

**02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION**

**031 BUREAU OF INSURANCE**

**Chapter 865: STANDARDS FOR FERTILITY COVERAGE**

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**Section 1. Authority and Purpose**

The Superintendent adopts this rule pursuant to 24-A M.R.S. §§ 212 and 4320-U(5) to implement the fertility care coverage requirements of 24-A M.R.S. § 4320-U.

**Section 2. Applicability and Scope**

This rule applies to all policies, contracts, riders, and endorsements delivered, issued, executed or renewed in this State on and after January 1, 2025 by a carrier as defined in this rule. Section 7 also applies to claims paid under coverage issued or renewed in 2024.

**Section 3. Definitions**

1. “Assisted hatching” means a micromanipulation technique in which a hole is artificially created in the outer shell of an embryo to assist with the potential implantation of that embryo.
2. “Carrier” has the same meaning as defined in 24-A M.R.S. §4302-A(1)(3).
3. “Cryopreservation” means the freezing of embryos, eggs, sperm, ovarian tissue, or testicular tissue.
4. “Egg retrieval” means a procedure by which eggs are collected from ovarian follicles, including all office visits, procedures, and laboratory and radiological tests performed in preparation for egg retrieval; the attempted or successful retrieval of the egg(s); and, if the retrieval is successful, culture and fertilization of the egg(s).

5. “Embryo” means a cell or group of cells that has the potential to develop into a live born human being if transferred into the body under conditions in which gestation may be reasonably expected to occur.
6. “Embryo transfer” means the placement of an embryo into the uterus or fallopian tube.
7. “Experimental fertility procedure” has the same meaning as defined in 24-A M.R.S. § 4320-U(1)(A).
8. “Federal Affordable Care Act” has the same meaning as defined in 24-A M.R.S. § 14.
9. “Fertility coverage” means coverage provided by a carrier for fertility diagnostic care, fertility preservation services, and fertility treatment.
10. “Fertility diagnostic care” has the same meaning as defined in 24-A M.R.S. § 4320-U(1)(B).
11. “Fertility patient” has the same meaning as defined in 24-A M.R.S. § 4320-U(1)(C).
12. “Fertility preservation services” has the same meaning as defined in 24-A M.R.S. § 4320-U(1)(D).
13. “Fertility treatment” has the same meaning as defined in 24-A M.R.S. § 4320-U(1)(E).
14. “Fertilization” means the penetration of the egg by the sperm.
15. “Gamete intrafallopian tube transfer” means the direct transfer of a sperm/egg mixture into the fallopian tube by laparoscopy.
16. “Gestational carrier” means a person who carries an embryo that was not formed from the gestational carrier’s own egg, and who intends that a fertility patient, and not the gestational carrier, will be a parent of the child after birth.
17. “Iatrogenic infertility” means an impairment of fertility caused by surgery, radiation, chemotherapy, or other medical treatment affecting reproductive organs or processes.
18. “Infertility” has the same meaning as defined in 24-A M.R.S. § 4320-U(1)(G).
19. “Intracytoplasmic sperm injection” means a micromanipulation procedure whereby a single sperm is injected into the center of an egg.
20. “Intrauterine or vaginal insemination” means the introduction of sperm into the uterus, cervix, or vagina by noncoital methods for the purpose of conception.
21. “In vitro fertilization” means an assisted reproductive technology procedure whereby eggs are removed from the ovaries and fertilized outside the body. The resulting embryo is then transferred into the uterus.
22. “Maine Health Insurance Marketplace” has the same meaning as defined in 22 M.R.S. § 5403.

23. “Microsurgical sperm aspiration or extraction” means the techniques used to obtain sperm for use with intracytoplasmic sperm injection in cases of obstructive or nonobstructive azoospermia. It can involve the extraction of sperm and fluid from epididymal tubules or the provision of testicular tissue from which viable sperm may be extracted.
24. “Ovulation induction” means the use of drugs (oral or injected) to stimulate the ovaries to develop follicles and eggs.
25. “Standard-setting organization” means the American Society for Reproductive Medicine, the American College of Obstetrics and Gynecology, the Society for Assisted Reproductive Technology, or their respective successor organizations.
26. “Surrogate” means a person who carries an embryo that was formed from the surrogate’s own egg inseminated by the sperm of a fertility patient.
27. “Zygote intrafallopian tube transfer” means a procedure whereby an egg is fertilized in vitro and transferred to the fallopian tube at the pronuclear stage before cell division takes place.

#### **Section 4. Coverage Requirements**

1. In making coverage available under this rule, a carrier shall not discriminate against any class of enrollees protected by the Maine Human Rights Act, Title 5 M.R.S. Chapter 337. In particular, carriers shall make coverage available regardless of sexual orientation, gender identity or expression, and family composition, including single parents.
2. A carrier shall adopt and use guidelines no less favorable than those established and adopted by a standard-setting organization, including without limitation guidelines for:
  - (A) identifying experimental fertility procedures and treatments not covered for the diagnosis and treatment of infertility or for fertility preservation;
  - (B) identifying the required training, experience, and other standards for health care providers to provide fertility diagnostic care, fertility treatment, and fertility preservation services; and
  - (C) determining appropriate candidates for fertility care, including without limitation:
    - (1) enrollees with a medical need for fertility preservation services, including patients who expect to undergo treatment, as designated in the guidelines, that may directly or indirectly cause a risk of iatrogenic infertility, and
    - (2) enrollees who have been diagnosed by a physician as having a genetic trait associated with certain conditions that include, at a minimum, all those specified by the standard-setting organization designated by the carrier.

3. A carrier shall not impose a separate visit maximum or procedure maximum on any fertility treatment, except as expressly permitted in Section 6. A carrier shall not require a separate deductible for fertility coverage or any other separate cost sharing requirement except as permitted by Paragraph A of this subsection.
  - (A) A plan's medical coverage may not establish higher copayments for fertility coverage than for other comparable specialty services. After the deductible is satisfied, the enrollee's coinsurance may not exceed the greater of 20%, or the percentage specified in the plan for other comparable specialty services.
  - (B) A plan's prescription drug coverage may not establish less favorable terms for fertility drugs than for other comparable medications, including the assignment of fertility drugs to cost-sharing tiers.
  - (C) A carrier shall comply with any other restrictions on cost sharing required by applicable law.
4. A carrier shall not impose any preauthorization requirements or other utilization management requirements on fertility treatment other than requirements of general applicability that do not have the purpose or effect of defeating the purposes of this subsection. For example, if a carrier requires all hospitalizations or all surgeries to be preauthorized, and a particular fertility treatment involves a hospitalization or a surgical procedure, the carrier may require preauthorization of that hospitalization or surgical procedure.
5. A carrier may limit benefits required by this rule to services performed at facilities that conform to standards established by the carrier's designated standard-setting organization. A carrier shall not impose on facilities or other providers any additional standards in the policy or contract or in the certificate or evidence of coverage applicable to fertility services.

## **Section 5. Required Benefits**

Fertility coverage shall include, at a minimum, payment of benefits for the following services and procedures for fertility patients, subject to the limitations permitted by Section 6, when the service or procedure is recognized as medically appropriate, in light of the fertility patient's medical history, under guidelines adopted in compliance with this rule:

1. Intrauterine or vaginal insemination;
2. Assisted hatching;
3. Diagnosis and diagnostic tests;
4. Laboratory testing;
5. Ultrasounds and other imaging procedures;
6. Physical examinations;

7. Fresh and frozen embryo transfer, including the transfer of donor embryos;
8. Egg retrievals, including, when a live donor is used in an egg retrieval, the donor's associated medical costs until the donor is released from treatment by the reproductive endocrinologist; covered medical costs include without limitation physical examination, laboratory screening, psychological screening, prescription drugs, monitoring follicle development, the retrieval procedure, and treatment of any direct medical complications of covered procedures;
9. Gamete intrafallopian tube transfer and zygote intrafallopian tube transfer;
10. Intracytoplasmic sperm injections;
11. In vitro fertilization, including in vitro fertilization using donor eggs and in vitro fertilization where the embryo is transferred to a gestational carrier or surrogate;
12. Medications, including injectable fertility medications, even if the contract or policy does not provide prescription drug benefits. Where a contract or policy provides both prescription drug and medical and hospital benefits, fertility drugs shall be covered under the prescription drug coverage;
13. Ovulation induction;
14. Surgery, including but not limited to microsurgical sperm aspiration or extraction; and
15. Costs associated with cryopreservation and storage of embryos, eggs, sperm, ovarian tissue, and testicular tissue for up to five years.

**Section 6. Permissible Benefit Limitations and Exclusions**

1. Benefits for intrauterine or vaginal insemination may be limited to three lifetime cycles.
2. Benefits for egg retrieval may be subject to a lifetime limit of four completed egg retrievals.
3. Benefits for any combination of gamete intrafallopian transfer (GIFT), zygote intrafallopian transfer (ZIFT), or fresh or frozen embryo transfer (FET) may be limited to two lifetime cycles.
4. In calculating any lifetime limit permitted by this rule, procedures where the cost was not covered by any carrier, self-insured health plan, or governmental program shall not count toward the limit, and a covered procedure shall only be counted against the lifetime limit for the individual fertility patient who filed the claim.
5. This rule does not prohibit coverage exclusions for the following services:
  - (A) Reversal of voluntary sterilization;
  - (B) Nonmedical costs of an egg or sperm donor, gestational carrier, or surrogate;

- (C) Maternity care and prenatal care services, or services to treat complications of pregnancy or childbirth, rendered to a gestational carrier or surrogate who is not covered by the carrier's policy or contract;
  - (D) Experimental fertility procedures;
  - (E) Ovulation kits and sperm testing kits and supplies designed for home use;
  - (F) In vitro fertilization, gamete intrafallopian tube transfer, and zygote intrafallopian tube transfer for persons who have not used all reasonable less expensive and medically appropriate treatments for infertility;
  - (G) In vitro fertilization or gamete intrafallopian tube transfer involving eggs that were collected from a fertility patient who had exceeded the limit of four covered completed egg retrievals; and
  - (H) In vitro fertilization when the resulting embryos are to be transferred to a fertility patient who has exceeded the limit of two covered embryo transfer cycles.
6. Any other limitations or exclusions on fertility coverage must be consistent with the carrier's clinical guidelines, which must comply with the requirements of this rule. The carrier shall adopt and maintain its clinical guidelines in writing, citing with specificity any data or scientific reference relied upon, and make them available to any enrollee upon request.

#### **Section 7. Benefit Mandate Defrayal**

1. This section establishes the method for reporting by carriers and payment of reimbursement if some or all of the benefits required by this rule are subject to cost defrayal under the federal Affordable Care Act.
2. For the purposes of this subsection, benefits subject to cost defrayal are benefits that:
  - (A) Are required by and do not exceed the limitations in 24-A M.R.S. § 4320-U or in this rule;
  - (B) Are provided by a health plan purchased on the Maine Health Insurance Marketplace;
  - (C) Include only the carrier's share of the claim payment required by Subsection 4(2) and not any additional amount voluntarily offered by the carrier;
  - (D) Were not within the scope of coverage of the benchmark plan used to define the required essential health benefits under 24-A M.R.S. § 4320-D(2), as in effect at the time of enactment of 24-A M.R.S. § 4320-U; and
  - (E) Have been determined by the Superintendent, after consultation with the federal Centers for Medicare and Medicaid Services, to be subject to the federal Affordable Care Act's requirement to defray the cost of those benefits.

### 3. Reporting Process

- (A) A carrier seeking reimbursement for benefits subject to cost defrayal shall, on or before April 15 of each year, submit to the Bureau a request that includes the following information for the preceding calendar year:
- (1) the number of individuals who received benefits subject to defrayal during the preceding calendar year;
  - (2) the amounts allowed, incurred, and paid by the carrier for benefits subject to defrayal relating to services rendered during the preceding calendar year;
  - (3) any amounts previously incurred for benefits subject to defrayal but previously reported as unpaid;
  - (4) any durational limit, amount limit, deductible, copayment, and coinsurance for the fertility treatment; and
  - (5) any other information required by the Superintendent.
- (B) A request for reimbursement shall be submitted in an electronic format prescribed by the Superintendent.

### 4. Rate Filing Modifications.

A carrier that expects to be eligible to receive a reimbursement under this section shall:

- (A) Modify the federal rate filing template to exclude the expected reimbursement amount from the rates submitted on both the Unified Rate Review Template and the Rate Data Template;
- (B) Indicate in the rate filing's actuarial memorandum:
- (1) The reimbursement amount the carrier anticipates for benefits subject to defrayal; and
  - (2) That the cost of benefits subject to defrayal is not included in the premiums;
- (C) In the Plans and Benefits Template:
- (1) Indicate in the "Benefits Information" field that the carrier covers benefits subject to defrayal, and select "Not EHB" for the "EHB Variance Reason" field; and
  - (2) Not factor benefits subject to defrayal into the calculation for the "EHB Percent of Total Premium" field on the Plans and Benefits Template; and

(D) Benefits subject to defrayal may not include benefits subject to defrayal in the total premium from which the “EHB Percent of Total Premium” field is calculated.

5. Claims Auditing.

The Bureau may audit a carrier’s reimbursement report, including its process for determining which claims are eligible for reimbursement under this section.

**Section 8. Severability**

If any section, term, or provision of this rule shall be deemed invalid for any reason, any remaining section, term, or provision shall remain in full force and effect.

**Section 9. Effective Date**

This rule is effective [date].