DEPARTMENT OF REGULATORY AGENCIES

Division of Insurance

3 CCR 702-4

LIFE, ACCIDENT AND HEALTH

Emergency Regulation 23-E-07

CONTRACEPTIVE BENEFIT REQUIREMENTS FOR HEALTH BENEFIT PLANS

Section 1 Authority

This emergency regulation is promulgated and adopted by the Commissioner of Insurance under the authority of §§ 10-16-109 and 10-16-104.2, C.R.S.

Section 2 Scope and Purpose

The purpose of this emergency regulation is to implement SB23-284 and ensure carriers offering health benefit plans or pharmacy benefit managers acting on behalf of carriers are providing coverage for contraception in accordance with the Public Health Service Act, as amended by the Affordable Care Act, and clarified in federal guidance from the U.S. Departments of Health and Human Services, Labor, and the Treasury.

The Division of Insurance finds, pursuant to § 24-4-103(6)(a), C.R.S, that immediate adoption of this emergency regulation is imperatively necessary to comply with state law and for the preservation of public health, safety, or welfare and compliance with the requirements of § 24-4-103, C.R.S., would be contrary to the public interest. On May 30, 2023, SB23-284, Ensure 12-month Contraception Coverage, was signed. This legislation takes effect on the day following the expiration of the ninety-day period after final adjournment of the General Assembly. This emergency regulation implements the new requirements in § 10-16-104.2, C.R.S., to ensure that carriers offering health benefit plans or pharmacy benefit managers acting on behalf of carriers comply with contraceptive coverage requirements in their 2024 health benefit plans.

Section 3 Applicability

The requirements and provisions of this emergency regulation apply to carriers and pharmacy benefit management firms acting on behalf of carriers offering non-grandfathered individual, small group, and/or

large group health benefit plans and student health insurance coverage. This emergency regulation does not apply to grandfathered health benefit plans.

Section 4 Definitions

A. "Affordable Care Act" means, for the purposes of this regulation, The Patient Protection and Affordable Care Act, Pub. L.111-148, and the Health Care and Education Reconciliation Act of 2010, Pub. L 111-152.

B. "Carrier" means a carrier, as defined in § 10-16-102(8), C.R.S., offering a health benefit plan and shall include a pharmacy benefit manager acting on behalf of the carrier.

C. "Contraceptive" or "contraception" shall have the same meaning as defined in § 2-4-401(1.5), C.R.S.

D. "Dispensing entity" shall have the same meaning as defined in § 10-16-104.2(1)(c), C.R.S.

E. "Emergency contraception" means a drug approved by the FDA that prevents pregnancy after sexual intercourse, including, but not limited to, oral contraceptive pills; except that "emergency contraception" shall not include RU-486, mifepristone, or any other drug or device that induces a medical abortion, in accordance with § 25-3-110, C.R.S.

F. "Expedited exception request" means, for the purposes of this regulation, a coverage determination no later than twenty-four (24) hours following the carrier's receipt of the request.

G. "Food and Drug Administration" or "FDA" means, for the purposes of this regulation, the Food and Drug Administration in the United States Department of Health and Human Services.

H. "Grandfathered health benefit plan" shall have the same meaning as defined in § 10-16-102(31), C.R.S.

I. "Health benefit plan" shall have the same meaning defined in § 10-16-102(32), C.R.S.

J. "Health Resources and Services Administration" or "HRSA" means, for the purposes of this regulation, the Health Resources and Services Administration in the United States Department of Health and Human Services.

K. "Health care provider," or "provider" shall have the same meaning as defined in § 10-16-102(56), C.R.S.

L. "Pharmacy benefit management firm," "pharmacy benefit manager," or "PBM" shall have the same meaning as defined in § 10-16-102(49), C.R.S.

M. "Prescription drug" shall have the same meaning as defined in § 12-280-103(42), C.R.S.; except that the term includes only prescription drugs that are intended for human use.

N. "Prior authorization" shall have the same meaning as defined in § 10-16-112.5(7)(d), C.R.S.

O. "Step therapy" or "fail first" shall have the same meaning as defined in § 10-16-145(1)(g), C.R.S.

P. "Therapeutic equivalent" shall have the same meaning as defined in § 12-280-103(52), C.R.S.

Section 5 Rules

A. Carriers shall cover all FDA-approved, cleared, or granted contraception, whether or not the item or service is identified in the current FDA Birth Control Guide, and contraceptive care outlined in the HRSA Women's Preventive Services Guidelines as a preventive care service without consumer cost sharing in accordance with the requirements found in Section 2713 of the Public Health Service Act, as added by the Affordable Care Act. These forms of contraception include over-the-counter emergency contraception with a prescription and elective sterilization procedures for people who menstruate.

B. Carriers shall cover, without cost sharing, items and services that are integral to the furnishing of an FDA-approved, cleared or granted contraceptive or contraceptive care, regardless of whether the item or service was billed separately. This coverage must include the clinical services and patient education and counseling needed for provision of the contraceptive product or service and any follow-up care, including laboratory tests integral to the furnishing of an FDA-approved, cleared, or granted contraceptive.

C. If the attending health care provider, in their reasonable professional judgment, determines that the use of an alternative contraceptive, whether that contraceptive is on the carrier's formulary or not, is medically necessary with respect to a covered person, the health care provider's determination shall be final, and a carrier must cover the contraceptive without prior authorization, step therapy, or cost-sharing. If a carrier requires a written request for contraceptives not currently on the plan's prescription drug formulary, the carrier shall use the standard exception form included in Appendix A and make such form available in paper and electronic format to providers and enrollees with other information regarding the exception process and with other plan materials.

D. A carrier that receives an exception request for an alternative contraceptive on the formulary or a non-formulary contraceptive shall consider that request as an expedited exception request.

E. Carriers are prohibited from requiring prior authorization, step therapy, or other utilization management practices as a prerequisite to covering a contraception, whether that contraceptive is on the carrier's formulary or not, that the covered person's health care provider has determined is medically necessary with respect to the covered person. Carriers are specifically prohibited from:

1. Requiring prior authorization or denying coverage for a single-source brand name contraceptive with no therapeutic or pharmaceutical equivalent if the covered person's health care provider determines the product is medically necessary with respect to that person.

2. Requiring a covered person to undergo step therapy using numerous other FDA-approved, cleared, or granted contraceptive products within the same contraceptive category prior to coverage if the person's health care provider determines the product is medically necessary with respect to that person.

3. Requiring a covered person to undergo step therapy using numerous other FDA-approved, cleared, or granted contraception in other contraceptive categories prior to coverage if the person's health care provider determines the product is medically necessary with respect to that person.

4. Imposing age limits on contraceptive coverage.

5. Imposing quantity or fill limits on contraceptives that are not based on the clinical evidence base or that result in a covered person receiving less than a twelve-months' supply of a contraceptive.

G. Carriers shall reimburse a provider or in-network dispensing entity for the single dispensing or furnishing of a contraceptive intended to last for a duration of twelve months, dispensed or furnished at one time.

H. Carriers shall cover without cost sharing over-the-counter (OTC) oral and emergency contraception without a prescription. Carriers are required to cover these products without cost sharing including when they are prescribed for advanced provision.

I. Carriers must assure that all covered services, including contraceptive services, are accessible without unreasonable delay consistent with Section 10-16-704, C.R.S, and Colorado Insurance Regulation 4-2-53. If there is no participating provider within the network adequacy geographic access standards in Colorado Insurance Regulation 4-2-53, carriers must provide an easily accessible, and timely process for individuals to obtain in-network cost-sharing of contraceptive services from out-of-network providers or facilities consistent with Section 10-16-704(2), C.R.S.

Section 6 Incorporation by Reference

The Women's Preventive Services Guidelines, published by the Health Resources and Services Administration, shall mean the Women's Preventive Services Guidelines published by the Health Resources and Services Administration, as published on the effective date of this regulation and does not include later amendments to, or editions of the Women's Preventive Services Guidelines published by the Health Resources and Services Administration. The Women's Preventive Services Guidelines published by the Health Resources and Services Administration may be examined during regular business hours at the Colorado Division of Insurance, 1560 Broadway, Suite 850, Denver, Colorado 80202 or by visiting the Health Resources and Services Administration website at https://www.hrsa.gov/womens-guidelines Certified copies of the Women's Preventive Services Guidelines, published by the Health Resources and Services Administration are available from the Colorado Division of Insurance for a fee.

Section 7 Severability

If any provision of this emergency regulation or the application of it to any person or circumstance is for any reason held to be invalid, the remainder of the regulation shall not be affected.

Section 8 Enforcement

Noncompliance with this emergency regulation may result in the imposition of any of the sanctions made available in the Colorado statutes pertaining to the business of insurance, or other laws, which include the imposition of civil penalties, issuance of cease and desist orders, and/or suspensions or revocations of license, subject to the requirements of due process.

Section 9 Effective Date

This emergency regulation shall become effective on August 7, 2023.

Section 10 History

Emergency regulation effective August 7, 2023.

Appendix A: Standard Exception Form for Contraceptives

REQUEST FOR AN ALTERNATIVE CONTRACEPTIVE FOR PATIENTS COVERED UNDER A COLORADO HEALTH BENEFIT PLAN (other than self funded ERISA coverage, Medicaid, Medicare, and TRICARE)

Carriers must cover a non-formulary contraceptive without cost-sharing upon the recommendation of the patient's health care provider.

If the carrier, or pharmacy benefit management firm acting on behalf of a carrier, requires a written request for a non-formulary contraceptive, the provider must complete this form and send it to the patient's health benefit plan to obtain coverage of a contraceptive that is not on the plan's prescription drug formulary, but is determined to be medically necessary for the patient by the provider.

Patient Information		
Name		**Date of Birth**
Address		
City	**State**	**Zip Code**
Health Insurer Name	**Patient's Member ID #**	

Attending Health Care Provider Information		
Name		
Address		
City	**State**	**Zip Code**
Office Phone	**Fax**	
Tax ID # / NPI # (if available)	**Facility Name (if applicable)**	
Office Point of Contact	**Preferred Contact Method**	

Alternative Contraceptive Request (to be completed by the attending health care provider)

The covered therapeutic and pharmaceutical equivalent versions of a contraceptive are: (check one)

□ Not available; OR
□ Deemed medically inappropriate

Requested Alternative Contraceptive: (complete applicable items)
I, the patient's attending health care provider, in my reasonable professional judgment, have determined that the use of the non covered therapeutic or pharmaceutical equivalent of a contraceptive listed below is warranted.

Contraceptive Name	**Strength**	**Quantity per Month**
J-code	**Units Requested**[1]	**Proposed Date of Service**
□ **Check if a generic equivalent may be substituted for the requested contraceptive drug, device, or product.**		

Exception Request

NOTE: Per Colorado law, a carrier that receives this exception request for a non-formulary contraceptive shall consider that request as an expedited exception request and must respond within 24 hours following receipt of this request. Carriers are prohibited from requiring a covered person, a person's authorized representative, or an individual's provider to appeal an adverse benefit determination for a contraceptive using the carrier's internal claims and appeals process.

Signature

I certify that the information provided in this form is accurate to the best of my knowledge.

Health Care Provider's Signature	**Date**

Send the completed form to:

[1] Pursuant to section § 10-16-104.2, Colorado Revised Statute, carriers must reimburse a participating provider for prescription contraceptives intended to last for a 12-month period.

Fax Number:
[Insert carrier fax number(s)]

Email:
[Insert carrier email address for exceptions requests]