283.8 ARTICLE 8 283.9 HEALTH CARE DELIVERY

283.10 Section 1. [62A.67] SHORT TITLE.

283.11 Sections 62A.67 to 62A.672 may be cited as the "Minnesota Telemedicine Act."

283.12 EFFECTIVE DATE. This section is effective January 1, 2016.

283.13 Sec. 2. [62A.671] DEFINITIONS.

283.14 <u>Subdivision 1.</u> <u>Applicability.</u> For purposes of sections 62A.67 to 62A.672, the 283.15 terms defined in this section have the meanings given.

283.16 Subd. 2. Distant site. "Distant site" means a site at which a licensed health care 283.17 provider is located while providing health care services or consultations by means of 283.18 telemedicine.

283.19 Subd. 3. **Health care provider**. "Health care provider" has the meaning provided 283.20 in section 62A.63, subdivision 2.

283.21Subd. 4.Health carrier."Health carrier" has the meaning provided in section283.2262A.011, subdivision 2.

283.23 Subd. 5. Health plan. "Health plan" means a health plan as defined in section
283.24 62A.011, subdivision 3, and includes dental plans as defined in section 62Q.76, subdivision
283.25 3, but does not include dental plans that provide indemnity-based benefits, regardless of
283.26 expenses incurred and are designed to pay benefits directly to the policyholder.

283.27 <u>Subd. 6.</u> Licensed health care provider. "Licensed health care provider" means a 283.28 health care provider who is:

283.29 (1) licensed under chapter 147, 147A, 148, 148B, 148E, 148F, 150A, or 153; a 283.30 mental health professional as defined under section 245.462, subdivision 18, or 245.4871, 283.31 subdivision 27; or vendor of medical care defined in section 256B.02, subdivision 7; and

284.1 (2) authorized within their respective scope of practice to provide the particular 284.2 service with no supervision or under general supervision.

284.3 Subd. 7. Originating site. "Originating site" means a site including, but not limited

284.4 to, a health care facility at which a patient is located at the time health care services are

284.5 provided to the patient by means of telemedicine.

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176.1 ARTICLE 6 176.2 PUBLIC HEALTH AND HEALTH CARE DELIVERY

176.3 Section 1. [62A.67] SHORT TITLE.

176.4 Sections 62A.67 to 62A.672 may be cited as the "Minnesota Telemedicine Act."

176.5 **EFFECTIVE DATE.** This section is effective January 1, 2017, and applies to 176.6 coverage offered, sold, issued, or renewed on or after that date.

176.7 Sec. 2. [62A.671] DEFINITIONS.

176.8 <u>Subdivision 1.</u> <u>Applicability.</u> For purposes of sections 62A.67 to 62A.672, the 176.9 terms defined in this section have the meanings given.

176.10 Subd. 2. **Distant site.** "Distant site" means a site at which a licensed health care 176.11 provider is located while providing health care services or consultations by means of 176.12 telemedicine.

176.13 Subd. 3. Health care provider. "Health care provider" has the meaning provided 176.14 in section 62A.63, subdivision 2.

176.15 Subd. 4. Heath carrier. "Health carrier" has the meaning provided in section 176.16 62A.011, subdivision 2.

176.17 Subd. 5. Health plan. "Health plan" means a health plan as defined in section
176.18 62A.011, subdivision 3, and includes dental plans as defined in section 62Q.76, subdivision
176.19 3, but does not include dental plans that provide indemnity-based benefits, regardless of
176.20 expenses incurred and are designed to pay benefits directly to the policyholder.

176.21 Subd. 6. Licensed health care provider. "Licensed health care provider" means a 176.22 health care provider who is:

176.23 (1) licensed under chapter 147, 147A, 148, 148B, 148B, 148F, 150A, or 153; a 176.24 mental health professional as defined under section 245.462, subdivision 18, or 245.4871, 176.25 subdivision 27; or a vendor of medical care as defined in section 256B.02, subdivision 176.26 7; and

176.27 (2) authorized within their respective scope of practice to provide the particular 176.28 service with no supervision or under general supervision.

176.29 <u>Subd. 7.</u> Originating site. "Originating site" means a site including, but not limited 176.30 to, a health care facility at which a patient is located at the time health care services are 176.31 provided to the patient by means of telemedicine. Health Care Delivery

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284.6 Subd. 8. Store-and-forward technology. "Store-and-forward technology" means

284.7 the transmission of a patient's medical information from an originating site to a health care 284.8 provider at a distant site without the patient being present, or the delivery of telemedicine

284.9 that does not occur in real time via synchronous transmissions.

284.10 Subd. 9. **Telemedicine.** "Telemedicine" means the delivery of health care services 284.11 or consultations while the patient is at an originating site and the licensed health care 284.12 provider is at a distant site. A communication between licensed health care providers 284.13 that consists solely of a telephone conversation, e-mail, or facsimile transmissions does 284.14 not constitute telemedicine consultations or services. Telemedicine may be provided by 284.15 means of real-time two-way, interactive audio and visual communications, including the 284.16 application of secure video conferencing or store-and-forward technology to provide or 284.17 support health care delivery, which facilitate the assessment, diagnosis, consultation, 284.18 treatment, education, and care management of a patient's health care.

284.19 **EFFECTIVE DATE.** This section is effective January 1, 2016.

284.20 Sec. 3. [62A.672] COVERAGE OF TELEMEDICINE SERVICES.

284.21 Subdivision 1. Coverage of telemedicine. (a) A health plan sold, issued, or renewed 284.22 by a health carrier for which coverage of benefits begins on or after January 1, 2017, shall 284.23 include coverage for telemedicine benefits in the same manner as any other benefits covered 284.24 under the policy, plan, or contract, and shall comply with the regulations of this section.

284.25 (b) Nothing in this section shall be construed to:

284.26 (1) require a health carrier to provide coverage for services that are not medically 284.27 necessary;

284.28 (2) prohibit a health carrier from establishing criteria that a health care provider 284.29 must meet to demonstrate the safety or efficacy of delivering a particular service via 284.30 telemedicine for which the health carrier does not already reimburse other health

284.31 care providers for delivering via telemedicine, so long as the criteria are not unduly 284.32 burdensome or unreasonable for the particular service; or

284.33 (3) prevent a health carrier from requiring a health care provider to agree to certain

284.34 documentation or billing practices designed to protect the health carrier or patients from

285.1 fraudulent claims so long as the practices are not unduly burdensome or unreasonable

285.2 for the particular service.

285.3 Subd. 2. Parity between telemedicine and in-person services. A health carrier

285.4 shall not exclude a service for coverage solely because the service is provided via

285.5 telemedicine and is not provided through in-person consultation or contact between a

285.6 licensed health care provider and a patient.

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176.32 Subd. 8. Store-and-forward technology. "Store-and-forward technology" means

176.33 the transmission of a patient's medical information from an originating site to a health care 177.1 provider at a distant site without the patient being present, or the delivery of telemedicine

177.2 that does not occur in real time via synchronous transmissions.

177.3 Subd. 9. Telemedicine. "Telemedicine" means the delivery of health care services
177.4 or consultations while the patient is at an originating site and the licensed health care
177.5 provider is at a distant site. A communication between licensed health care providers
177.6 that consists solely of a telephone conversation, e-mail, or facsimile transmissions does
177.7 not constitute telemedicine consultations or services. Telemedicine may be provided by
177.8 means of real-time two-way, interactive audio and visual communications, including the
177.9 application of secure video conferencing or store-and-forward technology to provide or
177.10 support health care delivery, which facilitate the assessment, diagnosis, consultation,
177.11 treatment, education, and care management of a patient's health care.

177.12 **EFFECTIVE DATE.** This section is effective January 1, 2017, and applies to 177.13 coverage offered, sold, issued, or renewed on or after that date.

177.14 Sec. 3. [62A.672] COVERAGE OF TELEMEDICINE SERVICES.

177.15 Subdivision 1. Coverage of telemedicine. (a) A health plan sold, issued, or renewed 177.16 by a health carrier for which coverage of benefits begins on or after January 1, 2017, shall 177.17 include coverage for telemedicine benefits in the same manner as any other benefits covered 177.18 under the policy, plan, or contract, and shall comply with the regulations of this section.

177.19 (b) Nothing in this section shall be construed to:

177.20 (1) require a health carrier to provide coverage for services that are not medically 177.21 necessary;

177.22 (2) prohibit a health carrier from establishing criteria that a health care provider
177.23 must meet to demonstrate the safety or efficacy of delivering a particular service via
177.24 telemedicine for which the health carrier does not already reimburse other health
177.25 care providers for delivering via telemedicine, so long as the criteria are not unduly
177.26 burdensome or unreasonable for the particular service; or

177.27 (3) prevent a health carrier from requiring a health care provider to agree to certain
177.28 documentation or billing practices designed to protect the health carrier or patients from
177.29 fraudulent claims so long as the practices are not unduly burdensome or unreasonable
177.30 for the particular service.

177.31 Subd. 2. **Parity between telemedicine and in-person services.** A health carrier 177.32 shall not exclude a service for coverage solely because the service is provided via 177.33 telemedicine and is not provided through in-person consultation or contact between a 177.34 licensed health care provider and a patient. 285.7 Subd. 3. Reimbursement for telemedicine services. (a) A health carrier shall

285.8 reimburse the distant site licensed health care provider for covered services delivered via 285.9 telemedicine on the same basis and at the same rate as the health carrier would apply to 285.10 those services if the services had been delivered in person by the distant site licensed 285.11 health care provider.

285.12 (b) It is not a violation of this subdivision for a health carrier to include a

285.13 deductible, co-payment, or coinsurance requirement for a health care service provided via 285.14 telemedicine, provided that the deductible, co-payment, or coinsurance is not in addition 285.15 to, and does not exceed, the deductible, co-payment, or coinsurance applicable if the same 285.16 services were provided through in-person contact.

285.17 Subd. 4. Originating site facility fee payment. If a health care provider provides
285.18 the facility used as the originating site for the delivery of telemedicine to a health carrier's
285.19 enrollee, the health carrier shall make a facility fee payment to the originating site health
285.20 care provider. The facility fee payment to the originating site health care provider shall be
285.21 in addition to the reimbursement to the distant site licensed health care provider specified
285.22 in subdivision 3. The facility fee payment shall not be subject to any patient coinsurance,
285.23 deductible, or co-payment obligation.

285.24 **EFFECTIVE DATE.** This section is effective January 1, 2016.

285.25 Sec. 4. Minnesota Statutes 2014, section 62J.497, subdivision 1, is amended to read:

285.26 Subdivision 1. **Definitions.** For the purposes of this section, the following terms 285.27 have the meanings given.

285.28 (a) "Backward compatible" means that the newer version of a data transmission 285.29 standard would retain, at a minimum, the full functionality of the versions previously 285.30 adopted, and would permit the successful completion of the applicable transactions with 285.31 entities that continue to use the older versions.

285.32 (b) "Dispense" or "dispensing" has the meaning given in section 151.01, subdivision 285.33 30. Dispensing does not include the direct administering of a controlled substance to a 285.34 patient by a licensed health care professional.

286.1 (c) "Dispenser" means a person authorized by law to dispense a controlled substance, 286.2 pursuant to a valid prescription.

286.3 (d) "Electronic media" has the meaning given under Code of Federal Regulations, 286.4 title 45, part 160.103.

178.1 Subd. 3. Reimbursement for telemedicine services. (a) A health carrier shall

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178.2 reimburse the distant site licensed health care provider for covered services delivered 178.3 via telemedicine commensurate with the cost of delivering health care services through

178.4 telemedicine. The distant site provider is responsible for reimbursing any fees to the originating site.

178.6 (b) It is not a violation of this subdivision for a health carrier to include a

178.7 deductible, co-payment, or coinsurance requirement for a health care service provided via 178.8 telemedicine, provided that the deductible, co-payment, or coinsurance is not in addition 178.9 to, and does not exceed, the deductible, co-payment, or coinsurance applicable if the same 178.10 services were provided through in-person contact.

178.11 **EFFECTIVE DATE.** This section is effective January 1, 2017, and applies to 178.12 coverage offered, sold, issued, or renewed on or after that date.

286.5 (e) "E-prescribing" means the transmission using electronic media of prescription 286.6 or prescription-related information between a prescriber, dispenser, pharmacy benefit 286.7 manager, or group purchaser, either directly or through an intermediary, including 286.8 an e-prescribing network. E-prescribing includes, but is not limited to, two-way 286.9 transmissions between the point of care and the dispenser and two-way transmissions 286.10 related to eligibility, formulary, and medication history information.

286.11 (f) "Electronic prescription drug program" means a program that provides for 286.12 e-prescribing.

286.13 (g) "Group purchaser" has the meaning given in section 62J.03, subdivision 6, but 286.14 does not include workers' compensation plans or the medical component of automobile 286.15 insurance coverage.

286.16 (h) "HL7 messages" means a standard approved by the standards development 286.17 organization known as Health Level Seven.

286.18 (i) "National Provider Identifier" or "NPI" means the identifier described under Code 286.19 of Federal Regulations, title 45, part 162.406.

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

286.21 (k) "NCPDP Formulary and Benefits Standard" means the National Council for 286.22 Prescription Drug Programs Formulary and Benefits Standard, Implementation Guide, 286.23 Version 1, Release 0, October 2005.

286.24 (1) "NCPDP SCRIPT Standard" means the National Council for Prescription Drug 286.25 Programs Prescriber/Pharmacist Interface SCRIPT Standard, Implementation Guide 286.26 Version 8, Release 1 (Version 8.1), October 2005, or the most recent standard adopted by 286.27 the Centers for Medicare and Medicaid Services for e-prescribing under Medicare Part 286.28 D as required by section 1860D-4(e)(4)(D) of the Social Security Act, and regulations 286.29 adopted under it. The standards shall be implemented according to the Centers for 286.30 Medicare and Medicaid Services schedule for compliance. Subsequently released 286.31 versions of the NCPDP SCRIPT Standard may be used, provided that the new version 286.32 of the standard is backward compatible to the current version adopted by the Centers for 286.33 Medicare and Medicaid Services.

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

286.35 (n) "Prescriber" means a licensed health care practitioner, other than a veterinarian, 286.36 as defined in section 151.01, subdivision 23.

287.1 (o) "Prescription-related information" means information regarding eligibility for 287.2 drug benefits, medication history, or related health or drug information.

287.3 (p) "Provider" or "health care provider" has the meaning given in section 62J.03, 287.4 subdivision 8.

287.5 (q) "Utilization review organization" has the meaning given in section 62M.02, 287.6 subdivision 21.

287.7 **EFFECTIVE DATE.** This section is effective August 1, 2015.

287.8 Sec. 5. Minnesota Statutes 2014, section 62J.497, subdivision 3, is amended to read:

287.9 Subd. 3. **Standards for electronic prescribing.** (a) Prescribers and dispensers 287.10 must use the NCPDP SCRIPT Standard for the communication of a prescription or 287.11 prescription-related information. The NCPDP SCRIPT Standard shall be used to conduct 287.12 the following transactions:

287.13 (1) get message transaction;

287.14 (2) status response transaction;

287.15 (3) error response transaction;

287.16 (4) new prescription transaction;

287.17 (5) prescription change request transaction;

287.18 (6) prescription change response transaction;

287.19 (7) refill prescription request transaction;

287.20 (8) refill prescription response transaction;

287.21 (9) verification transaction;

287.22 (10) password change transaction;

287.23 (11) cancel prescription request transaction; and

287.24 (12) cancel prescription response transaction.

287.25 (b) Providers, group purchasers, prescribers, and dispensers must use the NCPDP 287.26 SCRIPT Standard for communicating and transmitting medication history information.

287.27 (c) Providers, group purchasers, prescribers, and dispensers must use the NCPDP 287.28 Formulary and Benefits Standard for communicating and transmitting formulary and 287.29 benefit information.

287.30 (d) Group purchasers, prescribers, pharmacies, and utilization review organizations

287.31 must collaborate to develop processes to ensure notification to prescribers upon denial of a

287.32 claim for a prescribed drug that is not covered or is not included on the group purchaser's

287.33 formulary. The process must provide a list of covered drugs from the same class or

287.34 <u>classes as the drug originally prescribed</u>. If the NCPDP SCRIPT Standard or the NCPDP 287.35 Formulary and Benefits Standard do not allow for the inclusion of this information, group

288.1 purchasers, prescribers, pharmacies, and utilization review organizations must develop

288.2 telephone, facsimile, or other secure electronic processes to communicate this information

288.3 to the prescriber. The development of this process shall be done under the auspices of the

288.4 administrative uniformity committee and take into consideration capabilities available in 288.5 electronic medical records.

288.6 (d) (e) Providers, group purchasers, prescribers, and dispensers must use the national 288.7 provider identifier to identify a health care provider in e-prescribing or prescription-related 288.8 transactions when a health care provider's identifier is required.

288.9 (e) (f) Providers, group purchasers, prescribers, and dispensers must communicate 288.10 eligibility information and conduct health care eligibility benefit inquiry and response 288.11 transactions according to the requirements of section 62J.536.

288.12 **EFFECTIVE DATE.** This section is effective August 1, 2015.

288.13 Sec. 6. Minnesota Statutes 2014, section 62J.497, subdivision 4, is amended to read:

288.14 Subd. 4. **Development and use of uniform formulary exception form.** (a) The 288.15 commissioner of health, in consultation with the Minnesota Administrative Uniformity 288.16 Committee, shall develop by July 1, 2009, a uniform formulary exception form that allows 288.17 health care providers to request exceptions from group purchaser formularies using a 288.18 uniform form. Upon development of the form, all health care providers must submit 288.19 requests for formulary exceptions using the uniform form, and all group purchasers must 288.20 accept this form from health care providers.

288.21 (b) No later than January 1, 2011, The uniform formulary exception form must be
288.22 accessible and submitted by health care providers, and accepted and processed by group
288.23 purchasers, through secure electronic transmissions. No later than September 1, 2015,
288.24 the uniform formulary exception form shall be updated to reflect evolving pharmacy and
288.25 prior authorization requirements.

288.26 (c) Health care providers, group purchasers, prescribers, dispensers, and utilization
 288.27 review organizations using paper forms for prescription drug prior authorization or for
 288.28 medical exception requests as defined in section 62Q.85, subdivision 5, must only use the
 288.29 uniform formulary exception form.

288.30 **EFFECTIVE DATE.** This section is effective August 1, 2015.

288.31 Sec. 7. Minnesota Statutes 2014, section 62J.497, subdivision 5, is amended to read:

288.32 Subd. 5. **Electronic drug prior authorization standardization and transmission.** 288.33 (a) The commissioner of health, in consultation with the Minnesota e-Health Advisory 289.1 Committee and the Minnesota Administrative Uniformity Committee, shall, by February 289.2 15, 2010, identify an outline on how best to standardize drug prior authorization request 289.3 transactions between providers and group purchasers with the goal of maximizing 289.4 administrative simplification and efficiency in preparation for electronic transmissions.

289.5 (b) By January 1, 2014, the Minnesota Administrative Uniformity Committee shall 289.6 develop the standard companion guide by which providers and group purchasers will 289.7 exchange standard drug authorization requests using electronic data interchange standards, 289.8 if available, with the goal of alignment with standards that are or will potentially be used 289.9 nationally.

289.10 (c) Testing of the electronic drug prior authorization transmission must begin no 289.11 later than October 1, 2015.

289.12 (d) No later than January 1, 2016, drug prior authorization requests must be
289.13 accessible and submitted by health care providers, and accepted by group purchasers,
289.14 electronically through secure electronic transmissions. Facsimile shall not be considered
289.15 electronic transmission.

289.16 **EFFECTIVE DATE.** This section is effective August 1, 2015.

289.17 Sec. 8. Minnesota Statutes 2014, section 62M.01, subdivision 2, is amended to read:

289.18 Subd. 2. **Jurisdiction.** (a) Sections 62M.01 to 62M.16 62M.17 apply to any 289.19 insurance company licensed under chapter 60A to offer, sell, or issue a policy of accident 289.20 and sickness insurance as defined in section 62A.01; a health service plan licensed 289.21 under chapter 62C; a health maintenance organization licensed under chapter 62D; the 289.22 Minnesota Comprehensive Health Association created under chapter 62E; a community 289.23 integrated service network licensed under chapter 62N; an accountable provider network 289.24 operating under chapter 62T; a fraternal benefit society operating under chapter 64B; 289.25 a joint self-insurance employee health plan operating under chapter 62H; a multiple 289.26 employer welfare arrangement, as defined in section 3 of the Employee Retirement Income 289.27 Security Act of 1974 (ERISA), United States Code, title 29, section 1103, as amended; 289.28 a third-party administrator licensed under section 60A.23, subdivision 8, that provides 289.29 utilization review services for the administration of benefits under a health benefit plan 289.30 as defined in section 62M.02; or any entity performing utilization review on behalf of a 289.31 business entity in this state pursuant to a health benefit plan covering a Minnesota resident.

289.32 (b) Sections 62M.01 to 62M.17 do not apply to the medical assistance fee-for-service 289.33 program under chapter 256B, unless otherwise required in law or regulation.

289.34 **EFFECTIVE DATE.** This section is effective August 1, 2015.

290.1 Sec. 9. Minnesota Statutes 2014, section 62M.02, is amended by adding a subdivision 290.2 to read:

- 290.3 Subd. 10a. Drug. "Drug" has the meaning given in section 151.01, subdivision 5.
- 290.4 EFFECTIVE DATE. This section is effective August 1, 2015.

290.5 Sec. 10. Minnesota Statutes 2014, section 62M.02, is amended by adding a subdivision 290.6 to read:

290.7 Subd. 11a. Formulary. "Formulary" has the meaning given in section 62Q.85, 290.8 subdivision 1.

290.9 **EFFECTIVE DATE.** This section is effective August 1, 2015.

290.10 Sec. 11. Minnesota Statutes 2014, section 62M.02, subdivision 12, is amended to read:

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

290.14 (1) limited to disability or income protection coverage;

290.15 (2) automobile medical payment coverage;

290.16 (3) supplemental to liability insurance;

290.17 (4) designed solely to provide payments on a per diem, fixed indemnity, or 290.18 nonexpense incurred basis;

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

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

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

290.22 (8) workers' compensation.

290.23 **EFFECTIVE DATE.** This section is effective August 1, 2015.

290.24 Sec. 12. Minnesota Statutes 2014, section 62M.02, subdivision 14, is amended to read:

290.25 Subd. 14. **Outpatient services.** "Outpatient services" means procedures or services 290.26 performed on a basis other than as an inpatient, and includes obstetrical, psychiatric, 290.27 chemical dependency, dental, prescription drug, and chiropractic services.

290.28 EFFECTIVE DATE. This section is effective August 1, 2015.

290.29 Sec. 13. Minnesota Statutes 2014, section 62M.02, is amended by adding a subdivision 290.30 to read:

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

291.3 **EFFECTIVE DATE.** This section is effective August 1, 2015.

291.4 Sec. 14. Minnesota Statutes 2014, section 62M.02, is amended by adding a subdivision 291.5 to read:

291.6 Subd. 14c. **Prescription drug order**. "Prescription drug order" has the meaning 291.7 given in section 151.01, subdivision 16.

291.8 **EFFECTIVE DATE.** This section is effective August 1, 2015.

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

291.10 Subd. 15. Prior authorization. "Prior authorization" means utilization review
291.11 conducted prior to the delivery of a service, including an outpatient service. Prior
291.12 authorization includes, but is not limited to, preadmission review, pretreatment review,
291.13 quantity limits, step therapy, utilization, and case management. Prior authorization also
291.14 includes any utilization review organization's requirement that an enrollee or provider
291.15 notify the utilization review organization prior to providing a service, including an
291.16 outpatient service. Reviews performed for emergency medical assistance benefits, medical
291.17 assistance waivered services, or the Minnesota restricted recipient program are not prior
291.18 authorization.

291.19 **EFFECTIVE DATE.** This section is effective August 1, 2015.

291.20 Sec. 16. Minnesota Statutes 2014, section 62M.02, subdivision 17, is amended to read:

291.21 Subd. 17. Provider. "Provider" means a licensed health care facility, physician,291.22 pharmacist, or other health care professional that delivers health care services to an enrollee.

291.23 **EFFECTIVE DATE.** This section is effective August 1, 2015.

291.24 Sec. 17. Minnesota Statutes 2014, section 62M.02, is amended by adding a subdivision 291.25 to read:

291.26 Subd. 18a. **Quantity limit.** "Quantity limit" means a limit on the number of doses 291.27 of a prescription drug that are covered during a specific time period.

291.28 EFFECTIVE DATE. This section is effective August 1, 2015.

292.1 Sec. 18. Minnesota Statutes 2014, section 62M.02, is amended by adding a subdivision 292.2 to read:

292.3 Subd. 19a. Step therapy. "Step therapy" means clinical practice or other

292.4 evidence-based protocols or requirements that specify the sequence in which different

292.5 prescription drugs for a given medical condition are to be used by an enrollee before a

292.6 drug prescribed by a provider is covered. Step therapy does not include a requirement

292.7 for an enrollee to use a generic or biosimilar product considered by the Food and Drug

292.8 Administration to be therapeutically equivalent and interchangeable to a branded product,

292.9 provided the generic or biosimilar product has not previously been tried by the patient.

292.10 **EFFECTIVE DATE.** This section is effective August 1, 2015.

292.11 Sec. 19. Minnesota Statutes 2014, section 62M.05, subdivision 3a, is amended to read:

292.12 Subd. 3a. **Standard review determination.** (a) Notwithstanding subdivision 3b, an 292.13 initial determination on all requests for utilization review, except a determination related 292.14 to prescription drugs, must be communicated to the provider and enrollee in accordance 292.15 with this subdivision within ten business days of the request, provided that all information 292.16 reasonably necessary to make a determination on the request has been made available to 292.17 the utilization review organization.

292.18 (b) An initial determination for utilization review on all prescription drug requests

292.19 must be communicated to the provider and enrollee in accordance with this subdivision

292.20 within five business days of the request, provided that all information reasonably necessary

292.21 to make a determination on the request has been made available to the utilization review 292.22 organization.

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292.23 (c) When an initial determination is made to certify, notification must be provided 292.24 promptly by telephone to the provider. The utilization review organization shall send 292.25 written notification to the provider or shall maintain an audit trail of the determination 292.26 and telephone notification. For purposes of this subdivision, "audit trail" includes 292.27 documentation of the telephone notification, including the date; the name of the person 292.28 spoken to; the enrollee; the service, procedure, or admission certified; and the date of 292.29 the service, procedure, or admission. If the utilization review organization indicates 292.30 certification by use of a number, the number must be called the "certification number." 292.31 For purposes of this subdivision, notification may also be made by facsimile to a verified 292.32 number or by electronic mail to a secure electronic mailbox. These electronic forms of 292.33 notification satisfy the "audit trail" requirement of this paragraph.

292.34 (c) (d) When an initial determination is made not to certify, notification must be 292.35 provided by telephone, by facsimile to a verified number, or by electronic mail to a secure 293.1 electronic mailbox within one working day after making the determination to the attending 293.2 health care professional and hospital as applicable. Written notification must also be sent 293.3 to the hospital as applicable and attending health care professional if notification occurred 293.4 by telephone. For purposes of this subdivision, notification may be made by facsimile to a 293.5 verified number or by electronic mail to a secure electronic mailbox. Written notification 293.6 must be sent to the enrollee and may be sent by United States mail, facsimile to a verified 293.7 number, or by electronic mail to a secure mailbox. The written notification must include 293.8 the principal reason or reasons for the determination and the process for initiating an appeal 293.9 of the determination. Upon request, the utilization review organization shall provide the 293.10 provider or enrollee with the criteria used to determine the necessity, appropriateness, 293.11 and efficacy of the health care service and identify the database, professional treatment 293.12 parameter, or other basis for the criteria. Reasons for a determination not to certify may 293.13 include, among other things, the lack of adequate information to certify after a reasonable 293.14 attempt has been made to contact the provider or enrollee.

293.15 (d) (e) When an initial determination is made not to certify, the written notification 293.16 must inform the enrollee and the attending health care professional of the right to submit 293.17 an appeal to the internal appeal process described in section 62M.06 and the procedure 293.18 for initiating the internal appeal. The written notice shall be provided in a culturally and 293.19 linguistically appropriate manner consistent with the provisions of the Affordable Care 293.20 Act as defined under section 62A.011, subdivision 1a.

293.21 EFFECTIVE DATE. This section is effective August 1, 2015.

293.22 Sec. 20. Minnesota Statutes 2014, section 62M.05, subdivision 3b, is amended to read:

293.23 Subd. 3b. **Expedited review determination.** (a) An expedited initial determination 293.24 must be utilized if the attending health care professional believes that an expedited 293.25 determination is warranted.

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293.26 (b) Notification of an expedited initial determination to either certify or not to 293.27 certify, except a determination related to prescription drugs, must be provided to the 293.28 hospital, the attending health care professional, and the enrollee as expeditiously as the 293.29 enrollee's medical condition requires, but no later than 72 hours from the initial request. 293.30 When an expedited initial determination is made not to certify, the utilization review 293.31 organization must also notify the enrollee and the attending health care professional of the 293.32 right to submit an appeal to the expedited internal appeal as described in section 62M.06 293.33 and the procedure for initiating an internal expedited appeal.

293.34 (c) Notification of an expedited initial determination to either certify or not to
293.35 certify on all prescription drug requests must be provided to the hospital, the attending
294.1 health care professional, and the enrollee as expeditiously as the enrollee's medical
294.2 condition requires, but no later than 36 hours from the initial request, provided that all the
294.3 information reasonably necessary to make a determination has been made available to the
294.4 utilization review organization. For state public health care programs administered under
294.5 section 256B.69 and chapter 256L, notification must be provided to the hospital, attending
294.6 health care provider, or the enrollee as expeditiously as the enrollee's condition requires,
294.7 but no later than 36 hours from the initial request, provided that all the information
294.8 reasonably necessary to make a determination has been made available to the utilization
294.9 review organization. When an expedited initial determination is made not to certify, the
294.10 utilization review organization must also notify the enrollee and the attending health care
294.11 professional of the right to submit an appeal to the expedited internal appeal as described
294.12 in section 62M.06 and the procedure for initiating an internal expedited appeal.

294.13 **EFFECTIVE DATE.** This section is effective August 1, 2015.

294.14 Sec. 21. Minnesota Statutes 2014, section 62M.05, subdivision 4, is amended to read:

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

294.28 **EFFECTIVE DATE.** This section is effective January 1, 2017.

294.29 Sec. 22. Minnesota Statutes 2014, section 62M.06, subdivision 2, is amended to read:

294.30 Subd. 2. **Expedited appeal.** (a) When an initial determination not to certify a 294.31 health care service is made prior to or during an ongoing service requiring review 294.32 and the attending health care professional believes that the determination warrants an 294.33 expedited appeal, the utilization review organization must ensure that the enrollee and the 295.1 attending health care professional have an opportunity to appeal the determination over 295.2 the telephone on an expedited basis. In such an appeal, the utilization review organization 295.3 must ensure reasonable access to its consulting physician or health care provider.

295.4 (b) The utilization review organization shall notify the enrollee and attending
295.5 health care professional by telephone of its determination, except for determinations
295.6 related to prescription drugs, on the expedited appeal as expeditiously as the enrollee's
295.7 medical condition requires, but no later than 72 hours after receiving the expedited appeal.
295.8 The utilization review organization shall notify the enrollee and attending health care
295.9 professional by telephone of its determination on the expedited appeal of a prescription
295.10 drug request as expeditiously as the enrollee's medical condition requires, but no later than
295.11 36 hours after receiving the expedited appeal.

295.12 (c) If the determination not to certify is not reversed through the expedited appeal, 295.13 the utilization review organization must include in its notification the right to submit the 295.14 appeal to the external appeal process described in section 62Q.73 and the procedure for 295.15 initiating the process. This information must be provided in writing to the enrollee and 295.16 the attending health care professional as soon as practical.

295.17 **EFFECTIVE DATE.** This section is effective August 1, 2015.

295.18 Sec. 23. Minnesota Statutes 2014, section 62M.06, subdivision 3, is amended to read:

295.19 Subd. 3. **Standard appeal.** The utilization review organization must establish 295.20 procedures for appeals to be made either in writing or by telephone.

295.21 (a) A utilization review organization shall notify in writing the enrollee, attending 295.22 health care professional, and claims administrator of its determination on the appeal₂ 295.23 except for determinations related to prescription drugs, within 30 days upon receipt of the 295.24 notice of appeal. If the utilization review organization cannot make a determination within 295.25 30 days due to circumstances outside the control of the utilization review organization, the 295.26 utilization review organization may take up to 14 additional days to notify the enrollee, 295.27 attending health care professional, and claims administrator of its determination. If the 295.28 utilization review organization takes any additional days beyond the initial 30-day period 295.29 to make its determination, it must inform the enrollee, attending health care professional, 295.30 and claims administrator, in advance, of the extension and the reasons for the extension.

295.31 (b) A utilization review organization shall notify in writing the enrollee, attending

295.32 <u>health care professional, and claims administrator of its determination on the appeal on a</u> 295.33 prescription drug within 15 days upon receipt of the notice of appeal. If the utilization

295.35 prescription drug within 15 days upon receipt of the notice of appear. If the duffization 295.34 review organization cannot make a determination on a prescription drug within 15 days

295.35 due to circumstances outside the control of the utilization review organization, the

296.1 utilization review organization may take up to ten additional days to notify the enrollee,

296.2 attending health care professional, and claims administration of its determination. If the

296.3 utilization review organization takes any additional days beyond the initial 15-day period

296.4 to make its determination, it must inform the enrollee, attending health care professional,

296.5 and claims administrator, in advance, of the extension and the reasons for the extension.

296.6 (c) The documentation required by the utilization review organization may include 296.7 copies of part or all of the medical record and a written statement from the attending 296.8 health care professional.

296.9 (c) (d) Prior to upholding the initial determination not to certify for clinical reasons, 296.10 the utilization review organization shall conduct a review of the documentation by a 296.11 physician who did not make the initial determination not to certify.

296.12 (d) (e) The process established by a utilization review organization may include 296.13 defining a period within which an appeal must be filed to be considered. The time period 296.14 must be communicated to the enrollee and attending health care professional when the 296.15 initial determination is made.

296.16 (e) (f) An attending health care professional or enrollee who has been unsuccessful 296.17 in an attempt to reverse a determination not to certify shall, consistent with section 296.18 72A.285, be provided the following:

296.19 (1) a complete summary of the review findings;

296.20 (2) qualifications of the reviewers, including any license, certification, or specialty 296.21 designation; and

296.22 (3) the relationship between the enrollee's diagnosis and the review criteria used as 296.23 the basis for the decision, including the specific rationale for the reviewer's decision.

296.24 (f) (g) In cases of appeal to reverse a determination not to certify for clinical reasons, 296.25 the utilization review organization must ensure that a physician of the utilization review 296.26 organization's choice in the same or a similar specialty as typically manages the medical 296.27 condition, procedure, or treatment under discussion is reasonably available to review 296.28 the case.

296.29 (g) (h) If the initial determination is not reversed on appeal, the utilization review 296.30 organization must include in its notification the right to submit the appeal to the external 296.31 review process described in section 62Q.73 and the procedure for initiating the external 296.32 process.

296.33 **EFFECTIVE DATE.** This section is effective August 1, 2015.

297.1 Sec. 24. Minnesota Statutes 2014, section 62M.07, is amended to read: 297.2 **62M.07 PRIOR AUTHORIZATION OF SERVICES.**

297.3 (a) Utilization review organizations conducting prior authorization of services must 297.4 have written standards that meet at a minimum the following requirements:

297.5 (1) written procedures and criteria used to determine whether care is appropriate, 297.6 reasonable, or medically necessary;

297.7 (2) a system for providing prompt notification of its determinations to enrollees 297.8 and providers and for notifying the provider, enrollee, or enrollee's designee of appeal 297.9 procedures under clause (4);

297.10 (3) compliance with section 62M.05, subdivisions 3a and 3b, regarding time frames 297.11 for approving and disapproving prior authorization requests;

297.12 (4) written procedures for appeals of denials of prior authorization which specify the 297.13 responsibilities of the enrollee and provider, and which meet the requirements of sections 297.14 62M.06 and 72A.285, regarding release of summary review findings; and

297.15 (5) procedures to ensure confidentiality of patient-specific information, consistent 297.16 with applicable law.

297.17 (b) No utilization review organization, health plan company, or claims administrator 297.18 may conduct or require prior authorization of emergency confinement or emergency 297.19 treatment. The enrollee or the enrollee's authorized representative may be required to 297.20 notify the health plan company, claims administrator, or utilization review organization 297.21 as soon after the beginning of the emergency confinement or emergency treatment as 297.22 reasonably possible.

297.23 (c) If prior authorization for a health care service is required, the utilization review 297.24 organization, health plan company, or claim administrator must allow providers to submit 297.25 requests for prior authorization of the health care services without unreasonable delay 297.26 by telephone, facsimile, or voice mail or through an electronic mechanism 24 hours a 297.27 day, seven days a week. This paragraph does not apply to dental service covered under 297.28 MinnesotaCare, general assistance medical care, or medical assistance.

297.29 (d) Any prior authorization for a prescription drug must remain valid for the duration

297.30 of an enrollee's benefit year, or for the benefits offered under section 256B.69 or chapter 297.31 256L, any prior authorization for a prescription drug must remain valid for the duration of 297.32 the enrollee's enrollment or one year, whichever is shorter, provided the drug continues to 297.33 be prescribed for a patient with a condition that requires ongoing medication therapy, the 297.34 drug has not otherwise been deemed unsafe by the Food and Drug Administration, has not 297.35 been withdrawn by the manufacturer or the Food and Drug Administration, there is no 297.36 evidence of the enrollee's abuse or misuse of the medication, or no independent source of 298.1 research, clinical guidelines, or evidence-based standards has issued drug-specific warnings 298.2 or recommended changes in drug usage. This does not apply to individuals assigned to the

298.3 restricted recipient program under Minnesota Rules, parts 9505.2160 to 9505.2245.

298.4 (e) No utilization review organization, health plan company, or claims administrator
298.5 may impose step therapy requirements for enrollees currently taking a prescription drug,
298.6 as substantiated from available claims data or provider documentation, in one of the
298.7 following classes: (1) immunosuppressants; (2) antidepressants; (3) antipsychotics; (4)
298.8 anticonvulsants; (5) antiretrovirals; or (6) antineoplastics. This provision does not apply to
298.9 a patient who has initiated treatment for a condition with samples provided by a prescriber
298.10 and provided that any step therapy requirements subsequently applied are consistent
298.11 with evidence-based prescribing practices.

298.12 **EFFECTIVE DATE.** This section is effective January 1, 2017.

298.13 Sec. 25. Minnesota Statutes 2014, section 62M.09, subdivision 3, is amended to read:

298.14 Subd. 3. **Physician reviewer involvement.** (a) A physician must review all cases 298.15 in which the utilization review organization has concluded that a determination not to 298.16 certify for clinical reasons is appropriate.

298.17 (b) The physician conducting the review must be licensed in this state. This 298.18 paragraph does not apply to reviews conducted in connection with policies issued by a 298.19 health plan company that is assessed less than three percent of the total amount assessed 298.20 by the Minnesota Comprehensive Health Association.

298.21 (c) The physician should be reasonably available by telephone to discuss the 298.22 determination with the attending health care professional.

298.23 (d) This subdivision does not apply to outpatient mental health or substance abuse 298.24 services governed by subdivision 3a.

298.25 **EFFECTIVE DATE.** This section is effective January 1, 2017.

298.26 Sec. 26. Minnesota Statutes 2014, section 62M.10, subdivision 7, is amended to read:

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298.27 Subd. 7. **Availability of criteria.** Upon request, a utilization review organization 298.28 shall provide to an enrollee, a provider, and the commissioner of commerce the <u>written</u> 298.29 <u>clinical</u> criteria used to determine the medical necessity, appropriateness, and efficacy of a 298.30 procedure or service and identify the database, professional treatment guideline, or other 298.31 basis for the criteria. <u>This requirement may be met by posting the written clinical criteria</u> 298.32 <u>on the utilization review organization's public Web site or electronically distributing the</u> 298.33 information directly to the enrollee or provider.

299.1 EFFECTIVE DATE. This section is effective August 1, 2015.

299.2 Sec. 27. Minnesota Statutes 2014, section 62M.11, is amended to read: 299.3 **62M.11 COMPLAINTS TO COMMERCE OR HEALTH.**

299.4 Notwithstanding the provisions of sections 62M.01 to 62M.16, an enrollee or 299.5 provider may file a complaint regarding compliance with the requirements of this chapter 299.6 or regarding a determination not to certify directly to the commissioner responsible for 299.7 regulating the utilization review organization.

299.8 **EFFECTIVE DATE.** This section is effective August 1, 2015.

299.9 Sec. 28. [62M.17] REPORTING.

299.10 On August 1, 2016, and each August 1 thereafter, utilization review organizations 299.11 must report to the commissioner of health, on the forms and in the manner specified by the

299.12 commissioner, the following information:

299.13 (1) for medical exception requests, the 25 most frequently requested drugs by 299.14 exception type, including lack of available clinical alternative, ineffective formulary 299.15 drug, and dosage limits; and

299.16 (2) for prescription drug prior authorization requests:

299.17 (i) the number and rate of initial approvals by commercial product and by prepaid 299.18 medical assistance product types;

299.19 (ii) the number and rate of standard appeal approvals by commercial product and by 299.20 prepaid medical assistance product types;

299.21 (iii) the number and rate of expedited appeal approvals by commercial product and 299.22 by prepaid medical assistance product types;

299.23 (iv) for standard reviews, the range and average time from receipt of completed 299.24 request to notification of decision;

299.25 (v) for expedited reviews, the range and average time from receipt of completed 299.26 request to notification of decision;

299.27 (vi) for standard appeals, the range and average time from receipt of completed 299.28 request to notification of decision; and

299.29 (vii) for expedited appeals, the range and average time from receipt of completed 299.30 request to notification of decision.

299.31 **EFFECTIVE DATE.** This section is effective August 1, 2015.

300.1 Sec. 29. Minnesota Statutes 2014, section 62Q.02, is amended to read: 300.2 62Q.02 APPLICABILITY OF CHAPTER.

300.3 (a) This chapter applies only to health plans, as defined in section 62Q.01, and not to 300.4 other types of insurance issued or renewed by health plan companies, unless otherwise 300.5 specified.

300.6 (b) This chapter applies to a health plan company only with respect to health plans, 300.7 as defined in section 62Q.01, issued or renewed by the health plan company, unless 300.8 otherwise specified.

300.9 (c) If a health plan company issues or renews health plans in other states, this chapter 300.10 applies only to health plans issued or renewed in this state for Minnesota residents, or to 300.11 cover a resident of the state, unless otherwise specified.

300.12 (d) This chapter does not apply to public health care programs administered by the 300.13 commissioner of human services under chapter 256B or 256L, unless otherwise required 300.14 by law or regulation.

300.15 Sec. 30. [62Q.83] FREEDOM OF CHOICE FOR PHARMACY SERVICES.

300.16 Subdivision 1. Enrollee choice. No health plan company or pharmacy benefit
300.17 manager that covers pharmaceutical services, including prescription drug coverage, shall
300.18 limit or restrict an enrollee's ability to select a pharmacy or pharmacist of the enrollee's
300.19 choice if the pharmacy or pharmacist is licensed under chapter 151, and the pharmacy
300.20 or pharmacist has agreed to the terms of the health plan company's or pharmacy benefit
300.21 manager's provider contract.

300.22 This subdivision does not apply to an enrollee in the Minnesota restricted recipient 300.23 program pursuant to Minnesota Rules, part 9505.2238.

300.24 Subd. 2. **Provider network.** No health plan company or pharmacy benefit manager 300.25 shall deny a pharmacy or pharmacist the right to participate in any of its pharmacy network 300.26 contracts in this state or as a contracting provider in this state if the pharmacy or pharmacist 300.27 has a valid license under chapter 151, and the pharmacy or pharmacist agrees to accept the 300.28 terms and conditions offered by the health plan company or pharmacy benefit manager, 300.29 and agrees to provide pharmacy services that meet state and federal laws and regulations.

300.30 Subd. 3. Cost-sharing or other conditions. No health plan company or pharmacy

- 300.31 <u>benefit manager shall impose a co-payment, fee, or other cost-sharing requirement</u> 300.32 for selecting a pharmacy or pharmacist of the enrollee's choosing or impose other
- 300.33 conditions that limit or restrict an enrollee's ability to utilize a pharmacy of the enrollee's
- 300.34 choosing, unless the health plan company or pharmacy benefit manager imposes the
- 300.35 same cost-sharing requirements, fees, conditions, or limits upon an enrollee's selection of
- 301.1 any of the pharmacies within the health plan company's or pharmacy benefit manager's
- 301.2 provider network contracts in this state.
- 301.3 Subd. 4. Definitions. (a) For purposes of this section, the terms in this subdivision 301.4 have the meanings given.
- 301.5 (b) "Pharmacy" has the meaning given in section 151.01, subdivision 2, and includes 301.6 mail order pharmacies and specialty pharmacies.
- 301.7 (c) "Pharmacy benefit manager" has the meaning given in section 151.71, 301.8 subdivision 1.

301.9 **EFFECTIVE DATE.** This section is effective August 1, 2015, and applies to any 301.10 health plan issued or renewed on or after that date.

301.11 Sec. 31. [62Q.84] SERVICES PERFORMED BY A PHARMACIST.

- 301.12 A health plan company or pharmacy benefit manager, as defined under section
- 301.13 151.71, subdivision 1, shall provide payment for any health care service that is a covered
- 301.14 benefit and is performed by a licensed pharmacist if: (1) the service performed is within
- 301.15 the scope of practice of a licensed pharmacist under chapter 151; and (2) the health plan
- 301.16 would cover the service if the service was performed by a physician licensed under chapter
- 301.17 147; an advanced practice registered nurse licensed under section 148.211, subdivision
- 301.18 1a; or a physician assistant licensed under chapter 147A.

301.19 **EFFECTIVE DATE.** This section is effective August 1, 2015, and applies to any 301.20 health plan issued or renewed on or after that date.

301.21 Sec. 32. [62Q.85] PRESCRIPTION DRUG BENEFIT TRANSPARENCY AND 301.22 MANAGEMENT.

301.23 Subdivision 1. Definitions. (a) For purposes of this section, the following terms 301.24 have the meaning given them.

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

- 301.26 (c) "Formulary" means a list of prescription drugs that have been developed by 301.27 clinical and pharmacy experts and represents the health plan company's medically
- 301.28 appropriate and cost-effective prescription drugs approved for use.

301.29 (d) "Health plan company" has the meaning given in section 62Q.01, subdivision 4,

- 301.30 and includes an entity that performs pharmacy benefits management for the health plan 301.31 company. For purposes of this definition, "pharmacy benefits management" means the
- 301.32 administration or management of prescription drug benefits provided by the health plan
- 301.33 company for the benefit of its enrollees and may include, but is not limited to, procurement
- 302.1 of prescription drugs, clinical formulary development and management services, claims
- 302.2 processing, and rebate contracting and administration.
- 302.3 (e) "Prescription" has the meaning given in section 151.01, subdivision 16a.
- 302.4 Subd. 2. Prescription drug benefit disclosure. (a) A health plan company that
- 302.5 provides prescription drug benefit coverage and uses a formulary must make its formulary
- $302.6\ \underline{\text{and related benefit information available by electronic means and, upon request, in}$
- 302.7 writing, at least 30 days prior to annual renewal dates.

302.8 (b) Formularies must be organized and disclosed consistent with the most recent 302.9 version of the United States Pharmacopeia's (USP) Model Guidelines.

- 302.10 (c) For each item or category of items on the formulary, the specific enrollee benefit
- 302.11 terms must be identified, including enrollee cost-sharing and expected out-of-pocket costs.
- 302.12 <u>Subd. 3.</u> **Formulary changes.** (a) Once a formulary has been established, a health 302.13 plan company may, at any time during the enrollee's benefit year:
- 302.14 (1) expand its formulary by adding drugs to the formulary;
- 302.15 (2) reduce co-payments or coinsurance; or
- 302.16 (3) move a drug to a benefit category that reduces an enrollee's cost.
- 302.17 (b) A health plan company may remove a brand name drug from its formulary
- 302.18 or place a brand name drug in a benefit category that increases an enrollee's cost only
- 302.19 upon the addition to the formulary of an A-rated generic or multisource brand name
- 302.20 equivalent at a lower cost to the enrollee, and upon at least a 60-day notice to prescribers,
- 302.21 pharmacists, and affected enrollees.

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

302.29 (d) Managed care plans and county-based purchasing plans under section 256B.69

302.30 and chapter 256L, are prohibited from removing drugs from its formulary or moving 302.31 drugs to a benefit category that increases an enrollee's cost more than once annually unless

302.32 an A-rated generic or multisource brand name equivalent is added to the formulary. This

302.33 paragraph does not apply to any changes associated with drugs that have been deemed

- 302.34 unsafe by the Food and Drug Administration, that have been withdrawn by either the Food
- 302.35 and Drug Administration or the product manufacturer, or where an independent source
- 303.1 of research, clinical guidelines, or evidence-based standards has issued drug-specific
- 303.2 warnings or recommended changes in drug usage.

303.3 Subd. 4. Transition process. (a) A health plan company must establish and

303.4 maintain a transition process to prevent gaps in prescription drug coverage for both

- 303.5 new and continuing enrollees with ongoing prescription drug needs who are affected
- 303.6 by changes in formulary drug availability.

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

303.8 (c) Any enrollee cost-sharing applied must be based on the defined prescription drug 303.9 benefit terms and must be consistent with any cost-sharing that the health plan company 303.10 would charge for nonformulary drugs approved under a medication exceptions process.

303.11 (d) A health plan company must ensure that written notice is provided to each

303.12 affected enrollee and prescriber within three business days after adjudication of the 303.13 transition coverage.

303.14 Subd. 5. Medication exceptions process. (a) Each health plan company must

303.15 establish and maintain a medication exceptions process that allows enrollees, providers, 303.16 or an enrollee's authorized representative to request and obtain coverage approval for

303.16 or an enrollee's authorized representative to request and obtain coverage appl

303.17 medications in the following situations:

303.18 (1) there is no acceptable clinical alternative listed on the formulary to treat the 303.19 enrollee's disease or medical condition;

303.20 (2) the prescription listed on the formulary has been ineffective in the treatment of

303.21 an enrollee's disease or medical condition or, based on clinical and scientific evidence and

303.22 the relevant physical or mental characteristics of the enrollee, is likely to be ineffective or

303.23 adversely affect the drug's effectiveness or the enrollee's medication compliance; or

303.24 (3) the number of doses that are available under a dose restriction has been

303.25 ineffective in the treatment of the enrollee's disease or medical condition or, based on

303.26 clinical and scientific evidence and the relevant physical or mental characteristics of

303.27 the enrollee, is likely to be ineffective or adversely affect the drug's effectiveness or the

303.28 enrollee's medication compliance.

303.29 (b) An approved medication exception request must remain valid for the duration of
303.30 an enrollee's benefit term, or for benefits offered under section 265B.69 or chapter 256L,
303.31 for the duration of the enrollee's enrollment, or one year, whichever is shorter, provided
303.32 the medication continues to be prescribed for the same condition, and the medication has

303.33 not otherwise been withdrawn by the manufacturer or the Food and Drug Administration.

303.34 (c) The medication exceptions process must comply with the requirements of 303.35 chapter 62M.

304.1 Subd. 6. Prescription Drug Advisory Council. (a) A Prescription Drug Advisory

304.2 <u>Council has 11 members appointed by the commissioner of health with representation</u> 304.3 <u>as follows:</u>

304.4 (1) three patients;

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

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

304.7 (4) one pharmacist licensed in Minnesota;

- 304.8 (5) one person representing a health plan company;
- 304.9 (6) one person representing a pharmacy benefit manager;
- 304.10 (7) one person representing pharmaceutical manufacturers; and
- 304.11 (8) one person who purchases health benefits for a group or an employer.
- 304.12 (b) Terms and removal of public members are as provided in section 15.0575, except
- 304.13 that members will serve without compensation or expense reimbursement. A vacancy on
- 304.14 the council may be filled by the appointing authority for the remainder of the unexpired
- 304.15 term. Vacancies will be filled as provided in section 15.0597.
- 304.16 (c) The council shall select a chair from among its members. The chair may convene
- 304.17 meetings as necessary to conduct the duties prescribed by this section.
- 304.18 (d) The duty of the council is to provide guidance to the commissioner of health
- 304.19 in monitoring changes and trends in prescription drug coverage and formulary design.
- 304.20 The council must consult with the commissioner to assist the commissioner in preparing
- 304.21 the report required under paragraph (g).
- 304.22 (e) The commissioner of health will provide administrative support and meeting

304.23 space for the council to perform its duties.

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

304.25 (g) Beginning January 15, 2017, and on at least a biennial basis thereafter, the 304.26 commissioner, in consultation with the advisory group, shall submit a report to the chairs 304.27 and lead minority members of the legislative committees with jurisdiction over health care 304.28 coverage describing trends in prescription drug coverage, formulary design, medication 304.29 exception requests, and benefit design. Health plan companies, pharmacy benefit managers, 304.30 prescribers, and pharmacies must cooperate in providing information necessary for the 304.31 advisory group to carry out its responsibilities, provided the commissioner, in consultation 304.32 with the affected parties, does not determine the information to be of a proprietary nature.

304.33 **EFFECTIVE DATE.** Subdivisions 1 to 5 are effective January 1, 2017. Subdivision 304.34 <u>6 is effective August 1, 2015.</u>

304.35 Sec. 33. Minnesota Statutes 2014, section 62U.02, subdivision 1, is amended to read:

305.1 Subdivision 1. **Development.** (a) The commissioner of health shall develop a 305.2 standardized set of measures by which to assess the quality of health care services offered 305.3 by health care providers, including health care providers certified as health care homes 305.4 under section 256B.0751. Quality measures must be based on medical evidence and be 305.5 developed through a process in which providers participate. The measures shall be used 305.6 for the quality incentive payment system developed in subdivision 2 and must:

305.7 (1) include uniform definitions, measures, and forms for submission of data, to the 305.8 greatest extent possible;

305.9 (2) seek to avoid increasing the administrative burden on health care providers;

305.10 (3) be initially based on existing quality indicators for physician and hospital 305.11 services, which are measured and reported publicly by quality measurement organizations, 305.12 including, but not limited to, Minnesota Community Measurement and specialty societies;

305.13 (4) place a priority on measures of health care outcomes, rather than process 305.14 measures, wherever possible; and

305.15 (5) incorporate measures for primary care, including preventive services, coronary 305.16 artery and heart disease, diabetes, asthma, depression, and other measures as determined 305.17 by the commissioner.

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305.18 (b) Effective July 1, 2016, the commissioner shall stratify five quality measures by 305.19 race, ethnicity, preferred language, and country of origin. On or after January 1, 2018, the 305.20 commissioner may require measures to be stratified by other sociodemographic factors 305.21 that according to reliable data are correlated with health disparities and have an impact 305.22 on performance on quality or cost indicators. New methods of stratifying data under this 305.23 paragraph must be tested and evaluated through pilot projects prior to adding them to the 305.24 statewide system. In determining whether to add additional sociodemographic factors and 305.25 developing the methodology to be used, the commissioner shall consider the reporting 305.26 burden on providers and determine whether there are alternative sources of data that could 305.27 be used. The commissioner shall ensure that categories and data collection methods are 305.28 developed in consultation with those communities impacted by health disparities using 305.29 culturally appropriate community engagement principles and methods. The commissioner 305.30 shall implement this paragraph in coordination with the contracting entity retained under 305.31 section 62U.02, subdivision 4, in order to build upon the data stratification methodology 305.32 that has been developed and tested by the entity. Nothing in this paragraph expands or 305.33 changes the commissioner's authority to collect, analyze, or report health care data. Any 305.34 data collected to implement this paragraph must be data that is available or is authorized 305.35 to be collected under other laws. Nothing in this paragraph grants authority to the 306.1 commissioner to collect or analyze patient-level or patient-specific data of the patient 306.2 characteristics identified under this paragraph.

306.3 (b)(c) The measures shall be reviewed at least annually by the commissioner.

306.4 Sec. 34. Minnesota Statutes 2014, section 62U.02, subdivision 2, is amended to read:

306.5 Subd. 2. **Quality incentive payments.** (a) By July 1, 2009, the commissioner 306.6 shall develop a system of quality incentive payments under which providers are eligible 306.7 for quality-based payments that are in addition to existing payment levels, based upon 306.8 a comparison of provider performance against specified targets, and improvement over 306.9 time. The targets must be based upon and consistent with the quality measures established 306.10 under subdivision 1.

306.11 (b) To the extent possible, the payment system must adjust for variations in patient
306.12 population in order to reduce incentives to health care providers to avoid high-risk patients
306.13 or populations, including those with risk factors related to race, ethnicity, language,
306.14 country of origin, and sociodemographic factors.

306.15 (c) The requirements of section 62Q.101 do not apply under this incentive payment 306.16 system.

306.17 Sec. 35. Minnesota Statutes 2014, section 62U.02, subdivision 3, is amended to read:

306.18 Subd. 3. **Quality transparency.** (a) The commissioner shall establish standards for 306.19 measuring health outcomes, establish a system for risk adjusting quality measures, and 306.20 issue annual public reports on provider quality beginning July 1, 2010.

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306.21 (b) Effective July 1, 2017, the risk adjustment system established under this
 306.22 subdivision shall adjust for patient characteristics identified under subdivision 1, paragraph
 306.23 (b), that are correlated with health disparities and have an impact on performance on cost

306.25 actual-to-expected comparison that reflects the characteristics of the patient population 306.26 served by the clinic or hospital. The commissioner shall implement this paragraph in 306.27 coordination with any contracting entity retained under section 62U.02, subdivision 4.

306.28 (c) By January 1, 2010, physician clinics and hospitals shall submit standardized 306.29 electronic information on the outcomes and processes associated with patient care to 306.30 the commissioner or the commissioner's designee. In addition to measures of care 306.31 processes and outcomes, the report may include other measures designated by the 306.32 commissioner, including, but not limited to, care infrastructure and patient satisfaction. 306.33 The commissioner shall ensure that any quality data reporting requirements established 306.34 under this subdivision are not duplicative of publicly reported, communitywide quality 307.1 reporting activities currently under way in Minnesota. Nothing in this subdivision is 307.2 intended to replace or duplicate current privately supported activities related to quality 307.3 measurement and reporting in Minnesota.

307.4 Sec. 36. Minnesota Statutes 2014, section 62U.02, subdivision 4, is amended to read:

307.5 Subd. 4. **Contracting.** The commissioner may contract with a private entity or 307.6 consortium of private entities to complete the tasks in subdivisions 1 to 3. The private 307.7 entity or consortium must be nonprofit and have governance that includes representatives 307.8 from the following stakeholder groups: health care providers, including providers serving 307.9 high concentrations of patients and communities impacted by health disparities; health 307.10 plan companies; consumers, including consumers representing groups who experience 307.11 health disparities; employers or other health care purchasers; and state government. No 307.12 one stakeholder group shall have a majority of the votes on any issue or hold extraordinary 307.13 powers not granted to any other governance stakeholder.

307.14 Sec. 37. Minnesota Statutes 2014, section 144E.001, is amended by adding a 307.15 subdivision to read:

307.16 Subd. 5h. Community medical response emergency medical technician.

307.17 "Community medical response emergency medical technician" or "CEMT" means
307.18 a person who is certified as an emergency medical technician, who is a member of a
307.19 registered medical response unit under section 144E.275, and who meets the requirements
307.20 for additional certification as a CEMT as specified in section 144E.275, subdivision 7.

307.21 Sec. 38. Minnesota Statutes 2014, section 144E.275, subdivision 1, is amended to read:

307.22 Subdivision 1. **Definition.** For purposes of this section, the following definitions 307.23 apply:

186.1 Sec. 11. Minnesota Statutes 2014, section 144E.001, is amended by adding a 186.2 subdivision to read:

186.3 Subd. 5h. Community medical response emergency medical technician.

186.4 "Community medical response emergency medical technician" or "CEMT" means
186.5 a person who is certified as an emergency medical technician, who is a member of a
186.6 registered medical response unit under this chapter, and who meets the requirements for
186.7 additional certification as a CEMT as specified in section 144E.275, subdivision 7.

186.8 Sec. 12. Minnesota Statutes 2014, section 144E.275, subdivision 1, is amended to read:

186.9 Subdivision 1. **Definition.** For purposes of this section, the following definitions 186.10 apply:

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307.24 (a) "Medical response unit" means an organized service recognized by a local
307.25 political subdivision whose primary responsibility is to respond to medical emergencies to
307.26 provide initial medical care before the arrival of a licensed ambulance service. Medical
307.27 response units may also provide CEMT services as permitted under subdivision 7.

307.28 (b) "Specialized medical response unit" means an organized service recognized by a 307.29 board-approved authority other than a local political subdivision that responds to medical 307.30 emergencies as needed or as required by local procedure or protocol.

307.31 Sec. 39. Minnesota Statutes 2014, section 144E.275, is amended by adding a 307.32 subdivision to read:

308.1 Subd. 7. Community medical response emergency medical technician. (a) To be 308.2 eligible for certification by the board as a CEMT, an individual shall:

308.3 (1) be currently certified as an EMT or AEMT;

308.4 (2) have two years of service as an EMT or AEMT;

308.5 (3) be a member of a registered medical response unit as defined under this section;

308.6 (4) successfully complete a CEMT training program from a college or university that 308.7 has been approved by the board or accredited by a board-approved national accrediting 308.8 organization. The training must include clinical experience under the supervision of the 308.9 medical response unit medical director, an advanced practice registered nurse, a physician 308.10 assistant, or a public health nurse operating under the direct authority of a local unit 308.11 of government;

308.12 (5) successfully complete a training program that includes training in providing 308.13 culturally appropriate care; and

308.14 (6) complete a board-approved application form.

308.15 (b) A CEMT must practice in accordance with protocols and supervisory standards 308.16 established by the medical response unit medical director in accordance with section 308.17 144E.265.

308.18 (c) A CEMT may provide services within the CEMT skill set as approved by the 308.19 medical response unit medical director.

186.11 (a) "Medical response unit" means an organized service recognized by a local political
186.12 subdivision whose primary responsibility is to respond to medical emergencies to provide
186.13 initial medical care before the arrival of a licensed ambulance service. Medical response
186.14 units may, subject to requirements specified elsewhere in this chapter and only when
186.15 requested by the patient's primary physician, advanced practice registered nurse, physician
186.16 assistant, or care team, provide, at the direction of a medical director, episodic population
186.17 health support, episodic individual patient education, and prevention education programs.

186.18 (b) "Specialized medical response unit" means an organized service recognized by a 186.19 board-approved authority other than a local political subdivision that responds to medical 186.20 emergencies as needed or as required by local procedure or protocol.

186.21 Sec. 13. Minnesota Statutes 2014, section 144E.275, is amended by adding a 186.22 subdivision to read:

186.23 Subd. 7. **Community medical response emergency medical technician.** (a) To be 186.24 eligible for certification by the board as a CEMT, an individual shall:

186.25 (1) be currently certified as an EMT or AEMT;

186.26 (2) have two years of service as an EMT or AEMT;

186.27 (3) be a member of a registered medical response unit as defined in this chapter;

186.28 (4) successfully complete a CEMT training program from a college or university that 186.29 has been approved by the board or accredited by a board-approved national accrediting 186.30 organization. The training must include clinical experience under the supervision of the 186.31 medical response unit medical director, an advanced practice registered nurse, a physician 186.32 assistant, or a public health nurse operating under the direct authority of a local unit 186.33 of government; and

186.34 (5) complete a board-approved application form.

187.1 (b) A CEMT must practice in accordance with protocols and supervisory standards 187.2 established by the medical response unit medical director in accordance with section 187.3 144E.265.

187.4 (c) A CEMT may provide services as approved by the medical response unit medical 187.5 director.

308.20 (d) A CEMT may provide episodic individual patient education and prevention 308.21 education but only as directed by a patient care plan developed by the patient's primary

308.22 physician, an advanced practice registered nurse, or a physician assistant, in conjunction 308.23 with the medical response unit medical director and relevant local health care providers. 308.24 The patient care plan must ensure that the services provided by the CEMT are consistent 308.25 with services offered by the patient's health care home, if one exists, that the patient 308.26 receives the necessary services, and that there is no duplication of services to the patient.

308.27 (e) A CEMT is subject to all certification, disciplinary, complaint, and other 308.28 regulatory requirements that apply to EMTs under this chapter.

308.29 (f) A CEMT may not provide services as defined in section 144A.471, subdivisions 308.30 6 and 7, except a CEMT may provide verbal or visual reminders to the patient to:

308.31 (1) take a regularly scheduled medication, but not to provide or bring the patient 308.32 medication; and

308.33 (2) follow regularly scheduled treatment or exercise plans.

308.34 Sec. 40. Minnesota Statutes 2014, section 151.58, subdivision 2, is amended to read:

309.1 Subd. 2. **Definitions.** For purposes of this section only, the terms defined in this 309.2 subdivision have the meanings given.

309.3 (a) "Automated drug distribution system" or "system" means a mechanical system 309.4 approved by the board that performs operations or activities, other than compounding or 309.5 administration, related to the storage, packaging, or dispensing of drugs, and collects, 309.6 controls, and maintains all required transaction information and records.

309.7 (b) "Health care facility" means a nursing home licensed under section 144A.02; 309.8 a housing with services establishment registered under section 144D.01, subdivision 4, 309.9 in which a home provider licensed under chapter 144A is providing centralized storage 309.10 of medications; <u>a boarding care home licensed under sections 144.50 to 144.58 that is</u> 309.11 <u>providing centralized storage of medications;</u> or a Minnesota sex offender program facility 309.12 operated by the Department of Human Services.

309.13 (c) "Managing pharmacy" means a pharmacy licensed by the board that controls and 309.14 is responsible for the operation of an automated drug distribution system.

309.15 Sec. 41. Minnesota Statutes 2014, section 151.58, subdivision 5, is amended to read:

309.16 Subd. 5. **Operation of automated drug distribution systems.** (a) The managing 309.17 pharmacy and the pharmacist in charge are responsible for the operation of an automated 309.18 drug distribution system.

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187.6 (d) A CEMT may provide episodic individual patient education and prevention
187.7 education only as directed by a patient care plan developed by the patient's primary
187.8 physician, an advanced practice registered nurse, or a physician assistant, in conjunction
187.9 with the medical response unit medical director and relevant local health care providers.
187.10 The care plan must ensure that the services provided by the CEMT are consistent with
187.11 services offered by the patient's health care home, if one exists, that the patient receives
187.12 the necessary services, and that there is no duplication of services to the patient.

187.13 (e) A CEMT is subject to all certification, disciplinary, complaint, and other 187.14 regulatory requirements that apply to EMTs under this chapter.

187.15 (f) A CEMT may not provide services defined in section 144A.471, subdivisions 6 187.16 and 7, except a CEMT may provide verbal or visual reminders to the patient to:

187.17 (1) take a regularly scheduled medication, but not to provide or bring the patient 187.18 medication; and

187.19 (2) follow regularly scheduled treatment or exercise plans.

ARTICLE 1, SECTIONS 3 AND 4.

5.15 Sec. 3. Minnesota Statutes 2014, section 151.58, subdivision 2, is amended to read:

5.16 Subd. 2. **Definitions.** For purposes of this section only, the terms defined in this 5.17 subdivision have the meanings given.

5.18 (a) "Automated drug distribution system" or "system" means a mechanical system5.19 approved by the board that performs operations or activities, other than compounding or5.20 administration, related to the storage, packaging, or dispensing of drugs, and collects,5.21 controls, and maintains all required transaction information and records.

5.22 (b) "Health care facility" means a nursing home licensed under section 144A.02;
5.23 a housing with services establishment registered under section 144D.01, subdivision 4,
5.24 in which a home provider licensed under chapter 144A is providing centralized storage
5.25 of medications; <u>a boarding care home licensed under sections 144.50 to 144.58 that is</u>
5.26 providing centralized storage of medications; or a Minnesota sex offender program facility
5.27 operated by the Department of Human Services.

5.28 (c) "Managing pharmacy" means a pharmacy licensed by the board that controls and 5.29 is responsible for the operation of an automated drug distribution system.

5.30 Sec. 4. Minnesota Statutes 2014, section 151.58, subdivision 5, is amended to read:

5.31 Subd. 5. Operation of automated drug distribution systems. (a) The managing5.32 pharmacy and the pharmacist in charge are responsible for the operation of an automated5.33 drug distribution system.

309.19 (b) Access to an automated drug distribution system must be limited to pharmacy 309.20 and nonpharmacy personnel authorized to procure drugs from the system, except that field 309.21 service technicians may access a system located in a health care facility for the purposes of 309.22 servicing and maintaining it while being monitored either by the managing pharmacy, or a 309.23 licensed nurse within the health care facility. In the case of an automated drug distribution 309.24 system that is not physically located within a licensed pharmacy, access for the purpose 309.25 of procuring drugs shall be limited to licensed nurses. Each person authorized to access 309.26 the system must be assigned an individual specific access code. Alternatively, access to 309.27 the system may be controlled through the use of biometric identification procedures. A 309.28 policy specifying time access parameters, including time-outs, logoffs, and lockouts, 309.29 must be in place.

309.30 (c) For the purposes of this section only, the requirements of section 151.215 are met 309.31 if the following clauses are met:

309.32 (1) a pharmacist employed by and working at the managing pharmacy, or at a 309.33 pharmacy that is acting as a central services pharmacy for the managing pharmacy, 309.34 pursuant to Minnesota Rules, part 6800.4075, must review, interpret, and approve all 309.35 prescription drug orders before any drug is distributed from the system to be administered 310.1 to a patient. A pharmacy technician may perform data entry of prescription drug orders 310.2 provided that a pharmacist certifies the accuracy of the data entry before the drug can 310.3 be released from the automated drug distribution system. A pharmacist employed by 310.4 and working at the managing pharmacy must certify the accuracy of the filling of any 310.5 cassettes, canisters, or other containers that contain drugs that will be loaded into the 310.6 automated drug distribution system, unless the filled cassettes, canisters, or containers 310.7 have been provided by a repackager registered with the United States Food and Drug 310.8 Administration and licensed by the board as a manufacturer; and

310.9 (2) when the automated drug dispensing system is located and used within the 310.10 managing pharmacy, a pharmacist must personally supervise and take responsibility for all 310.11 packaging and labeling associated with the use of an automated drug distribution system.

310.12 (d) Access to drugs when a pharmacist has not reviewed and approved the 310.13 prescription drug order is permitted only when a formal and written decision to allow such 310.14 access is issued by the pharmacy and the therapeutics committee or its equivalent. The 310.15 committee must specify the patient care circumstances in which such access is allowed, 310.16 the drugs that can be accessed, and the staff that are allowed to access the drugs. April 30, 2015 09:35 PM

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

6.12 (c) For the purposes of this section only, the requirements of section 151.215 are met 6.13 if the following clauses are met:

6.14 (1) a pharmacist employed by and working at the managing pharmacy, or at a
6.15 pharmacy that is acting as a central services pharmacy for the managing pharmacy,
6.16 pursuant to Minnesota Rules, part 6800.4075, must review, interpret, and approve all
6.17 prescription drug orders before any drug is distributed from the system to be administered
6.18 to a patient. A pharmacy technician may perform data entry of prescription drug orders
6.19 provided that a pharmacist certifies the accuracy of the data entry before the drug can
6.20 be released from the automated drug distribution system. A pharmacist employed by
6.21 and working at the managing pharmacy must certify the accuracy of the filling of any
6.22 cassettes, canisters, or other containers that contain drugs that will be loaded into the
6.23 automated drug distribution system, unless the filled cassettes, canisters, or containers
6.24 have been provided by a repackager registered with the United States Food and Drug
6.25 Administration and licensed by the board as a manufacturer; and

6.26 (2) when the automated drug dispensing system is located and used within the6.27 managing pharmacy, a pharmacist must personally supervise and take responsibility for all6.28 packaging and labeling associated with the use of an automated drug distribution system.

6.29 (d) Access to drugs when a pharmacist has not reviewed and approved the6.30 prescription drug order is permitted only when a formal and written decision to allow such6.31 access is issued by the pharmacy and the therapeutics committee or its equivalent. The6.32 committee must specify the patient care circumstances in which such access is allowed,6.33 the drugs that can be accessed, and the staff that are allowed to access the drugs.

310.17 (e) In the case of an automated drug distribution system that does not utilize bar 310.18 coding in the loading process, the loading of a system located in a health care facility may 310.19 be performed by a pharmacy technician, so long as the activity is continuously supervised, 310.20 through a two-way audiovisual system by a pharmacist on duty within the managing 310.21 pharmacy. In the case of an automated drug distribution system that utilizes bar coding 310.22 in the loading process, the loading of a system located in a health care facility may be 310.23 performed by a pharmacy technician or a licensed nurse, provided that the managing 310.24 pharmacy retains an electronic record of loading activities.

310.25 (f) The automated drug distribution system must be under the supervision of a 310.26 pharmacist. The pharmacist is not required to be physically present at the site of the 310.27 automated drug distribution system if the system is continuously monitored electronically 310.28 by the managing pharmacy. A pharmacist on duty within a pharmacy licensed by the 310.29 board must be continuously available to address any problems detected by the monitoring 310.30 or to answer questions from the staff of the health care facility. The licensed pharmacy 310.31 may be the managing pharmacy or a pharmacy which is acting as a central services 310.32 pharmacy, pursuant to Minnesota Rules, part 6800.4075, for the managing pharmacy.

310.33 Sec. 42. Minnesota Statutes 2014, section 256B.0625, subdivision 3b, is amended to 310.34 read:

311.1 Subd. 3b. Telemedicine consultations services. (a) Medical assistance covers
311.2 medically necessary services and consultations delivered by a licensed health care provider
311.3 via telemedicine consultations. Telemedicine consultations must be made via two-way;
311.4 interactive video or store-and-forward technology. Store-and-forward technology includes
311.5 telemedicine consultations that do not occur in real time via synchronous transmissions;
311.6 and that do not require a face-to-face encounter with the patient for all or any part of any
311.7 such telemedicine consultation. The patient record must include a written opinion from the
311.8 consulting physician providing the telemedicine consultation. A communication between
311.9 two physicians that consists solely of a telephone conversation is not a telemedicine
311.10 consultation in the same manner as if the service or consultation was delivered in person.
311.11 Coverage is limited to three telemedicine consultations services per recipient enrollee per
311.12 calendar week. Telemedicine consultations services shall be paid at the full allowable rate.

311.13 (b) The commissioner shall establish criteria that a health care provider must attest 311.14 to in order to demonstrate the safety or efficacy of delivering a particular service via

311.15 telemedicine. The attestation may include that the health care provider:

311.16 (1) has identified the categories or types of services the health care provider will 311.17 provide via telemedicine;

311.18 (2) has written policies and procedures specific to telemedicine services that are 311.19 regularly reviewed and updated;

311.20 (3) has policies and procedures that adequately address patient safety before, during, 311.21 and after the telemedicine service is rendered;

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

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

195.20 Sec. 22. Minnesota Statutes 2014, section 256B.0625, subdivision 3b, is amended to 195.21 read:

195.22 Subd. 3b. **Telemedicine consultations services.** (a) Medical assistance covers 195.23 medically necessary services and consultations delivered by a licensed health care provider 195.24 via telemedicine consultations. Telemedicine consultations must be made via two-way, 195.25 interactive video or store-and-forward technology. Store-and-forward technology includes 195.26 telemedicine consultations that do not occur in real time via synchronous transmissions, 195.27 and that do not require a face-to-face encounter with the patient for all or any part of any 195.28 such telemedicine consultation. The patient record must include a written opinion from the 195.29 consulting physician providing the telemedicine consultation. A communication between 195.30 two physicians that consists solely of a telephone conversation is not a telemedicine 195.31 consultation in the same manner as if the service or consultation was delivered in person. 195.32 Coverage is limited to three telemedicine consultations services per recipient enrollee per 195.33 calendar week. Telemedicine consultations services shall be paid at the full allowable rate.

- 196.1 (b) The commissioner shall establish criteria that a health care provider must attest
- 196.2 to in order to demonstrate the safety or efficacy of delivering a particular service via
- 196.3 telemedicine. The attestation may include that the health care provider:

196.4 (1) has identified the categories or types of services the health care provider will 196.5 provide via telemedicine;

196.6 (2) has written policies and procedures specific to telemedicine services that are 196.7 regularly reviewed and updated;

196.8 (3) has policies and procedures that adequately address patient safety before, during, 196.9 and after the telemedicine service is rendered;

311.22 (4) has established protocols addressing how and when to discontinue telemedicine 311.23 services; and

311.24 (5) has an established quality assurance process related to telemedicine services.

311.25 (c) As a condition of payment, a licensed health care provider must document
311.26 each occurrence of a health service provided by telemedicine to a medical assistance
311.27 enrollee. Health care service records for services provided by telemedicine must meet
311.28 the requirements set forth in Minnesota Rules, part 9505.2175, subparts 1 and 2, and
311.29 must document:

311.30 (1) the type of service provided by telemedicine;

311.31 (2) the time the service began and the time the service ended, including an a.m. and 311.32 p.m. designation;

311.33 (3) the licensed health care provider's basis for determining that telemedicine is an 311.34 appropriate and effective means for delivering the service to the enrollee;

311.35 (4) the mode of transmission of the telemedicine service and records evidencing that 311.36 a particular mode of transmission was utilized;

312.1 (5) the location of the originating site and the distant site;

312.2 (6) if the claim for payment is based on a physician's telemedicine consultation

312.3 with another physician, the written opinion from the consulting physician providing the

312.4 telemedicine consultation; and

312.5 (7) compliance with the criteria attested to by the health care provider in accordance 312.6 with paragraph (b).

312.7 (d) If a health care provider provides the facility used as the originating site for the

312.8 delivery of telemedicine to a patient, the commissioner shall make a facility fee payment

312.9 to the originating site health care provider in an amount equivalent to the originated site

312.10 fee paid by Medicare. No facility fee shall be paid to a health care provider that is being

312.11 paid under a cost-based methodology or if Medicare has already paid the facility fee for an 312.12 enrollee who is dually eligible for Medicare and medical assistance.

312.13 (e) For purposes of this subdivision, "telemedicine" is defined under section

312.14 62A.671, subdivision 9; "licensed health care provider" is defined under section 62A.671, 312.15 subdivision 6; "health care provider" is defined under section 62A.671, subdivision 3; and

312.15 subdivision 0, nearly care provider is defined under section 02A.071, subdivision 7.

196.10 (4) has established protocols addressing how and when to discontinue telemedicine 196.11 services; and

196.12 (5) has an established quality assurance process related to telemedicine services.

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196.13 (c) As a condition of payment, a licensed health care provider must document
196.14 each occurrence of a health service provided by telemedicine to a medical assistance
196.15 enrollee. Health care service records for services provided by telemedicine must meet
196.16 the requirements set forth in Minnesota Rules, chapter 9505.2175, subparts 1 and 2,
196.17 and must document:

196.18 (1) the type of service provided by telemedicine;

196.19 (2) the time the service began and the time the service ended, including an a.m. and 196.20 p.m. designation;

196.21 (3) documentation of the licensed health care provider's basis for determining that196.22 telemedicine is an appropriate and effective means for delivering the service to the enrollee;

196.23 (4) the mode of transmission of the telemedicine service and records evidencing that 196.24 a particular mode of transmission was utilized;

196.25 (5) the location of the originating site and the distant site;

196.26 (6) if the claim for payment is based on a physician's telemedicine consultation
196.27 with another physician, the written opinion from the consulting physician providing the
196.28 telemedicine consultation; and

196.29 (7) documentation of compliance with the criteria attested to by the health care 196.30 provider in accordance with paragraph (b).

196.31 (d) If a health care provider provides the facility used as the originating site for the 196.32 delivery of telemedicine to a patient, the commissioner shall make a facility fee payment 196.33 to the originating site health care provider in an amount equivalent to the originated site 196.34 fee paid by Medicare. No facility fee shall be paid to a health care provider that is being 196.35 paid under a cost-based methodology or if Medicare has already paid the facility fee for an 196.36 enrollee who is dually eligible for Medicare and medical assistance.

197.1 (e) For purposes of this subdivision, "telemedicine" is defined under section
197.2 62A.671, subdivision 9; "licensed health care provider" is defined under section 62A.671,
197.3 subdivision 6; "health care provider" is defined under section 62A.671, subdivision 3; and
197.4 "originating site" is defined under section 62A.671, subdivision 7.

197.5 (f) The criteria described in section 256B.0625, subdivision 3b, paragraph (b), shall 197.6 not apply to managed care organizations and county-based purchasing plans, which may 197.7 establish criteria as described in section 62A.672, subdivision 1, paragraph (b), clause (2), 197.8 for the coverage of telemedicine services.

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312.17 **EFFECTIVE DATE.** This section is effective January 1, 2016.

312.18 Sec. 43. Minnesota Statutes 2014, section 256B.0625, subdivision 13, is amended to 312.19 read:

312.20 Subd. 13. **Drugs.** (a) Medical assistance covers drugs, except for fertility drugs 312.21 when specifically used to enhance fertility, if prescribed by a licensed practitioner and 312.22 dispensed by a licensed pharmacist, by a physician enrolled in the medical assistance 312.23 program as a dispensing physician, or by a physician, physician assistant, or a nurse 312.24 practitioner employed by or under contract with a community health board as defined in 312.25 section 145A.02, subdivision 5, for the purposes of communicable disease control.

312.26 (b) The dispensed quantity of a prescription drug must not exceed a 34-day supply, 312.27 unless authorized by the commissioner.

312.28 (c) For the purpose of this subdivision and subdivision 13d, an "active 312.29 pharmaceutical ingredient" is defined as a substance that is represented for use in a drug 312.30 and when used in the manufacturing, processing, or packaging of a drug becomes an 312.31 active ingredient of the drug product. An "excipient" is defined as an inert substance 312.32 used as a diluent or vehicle for a drug. The commissioner shall establish a list of active 312.33 pharmaceutical ingredients and excipients which are included in the medical assistance 312.34 formulary. Medical assistance covers selected active pharmaceutical ingredients and 313.1 excipients used in compounded prescriptions when the compounded combination is 313.2 specifically approved by the commissioner or when a commercially available product:

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

313.4 (2) does not exist in the same combination of active ingredients in the same strengths 313.5 as the compounded prescription; and

313.6 (3) cannot be used in place of the active pharmaceutical ingredient in the 313.7 compounded prescription.

197.9 **EFFECTIVE DATE.** This section is effective January 1, 2017, and applies to 197.10 coverage offered, sold, issued, or renewed on or after that date.

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ARTICLE 1, SECTIONS 9 AND 10.

12.21 Sec. 9. Minnesota Statutes 2014, section 256B.0625, subdivision 13, is amended to read:

12.22 Subd. 13. **Drugs.** (a) Medical assistance covers drugs, except for fertility drugs 12.23 when specifically used to enhance fertility, if prescribed by a licensed practitioner and 12.24 dispensed by a licensed pharmacist, by a physician enrolled in the medical assistance 12.25 program as a dispensing physician, or by a physician, physician assistant, or a nurse 12.26 practitioner employed by or under contract with a community health board as defined in 12.27 section 145A.02, subdivision 5, for the purposes of communicable disease control.

12.28 (b) The dispensed quantity of a prescription drug must not exceed a 34-day supply, 12.29 unless authorized by the commissioner.

12.30 (c) For the purpose of this subdivision and subdivision 13d, an "active 12.31 pharmaceutical ingredient" is defined as a substance that is represented for use in a drug 12.32 and when used in the manufacturing, processing, or packaging of a drug becomes an 12.33 active ingredient of the drug product. An "excipient" is defined as an inert substance 12.34 used as a diluent or vehicle for a drug. The commissioner shall establish a list of active 12.35 pharmaceutical ingredients and excipients which are included in the medical assistance 13.1 formulary. Medical assistance covers selected active pharmaceutical ingredients and 13.2 excipients used in compounded prescriptions when the compounded combination is 13.3 specifically approved by the commissioner or when a commercially available product:

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

13.5 (2) does not exist in the same combination of active ingredients in the same strengths 13.6 as the compounded prescription; and

13.7 (3) cannot be used in place of the active pharmaceutical ingredient in the 13.8 compounded prescription.

313.8 (d) Medical assistance covers the following over-the-counter drugs when prescribed 313.9 by a licensed practitioner or by a licensed pharmacist who meets standards established by 313.10 the commissioner, in consultation with the board of pharmacy: antacids, acetaminophen, 313.11 family planning products, aspirin, insulin, products for the treatment of lice, vitamins for 313.12 adults with documented vitamin deficiencies, vitamins for children under the age of seven 313.13 and pregnant or nursing women, and any other over-the-counter drug identified by the 313.14 commissioner, in consultation with the formulary committee, as necessary, appropriate, 313.15 and cost-effective for the treatment of certain specified chronic diseases, conditions, 313.16 or disorders, and this determination shall not be subject to the requirements of chapter 313.17 14. A pharmacist may prescribe over-the-counter medications as provided under this 313.18 paragraph for purposes of receiving reimbursement under Medicaid. When prescribing 313.19 over-the-counter drugs under this paragraph, licensed pharmacists must consult with 313.20 the recipient to determine necessity, provide drug counseling, review drug therapy 313.21 for potential adverse interactions, and make referrals as needed to other health care 313.22 professionals. Over-the-counter medications must be dispensed in a quantity that is the 313.23 lower lowest of: (1) the number of dosage units contained in the manufacturer's original 313.24 package; and (2) the number of dosage units required to complete the patient's course of 313.25 therapy; or (3) if applicable, the number of dosage units dispensed from a system using 313.26 retrospective billing, as provided under subdivision 13e, paragraph (b).

313.27 (e) Effective January 1, 2006, medical assistance shall not cover drugs that
313.28 are coverable under Medicare Part D as defined in the Medicare Prescription Drug,
313.29 Improvement, and Modernization Act of 2003, Public Law 108-173, section 1860D-2(e),
313.30 for individuals eligible for drug coverage as defined in the Medicare Prescription
313.31 Drug, Improvement, and Modernization Act of 2003, Public Law 108-173, section
313.21 860D-1(a)(3)(A). For these individuals, medical assistance may cover drugs from the
313.33 drug classes listed in United States Code, title 42, section 1396r-8(d)(2), subject to this
313.35 title 42, section 1396r-8(d)(2)(E), shall not be covered.

314.1 (f) Medical assistance covers drugs acquired through the federal 340B Drug Pricing 314.2 Program and dispensed by 340B covered entities and ambulatory pharmacies under 314.3 common ownership of the 340B covered entity. Medical assistance does not cover drugs 314.4 acquired through the federal 340B Drug Pricing Program and dispensed by 340B contract 314.5 pharmacies.

314.6 **EFFECTIVE DATE.** This section is effective January 1, 2016, or upon federal 314.7 approval, whichever is later.

314.8 Sec. 44. Minnesota Statutes 2014, section 256B.0625, subdivision 13e, is amended to 314.9 read:

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13.9 (d) Medical assistance covers the following over-the-counter drugs when prescribed
13.10 by a licensed practitioner or by a licensed pharmacist who meets standards established by
13.11 the commissioner, in consultation with the board of pharmacy: antacids, acetaminophen,
13.12 family planning products, aspirin, insulin, products for the treatment of lice, vitamins for
13.13 adults with documented vitamin deficiencies, vitamins for children under the age of seven
13.14 and pregnant or nursing women, and any other over-the-counter drug identified by the
13.15 commissioner, in consultation with the formulary committee, as necessary, appropriate,
13.16 and cost-effective for the treatment of certain specified chronic diseases, conditions,
13.17 or disorders, and this determination shall not be subject to the requirements of chapter
13.18 14. A pharmacist may prescribe over-the-counter medications as provided under this
13.19 paragraph for purposes of receiving reimbursement under Medicaid. When prescribing
13.20 over-the-counter drugs under this paragraph, licensed pharmacists must consult with the
13.21 recipient to determine necessity, provide drug counseling, review drug therapy for potential
13.22 adverse interactions, and make referrals as needed to other health care professionals.
13.23 Over-the-counter medications must be dispensed in a quantity that is the lower lowest of:

13.24 (1) the number of dosage units contained in the manufacturer's original package; and

13.25 (2) the number of dosage units required to complete the patient's course of therapy; or

13.26 (3) if applicable, the number of dosage units dispensed from a system using 13.27 retrospective billing, as provided under subdivision 13e, paragraph (b).

13.28 (e) Effective January 1, 2006, medical assistance shall not cover drugs that
13.29 are coverable under Medicare Part D as defined in the Medicare Prescription Drug,
13.30 Improvement, and Modernization Act of 2003, Public Law 108-173, section 1860D-2(e),
13.31 for individuals eligible for drug coverage as defined in the Medicare Prescription
13.32 Drug, Improvement, and Modernization Act of 2003, Public Law 108-173, section
13.33 1860D-1(a)(3)(A). For these individuals, medical assistance may cover drugs from the
13.34 drug classes listed in United States Code, title 42, section 1396r-8(d)(2), subject to this
13.35 subdivision and subdivisions 13a to 13g, except that drugs listed in United States Code,
13.36 title 42, section 1396r-8(d)(2)(E), shall not be covered.

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

14.6 **EFFECTIVE DATE.** This section is effective January 1, 2016, or upon federal 14.7 approval, whichever is later.

14.8 Sec. 10. Minnesota Statutes 2014, section 256B.0625, subdivision 13e, is amended to 14.9 read:

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314.10 Subd. 13e. Payment rates. (a) The basis for determining the amount of payment 314.11 shall be the lower of the actual acquisition costs of the drugs or the maximum allowable 314.12 cost by the commissioner plus the fixed dispensing fee; or the usual and customary price 314.13 charged to the public. The amount of payment basis must be reduced to reflect all discount 314.14 amounts applied to the charge by any provider/insurer agreement or contract for submitted 314.15 charges to medical assistance programs. The net submitted charge may not be greater 314.16 than the patient liability for the service. The pharmacy dispensing fee shall be \$3.65 314.17 for legend prescription drugs, except that the dispensing fee for intravenous solutions 314.18 which must be compounded by the pharmacist shall be \$8 per bag, \$14 per bag for cancer 314.19 chemotherapy products, and \$30 per bag for total parenteral nutritional products dispensed 314.20 in one liter quantities, or \$44 per bag for total parenteral nutritional products dispensed in 314.21 quantities greater than one liter. The pharmacy dispensing fee for over the counter drugs 314.22 shall be \$3.65, except that the fee shall be \$1.31 for retrospectively billing pharmacies 314.23 when billing for quantities less than the number of units contained in the manufacturer's 314.24 original package. Actual acquisition cost includes quantity and other special discounts 314.25 except time and cash discounts. The actual acquisition cost of a drug shall be estimated 314.26 by the commissioner at wholesale acquisition cost plus four percent for independently 314.27 owned pharmacies located in a designated rural area within Minnesota, and at wholesale 314.28 acquisition cost plus two percent for all other pharmacies. A pharmacy is "independently 314.29 owned" if it is one of four or fewer pharmacies under the same ownership nationally. A 314.30 "designated rural area" means an area defined as a small rural area or isolated rural area 314.31 according to the four-category classification of the Rural Urban Commuting Area system 314.32 developed for the United States Health Resources and Services Administration. Effective 314.33 January 1, 2014, the actual acquisition cost of a drug acquired through the federal 340B 314.34 Drug Pricing Program shall be estimated by the commissioner at wholesale acquisition 314.35 cost minus 40 percent. Wholesale acquisition cost is defined as the manufacturer's list 315.1 price for a drug or biological to wholesalers or direct purchasers in the United States, not 315.2 including prompt pay or other discounts, rebates, or reductions in price, for the most 315.3 recent month for which information is available, as reported in wholesale price guides or 315.4 other publications of drug or biological pricing data. The maximum allowable cost of a 315.5 multisource drug may be set by the commissioner and it shall be comparable to, but no 315.6 higher than, the maximum amount paid by other third-party payors in this state who have 315.7 maximum allowable cost programs. Establishment of the amount of payment for drugs 315.8 shall not be subject to the requirements of the Administrative Procedure Act.

315.9 (b) Pharmacies dispensing prescriptions to residents of long-term care facilities
315.10 using an automated drug distribution system meeting the requirements of section 151.58,
315.11 or a packaging system meeting the packaging standards set forth in Minnesota Rules, part
315.12 6800.2700, that govern the return of unused drugs to the pharmacy for reuse, may employ
315.13 retrospective billing for prescription drugs dispensed to long-term care facility residents.
315.14 <u>A retrospectively billing pharmacy must submit a claim only for the quantity of medication</u>
315.15 used by the enrolled recipient during the defined billing period. A retrospectively billing
315.16 pharmacy must use a billing period not less than one calendar month or 30 days.

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14.10 Subd. 13e. Payment rates. (a) The basis for determining the amount of payment 14.11 shall be the lower of the actual acquisition costs of the drugs or the maximum allowable 14.12 cost by the commissioner plus the fixed dispensing fee; or the usual and customary price 14.13 charged to the public. The amount of payment basis must be reduced to reflect all discount 14.14 amounts applied to the charge by any provider/insurer agreement or contract for submitted 14.15 charges to medical assistance programs. The net submitted charge may not be greater 14.16 than the patient liability for the service. The pharmacy dispensing fee shall be \$3.65 14.17 for legend prescription drugs, except that the dispensing fee for intravenous solutions 14.18 which must be compounded by the pharmacist shall be \$8 per bag, \$14 per bag for cancer 14.19 chemotherapy products, and \$30 per bag for total parenteral nutritional products dispensed 14.20 in one liter quantities, or \$44 per bag for total parenteral nutritional products dispensed in 14.21 quantities greater than one liter. The pharmacy dispensing fee for over-the-counter drugs 14.22 shall be \$3.65, except that the fee shall be \$1.31 for retrospectively billing pharmacies 14.23 when billing for quantities less than the number of units contained in the manufacturer's 14.24 original package. Actual acquisition cost includes quantity and other special discounts 14.25 except time and cash discounts. The actual acquisition cost of a drug shall be estimated 14.26 by the commissioner at wholesale acquisition cost plus four percent for independently 14.27 owned pharmacies located in a designated rural area within Minnesota, and at wholesale 14.28 acquisition cost plus two percent for all other pharmacies. A pharmacy is "independently 14.29 owned" if it is one of four or fewer pharmacies under the same ownership nationally. A 14.30 "designated rural area" means an area defined as a small rural area or isolated rural area 14.31 according to the four-category classification of the Rural Urban Commuting Area system 14.32 developed for the United States Health Resources and Services Administration. Effective 14.33 January 1, 2014, the actual acquisition cost of a drug acquired through the federal 340B 14.34 Drug Pricing Program shall be estimated by the commissioner at wholesale acquisition 14.35 cost minus 40 percent. Wholesale acquisition cost is defined as the manufacturer's list 15.1 price for a drug or biological to wholesalers or direct purchasers in the United States, not 15.2 including prompt pay or other discounts, rebates, or reductions in price, for the most 15.3 recent month for which information is available, as reported in wholesale price guides or 15.4 other publications of drug or biological pricing data. The maximum allowable cost of a 15.5 multisource drug may be set by the commissioner and it shall be comparable to, but no 15.6 higher than, the maximum amount paid by other third-party payors in this state who have 15.7 maximum allowable cost programs. Establishment of the amount of payment for drugs 15.8 shall not be subject to the requirements of the Administrative Procedure Act.

15.9 (b) Pharmacies dispensing prescriptions to residents of long-term care facilities
15.10 using an automated drug distribution system meeting the requirements of section 151.58,
15.11 or a packaging system meeting the packaging standards set forth in Minnesota Rules, part
15.12 6800.2700, that govern the return of unused drugs to the pharmacy for reuse, may employ
15.13 retrospective billing for prescriptions dispensed to long-term care facility residents. A
15.14 retrospectively billing pharmacy must submit a claim only for the quantity of medication
15.15 used by the enrolled recipient during the defined billing period. A retrospectively billing
15.16 pharmacy must use a billing period of not less than one calendar month or 30 days.

315.17 (c) An additional dispensing fee of \$.30 may be added to the dispensing fee paid to 315.18 pharmacists for legend drug prescriptions dispensed to residents of long-term care facilities 315.19 when a unit dose blister card system, approved by the department, is used. Under this type 315.20 of dispensing system, the pharmacist must dispense a 30-day supply of drug. The National 315.21 Drug Code (NDC) from the drug container used to fill the blister card must be identified on 315.22 the claim to the department. The unit dose blister card containing the drug must meet the 315.23 packaging standards set forth in Minnesota Rules, part 6800.2700, that govern the return of 315.24 unused drugs to the pharmacy for reuse. The <u>A</u> pharmacy provider will be using packaging 315.25 that meets the standards set forth in Minnesota Rules, part 6800.2700, is required to credit 315.26 the department for the actual acquisition cost of all unused drugs that are eligible for reuse, 315.27 unless the pharmacy is using retrospective billing. The commissioner may permit the drug 315.28 clozapine to be dispensed in a quantity that is less than a 30-day supply.

315.29 (e) (d) Whenever a maximum allowable cost has been set for a multisource drug, 315.30 payment shall be the lower of the usual and customary price charged to the public or the 315.31 maximum allowable cost established by the commissioner unless prior authorization 315.32 for the brand name product has been granted according to the criteria established by 315.33 the Drug Formulary Committee as required by subdivision 13f, paragraph (a), and the 315.34 prescriber has indicated "dispense as written" on the prescription in a manner consistent 315.35 with section 151.21, subdivision 2.

316.1 (d) (e) The basis for determining the amount of payment for drugs administered in 316.2 an outpatient setting shall be the lower of the usual and customary cost submitted by 316.3 the provider, 106 percent of the average sales price as determined by the United States 316.4 Department of Health and Human Services pursuant to title XVIII, section 1847a of the 316.5 federal Social Security Act, the specialty pharmacy rate, or the maximum allowable cost 316.6 set by the commissioner. If average sales price is unavailable, the amount of payment 316.7 must be lower of the usual and customary cost submitted by the provider, the wholesale 316.8 acquisition cost, the specialty pharmacy rate, or the maximum allowable cost set by the 316.9 commissioner. Effective January 1, 2014, the commissioner shall discount the payment 316.10 rate for drugs obtained through the federal 340B Drug Pricing Program by 20 percent. The 316.11 payment for drugs administered in an outpatient setting shall be made to the administering 316.12 facility or practitioner. A retail or specialty pharmacy dispensing a drug for administration 316.13 in an outpatient setting is not eligible for direct reimbursement.

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15.17 (c) An additional dispensing fee of \$.30 may be added to the dispensing fee paid to 15.18 pharmacists for legend drug prescriptions dispensed to residents of long-term care facilities 15.19 when a unit dose blister card system, approved by the department, is used. Under this type 15.20 of dispensing system, the pharmacist must dispense a 30-day supply of drug. The National 15.21 Drug Code (NDC) from the drug container used to fill the blister card must be identified on 15.22 the claim to the department. The unit dose blister card containing the drug must meet the 15.23 packaging standards set forth in Minnesota Rules, part 6800.2700, that govern the return 15.24 of unused drugs to the pharmacy for reuse. The <u>A</u> pharmacy provider <u>using packaging</u> 15.25 <u>that meets the standards set forth in Minnesota Rules, part 6800.2700, subpart 2</u>, will be 15.26 required to credit the department for the actual acquisition cost of all unused drugs that are 15.27 eligible for reuse, <u>unless the pharmacy is using retrospective billing</u>. The commissioner 15.28 may permit the drug clozapine to be dispensed in a quantity that is less than a 30-day supply.

15.29 (e) (d) Whenever a maximum allowable cost has been set for a multisource drug, 15.30 payment shall be the lower of the usual and customary price charged to the public or the 15.31 maximum allowable cost established by the commissioner unless prior authorization 15.32 for the brand name product has been granted according to the criteria established by 15.33 the Drug Formulary Committee as required by subdivision 13f, paragraph (a), and the 15.34 prescriber has indicated "dispense as written" on the prescription in a manner consistent 15.35 with section 151.21, subdivision 2.

16.1 (d) (e) The basis for determining the amount of payment for drugs administered in 16.2 an outpatient setting shall be the lower of the usual and customary cost submitted by 16.3 the provider, 106 percent of the average sales price as determined by the United States 16.4 Department of Health and Human Services pursuant to title XVIII, section 1847a of the 16.5 federal Social Security Act, the specialty pharmacy rate, or the maximum allowable cost 16.6 set by the commissioner. If average sales price is unavailable, the amount of payment 16.7 must be lower of the usual and customary cost submitted by the provider, the wholesale 16.8 acquisition cost, the specialty pharmacy rate, or the maximum allowable cost set by the 16.9 commissioner. Effective January 1, 2014, the commissioner shall discount the payment 16.10 rate for drugs obtained through the federal 340B Drug Pricing Program by 20 percent. The 16.11 payment for drugs administered in an outpatient setting shall be made to the administering 16.12 facility or practitioner. A retail or specialty pharmacy dispensing a drug for administration 16.13 in an outpatient setting is not eligible for direct reimbursement.

316.14 (e) (f) The commissioner may negotiate lower reimbursement rates for specialty 316.15 pharmacy products than the rates specified in paragraph (a). The commissioner may 316.16 require individuals enrolled in the health care programs administered by the department 316.17 to obtain specialty pharmacy products from providers with whom the commissioner has 316.18 negotiated lower reimbursement rates. Specialty pharmacy products are defined as those 316.19 used by a small number of recipients or recipients with complex and chronic diseases 316.20 that require expensive and challenging drug regimens. Examples of these conditions 316.21 include, but are not limited to: multiple sclerosis, HIV/AIDS, transplantation, hepatitis 316.22 C, growth hormone deficiency, Crohn's Disease, rheumatoid arthritis, and certain forms 316.23 of cancer. Specialty pharmaceutical products include injectable and infusion therapies, 316.24 biotechnology drugs, antihemophilic factor products, high-cost therapies, and therapies 316.25 that require complex care. The commissioner shall consult with the formulary committee 316.26 to develop a list of specialty pharmacy products subject to this paragraph. In consulting 316.27 with the formulary committee in developing this list, the commissioner shall take into 316.28 consideration the population served by specialty pharmacy products, the current delivery 316.29 system and standard of care in the state, and access to care issues. The commissioner shall 316.30 have the discretion to adjust the reimbursement rate to prevent access to care issues.

316.31 (f) (g) Home infusion therapy services provided by home infusion therapy 316.32 pharmacies must be paid at rates according to subdivision 8d.

316.33 **EFFECTIVE DATE.** This section is effective January 1, 2016, or upon federal 316.34 approval, whichever is later.

317.1 Sec. 45. Minnesota Statutes 2014, section 256B.072, is amended to read:
317.2 256B.072 PERFORMANCE REPORTING AND QUALITY IMPROVEMENT
317.3 SYSTEM.

317.4 (a) The commissioner of human services shall establish a performance reporting 317.5 system for health care providers who provide health care services to public program 317.6 recipients covered under chapters 256B, 256D, and 256L, reporting separately for 317.7 managed care and fee-for-service recipients.

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16.14 (e) (f) The commissioner may negotiate lower reimbursement rates for specialty 16.15 pharmacy products than the rates specified in paragraph (a). The commissioner may 16.16 require individuals enrolled in the health care programs administered by the department 16.17 to obtain specialty pharmacy products from providers with whom the commissioner has 16.18 negotiated lower reimbursement rates. Specialty pharmacy products are defined as those 16.19 used by a small number of recipients or recipients with complex and chronic diseases 16.20 that require expensive and challenging drug regimens. Examples of these conditions 16.21 include, but are not limited to: multiple sclerosis, HIV/AIDS, transplantation, hepatitis 16.22 C, growth hormone deficiency, Crohn's Disease, rheumatoid arthritis, and certain forms 16.23 of cancer. Specialty pharmaceutical products include injectable and infusion therapies, 16.24 biotechnology drugs, antihemophilic factor products, high-cost therapies, and therapies 16.25 that require complex care. The commissioner shall consult with the formulary committee 16.26 to develop a list of specialty pharmacy products subject to this paragraph. In consulting 16.27 with the formulary committee in developing this list, the commissioner shall take into 16.28 consideration the population served by specialty pharmacy products, the current delivery 16.29 system and standard of care in the state, and access to care issues. The commissioner shall 16.30 have the discretion to adjust the reimbursement rate to prevent access to care issues.

16.31 (f) (g) Home infusion therapy services provided by home infusion therapy 16.32 pharmacies must be paid at rates according to subdivision 8d.

16.33 **EFFECTIVE DATE.** This section is effective January 1, 2016, or upon federal 16.34 approval, whichever is later.

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317.8 (b) The measures used for the performance reporting system for medical groups 317.9 shall include measures of care for asthma, diabetes, hypertension, and coronary artery 317.10 disease and measures of preventive care services. The measures used for the performance 317.11 reporting system for inpatient hospitals shall include measures of care for acute myocardial 317.12 infarction, heart failure, and pneumonia, and measures of care and prevention of surgical 317.13 infections. In the case of a medical group, the measures used shall be consistent with 317.14 measures published by nonprofit Minnesota or national organizations that produce and 317.15 disseminate health care quality measures or evidence-based health care guidelines. In 317.16 the case of inpatient hospital measures, the commissioner shall appoint the Minnesota 317.17 Hospital Association and Stratis Health to advise on the development of the performance 317.18 measures to be used for hospital reporting. To enable a consistent measurement process 317.19 across the community, the commissioner may use measures of care provided for patients in 317.20 addition to those identified in paragraph (a). The commissioner shall ensure collaboration 317.21 with other health care reporting organizations so that the measures described in this 317.22 section are consistent with those reported by those organizations and used by other 317.23 purchasers in Minnesota.

317.24 (c) The commissioner may require providers to submit information in a required317.25 format to a health care reporting organization or to cooperate with the information collection317.26 procedures of that organization. The commissioner may collaborate with a reporting317.27 organization to collect information reported and to prevent duplication of reporting.

317.28 (d) By October 1, 2007, and annually thereafter, the commissioner shall report 317.29 through a public Web site the results by medical groups and hospitals, where possible, 317.30 of the measures under this section, and shall compare the results by medical groups and 317.31 hospitals for patients enrolled in public programs to patients enrolled in private health 317.32 plans. To achieve this reporting, the commissioner may collaborate with a health care 317.33 reporting organization that operates a Web site suitable for this purpose.

317.34 (e) Performance measures must be stratified as provided under section 62U.02,
317.35 subdivision 1, paragraph (b), and risk-adjusted as specified in section 62U.02, subdivision
317.36 3, paragraph (b).

318.1 Sec. 46. Minnesota Statutes 2014, section 256B.69, subdivision 6, is amended to read:

318.2 Subd. 6. **Service delivery.** (a) Each demonstration provider shall be responsible for 318.3 the health care coordination for eligible individuals. Demonstration providers:

318.4 (1) shall authorize and arrange for the provision of all needed health services
318.5 including but not limited to the full range of services listed in sections 256B.02,
318.6 subdivision 8, and 256B.0625 in order to ensure appropriate health care is delivered to
318.7 enrollees. Notwithstanding section 256B.0621, demonstration providers that provide
318.8 nursing home and community-based services under this section shall provide relocation
318.9 service coordination to enrolled persons age 65 and over;

318.10 (2) shall accept the prospective, per capita payment from the commissioner in return 318.11 for the provision of comprehensive and coordinated health care services for eligible 318.12 individuals enrolled in the program;

318.13 (3) may contract with other health care and social service practitioners to provide 318.14 services to enrollees; and

318.15 (4) shall institute recipient grievance procedures according to the method established 318.16 by the project, utilizing applicable requirements of chapter 62D. Disputes not resolved 318.17 through this process shall be appealable to the commissioner as provided in subdivision 11.

318.18 (b) Demonstration providers must comply with the standards for claims settlement 318.19 under section 72A.201, subdivisions 4, 5, 7, and 8, when contracting with other health 318.20 care and social service practitioners to provide services to enrollees. A demonstration 318.21 provider must pay a clean claim, as defined in Code of Federal Regulations, title 42, 318.22 section 447.45(b), within 30 business days of the date of acceptance of the claim.

318.23 (c) Managed care plans and county-based purchasing plans must comply with 318.24 chapter 62M and section 62Q.85.

318.25 **EFFECTIVE DATE.** This section is effective January 1, 2016.

318.26 Sec. 47. PRESCRIPTION DRUG ADVISORY COUNCIL.

318.27 The commissioner of health shall make the first appointments to the Prescription
318.28 Drug Advisory Council established in Minnesota Statutes, section 62Q.85, subdivision 6,
318.29 by October 2, 2015, and convene the first meeting by November 1, 2015. The council
318.30 shall select a chair from among its members at the first meeting of the council.

318.31 EFFECTIVE DATE. This section is effective August 1, 2015.

319.1 Sec. 48. <u>PROPOSAL FOR CHILD PROTECTION FOCUSED "COMMUNITY</u> 319.2 <u>MEDICAL RESPONSE EMERGENCY MEDICAL TECHNICIAN" (CEMT)</u> 319.3 MODEL.

319.4 The commissioner shall develop a proposal for a pilot project to create a

319.5 community-based support system that coordinates services between child protection
319.6 services and community emergency medical technicians. This pilot project model shall
319.7 be developed with the input of stakeholders that represent both child protection services
319.8 and community emergency medical technicians. The model must be designed so that the
319.9 collaborative effort results in increased safety for children and increased support for
319.10 families. The pilot project model must be reviewed by the Task Force on the Protection of

319.11 <u>Children, and the commissioner shall make recommendations for the pilot project to the</u> 319.12 members of the legislative committees with primary jurisdiction over CEMT and child

319.13 protection issues no later than January 15, 2016.

319.14 Sec. 49. <u>COMMUNITY MEDICAL RESPONSE EMERGENCY MEDICAL</u> 319.15 <u>TECHNICIAN SERVICES COVERED UNDER THE MEDICAL ASSISTANCE</u> 319.16 **PROGRAM.**

319.17 (a) The commissioner of human services, in consultation with representatives of
319.18 emergency medical service providers, public health nurses, community health workers,
319.19 the Minnesota State Fire Chiefs Association, the Minnesota Professional Firefighters
319.20 Association, the Minnesota State Firefighters Department Association, Minnesota
319.21 Academy of Family Physicians, Minnesota Licensed Practical Nurses Association,
319.22 Minnesota Nurses Association, and local public health agencies, shall determine specified
319.23 services and payment rates for these services to be performed by community medical
319.24 response emergency medical technicians certified under Minnesota Statutes, section
319.25 144E.275, subdivision 7, and covered by medical assistance under Minnesota Statutes,
319.26 section 256B.0625. Services must be in the CEMT skill set and may include interventions
319.27 intended to prevent avoidable ambulance transportation or hospital emergency department
319.28 use.

319.29 (b) In order to be eligible for payment, services provided by a community medical 319.30 response emergency medical technician must be:

319.31 (1) ordered by a medical response unit medical director;

319.32 (2) part of a patient care plan that has been developed in coordination with the 319.33 patient's primary physician, advanced practice registered nurse, and relevant local health 319.34 care providers; and

320.1 (3) billed by an eligible medical assistance enrolled provider that employs or 320.2 contracts with the community medical response emergency medical technician.

320.3 In determining the community medical response emergency medical technician services

320.4 to include under medical assistance coverage, the commissioner of human services shall

320.5 consider the potential of hospital admittance and emergency room utilization reductions as

320.6 well as increased access to quality care in rural communities.

197.11 Sec. 23. <u>COMMUNITY MEDICAL RESPONSE EMERGENCY MEDICAL</u> 197.12 <u>TECHNICIAN SERVICES COVERED UNDER THE MEDICAL ASSISTANCE</u> 197.13 <u>PROGRAM.</u>

197.14 (a) The commissioner of human services, in consultation with representatives of
197.15 emergency medical service providers, public health nurses, community health workers,
197.16 the Minnesota State Fire Chiefs Association, the Minnesota Professional Firefighters
197.17 Association, the Minnesota State Firefighters Department Association, Minnesota
197.18 Academy of Family Physicians, Minnesota Licensed Practical Nurses Association,
197.19 Minnesota Nurses Association, and local public health agencies, shall determine specified
197.20 services and payment rates for these services to be performed by community medical
197.21 response emergency medical technicians certified under Minnesota Statutes, section
197.22 144E.275, subdivision 7, and covered by medical assistance under Minnesota Statutes,
197.23 section 256B.0625. Services may include interventions intended to prevent avoidable
197.24 ambulance transportation or hospital emergency department use, care coordination,
197.25 diagnosis-related patient education, and population-based preventive education.

197.26 (b) In order to be eligible for payment, services provided by a community medical 197.27 response emergency medical technician must be:

197.28 (1) ordered by a medical response unit medical director;

197.29 (2) part of a patient care plan that has been developed in coordination with the 197.30 patient's primary physician, advanced practice registered nurse, and relevant local health 197.31 care providers; and

197.32 (3) billed by an eligible medical assistance-enrolled provider that employs or 197.33 contracts with the community medical response emergency medical technician.

198.1 In determining the community medical response emergency medical technician services
 198.2 to include under medical assistance coverage, the commissioner of human services shall
 198.3 consider the potential of hospital admittance and emergency room utilization reductions as
 198.4 well as increased access to quality care in rural communities.

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320.7 (c) The commissioner of human services shall submit the list of services to be

320.8 covered by medical assistance to the chairs and ranking minority members of the

320.9 legislative committees with jurisdiction over health and human services policy and

320.10 spending by February 15, 2016. These services shall not be covered by medical assistance

320.11 until legislation providing coverage for the services is enacted in law.

320.12 Sec. 50. <u>EVALUATION OF COMMUNITY MEDICAL RESPONSE</u> 320.13 <u>EMERGENCY MEDICAL TECHNICIAN SERVICES.</u>

320.14 If legislation is enacted to cover community medical response emergency medical 320.15 technician services with medical assistance, the commissioner of human services shall 320.16 evaluate the effect of medical assistance and MinnesotaCare coverage for those services 320.17 on the cost and quality of care under those programs and the coordination of those services 320.18 with the health care home services. The commissioner shall present findings to the chairs 320.19 and ranking minority members of the legislative committees with jurisdiction over health 320.20 and human services policy and spending by December 1, 2017. The commissioner shall 320.21 require medical assistance and MinnesotaCare enrolled providers that employ or contract 320.22 with community medical response emergency medical technicians to provide to the 320.23 commissioner, in the form and manner specified by the commissioner, the utilization, cost, 320.24 and quality data necessary to conduct this evaluation.

320.25 Sec. 51. **REVISOR INSTRUCTION.**

320.26 The revisor of statutes shall change "sections 62M.01 to 62M.16" to "sections 320.27 62M.01 to 62M.17" wherever the term appears in Minnesota Statutes, chapter 62M.

320.28 EFFECTIVE DATE. This section is effective August 1, 2015.

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198.5 (c) The commissioner of human services shall submit the list of services to be
198.6 covered by medical assistance to the chairs and ranking minority members of the
198.7 legislative committees with jurisdiction over health and human services policy and finance
198.8 by February 15, 2016. These services shall not be covered by medical assistance until
198.9 legislation providing coverage for the services is enacted in law.

198.10 Sec. 24. EVALUATION OF COMMUNITY ADVANCED EMERGENCY 198.11 MEDICAL TECHNICIAN SERVICES.

198.12 If legislation is enacted to cover community advanced emergency medical technician
198.13 services with medical assistance, the commissioner of human services shall evaluate
198.14 the effect of medical assistance and MinnesotaCare coverage for those services on the
198.15 cost and quality of care under those programs and the coordination of those services
198.16 with the health care home services. The commissioner shall present findings to the
198.17 chairs and ranking minority members of the legislative committees with jurisdiction over
198.18 health and human services policy and finance by December 1, 2017. The commissioner
198.19 shall require medical assistance- and MinnesotaCare-enrolled providers that employ or
198.20 contract with community medical response emergency medical technicians to provide to
198.21 the commissioner, in the form and manner specified by the commissioner, the utilization,
198.22 cost, and quality data necessary to conduct this evaluation.