STATE OF MAINE
DEPARTMENT OF PROFESSIONAL & FINANCIAL REGULATION
BUREAU OF INSURANCE

Janet T. Mills
Governor

Anne L. Head
DPFR Commissioner

Timothy N. Schott
Acting Superintendent

BUREAU OF INSURANCE
REQUEST FOR COMMENTS ON REVISIONS TO PROPOSED 02-031 C.M.R. CHAPTER 865 STANDARDS FOR FERTILITY COVERAGE

Notice is hereby given that the Bureau of Insurance requests additional comments on the attached revisions to Proposed Rule Chapter 865, "Standards for Fertility Coverage." This rule was proposed pursuant to 24-A M.R.S. §§ 212 and 4320-U to establish standards to implement the fertility care coverage requirements of 24-A M.R.S. § 4320-U.

On May 22, 2023, the Bureau published a Notice of Rulemaking setting the public hearing at 1:30 p.m. on June 20, 2023, and closing the comment period at 4:30 p.m. on June 30, 2023. On May 22, 2023, the Bureau posted the Proposed Rule to its website, distributed it to subscribers to the Bureau's e-mail subscription service, and filed a Rule-Making Fact Sheet with the Maine Secretary of State, published in the State Rulemaking Register on May 31, 2023, and with the Executive Director of the Legislative Council.

The public hearing took place as scheduled by videoconference. The Bureau received extensive comments both at the hearing and in writing. After reviewing the comments, we have determined that substantial changes from the Proposed Rule are appropriate.

Pursuant to 5 M.R.S. § 8052(5)(B), "If an agency determines that a rule that the agency intends to adopt is substantially different from the proposed rule, the agency shall request comments from the public concerning the changes from the proposed rule." Therefore, we are requesting further written comment on the proposed revisions. Comments must be received no later than December 15, 2023 at 4:30 p.m. and should be addressed to: Karma Lombard, 34 State House Station, Augusta, ME 04333-0034 or Karma.Y.Lombard@maine.gov

In addition to comments on specific proposed revisions, comments would be particularly helpful in the following general areas, with specific language suggestions if possible:

- Whether the proposed limits on coverage reflect the best allocation of the funding resources the Legislature has provided for benefit defrayal;
- Whether various technical changes we have proposed to the rule, including changes to definitions and medical terminology, are accurate, or whether they are worded in ways that might have unintended consequences;
- If we were to modify or eliminate technology-specific requirements, to anticipate future advances in technology, what replacement language would best ensure a level of coverage that meets the statute, without expanding into services or procedures that do not represent an accepted standard of care or that are considered experimental;
- Are there other methods of facilitating the defrayal reimbursement process that would be more efficient for the State, the policyholders, and the carriers? If we substitute a

prospective reimbursement methodology in place of the proposed retrospective methodology, how would that mechanism be structured and implemented? and

- If the legislatively budgeted defrayal funds are, or are anticipated to be, fully expended, what options are there for reimbursing individuals or carriers as required by the ACA? Additional information on other states' experience in this area, including information on whether other state agency(ies) or other entities have successfully facilitated the defrayal process, would also be helpful.

October 31, 2023

Timothy N. Schott, Acting Superintendent

Office Location: 76 Northern Avenue, Gardiner, Maine 04345
Mailing Address: 34 State House Station, Augusta, Maine 04333
www.maine.gov/insurance

Phone: (207) 624-8475 TTY: Please Call Maine Relay 711 Consumer Assistance: 1-800-300-5000 Fax: (207) 624-8599

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

~~2.~~ 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.

~~3.~~ 2. "Carrier" has the same meaning as defined in 24-A M.R.S. §4302-A(1)(3).

~~4.~~ 3. "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).

~~5.~~ 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, ovarian tissue, or testicular tissue.

~~6.~~ 5. "Egg retrieval" means a procedure by which eggs are collected from a woman's ovarian follicles.

~~7.~~ 6. "Embryo" means a ~~fertilized egg that has begun cell division~~ 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.

~~8.~~ 7. "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.~~ 8. "Experimental fertility procedure" has the same meaning as defined in 24-A M.R.S. § 4320-U(1)(A).

~~10.~~ 9. "Federal Affordable Care Act" has the same meaning as defined in 24-A M.R.S. § 14.

~~11.~~ 10. "Fertility coverage" means coverage provided by a carrier for fertility diagnostic care, fertility preservation services, and fertility treatment.

~~12.~~ 11. "Fertility diagnostic care" has the same meaning as defined in 24-A M.R.S. § 4320-U(1)(B).

~~13.~~ 12. "Fertility patient" has the same meaning as defined in 24-A M.R.S. § 4320-U(1)(C).

~~14.~~ 13. "Fertility preservation services" has the same meaning as defined in 24-A M.R.S. § 4320-U(1)(D).

~~15.~~ 14. "Fertility treatment" has the same meaning as defined in 24-A M.R.S. § 4320-U(1)(E).

~~16.~~ 15. "Fertilization" means the penetration of the egg by the sperm.

~~17.~~ 16. "Gamete intrafallopian tube transfer" means the direct transfer of a sperm/egg mixture into the fallopian tube by laparoscopy.

~~18.~~ 17. "Gestational carrier" means a ~~woman~~ person who ~~has become pregnant with~~ carries an embryo ~~or embryos~~ that ~~are not part of her genetic or biologic entity~~ was not formed from the gestational carrier's own egg, and who intends ~~to give the child to~~ that one or both of the ~~biological~~ genetic parents, and not the gestational carrier, will be a parent of the child after birth.

~~19.~~ 18. "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(1)(G).

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

~~1.~~ 21. "~~Artificial~~ Intrauterine or vaginal insemination" means the introduction of sperm into ~~a woman's vagina or~~ the uterus, cervix, or vagina by noncoital methods for the purpose of conception~~, including intrauterine insemination~~.

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

23. "Maine Health Insurance Marketplace" has the same meaning as defined in 22 M.R.S. § 5403.

24. "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.

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 their respective successor organizations.

27. "Surrogate" means a ~~woman~~ person who carries an embryo that was formed from ~~her~~ the surrogate's own egg inseminated by the sperm of a fertility patient.

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.

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 1 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.

~~1.~~ 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 ~~procedures and treatments to diagnose and treat infertility~~ fertility diagnostic care, fertility treatment, and fertility preservation services; and

(C) determining appropriate candidates for fertility treatment, including without limitation ~~enrollees~~:

(1) enrollees with a medical need for fertility preservation, 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.

~~2.~~ 3. 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, except as expressly permitted in Section 6. 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 the enrollee's coinsurance may not exceed the greater of 20%, 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.~~ 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.

~~4.~~ 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. ~~Artificial~~ Intrauterine or vaginal insemination;

2. Assisted hatching;

3. Diagnosis and diagnostic tests;

4. Laboratory testing;

5. Ultrasounds and other imaging procedures;

6. Physical examinations;

~~4.~~ 7. Fresh and frozen embryo transfer;

~~5.~~ 8. Egg retrievals, ~~unless the egg retrieval patient has already undergone four completed egg retrievals, provided that:~~

~~(A)~~ ~~Where~~ including, when a live donor is used in an egg retrieval, the donor's associated medical costs ~~of the donor associated with the retrieval shall be covered~~ until the donor is released from treatment by the reproductive endocrinologist; ~~donor~~ covered medical costs include without limitation physical examination, laboratory screening, psychological screening, ~~and~~ prescription drugs, monitoring follicle development, the retrieval procedure, and treatment of any direct medical complications of covered procedures;

~~(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.~~ 9. Gamete intrafallopian tube transfer and zygote intrafallopian tube transfer;

~~7.~~ 10. Intracytoplasmic sperm injections;

~~8.~~ 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;

~~9.~~ 12. Medications, including injectable ~~infertility~~ 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, ~~infertility~~ fertility drugs shall be covered under the prescription drug coverage;

~~10.~~ 13. Ovulation induction;

~~11.~~ 14. Surgery, including but not limited to microsurgical sperm aspiration or extraction; and

~~12.~~ 15. Costs associated with cryopreservation and storage of ~~sperm, eggs, and~~ 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.

~~2.~~ 3. 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~~;~~.

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.

~~3.~~ 5. This rule does not prohibit coverage exclusions for the following services:

(A) Reversal of voluntary sterilization;

~~(C)~~ (B) Nonmedical costs of an egg or sperm donor, gestational carrier, or surrogate;

~~(B)~~ (C) ~~Medical~~ Maternity care and prenatal care services, or services to treat complications of pregnancy or childbirth, rendered to a gestational carrier or surrogate ~~for purposes of childbearing, where the 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; and

(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~~ involving eggs or the resulting embryos when the eggs were collected after the fertility patient has exceeded the limit of four covered completed egg retrievals.

~~4.~~ 6. 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, 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; 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 Carriers may not include an adjustment to the following year's rates to account for a legislative funding deficit without the specific approval of the Superintendent. 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], but does not require carriers to withdraw or amend forms approved by the Superintendent before the effective date of this rule for coverage periods commencing in 2024.