

**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. Scope**

This rule applies to all policies, contracts, riders, and endorsements delivered, issued, executed or renewed in this State on and after January 1, 2024 by a carrier as defined in this rule.

**Section 3. Definitions**

1. ~~“Artificial insemination”~~ means the introduction of sperm into a ~~woman’s~~ vagina or uterus by noncoital methods for the purpose of conception, including intrauterine insemination.
2. “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.
3. “Carrier” has the same meaning as defined in 24-A M.R.S. §4302-A(1)(3).
4. ~~“Completed egg retrieval” means 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).~~

**Commented [RNE1]:** A separate definition of "completed egg retrieval" is not needed.

4. ~~“Cryopreservation” means the freezing of embryos in liquid nitrogen until such time as required for a frozen embryo transfer, or the freezing of eggs and sperm or gametes, ovarian tissue, or testicular tissue.;~~
5. ~~“Donor” has the same meaning as defined in 19A M.R.S. §§ 1832, 1922.~~
6. ~~“Egg retrieval” means a procedure by which eggs are collected from a woman’s ovarian follicles, including all office visits, procedures, 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).~~
6. -
7. ~~“Embryo” means a fertilized egg that has begun cell division has the same meaning as defined in 19A M.R.S. § 1832.~~
8. ~~“Embryo transfer” means the placement of an embryo into the uterus through the cervix, or, in the case of zygote intrafallopian tube transfer, the placement of an embryo in the fallopian tube. Embryo transfer includes the transfer of cryopreserved embryos and donor embryos.~~
9. “Experimental fertility procedure” has the same meaning as defined in 24-A M.R.S. § 4320-U.
10. “Federal Affordable Care Act” has the same meaning as defined in 24-A M.R.S. § 14.
11. “Fertility coverage” means coverage provided by a carrier for fertility diagnostic care, fertility preservation services, and fertility treatment.
12. “Fertility diagnostic care” has the same meaning as defined in 24-A M.R.S. § 4320-U.
13. “Fertility patient” has the same meaning as defined in 24-A M.R.S. § 4320-U.
14. “Fertility preservation services” has the same meaning as defined in 24-A M.R.S. § 4320-U.
15. “Fertility treatment” has the same meaning as defined in 24-A M.R.S. § 4320-U.
16. “Fertilization” means the penetration of the egg by the sperm.
- 16,17. ~~“Gamete” has the same meaning as defined in 24-A M.R.S. § 4320-U.~~
17. ~~“Gamete intrafallopian tube transfer” means the direct transfer of a sperm/egg mixture into the fallopian tube by laparoscopy.~~
18. ~~“Gestational carrier” has the same meaning as defined in 19A M.R.S. §§ 1832, 1922, and who intends to give the child to one or both of the biological parents after birth.~~
18. -
19. ~~“Iatrogenic infertility” means an impairment of fertility caused by surgery, radiation, chemotherapy, or other medical treatment affecting reproductive organs or processes.~~
- 20,19. “Infertility” has the same meaning as defined in 24-A M.R.S. § 4320-U.

**Commented [CT2]:** Donor embryos are also cryopreserved so this is confusing.

**Commented [RNE3]:** GIFT and ZIFT are not longer performed and do not need to be referenced in these rules.

**Commented [CT4]:** This is legally inaccurate. Gestational Carriers do not "give" the child to the Intended Parents.

**Commented [RNE5]:** This definition is not needed.

21-20. “Intracytoplasmic sperm ~~injection~~ ~~means~~ injection “means a micromanipulation procedure whereby a single sperm is injected into the center of an egg.

22-21. “In vitro fertilization” means an assisted reproductive technology procedure whereby eggs are removed from ~~a woman’s~~ ~~the~~ ovaries and fertilized outside ~~the~~ ~~her~~ body. The resulting embryo is then transferred into a ~~woman’s~~ uterus.

- ~~22-22.~~ “Maine Health Insurance Marketplace” has the same meaning as defined in 22 M.R.S. § 5403.
23. “Microsurgical sperm aspiration” means the techniques used to obtain sperm for use with intracytoplasmic sperm injection in cases of obstructive 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. “Microsurgical Testicular Sperm Extraction” (mTESE) means the techniques used to obtain sperm for use with intracytoplasmic sperm injection (ICSI) in cases of non-obstructive azoospermia. It involves the microsurgical extraction of testicular tissue from which viable sperm may be utilized for ICSI. As for Epididymal sperm, this testis tissue may undergo cryopreservation.
25. “Ovulation induction” means the use of drugs (oral or injected) to stimulate the ovaries to develop follicles and eggs.
26. “Standard-setting organization” means the American Society for Reproductive Medicine, ~~the American College of Obstetrics and Gynecology, the Society for Assisted Reproductive Technology,~~ or ~~its~~their respective successor organizations.
- ~~“Surrogate” means a woman who carries an embryo that was formed from her own egg inseminated by the sperm of a fertility patient.~~
27. “Voluntary Sterilization” means a sterilization performed with the primary purpose of preventing future pregnancy, except that a sterilization performed to prevent future pregnancy, when such pregnancy should be avoided for a medical reason, is not deemed voluntary sterilization.
- ~~28. “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.~~

**Commented [RNE6]:** This is referenced in “gestational carrier” definition from the Maine Parentage Act

**Commented [CT7]:** Need to protect the women who lose their uterus due to cancer, hemorrhage, etc. and women who cannot safely get pregnant but can still safely have children through gestational carrier.

#### Section 4. Coverage Requirements

1. 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;
  - (B) identifying the required training, experience, and other standards for health care providers to provide procedures and treatments to diagnose and treat infertility; and
  - (C) determining those that are fertility patients appropriate candidates for fertility treatment -in accordance with the requirements of 24-A M.R.S. § including without limitation enrollees:
    - ~~(1) — with iatrogenic infertility, and~~
    - ~~(2) — 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.~~

2. A carrier shall not impose a separate visit maximum or procedure maximum on any fertility treatment ~~other than limiting coverage for egg retrievals to the first four completed egg retrievals over the lifetime of the egg retrieval patient.~~ A carrier shall not require a separate deductible for fertility coverage or require higher copayments for fertility coverage than the plan specifies for other comparable specialty services. After the deductible is satisfied, a carrier must pay at least 80% of the cost of fertility coverage,

**Commented [CT8]:** This is not allowed under ACA because treats infertility as a pre-existing condition. This is also not allowed under this law because this is an arbitrary limit, not based on any medical standards, and also gives men different coverage than women receive, both of which are specifically not allowed under this law.

or the percentage specified in the plan for other comparable specialty services, whichever is less. A carrier shall comply with any other restrictions on cost sharing required by the Clear Choice program or other applicable law.

3. 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.
4. 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 when recognized as medically appropriate, in light of the fertility patient's medical history,~~ under guidelines adopted in compliance with this rule:

1. ~~Artificial i~~nsemination;
2. Assisted hatching;
3. Diagnosis and diagnostic tests;
4. Fresh and frozen embryo transfer;
5. Egg retrievals, ~~unless the egg retrieval patient has already undergone four completed egg retrievals,~~ provided that:
  - (A) Where a live donor is used in an egg retrieval, the medical costs of the donor associated with the retrieval shall be covered until the donor is released from treatment by the reproductive endocrinologist; donor medical costs include without limitation physical examination, laboratory screening, psychological screening, ~~and~~ prescription drugs, ~~egg retrieval expenses, and any medical complications of the donor;~~
  - (B) ~~Egg retrievals where the cost was not covered by any carrier, self-insured health plan, or governmental program shall not count toward the four completed egg retrieval limit;~~
6. ~~Gamete intrafallopian tube transfer and zygote intrafallopian tube transfer;~~
7. ~~6.~~ Intracytoplasmic sperm injections;

Commented [CT9]: See above comment on cycle limits.

Commented [CT10]: See above comment about cycle limits.

7. ~~In vitro fertilization, including in vitro fertilization using donor eggs-gametes and in vitro fertilization where the embryo is transferred to a gestational carrier;~~
8. Laboratory testing;
9. Medications, including injectable ~~in~~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, ~~in~~fertility drugs shall be covered under the prescription drug coverage;
10. Ovulation induction;
- ~~10,11. Physical examinations;~~
12. Surgery, including ~~but not limited to~~ microsurgical sperm aspiration ~~and~~ microsurgical testicular sperm extraction
- ~~11,13. Ultrasounds and other imaging procedures; and~~
14. Costs associated with cryopreservation and storage of sperm, eggs, and embryos; and
15. Fertility Preservation services.

~~12. \_\_\_\_\_~~

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

1. ~~Benefits for intrauterine insemination may be limited to three lifetime cycles;~~
2. ~~Benefits for any combination of in vitro fertilization (IVF), gamete intrafallopian transfer (GIFT), zygote intrafallopian transfer (ZIFT), or fresh or frozen embryo transfer (FET) may be limited to two lifetime cycles;~~
- 3-1. This rule does not prohibit coverage exclusions for the following services:
- (A) Reversal of voluntary sterilization;
  - (B) ~~Medical~~ Maternity care services rendered to a gestational carrier ~~for purposes of childbearing~~ where the gestational carrier is not covered by the carrier's policy or contract;
  - (C) Nonmedical costs of ~~an egg or sperm~~ a gamete donor;
  - (D) Experimental fertility procedures;
  - (E) Ovulation kits and sperm testing kits and supplies designed for at home use; and

**Commented [CT11]:** This is not consistent with medical standards. Certain fertility patients (but not all) can benefit from additional cycles of intrauterine insemination. Also, what if the patient wants 4 kids. Also, lifetime limits not allowed under ACA.

**Commented [RNE12]:** This should not say "medical" because IVF with a gestational carrier or traditional surrogate IS a covered benefit.

(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, or who have exceeded the limit of four covered completed egg retrievals.~~

4. Any other limitations or exclusions on fertility coverage must be consistent with the carrier's clinical guidelines, which guidelines must comply with the requirements of this rule. The carrier shall adopt and maintain its clinical guidelines in writing and make them available to any enrollee upon request. ~~Any clinical guidelines must cite with specificity any data or scientific reference relied upon. Footnotes or end notes are equally acceptable provided that body of the clinic guidelines indicates the relevant endnotes. A list of endnotes that does not refer back to the relevant text does not meet the requirements of this rule.~~

**Commented [RNE13]:** This language should be deleted as it is not clear how "reasonable" or "medically appropriate" would be decided or by whom. Any limits should be based on current clinical guidelines and the individual patient's medical history.

**Commented [CT14]:** This means that if a particular piece of clinical evidence is used for decisions about care, they need to be referenced directly via a footnote, not just grouped in end notes at the end. In other states, we have experienced outdated clinical information being used to limit access, and it is very difficult to determine which source is being cited so that it can be reviewed and potentially refuted.



**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. [This section would only be triggered by the promulgation of federal regulations implementing and outlining the cost defrayal process.](#)
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; and
  - (D) 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.
  - (C) Availability of funding.
    - (1) Subject to availability of funding, carriers shall be reimbursed for all paid claims that are within the scope of the State's defrayal obligation.

- (2) If legislative funding is less than the aggregate amount of valid reimbursement requests, each carrier's reimbursement shall be prorated and the unpaid balance shall be carried over to the next reimbursement year, unless a rate adjustment under Subsection (3) is approved.
- (3) With the approval of the Superintendent, carriers may include an adjustment to the following year's rates to account for a legislative funding deficit. Any adjustment shall be clearly delineated in the actuarial memorandum supporting the rates.

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].

