COMMERCE DEPARTMENT

Evaluation of SF XXXX – Coverage for Over-the-Counter Contraceptives

Report to the Minnesota Legislature Pursuant to Minn. Stat. § 62J.26

January 28, 2025

Report Prepared By

This report was prepared by the American Institutes for Research (AIR) at the request of the Minnesota Department of Commerce. AIR created this document for internal use by the Minnesota Department of Commerce pursuant to Contract No. 216732. The document assumes reader familiarity with the proposed mandated health benefits currently under consideration by the Minnesota State Legislature. The document was prepared solely to assist the Minnesota Department of Commerce. No other use of this document or the information or conclusions contained herein is authorized. The period of data collection for any policies and literature analyzed for the proposed mandate ended on December 31, 2024.

Defrayal analysis completed by the Minnesota Department of Commerce is independent of AIR's evaluation.

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As requested by Minnesota Statute § 3.197: This report cost approximately $7,387.00 to prepare, including staff time, printing and mailing expenses.

Upon request, this material will be made available in an alternative format such as large print, Braille or audio recording. Printed on recycled paper. A 508 compliant version of this report is forthcoming.

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Introduction

In accordance with Minn. Stat. § 62J.26, the Minnesota Department of Commerce (Commerce), in consultation with the Minnesota Department of Health (MDH) and Minnesota Management and Budget (MMB), performs an evaluation of benefit mandate proposals. For evaluation criteria and required evaluation components, please review the Evaluation Report Methodology, available at https://mn.gov/commerce/insurance/industry/policy-data-reports/62j-reports/.

Bill Requirements

Senate File (SF) XXXX is sponsored by Senator Lindsey Port. At the time Commerce received the request for evaluation, the bill had not yet been introduced.

If enacted, this bill would require a health issuer to provide coverage for all over-the-counter (OTC) contraceptives purchased at a pharmacy without a prescription, regardless of the brand, type, quantity, or purchase frequency.

The proposed mandate would update the statutory definition of "contraceptive method" to be broader and include prescription or OTC contraceptives. Additionally, this proposed mandate would require Medical Assistance to cover OTC contraceptives.

The proposed mandate also requires Commerce to work with the Departments of Health and Human Services to provide public information about OTC contraceptive coverage and produce a report on information and data regarding usage and related costs to health plans and the State for this mandate by March 31, 2027, and annually thereafter.

This proposed mandate would apply to fully insured small and large group commercial health plans, individual market plans, the State Employee Group Insurance Program (SEGIP), and Minnesota Health Care Programs (e.g., Medical Assistance and MinnesotaCare). This would not apply to self-insured employer plans, grandfathered plans, and Medicare supplemental policies.

This bill would amend Minn. Stat. § 62Q.522, subdivisions 1 and 2 and Minn. Stat. § 256B.0625, subdivision 13.

Key Terms

For the purpose of this bill and its evaluation:

- “Over-the-counter contraceptive" or "OTC contraceptive" means a drug, device, or other product that is approved by the United States Food and Drug Administration (FDA) to prevent unintended pregnancy and does not require a prescription.
- “Prescription contraceptive" means a drug, device, or other product that is approved by the FDA to prevent unintended pregnancy and requires a prescription.

Related Health Conditions and Associated Services

Lack of access to contraceptives may be a leading cause for inconsistent use of contraceptives and may result in unwanted pregnancies.[1] Unwanted and/or unintended pregnancy can put both the mother and baby at higher risk for certain outcomes during and after pregnancy, such as maternal depression, maternal experience of intimate partner violence, and low infant birth weight.[2]

There are several OTC contraceptives available at pharmacies which include,[3] but are not limited to:

- OTC birth control pill;
- Condoms;
- Spermicide gel;
- Contraceptive sponges; and
- Emergency contraceptives.

Public Comments Summary

Commerce solicited public input on the potential health benefit mandate through a request for information (RFI) posted to Commerce's website and the Minnesota State Register. The summary below represents only the opinions and input of the individuals and/or organizations who responded to the RFI.

Key Stakeholder Comment Themes

For this proposed mandate, Commerce received RFI responses from four commercial health issuers, two health care organizations, and four advocacy organizations.

Coverage for OTC Contraception. Several respondents noted that some Minnesota health issuers already provide coverage of some FDA-approved OTC contraceptives at no cost-sharing. One respondent highlighted that CVS Caremark, who manages prescription drug plans for more than 100 million patients nationally, added Opill to their preventive services/oral contraceptives list at no cost-sharing. Another respondent noted that there are over 100 countries that currently provide OTC contraceptive pills without prescription, and nine U.S. states and the District of Columbia require coverage for OTC contraceptives without a prescription. This respondent also noted that Plan B is available without a prescription or co-pay in the U.S. military health insurance plan, and that Medicare Advantage covers OTC products without cost-sharing or prescription. Several respondents said that there are concerns about reimbursement for OTC contraceptives purchased at non-health care facilities, particularly for Medical Assistance and MinnesotaCare, as existing rules prohibit direct reimbursement to members.

Concerns Related to Fraud and/or Misuse. One respondent flagged the potential for misuse of OTC contraceptives, and suggested controlling the quantity that can be prescribed and purchased. Several respondents noted the importance of prescriptions for ensuring appropriate coverage and containing costs.

However, one respondent reported that in states where OTC contraception is covered without prescription or cost-sharing, there has been no evidence of fraud, misuse, or abuse.

Related Policy. One respondent recommended revisions for Minn. Stat. § 62A.15, 62D.1071, 151.01 and 151.37 to allow for pharmacists to prescribe OTC contraceptives, rather than eliminating prescription requirements. Additionally, one respondent noted that the legislature should consider the impact of the recently enacted changes to contraceptive coverage in Minn. Stat. § 62Q.522 and 62Q.523 before considering additional changes to contraceptive coverage.

Health Care Access. One respondent noted that current prescription requirements can limit or delay access to an individual's preferred method of contraception, which may result in inconsistent use. Respondents in favor of the mandate noted the importance of access to both prescription and OTC contraception in prevention of sexually transmitted infections, as not all forms of contraception that are available by prescription address this consideration.

Health Outcomes. Several respondents noted the importance of this mandate for addressing health and quality of life outcomes for individuals where cost and prescription are barriers for contraceptive access. One respondent noted the alignment of this mandate's coverage requirements with current standards of care and recommendations put forth by the American College of Obstetricians and Gynecologists, the American Academy of Family Physicians, the American Medical Association, and the American Public Health Association, all of which support OTC contraceptive access without prescription. Respondents in favor of this mandate provided studies related to the association between access to contraception, reduced morbidity and mortality, and healthier pregnancies and infants, as unplanned pregnancies have an increased chance of negative outcomes such as preterm delivery, low infant birth weight, and maternal morbidity and mortality.

Health and Socioeconomic Equity. Several respondents noted that contraceptive access is critical to promote positive individual health and economic outcomes and noted that women face fewer health and economic inequities in states with more expansive reproductive health care access. Several respondents provided studies to be considered in assessing the impact of the proposed coverage. These studies broadly relate to contraception access, safety and reliability, and health and socioeconomic impacts (See Appendix B).

General Comments. Another respondent highlighted Minnesota's implementation of Minn. Stat. § 62M.07, effective January 1, 2026, which prohibits prior authorization for certain medical conditions, including outpatient mental health or substance use disorder treatment, antineoplastic cancer treatment per National Comprehensive Cancer Network® guidelines (excluding medications), preventative services, pediatric hospice care, neonatal abstinence program treatment by pediatric pain or palliative care specialists, and chronic condition treatment. The respondent suggested that many of this year's proposed benefit mandates fall under this new statute and expressed concerns that removing prior authorization could increase health care costs and negatively affect health outcomes for Minnesotans.

Another respondent noted that all of the proposed health benefit mandates have the potential to broadly improve health outcomes for Minnesotans by enhancing their quality of life, supporting individuals, families, and caregivers, and increasing workforce participation, while also benefiting the broader health care system.

Cost Estimates Provided in Stakeholder Comments

Stakeholders and MMB provided the following cost estimates related to the proposed benefit mandate:

- MMB's health plan administrators estimated the average state fiscal impact of the proposed mandate to be $0.09 per member per month (PMPM), as the bill would expand the current health care coverage for OTC contraceptives.
- Currently certain types of OTC contraceptives are covered by some commercial health plans in Minnesota. Some respondents noted that if this mandate were passed, respondents estimated a cost increase of up to $2.20 PMPM.

Stakeholders' results may or may not reflect generalizable estimates for the mandate, depending on the methodology, data sources, and assumptions used for analysis.

Evaluation Limitations

An evaluation of the potential public health and economic impacts for this mandate was limited by several factors. Uncovered claims are excluded from the Minnesota All Payer Claims Database (MN APCD), which would be needed to estimate the degree of unmet need and potential utilization figures for a credible cost analysis of the proposed mandate. Additionally, the expanded contraceptive coverage of the mandate would apply to Opill, amongst other OTC contraceptives, which was FDA approved in 2023. As a result, cost and utilization data on this medication is not yet available in the MN APCD. There are studies that address the importance of OTC contraceptive options, safety of Opill, barriers for access, and associated disparities related to contraceptive access. However, there were no studies specifically addressing the aggregate potential impact of the proposed coverage in Minnesota.

State Fiscal Impact

The potential state fiscal impact of this proposed mandate includes the estimated cost to SEGIP as assessed by MMB in consultation with health plan administrators, the cost of defrayal of benefit mandates as understood under the Patient Protection and Affordable Care Act (ACA), and the potential impact to Minnesota Health Care Programs.

- MMB estimates the cost of this proposed mandate for the state plan to be $70,200 for partial Fiscal Year 2026 (FY 2026) and $147,420 for FY 2027.
- There are no estimated defrayal costs associated with this proposed mandate.
- The proposed mandate would apply to Minnesota Health Care Programs (e.g., Medical Assistance and MinnesotaCare) and may have a cost.

Fiscal Impact Estimate for SEGIP

MMB provided SEGIP's fiscal impact analysis, which is based on current claims data for OTC contraceptive prescriptions and may include cost-sharing and quantity limits. MMB's analysis predicted a PMPM fiscal impact ranging from $0.07 to $0.10 PMPM, with an average cost of $0.09 PMPM. MMB noted this fiscal estimate assumes a prescription is required to process the OTC contraceptive claim and may have quantity limitations. They are not able to provide fiscal impact estimates without the prescription requirement or quantity limits as this estimate is based on current coverage requirements. The partial fiscal year impact of the proposed mandate on SEGIP is estimated to be $70,200 for partial FY 2026 ($0.09 PMPM medical cost × 130,000 members × 6 months). The estimated impact for FY 2027 equals $147,420, and the amount is estimated to increase by a 5% annual inflation factor each of the following years.

Patient Protection and Affordable Care Act Mandate Impact and Analysis

States may require qualified health plan issuers to cover benefits in addition to the 10 essential health benefits (EHBs) defined by the ACA but must defray the costs, either through payments to individual enrollees or directly to issuers, and can partially defray the costs of proposed mandates if some of the care, treatment, or services are already covered in the state's benchmark plan or mandated by federal law, pursuant to section 1311(d)(3)(b) of the ACA. For further defrayal requirements and methodology, please visit https://mn.gov/commerce/insurance/industry/policy-data-reports/62j-reports/.

If enacted, this proposed mandate would not constitute an additional benefit mandate requiring defrayal, as it does not relate to any new requirements for specific care, treatment, or services that are not already covered by Minnesota's benchmark plan or the ACA. Prescription medications with estrogen and progesterone are included in the Minnesota EHB benchmark plan[4] and OTC products with a prescription are covered under the ACA[5].

Fiscal Impact of State Public Programs

This proposed mandate would apply to Minnesota Health Care Programs (e.g., Medical Assistance and MinnesotaCare). Medical Assistance and MinnesotaCare do cover various birth control methods.[6] However, the proposed mandate may have a cost based on the specific coverage requirements of the proposed mandate. Medical Assistance and MinnesotaCare may not cover all OTC contraceptives products, and a prescription is required for federal funding. However, a fiscal estimate has not yet been completed on this proposed mandate.

Appendix A. Bill Text

Section 1. Minnesota Statutes 2023 Supplement, section 62Q.522, subdivision 1, is amended to read:

Subdivision 1. **Definitions.**

(a) The definitions in this subdivision apply to this section.

(b) "Closely held for-profit entity" means an entity that:

(1) is not a nonprofit entity;

(2) has more than 50 percent of the value of its ownership interest owned directly or indirectly by five or fewer owners; and

(3) has no publicly traded ownership interest.

For purposes of this paragraph:

(i) ownership interests owned by a corporation, partnership, limited liability company, estate, trust, or similar entity are considered owned by that entity's shareholders, partners, members, or beneficiaries in proportion to their interest held in the corporation, partnership, limited liability company, estate, trust, or similar entity;

(ii) ownership interests owned by a nonprofit entity are considered owned by a single owner;

(iii) ownership interests owned by all individuals in a family are considered held by a single owner. For purposes of this item, "family" means brothers and sisters, including half-brothers and half-sisters, a spouse, ancestors, and lineal descendants; and

(iv) if an individual or entity holds an option, warrant, or similar right to purchase an ownership interest, the individual or entity is considered to be the owner of those ownership interests.

(c) "Contraceptive method" means a ~~drug, device, or other product approved by the Food and Drug Administration to prevent unintended pregnancy~~ prescription contraceptive or over-the-counter contraceptive.

(d) "Contraceptive service" or "service" means consultation, examination, procedures, and medical services related to the prevention of unintended pregnancy, excluding vasectomies. This includes but is not limited to voluntary sterilization procedures, patient education, counseling on contraceptives, and follow-up services related to contraceptive methods or services, management of side effects, counseling for continued adherence, and device insertion or removal.

(e) "Eligible organization" means an organization that opposes providing coverage for some or all contraceptive methods or services on account of religious objections and that is:

(1) organized as a nonprofit entity and holds itself out to be religious; or

(2) organized and operates as a closely held for-profit entity, and the organization's owners or highest governing body has adopted, under the organization's applicable rules of governance and consistent with state law, a resolution or similar action establishing that the organization objects to covering some or all contraceptive methods or services on account of the owners' sincerely held religious beliefs.

(f) "Exempt organization" means an organization that is organized and operates as a nonprofit entity and meets the requirements of section 6033(a)(3)(A)(i) or (iii) of the Internal Revenue Code of 1986, as amended.

(g) "Medical necessity" includes but is not limited to considerations such as severity of side effects, difference in permanence and reversibility of a contraceptive method or service, and ability to adhere to the appropriate use of the contraceptive method or service, as determined by the attending provider.

(h) "Over-the-counter contraceptive" or "OTC contraceptive" means a drug, device, or other product that:

(1) is approved by the Food and Drug Administration to prevent unintended pregnancy; and

(2) does not require a prescription.

(i) "Pharmacy" has the meaning given in section 151.01.

(j) "Prescription contraceptive" means a drug, device, or other product that:

(1) is approved by the Food and Drug Administration to prevent unintended pregnancy; and

(2) requires a prescription.

~~(h)~~ (k) "Therapeutic equivalent version" means a drug, device, or product that can be expected to have the same clinical effect and safety profile when administered to a patient under the conditions specified in the labeling, and that:

(1) is approved as safe and effective;

(2) is a pharmaceutical equivalent:

(i) containing identical amounts of the same active drug ingredient in the same dosage form and route of administration; and

(ii) meeting compendial or other applicable standards of strength, quality, purity, and identity;

(3) is bioequivalent in that:

(i) the drug, device, or product does not present a known or potential bioequivalence problem and meets an acceptable in vitro standard; or

(ii) if the drug, device, or product does present a known or potential bioequivalence problem, it is shown to meet an appropriate bioequivalence standard;

(4) is adequately labeled; and

(5) is manufactured in compliance with current manufacturing practice regulations.

EFFECTIVE DATE. This section is effective January 1, 2026, and applies to health plans offered, issued, or renewed on or after that date.

Sec. 2. Minnesota Statutes 2023 Supplement, section 62Q.522, subdivision 2, is amended to read:

Subd. 2. **Required coverage**; cost sharing prohibited.

(a) A health plan must provide coverage for contraceptive methods and services.

(b) A health plan company must not impose cost-sharing requirements, including co-pays, deductibles, or coinsurance, for contraceptive methods or services.

(c) A health plan company must not impose any referral requirements, restrictions, or delays for contraceptive methods or services.

(d) A health plan must include at least one of each type of Food and Drug Administration approved contraceptive method in its formulary. Subject to paragraph (g), if more than one therapeutic equivalent version of a contraceptive method is approved, a health plan must include at least one therapeutic equivalent version in its formulary, but is not required to include all therapeutic equivalent versions.

(e) For each health plan, a health plan company must list the contraceptive methods and services that are covered without cost-sharing in a manner that is easily accessible to enrollees, health care providers, and representatives of health care providers. The list for each health plan must be promptly updated to reflect changes to the coverage.

(f) If an enrollee's attending provider recommends a particular contraceptive method or service based on a determination of medical necessity for that enrollee, the health plan must cover that contraceptive method or service without cost-sharing. The health plan company issuing the health plan must defer to the attending provider's determination that the particular contraceptive method or service is medically necessary for the enrollee.

(g) Notwithstanding paragraph (d), a health plan must cover all types and brands of OTC contraceptives purchased at a pharmacy without requiring a prescription.

(h) A health plan must cover all OTC contraceptives purchased at a pharmacy at the point-of-sale without requiring a prescription.

(i) A health plan must not limit the type, quantity, or purchase frequency, nor impose any restriction or requirement based on prescription status, of OTC contraceptives purchased at a pharmacy.

(j) If the application of this subdivision before an enrollee has met their health plan's deductible would result in: (1) health savings account ineligibility under United States Code, title 26, section 223; or (2) catastrophic health plan ineligibility under United States Code, title 42,section 18022(e), then this subdivision applies to contraceptive methods and services only after the enrollee has met their health plan's deductible.

EFFECTIVE DATE. This section is effective January 1, 2026, and applies to health plans offered, issued, or renewed on or after that date.

Sec. 3. Minnesota Statutes 2023 Supplement, section 256B.0625, subdivision 13, is amended to read:

Subd. 13. **Drugs.**

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

(b) The dispensed quantity of a prescription drug must not exceed a 34-day supply unless authorized by the commissioner or as provided in paragraph (h) or the drug appears on the 90-day supply list published by the commissioner. The 90-day supply list shall be published by the commissioner on the department's website. The commissioner may add to, delete from, and otherwise modify the 90-day supply list after providing public notice and the opportunity for a 15-day public comment period. The 90-day supply list may include cost-effective generic drugs and shall not include controlled substances.

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

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

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

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

(d) Medical assistance covers the following over-the-counter drugs:

(1) when prescribed by a licensed practitioner or by a licensed pharmacist who meets standards established by the commissioner, in consultation with the board of pharmacy:

(i) antacids~~,~~;

(ii) acetaminophen~~,~~;

(iii) family planning products~~,~~;

(iv) aspirin~~,~~;

(v) insulin~~,~~;

(vi) products for the treatment of lice~~,~~;

(vii) vitamins for adults with documented vitamin deficiencies~~,~~;

(viii) vitamins for children under the age of seven and pregnant or nursing women~~,~~;and

(ix) any other over-the-counter drug identified by the commissioner, in consultation with the Formulary Committee, as necessary, appropriate, and cost-effective for the treatment of certain specified chronic diseases, conditions, or disorders~~,~~; and

(2) all over-the-counter contraceptives, as defined in section 62Q.522, regardless of whether the drug has been prescribed. ~~this~~ A determination ~~shall~~ by the commissioner under clause (1), item (ix), is not ~~be~~ subject to the requirements of chapter 14. A pharmacist may prescribe over-the-counter medications as provided under this paragraph for purposes of receiving reimbursement under Medicaid. When prescribing over-the-counter drugs under this paragraph, licensed pharmacists must consult with the recipient to determine necessity, provide drug counseling, review drug therapy for potential adverse interactions, and make referrals as needed to other health care professionals.

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

(f) Medical assistance covers drugs acquired through the federal 340B Drug Pricing Program and dispensed by 340B covered entities and ambulatory pharmacies under common ownership of the 340B

covered entity. Medical assistance does not cover drugs acquired through the federal 340B Drug Pricing Program and dispensed by 340B contract pharmacies.

(g) Notwithstanding paragraph (a), medical assistance covers self-administered hormonal contraceptives prescribed and dispensed by a licensed pharmacist in accordance with section 151.37, subdivision 14; nicotine replacement medications prescribed and dispensed by a licensed pharmacist in accordance with section 151.37,subdivision 15; and opiate antagonists used for the treatment of an acute opiate overdose prescribed and dispensed by a licensed pharmacist in accordance with section 151.37, subdivision 16.

(h) Medical assistance coverage for a prescription contraceptive must provide a 12-month supply for any prescription contraceptive if a 12-month supply is prescribed by the prescribing health care provider. The prescribing health care provider must determine the appropriate duration for which to prescribe the prescription contraceptives, up to 12 months. For purposes of this paragraph, "prescription contraceptive" means any drug or device that requires a prescription and is approved by the Food and Drug Administration to prevent pregnancy. Prescription contraceptive does not include an emergency contraceptive drug approved to prevent pregnancy when administered after sexual contact. For purposes of this paragraph, "health plan" has the meaning provided in section 62Q.01, subdivision 3.

EFFECTIVE DATE. This section is effective January 1, 2026.

Sec. 4. **OUTREACH AND REPORTS.**

(a) The Department of Commerce must work with the Departments of Health and Human Services to provide public information about over-the-counter contraception coverage.

(b) The Department of Commerce must work with the Departments of Health and Human Services and provide a report by March 31, 2027, and annually thereafter, to the standing committees of the legislature with oversight of issues relating to commerce, health, and human services. The report must include information and data regarding the use of coverage and related costs to health plans and the state for the provision of over-the-counter contraceptives.

Appendix B. Resources Provided by Public Comments

The following citations were provided by RFI respondents related to the potential impact of the proposed health benefit mandate. These sources are provided independent of Commerce's evaluation and have not been assessed for quality and/or relevancy to the proposed health benefit mandate.

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5. Dennis A, Grossman D. Barriers to contraception and interest in over-the-counter access among low-income women: a qualitative study. *Sex Reprod Health*. 2012;44(2):84-91. doi:10.1363/440841244

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