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SENATE STATE OF MINNESOTA NINETIETH SESSION

OFFICIAL STATUS

S.F. No. 409

| 01/26/2017 03/08/2017 | 402 | Introduction and first reading Referred to Health and Human Services Finance and Policy Author added Marty |
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| | | A bill for an act |
| a 12-r requir medic | nonth suppl ring health p cal services, | ; requiring health plans and public health care programs to cover y of prescription contraceptives; providing religious exemptions; plans to cover contraceptive methods, sterilization, and related patient education, and counseling; amending Minnesota Statutes 6B.0625, subdivision 13; proposing coding for new law in |

Minnesota Statutes, chapter 62Q. 1.7

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA: 1.8

Section 1. [62Q.521] COVERAGE OF CONTRACEPTIVE METHODS AND 1.9

COUNSELING. 1.10

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- Subdivision 1. Citation. This section may be cited as the "Contraceptive Health Equity 1.11
- and Employee Rights Act." 1.12
- Subd. 2. Definitions. (a) The definitions in this subdivision apply to this section. 1.13

(b) "Contraceptive services" means consultation, examination, procedures, and medical 1.14

services related to the use of contraceptive methods, including natural family planning, to 1.15

- prevent an unintended pregnancy. 1.16
- (c) "Medical necessity" includes but is not limited to considerations such as severity of 1.17
- side effects, differences in permanence and reversibility of a contraceptive, and ability to 1.18
- adhere to the appropriate use of the item or service, as determined by the attending provider. 1.19
- (d) "Therapeutic equivalent version" means drugs, devices, or products that can be 1.20

expected to have the same clinical effect and safety profile when administered to patients 1.21

- under the conditions specified in the labeling and that: 1.22
- (1) are approved as safe and effective; 1.23

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| 2.1 | (2) are pharmaceutical equivalents in that they contain identical amounts of the same |
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| 2.2 | active drug ingredient in the same dosage form and route of administration, and they meet |
| 2.3 | compendial or other applicable standards of strength, quality, purity, and identity; |
| 2.4 | (3) are bioequivalent in that (i) they do not present a known or potential bioequivalence |
| 2.5 | problem and meet an acceptable in vitro standard; or (ii) if they do present a known or |
| 2.6 | potential bioequivalence problem, they are shown to meet an appropriate bioequivalence |
| 2.7 | standard; |
| 2.8 | (4) are adequately labeled; and |
| 2.9 | (5) are manufactured in compliance with current good manufacturing practice regulations. |
| 2.10 | Subd. 3. Scope of coverage. This section applies to all health plans. |
| 2.11 | Subd. 4. Required coverage; cost sharing prohibited. (a) A health plan that provides |
| 2.12 | prescription drug coverage must cover: |
| 2.13 | (1) all contraceptive drugs, devices, and other products approved by the Food and Drug |
| 2.14 | Administration, including all over-the-counter contraceptive drugs, devices, and products |
| 2.15 | approved by the Food and Drug Administration, but excluding male condoms; |
| 2.16 | (2) voluntary sterilization procedures; |
| 2.17 | (3) contraceptive services, patient education, and counseling on contraception; and |
| 2.18 | (4) follow-up services related to the drugs, devices, products, and procedures covered |
| 2.19 | under this subdivision, including but not limited to management of side effects, counseling |
| 2.20 | for continued adherence, and device insertion and removal. |
| 2.21 | (b) For coverage required by this subdivision, a health plan must not impose cost-sharing |
| 2.22 | requirements, restrictions, or delays. |
| 2.23 | (c) If the Food and Drug Administration has approved one or more therapeutic equivalent |
| 2.24 | versions of a contraceptive drug, device, or product, a health plan is not required to include |
| 2.25 | all therapeutic equivalent versions in its formulary, so long as at least one version is included |
| 2.26 | and covered without cost sharing according to this subdivision. |
| 2.27 | (d) If an individual's attending provider recommends a particular service or item approved |
| 2.28 | by the Food and Drug Administration based on a determination of medical necessity for |
| 2.29 | that individual, the health plan must cover that service or item without cost sharing. The |
| 2.30 | health plan company issuing the health plan must defer to the determination of the individual's |
| 2.31 | attending physician that the service or item is medically necessary for the individual. |
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| 3.1 | (e) If a contraceptive drug, device, or product is not covered by a health plan, the health |
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| 3.2 | plan company must have an easily accessible, transparent, and expedient process that is not |
| 3.3 | unduly burdensome to the individual, a representative of the individual, or a provider, to |
| 3.4 | ensure coverage without cost sharing. |
| 3.5 | Subd. 5. Exempted coverage. (a) A health plan company that has issued or renewed a |
| 3.6 | health plan to a Minnesota employer to cover employees and their dependents shall provide |
| 3.7 | a basis for eligible employers to be exempted from the required coverage under subdivision |
| 3.8 | 4. For purposes of this section, an eligible employer includes: |
| 3.9 | (1) any organization that would qualify under Code of Federal Regulations, title 45, |
| 3.10 | section 147.13, paragraph (b); or |
| 3.11 | (2) any employer organized as a closely held, for-profit corporation that: |
| 3.12 | (i) provides a health plan to cover employees and their dependents; |
| 3.13 | (ii) has employment policies that are derived from principal shareholder beliefs; and |
| 3.14 | (iii) limits or proposes to limit the availability of specific employee benefits due to those |
| 3.15 | beliefs. |
| 3.16 | (b) An eligible employer and a health plan company shall follow the contraceptive |
| 3.17 | coverage procedures adopted under Code of Federal Regulations, title 45, section 147.131, |
| 3.18 | including, but not limited to, the eligible employer issuing a self-certification described in |
| 3.19 | Code of Federal Regulations, title 45, section 147.131, paragraph (b)(4), and the health plan |
| 3.20 | company providing coverage required under subdivision 4 to employees or dependents of |
| 3.21 | an eligible employer at no additional charge to the employee or eligible employer, as |
| 3.22 | described in Code of Federal Regulations, title 45, section 147.131, paragraph (c). |
| 3.23 | Subd. 6. Expiration. This section expires if any federal law, rule, opinion, or guidance |
| 3.24 | is enacted, adopted, or issued that would require the state to defray the cost of coverage |
| 3.25 | required by subdivision 4. The commissioner of commerce shall notify the revisor of statutes |
| 3.26 | if this section expires. The state shall not assume any obligation for the cost of coverage |
| 3.27 | specified in subdivision 4, paragraph (a). |
| 3.28 | EFFECTIVE DATE. This section is effective January 1, 2018, and applies to coverage |
| 3.29 | offered, sold, issued, or renewed on or after that date. |

| | SUPPLY REQUIREMENTS. |
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| | Subdivision 1. Scope of coverage. All health plans that provide prescription contraceptive |
| (| coverage must comply with the requirements of this section. |
| | Subd. 2. Definitions. For purposes of this section, "prescription contraceptive" means |
| 2 | any drug or device that requires a prescription and is approved by the Food and Drug |
| <u> </u> | Administration to prevent pregnancy. |
| | Subd. 3. Required coverage. Health plan coverage for a prescription contraceptive mus |
| E | provide: |
| | (1) a three-month supply for the first dispensing of a covered prescription contraceptive |
| 2 | and |
| | (2) a 12-month supply for any subsequent dispensing of the same prescription |
| (| contraceptive, regardless of whether the insured was covered by the health plan at the time |
| (| of the first dispensing. |
| | EFFECTIVE DATE. This section is effective January 1, 2018, and applies to coverage |
| (| offered, sold, issued, or renewed on or after that date. |
| | Sec. 3. Minnesota Statutes 2016, section 256B.0625, subdivision 13, is amended to read |
| | Subd. 13. Drugs. (a) Medical assistance covers drugs, except for fertility drugs when |
| S | specifically used to enhance fertility, if prescribed by a licensed practitioner and dispense |
| 1 | by a licensed pharmacist, by a physician enrolled in the medical assistance program as a |
| (| dispensing physician, or by a physician, physician assistant, or a nurse practitioner employed |
| 1 | by or under contract with a community health board as defined in section 145A.02, |
| | subdivision 5, for the purposes of communicable disease control. |
| | (b) The dispensed quantity of a prescription drug must not exceed a 34-day supply, |
| | unless authorized by the commissioner and except as provided in paragraph (g). |
| | (c) For the purpose of this subdivision and subdivision 13d, an "active pharmaceutical |
| | ingredient" is defined as a substance that is represented for use in a drug and when used in |
| | the manufacturing, processing, or packaging of a drug becomes an active ingredient of the |
| , | drug product. An "excipient" is defined as an inert substance used as a diluent or vehicle |
| | for a drug. The commissioner shall establish a list of active pharmaceutical ingredients and |
| | excipients which are included in the medical assistance formulary. Medical assistance cover |
| | selected active pharmaceutical ingredients and excipients used in compounded prescription |

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when the compounded combination is specifically approved by the commissioner or when
a commercially available product:

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

5.4 (2) does not exist in the same combination of active ingredients in the same strengths5.5 as the compounded prescription; and

5.6 (3) cannot be used in place of the active pharmaceutical ingredient in the compounded5.7 prescription.

(d) Medical assistance covers the following over-the-counter drugs when prescribed by 5.8 a licensed practitioner or by a licensed pharmacist who meets standards established by the 5.9 commissioner, in consultation with the board of pharmacy: antacids, acetaminophen, family 5.10 planning products, aspirin, insulin, products for the treatment of lice, vitamins for adults 5.11 with documented vitamin deficiencies, vitamins for children under the age of seven and 5.12 pregnant or nursing women, and any other over-the-counter drug identified by the 5.13 commissioner, in consultation with the formulary committee, as necessary, appropriate, and 5.14 cost-effective for the treatment of certain specified chronic diseases, conditions, or disorders, 5.15 and this determination shall not be subject to the requirements of chapter 14. A pharmacist 5.16 may prescribe over-the-counter medications as provided under this paragraph for purposes 5.17 of receiving reimbursement under Medicaid. When prescribing over-the-counter drugs under 5.18 this paragraph, licensed pharmacists must consult with the recipient to determine necessity, 5.19 provide drug counseling, review drug therapy for potential adverse interactions, and make 5.20 referrals as needed to other health care professionals. Over-the-counter medications must 5.21 be dispensed in a quantity that is the lowest of: (1) the number of dosage units contained in 5.22 the manufacturer's original package; (2) the number of dosage units required to complete 5.23 the patient's course of therapy; or (3) if applicable, the number of dosage units dispensed 5.24 from a system using retrospective billing, as provided under subdivision 13e, paragraph 5.25 5.26 (b).

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

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| 6.1 | 13g, except | that drugs listed in | United States Code | e, title 42, section 1396 | or-8(d)(2)(E), shall |
| 6.2 | not be cover | red. | | | |
| 6.3 | (f) Medi | cal assistance cove | ers drugs acquired th | brough the federal 340 | B Drug Pricing |

6.4 Program and dispensed by 340B covered entities and ambulatory pharmacies under common
6.5 ownership of the 340B covered entity. Medical assistance does not cover drugs acquired
6.6 through the federal 340B Drug Pricing Program and dispensed by 340B contract pharmacies.

6.7 (g) Medical assistance coverage for a prescription contraceptive must provide:

6.8 (1) a three-month supply for the first dispensing of a covered prescription contraceptive;

- 6.9 <u>and</u>
- 6.10 (2) a 12-month supply for any subsequent dispensing of the same prescription

6.11 contraceptive, regardless of whether the insured was covered by medical assistance or the

- 6.12 <u>health plan at the time of the first dispensing.</u>
- 6.13 For purposes of this paragraph, "prescription contraceptive" means any drug or device that
- 6.14 requires a prescription and is approved by the Food and Drug Administration to prevent
- 6.15 pregnancy. For purposes of this paragraph, "health plan" has the meaning provided in section
- 6.16 <u>62Q.01</u>, subdivision 3.

6.17 **EFFECTIVE DATE.** This section applies to medical assistance and MinnesotaCare

6.18 <u>coverage effective January 1, 2018.</u>