for Medicare and Medicaid Services for e-prescribing under Medicare Part D as required by section 1860D-4(e)(4)(D) of the Social Security Act, and regulations adopted under it. The standards shall be implemented according to the Centers for Medicare and Medicaid Services schedule for compliance. Subsequently released versions of the NCPDP SCRIPT Standard may be used, provided that the new version of the standard is backward compatible to the current version adopted by the Centers for Medicare and Medicaid Services.

(m) "Pharmacy" has the meaning given in section 151.01, subdivision 2.

(n) "Prescriber" means a licensed health care practitioner, other than a veterinarian, as defined in section 151.01, subdivision 23.

(o) "Prescription-related information" means information regarding eligibility for drug benefits, medication history, or related health or drug information.

(p) "Provider" or "health care provider" has the meaning given in section 62J.03, subdivision 8.

(q) "Utilization review organization" has the meaning given in section 62M.02, subdivision 21.

Sec. 2. Minnesota Statutes 2014, section 62J.497, subdivision 3, is amended to read:

Subd. 3. **Standards for electronic prescribing.** (a) Prescribers and dispensers must use the NCPDP SCRIPT Standard for the communication of a prescription or prescription-related information. The NCPDP SCRIPT Standard shall be used to conduct the following transactions:

(1) get message transaction;

(2) status response transaction;

(3) error response transaction;

(4) new prescription transaction;

(5) prescription change request transaction;

(6) prescription change response transaction;

(7) refill prescription request transaction;

(8) refill prescription response transaction;

(9) verification transaction;

(10) password change transaction;

(11) cancel prescription request transaction; and

(12) cancel prescription response transaction.

(b) Providers, group purchasers, prescribers, and dispensers must use the NCPDP SCRIPT Standard for communicating and transmitting medication history information.

(c) Providers, group purchasers, prescribers, and dispensers must use the NCPDP Formulary and Benefits Standard for communicating and transmitting formulary and benefit information.

(d) Group purchasers and utilization review organizations must develop processes to ensure notification to prescribers upon denial of a claim for a prescribed drug that is not covered or is not included on the group purchaser's formulary. The process must provide a list of covered drugs from the same class or classes as the drug originally prescribed. If the NCPDP SCRIPT Standard or the NCPDP Formulary and Benefits Standard do not allow for the inclusion of this information, group purchasers and utilization review organizations must develop telephone, facsimile, or other secure electronic processes to communicate this information to the prescriber.

~~(d)~~ (e) Providers, group purchasers, prescribers, and dispensers must use the national provider identifier to identify a health care provider in e-prescribing or prescription-related transactions when a health care provider's identifier is required.

~~(e)~~ (f) Providers, group purchasers, prescribers, and dispensers must communicate eligibility information and conduct health care eligibility benefit inquiry and response transactions according to the requirements of section 62J.536.

Sec. 3. Minnesota Statutes 2014, section 62J.497, subdivision 4, is amended to read:

Subd. 4. **Development and use of uniform formulary exception form.** (a) The commissioner of health, in consultation with the Minnesota Administrative Uniformity Committee, shall develop by July 1, 2009, a uniform formulary exception form that allows health care providers to request exceptions from group purchaser formularies using a uniform form. Upon development of the form, all health care providers must submit requests for formulary exceptions using the uniform form, and all group purchasers must accept this form from health care providers.

(b) ~~No later than January 1, 2011,~~ The uniform formulary exception form must be accessible and submitted by health care providers, and accepted and processed by group purchasers, through secure electronic transmissions.

(c) Health care providers, group purchasers, prescribers, dispensers, and utilization review organizations using paper forms for prescription drug prior authorization or for medical exception requests as defined in section 62Q.83, subdivision 5, must only use the uniform formulary exception form.

Sec. 4. Minnesota Statutes 2014, section 62M.02, is amended by adding a subdivision to read:

Subd. 10a. **Drug.** "Drug" has the meaning given in section 151.01, subdivision 5.

Sec. 5. Minnesota Statutes 2014, section 62M.02, is amended by adding a subdivision to read:

Subd. 11a. **Formulary.** "Formulary" has the meaning given in section 62Q.83, subdivision 1.

Sec. 6. Minnesota Statutes 2014, section 62M.02, subdivision 12, is amended to read:

Subd. 12. **Health benefit plan.** "Health benefit plan" means a policy, contract, or certificate issued by a health plan company for the coverage of medical, dental, prescription drug, or hospital benefits. A health benefit plan does not include coverage that is:

(1) limited to disability or income protection coverage;

(2) automobile medical payment coverage;

(3) supplemental to liability insurance;

(4) designed solely to provide payments on a per diem, fixed indemnity, or nonexpense incurred basis;

(5) credit accident and health insurance issued under chapter 62B;

(6) blanket accident and sickness insurance as defined in section 62A.11;

(7) accident only coverage issued by a licensed and tested insurance agent; or

(8) workers' compensation.

Sec. 7. Minnesota Statutes 2014, section 62M.02, subdivision 14, is amended to read:

Subd. 14. **Outpatient services.** "Outpatient services" means procedures or services performed on a basis other than as an inpatient, and includes obstetrical, psychiatric, chemical dependency, dental, prescription drug, and chiropractic services.

Sec. 8. Minnesota Statutes 2014, section 62M.02, is amended by adding a subdivision to read:

Subd. 14b. **Prescription.** "Prescription" has the meaning given in section 151.01, subdivision 16a.

Sec. 9. Minnesota Statutes 2014, section 62M.02, is amended by adding a subdivision to read:

Subd. 14c. **Prescription drug order.** "Prescription drug order" has the meaning given in section 151.01, subdivision 16.

Sec. 10. Minnesota Statutes 2014, section 62M.02, subdivision 15, is amended to read:

Subd. 15. **Prior authorization.** "Prior authorization" means utilization review conducted prior to the delivery of a service, including an outpatient service. Prior authorization includes, but is not limited to, preadmission review, pretreatment review, quantity limits, step therapy, utilization, and case management. Prior authorization also includes any utilization review organization's requirement that an enrollee or provider notify the utilization review organization prior to providing a service, including an outpatient service.

Sec. 11. Minnesota Statutes 2014, section 62M.02, subdivision 17, is amended to read:

Subd. 17. **Provider.** "Provider" means a licensed health care facility, physician, pharmacist, or other health care professional that delivers health care services to an enrollee.

Sec. 12. Minnesota Statutes 2014, section 62M.02, is amended by adding a subdivision to read:

Subd. 18a. **Quantity limit.** "Quantity limit" means a limit on the number of doses of a prescription drug that are covered during a specific time period.

Sec. 13. Minnesota Statutes 2014, section 62M.02, is amended by adding a subdivision to read:

Subd. 19a. **Step therapy.** "Step therapy" means clinical practice or other evidence-based protocols or requirements that specify the sequence in which different prescription drugs for a given medical condition are to be used by an enrollee before a drug prescribed by a provider is covered.

Sec. 14. Minnesota Statutes 2014, section 62M.05, subdivision 3a, is amended to read:

Subd. 3a. **Standard review determination.** (a) Notwithstanding subdivision 3b, an initial determination on all requests for utilization review must be communicated to the provider and enrollee in accordance with this subdivision within ~~ten~~ five business days of the request, provided that all information reasonably necessary to make a determination on the request has been made available to the utilization review organization.

(b) When an initial determination is made to certify, notification must be provided promptly by telephone to the provider. The utilization review organization shall send written notification to the provider or shall maintain an audit trail of the determination and telephone notification. For purposes of this subdivision, "audit trail" includes documentation of the telephone notification, including the date; the name of the person spoken to; the enrollee; the service, procedure, or admission certified; and the date of the service, procedure, or admission. If the utilization review organization indicates certification by use of a number, the number must be called the "certification number." For purposes of this subdivision, notification may also be made by facsimile to a verified number or by electronic mail to a secure electronic mailbox. These electronic forms of notification satisfy the "audit trail" requirement of this paragraph.

(c) When an initial determination is made not to certify, notification must be provided by telephone, by facsimile to a verified number, or by electronic mail to a secure electronic mailbox within one working day after making the determination to the attending health care professional and hospital as applicable. Written notification must also be sent to the hospital as applicable and attending health care professional if notification occurred by telephone. For purposes of this subdivision, notification may be made by facsimile to a verified number or by electronic mail to a secure electronic mailbox. Written notification must be sent to the enrollee and may be sent by United States mail, facsimile to a verified number, or by electronic mail to a secure mailbox. The written notification must include the principal reason or reasons for the determination and the process for initiating an appeal of the determination. Upon request, the utilization review organization shall provide the provider or enrollee with the criteria used to determine the necessity, appropriateness,

and efficacy of the health care service and identify the database, professional treatment parameter, or other basis for the criteria. Reasons for a determination not to certify may include, among other things, the lack of adequate information to certify after a reasonable attempt has been made to contact the provider or enrollee.

(d) When an initial determination is made not to certify, the written notification must inform the enrollee and the attending health care professional of the right to submit an appeal to the internal appeal process described in section 62M.06 and the procedure for initiating the internal appeal. The written notice shall be provided in a culturally and linguistically appropriate manner consistent with the provisions of the Affordable Care Act as defined under section 62A.011, subdivision 1a.

Sec. 15. Minnesota Statutes 2014, section 62M.05, subdivision 3b, is amended to read:

Subd. 3b. **Expedited review determination.** (a) An expedited initial determination must be utilized if the attending health care professional believes that an expedited determination is warranted.

(b) Notification of an expedited initial determination to either certify or not to certify must be provided to the hospital, the attending health care professional, and the enrollee as expeditiously as the enrollee's medical condition requires, but no later than ~~72~~ 36 hours from the initial request. When an expedited initial determination is made not to certify, the utilization review organization must also notify the enrollee and the attending health care professional of the right to submit an appeal to the expedited internal appeal as described in section 62M.06 and the procedure for initiating an internal expedited appeal.

Sec. 16. Minnesota Statutes 2014, section 62M.05, subdivision 4, is amended to read:

Subd. 4. **Failure to provide necessary information.** A utilization review organization must have written procedures to address the failure of a provider or enrollee to provide the necessary information for review, and to address processes by which the utilization review organization must track and manage review requests and documentation submitted by providers or enrollees. If the enrollee or provider will not release the necessary information to the utilization review organization, the utilization review organization may deny certification in accordance with its own policy or the policy described in the health benefit plan. If a utilization review organization fails to meet the timelines in subdivision 3a or 3b for a completed review request, or fails to notify the provider that information needed to conduct the review is incomplete, or if a utilization review organization fails to properly maintain submitted records for which the provider or enrollee has documentation of submission, the service shall be deemed approved.

Sec. 17. Minnesota Statutes 2014, section 62M.06, subdivision 2, is amended to read:

Subd. 2. **Expedited appeal.** (a) When an initial determination not to certify a health care service is made prior to or during an ongoing service requiring review and the attending health care professional believes that the determination warrants an expedited appeal, the utilization review organization must ensure that the enrollee and the attending health care professional have an opportunity to appeal the determination over the telephone on an expedited basis. In such an appeal, the utilization review organization must ensure reasonable access to its consulting physician or health care provider.

(b) The utilization review organization shall notify the enrollee and attending health care professional by telephone of its determination on the expedited appeal as expeditiously as the enrollee's medical condition requires, but no later than ~~72~~ 36 hours after receiving the expedited appeal.

(c) If the determination not to certify is not reversed through the expedited appeal, the utilization review organization must include in its notification the right to submit the appeal to the external appeal process described in section 62Q.73 and the procedure for initiating the process. This information must be provided in writing to the enrollee and the attending health care professional as soon as practical.

Sec. 18. Minnesota Statutes 2014, section 62M.06, subdivision 3, is amended to read:

Subd. 3. **Standard appeal.** The utilization review organization must establish procedures for appeals to be made either in writing or by telephone.

(a) A utilization review organization shall notify in writing the enrollee, attending health care professional, and claims administrator of its determination on the appeal within ~~30~~ 15 days upon receipt of the notice of appeal. If the utilization review organization cannot make a determination within ~~30~~ 15 days due to circumstances outside the control of the utilization review organization, the utilization review organization may take up to ~~14~~ ten additional days to notify the enrollee, attending health care professional, and claims administrator of its determination. If the utilization review organization takes any additional days beyond the initial ~~30-day~~ 15-day period to make its determination, it must inform the enrollee, attending health care professional, and claims administrator, in advance, of the extension and the reasons for the extension.

(b) The documentation required by the utilization review organization may include copies of part or all of the medical record and a written statement from the attending health care professional.

(c) Prior to upholding the initial determination not to certify for clinical reasons, the utilization review organization shall conduct a review of the documentation by a physician who did not make the initial determination not to certify.

(d) The process established by a utilization review organization may include defining a period within which an appeal must be filed to be considered. The time period must be communicated to the enrollee and attending health care professional when the initial determination is made.

(e) An attending health care professional or enrollee who has been unsuccessful in an attempt to reverse a determination not to certify shall, consistent with section 72A.285, be provided the following:

(1) a complete summary of the review findings;

(2) qualifications of the reviewers, including any license, certification, or specialty designation; and

(3) the relationship between the enrollee's diagnosis and the review criteria used as the basis for the decision, including the specific rationale for the reviewer's decision.

(f) In cases of appeal to reverse a determination not to certify for clinical reasons, the utilization review organization must ensure that a physician of the utilization review organization's choice in the same or a similar specialty as typically manages the medical condition, procedure, or treatment under discussion is reasonably available to review the case.

(g) If the initial determination is not reversed on appeal, the utilization review organization must include in its notification the right to submit the appeal to the external review process described in section 62Q.73 and the procedure for initiating the external process.

Sec. 19. Minnesota Statutes 2014, section 62M.07, is amended to read:

62M.07 PRIOR AUTHORIZATION OF SERVICES.

(a) Utilization review organizations conducting prior authorization of services must have written standards that meet at a minimum the following requirements:

(1) written procedures and criteria used to determine whether care is appropriate, reasonable, or medically necessary;

(2) a system for providing prompt notification of its determinations to enrollees and providers and for notifying the provider, enrollee, or enrollee's designee of appeal procedures under clause (4);

(3) compliance with section 62M.05, subdivisions 3a and 3b, regarding time frames for approving and disapproving prior authorization requests;

(4) written procedures for appeals of denials of prior authorization which specify the responsibilities of the enrollee and provider, and which meet the requirements of sections 62M.06 and 72A.285, regarding release of summary review findings; and

(5) procedures to ensure confidentiality of patient-specific information, consistent with applicable law.

(b) No utilization review organization, health plan company, or claims administrator may conduct or require prior authorization of emergency confinement or emergency treatment. The enrollee or the enrollee's authorized representative may be required to notify the health plan company, claims administrator, or utilization review organization as soon after the beginning of the emergency confinement or emergency treatment as reasonably possible.

(c) If prior authorization for a health care service is required, the utilization review organization, health plan company, or claim administrator must allow providers to submit requests for prior authorization of the health care services without unreasonable delay by telephone, facsimile, or voice mail or through an electronic mechanism 24 hours a day, seven days a week. This paragraph does not apply to dental service covered under MinnesotaCare, general assistance medical care, or medical assistance.

(d) Any authorization for a prescription drug must remain valid for the duration of an enrollee's contract term, provided the drug continues to be prescribed for a patient with a condition that requires ongoing medication therapy, provided the drug has not otherwise been deemed unsafe by the Food and Drug Administration, has not been withdrawn by the manufacturer or the Food and Drug Administration, or provided no independent source of research, clinical guidelines, or evidence-based standards has issued drug-specific warnings or recommended changes in drug usage.

(e) No utilization review organization, health plan company, or claims administrator may impose step therapy requirements for enrollees currently taking a prescription drug, as substantiated from available claims data or provider documentation, in one of the following classes: (1) immunosuppressants; (2) antidepressants; (3) antipsychotics; (4) anticonvulsants; (5) antiretrovirals; or (6) antineoplastics.

Sec. 20. Minnesota Statutes 2014, section 62M.09, subdivision 3, is amended to read:

Subd. 3. **Physician reviewer involvement.** (a) A physician must review all cases in which the utilization review organization has concluded that a determination not to certify for clinical reasons is appropriate.

(b) The physician conducting the review must be licensed in this state. ~~This paragraph does not apply to reviews conducted in connection with policies issued by a~~

~~health plan company that is assessed less than three percent of the total amount assessed by the Minnesota Comprehensive Health Association.~~

(c) The physician should be reasonably available by telephone to discuss the determination with the attending health care professional.

(d) This subdivision does not apply to outpatient mental health or substance abuse services governed by subdivision 3a.

Sec. 21. Minnesota Statutes 2014, section 62M.09, subdivision 6, is amended to read:

Subd. 6. **Physician consultants.** A utilization review organization must use physician consultants in the appeal process described in section 62M.06, subdivision 3. The physician consultants must be licensed in this state and must be board certified by the American Board of Medical Specialists or the American Board of Osteopathy.

Sec. 22. Minnesota Statutes 2014, section 62M.10, subdivision 7, is amended to read:

Subd. 7. **Availability of criteria.** Upon request, a utilization review organization shall provide to an enrollee, a provider, and the commissioner of commerce the written clinical criteria used to determine the medical necessity, appropriateness, and efficacy of a procedure or service and identify the database, professional treatment guideline, or other basis for the criteria.

Sec. 23. Minnesota Statutes 2014, section 62M.11, is amended to read:

62M.11 COMPLAINTS TO COMMERCE OR HEALTH.

Notwithstanding the provisions of sections 62M.01 to 62M.16, an enrollee or provider may file a complaint regarding compliance with the requirements of this chapter or regarding a determination not to certify directly to the commissioner responsible for regulating the utilization review organization.

Sec. 24. **[62M.17] REPORTING.**

Utilization review organizations must annually report to the commissioner of health, on the forms and in the manner specified by the commissioner, the following information:

(1) for medical exception requests, the 25 most frequently requested drugs by exception type, including lack of available clinical alternative, ineffective formulary drug, and dosage limits; and

(2) for prescription drug prior authorization requests:

(i) the number and rate of initial approvals by commercial product and by prepaid medical assistance product types;

(ii) the number and rate of standard appeal approvals by commercial product and by prepaid medical assistance product types;

(iii) the number and rate of expedited appeal approvals by commercial product and by prepaid medical assistance product types;

(iv) for standard reviews, the range and average time from receipt of completed request to notification of decision;

(v) for expedited reviews, the range and average time from receipt of completed request to notification of decision;

(vi) for standard appeals, the range and average time from receipt of completed request to notification of decision; and

(vii) for expedited appeals, the range and average time from receipt of completed request to notification of decision.

Sec. 25. **[62Q.83] PRESCRIPTION DRUG BENEFIT TRANSPARENCY AND MANAGEMENT.**

Subdivision 1. **Definitions.** (a) For purposes of this section, the following terms have the meaning given them.

(b) "Drug" has the meaning given in section 151.01, subdivision 5.

(c) "Formulary" means a list of prescription drugs that have been developed by clinical and pharmacy experts and represents the health plan company's medically appropriate and cost-effective prescription drugs approved for use.

(d) "Health plan company" has the meaning given in section 62Q.01, subdivision 4, and includes an entity that performs pharmacy benefits management for the health plan company. For purposes of this definition, "pharmacy benefits management" means the administration or management of prescription drug benefits provided by the health plan company for the benefit of its enrollees and may include, but is not limited to, procurement of prescription drugs, clinical formulary development and management services, claims processing, and rebate contracting and administration.

(e) "Prescription" has the meaning given in section 151.01, subdivision 16a.

Subd. 2. **Prescription drug benefit disclosure.** (a) A health plan company that provides prescription drug benefit coverage and uses a formulary must make its formulary and related benefit information available by electronic means and, upon request, in writing, at least 30 days prior to annual renewal dates.

(b) Formularies must be organized and disclosed consistent with the most recent version of the United States Pharmacopeia's (USP) Model Guidelines.

(c) For each item or category of items on the formulary, the specific enrollee benefit terms must be identified, including enrollee cost-sharing and expected out-of-pocket costs.

Subd. 3. **Formulary changes.** (a) Once a formulary has been established, a health plan company may, at any time during the enrollee's contract year:

(1) expand its formulary by adding drugs to the formulary;

(2) reduce co-payments or co-insurance; or

(3) move a drug to a benefit category that reduces an enrollee's cost.

(b) A health plan company may remove a brand name drug from its formulary or place a brand name drug in a benefit category that increases an enrollee's cost only upon the addition to the formulary of an A-rated generic or multisource brand name equivalent at a lower cost to the enrollee, and upon at least a 60-day notice to prescribers, pharmacists, and affected enrollees.

(c) A health plan company is prohibited from removing drugs from its formulary or moving drugs to a benefit category that increases an enrollee's cost during the enrollee's contract year. This paragraph does not apply to any changes associated with drugs that have been deemed unsafe by the Food and Drug Administration, that have been withdrawn by either the Food and Drug Administration or the product manufacturer, or where an independent source of research, clinical guidelines, or evidence-based standards has issued drug-specific warnings or recommended changes in drug usage.

Subd. 4. **Transition process.** (a) A health plan company must establish and maintain a transition process to prevent gaps in prescription drug coverage for both new and continuing enrollees with ongoing prescription drug needs who are affected by changes in formulary drug availability.

(b) The transition process must provide coverage for at least 60 days.

(c) Any enrollee cost-sharing applied must be based on the defined prescription drug benefit terms and must be consistent with any cost-sharing that the health plan company would charge for nonformulary drugs approved under a medication exceptions process.

(d) A health plan company must ensure that written notice is provided to each affected enrollee and prescriber within three business days after adjudication of the transition coverage.

Subd. 5. **Medical exceptions process.** (a) Each health plan company must establish and maintain a medical exceptions process that allows enrollees, providers, or an enrollee's authorized representative to request and obtain coverage approval in the following situations:

(1) there is no acceptable clinical alternative listed on the formulary to treat the enrollee's disease or medical condition;

(2) the prescription listed on the formulary has been ineffective in the treatment of an enrollee's disease or medical condition or, based on clinical and scientific evidence and the relevant physical or mental characteristics of the enrollee, is likely to be ineffective or adversely affect the drug's effectiveness or the enrollee's medication compliance; or

(3) the number of doses that are available under a dose restriction has been ineffective in the treatment of the enrollee's disease or medical condition or, based on clinical and scientific evidence and the relevant physical or mental characteristics of the enrollee, is likely to be ineffective or adversely affect the drug's effectiveness or the enrollee's medication compliance.

(b) An approved medical exception request must remain valid for the duration of an enrollee's contract term, provided the medication continues to be prescribed for the same condition, and provided the medication has not otherwise been withdrawn by the manufacturer or the Food and Drug Administration.

(c) The medical exceptions process must comply with the requirements of chapter 62M.

Subd. 6. **Prescription Drug Advisory Council.** (a) A Prescription Drug Advisory Council has 11 members appointed by the commissioner of health with representation as follows:

(1) three patients;

(2) one physician licensed to practice medicine in Minnesota;

(3) two nonphysicians who are licensed in Minnesota to prescribe prescription drugs;

(4) one pharmacist licensed in Minnesota;

(5) one person representing a health plan company;

(6) one person representing a pharmacy benefit manager;

(7) one person representing pharmaceutical manufacturers; and

(8) one person who purchases health benefits for a group or an employer.

(b) Terms and removal of public members are as provided in section 15.0575, except that members will serve without compensation or expense reimbursement. A vacancy on the council may be filled by the appointing authority for the remainder of the unexpired term. Vacancies will be filled as provided in section 15.0597.

(c) The council shall select a chair from among its members. The chair may convene meetings as necessary to conduct the duties prescribed by this section.

(d) The duty of the council is to provide guidance to the commissioner of health in monitoring changes and trends in prescription drug coverage and formulary design. The council must consult with the commissioner to assist the commissioner in preparing the report required under paragraph (g).

(e) The commissioner of health will provide administrative support and meeting space for the council to perform its duties.

(f) The Prescription Drug Advisory Council expires on January 30, 2021.

(g) Beginning January 15, 2017, and on at least a biennial basis thereafter, the commissioner, in consultation with the advisory group, shall submit a report to the chairs and lead minority members of the legislative committees with jurisdiction over health care coverage describing trends in prescription drug coverage, formulary design, medication exception requests, and benefit design. Health plan companies must cooperate in providing information necessary for the advisory group to carry out its responsibilities.

Sec. 26. Minnesota Statutes 2014, section 256B.0625, subdivision 13f, is amended to read:

Subd. 13f. **Prior authorization.** (a) The Formulary Committee shall review and recommend drugs which require prior authorization. The Formulary Committee shall establish general criteria to be used for the prior authorization of brand-name drugs for which generically equivalent drugs are available, but the committee is not required to review each brand-name drug for which a generically equivalent drug is available.

(b) Prior authorization may be required by the commissioner before certain formulary drugs are eligible for payment. The Formulary Committee may recommend drugs for prior authorization directly to the commissioner. The commissioner may also request that the Formulary Committee review a drug for prior authorization. Before the commissioner may require prior authorization for a drug:

(1) the commissioner must provide information to the Formulary Committee on the impact that placing the drug on prior authorization may have on the quality of patient care and on program costs, information regarding whether the drug is subject to clinical abuse or misuse, and relevant data from the state Medicaid program if such data is available;

(2) the Formulary Committee must review the drug, taking into account medical and clinical data and the information provided by the commissioner; and

(3) the Formulary Committee must hold a public forum and receive public comment for an additional 15 days.

The commissioner must provide a 15-day notice period before implementing the prior authorization and may only update prior authorization requirements on an annual basis unless a drug has been deemed unsafe by the Food and Drug Administration, has been withdrawn by the manufacturer or the Food and Drug Administration, or an independent source of research, clinical guidelines, or evidence-based standards has issued drug-specific warnings or recommended changes in drug usage.

(c) Except as provided in subdivision 13j, prior authorization shall not be required or utilized for any atypical antipsychotic drug prescribed for the treatment of mental illness if:

(1) there is no generically equivalent drug available; and

(2) the drug was initially prescribed for the recipient prior to July 1, 2003; or

(3) the drug is part of the recipient's current course of treatment.

This paragraph applies to any multistate preferred drug list or supplemental drug rebate program established or administered by the commissioner. Prior authorization shall automatically be granted for 60 days for brand name drugs prescribed for treatment of mental illness within 60 days of when a generically equivalent drug becomes available, provided that the brand name drug was part of the recipient's course of treatment at the time the generically equivalent drug became available.

(d) Prior authorization shall not be required or utilized for any antihemophilic factor drug prescribed for the treatment of hemophilia and blood disorders where there is no generically equivalent drug available if the prior authorization is used in conjunction with any supplemental drug rebate program or multistate preferred drug list established or administered by the commissioner.

(e) The commissioner may require prior authorization for brand name drugs whenever a generically equivalent product is available, even if the prescriber specifically indicates "dispense as written-brand necessary" on the prescription as required by section 151.21, subdivision 2.

(f) Notwithstanding this subdivision, the commissioner may automatically require prior authorization, for a period not to exceed 180 days, for any drug that is approved by the United States Food and Drug Administration on or after July 1, 2005. The 180-day period begins no later than the first day that a drug is available for shipment to pharmacies within the state. The Formulary Committee shall recommend to the commissioner general criteria to be used for the prior authorization of the drugs, but the committee is not required to review each individual drug. In order to continue prior authorizations for a drug after the 180-day period has expired, the commissioner must follow the provisions of this subdivision.

Sec. 27. Minnesota Statutes 2014, section 256B.69, subdivision 6, is amended to read:

Subd. 6. **Service delivery.** (a) Each demonstration provider shall be responsible for the health care coordination for eligible individuals. Demonstration providers:

(1) shall authorize and arrange for the provision of all needed health services including but not limited to the full range of services listed in sections 256B.02, subdivision 8, and 256B.0625 in order to ensure appropriate health care is delivered to

enrollees. Notwithstanding section 256B.0621, demonstration providers that provide nursing home and community-based services under this section shall provide relocation service coordination to enrolled persons age 65 and over;

(2) shall accept the prospective, per capita payment from the commissioner in return for the provision of comprehensive and coordinated health care services for eligible individuals enrolled in the program;

(3) may contract with other health care and social service practitioners to provide services to enrollees; and

(4) shall institute recipient grievance procedures according to the method established by the project, utilizing applicable requirements of chapter 62D. Disputes not resolved through this process shall be appealable to the commissioner as provided in subdivision 11.

(b) Demonstration providers must comply with the standards for claims settlement under section 72A.201, subdivisions 4, 5, 7, and 8, when contracting with other health care and social service practitioners to provide services to enrollees. A demonstration provider must pay a clean claim, as defined in Code of Federal Regulations, title 42, section 447.45(b), within 30 business days of the date of acceptance of the claim.

(c) Managed care plans and county-based purchasing plans must comply with chapter 62M and section 62Q.83.

Sec. 28. **PRESCRIPTION DRUG ADVISORY COUNCIL.**

The commissioner of health shall make the first appointments to the Prescription Drug Advisory Council established in Minnesota Statutes, section 62Q.83, subdivision 6, by October 2, 2015, and convene the first meeting by November 1, 2015. The council will select a chair from among its members at the first meeting of the council.

Sec. 29. **REVISOR INSTRUCTION.**

The revisor of statutes shall change "sections 62M.01 to 62M.16" to "sections 62M.01 to 62M.17" wherever the term appears in Minnesota Statutes, chapter 62M.