June 20, 2023

Department of Professional and Financial Regulation
Bureau of Insurance
c/o Karma Y. Lombard
34 State House Station
Augusta, ME 04333-0034
Karma.Y.Lombard@maine.gov

Re: Proposed Standards for Fertility Healthcare Coverage

Dear Department of Professional and Financial Regulation:

GLBTQ Legal Advocates & Defenders (GLAD), along with the American Society of Reproductive Medicine, writes to provide comment on the proposed standards for fertility healthcare coverage that are issued pursuant to 24-A M.R.S. § 4320-U. As you know, GLAD is a nonprofit organization working within New England and nationally to promote equality and justice on the basis of sexual orientation, gender identity and expression, and HIV status. Since our founding over forty years ago, promoting the security and well-being of children and families has been central to GLAD's work. The American Society for Reproductive Medicine (ASRM) is the nation's leading professional organization for reproductive health care. ASRM is dedicated to the advancement of the science and practice of reproductive medicine and accomplishes its mission through the pursuit of excellence in evidence-based, life-long education and learning, through the advancement and support of innovative research, through the development and dissemination of the highest ethical and quality standards in patient care, and through advocacy on behalf of physicians and affiliated healthcare providers and their patients.

We thank the Department for the work to date on these proposed regulations. GLAD was a strong supporter of 24-A M.R.S. § 4320-U, and GLAD and ASRM have vested interests in ensuring the regulations comply with and meet the salutary goals of the statute.

Maine has a long history of commitment to ensuring that all children and families – including LGBTQ families – can thrive. Many in the LGBTQ community use assisted reproduction or assisted reproduction and surrogacy to build their families, whether because of the need for access to gametes, embryos, or gestation or due to infertility. Unfortunately, access to fertility healthcare has been out of reach for many due to barriers to access, including cost. Through this new fertility healthcare coverage law, the Maine legislature passed a thoughtful provision that was intended to be inclusive of LGBTQ families because of the recognition that, in many states, LGBTQ families are excluded from coverage or face substantial barriers to access. The new statute intends to provide fertility healthcare coverage to those who are infertile, to those who are at increased risk for transmitting a serious genetic disease to their child, and to those who do not have the gametes or gestational capacity necessary to create a pregnancy. The goal of this statutory provision was to ensure that fertility healthcare is more accessible, in an equitable

manner, and to ensure that fertility healthcare decisions are grounded in the needs of individual patients in consultation with their medical provider.

We attach suggested edits to the proposed regulation, and we hope that you will incorporate these suggestions into the regulations. Through these suggestions, we aim to:

- Ensure the regulations align with, rather than conflict with, the authorizing statute;
- Ensure that LGBTQ families are treated equitably under the regulations as intended by the statute;
- Harmonize these regulations with other provisions of Maine law, namely, the Maine Parentage Act;
- Avoid requiring coverage for expensive procedures that have been shown ineffective and instead accommodate for changes in the standard of care as technology progresses; and
- Ensure coverage requirements align with standards of care that are inclusive of all fertility care patients' needs.

Although we cannot appear at the hearing on June 20, we would welcome meeting with the Department and other key stakeholders to discuss the regulations and to support this process to completion.

We look forward to hearing from you, and please do not hesitate to contact us.

Respectfully submitted,

Sincerely yours,
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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. "Assisted reproduction" means a method of causing pregnancy other than sexual intercourse and includes but is not limited to: A. Intrauterine or vaginal insemination; B. Donation of gametes; C. Donation of embryos; D. In vitro fertilization and transfer of embryos; and E. Intracytoplasmic sperm injection.

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 [PC1]: The regulations should be consistent with other Maine statutes. The law that seems most relevant is the Maine Parentage Act which defines many terms relating to assisted reproduction. The term "artificial insemination" is not a term used in the MPA. I've included the definition of Assisted Reproduction from the MPA. See https://legislature.maine.gov/statutes/19-A/title19-Asec1832.html

Commented [KK2]: A definition of insemination could be adapted from ASRM instead or in addition to a definition of assisted reproduction: the placement of sperm via a syringe into a vagina, uterus, or cervix for the purpose of producing a pregnancy.

Deleted: Artificial insemination

Deleted: the introduction of sperm into a woman's vagina or uterus by noncoital methods for the purpose of conception, including intrauterine insemination.

Commented [KK3]: ASRM has issued practice guidelines indicating there is insufficient evidence to support use of assisted hatching: https://www.asrm.org/globalassets/asrm/asrm-content/news-and-publications/practice-guidelines/for-non-members/role_of_assisted_hatching_in_ivf.pdf

Commented [PC4]: This could likely be a simpler definition: "means an egg retrieval in which the retrieval procedure occurs."

5. "Cryopreservation" means the freezing of embryos or gametes.

6. "Donor" has the same meaning as defined in 19A M.R.S. §§ 1832, 1922.

7. "Egg retrieval" means all office visits, procedures and laboratory and radiological tests performed in preparation for egg retrieval; including ovulation induction; the attempted or successful retrieval of the egg(s); and, if the retrieval is successful, culture and fertilization of the egg(s).

8. "Embryo" has the same meaning as defined in 19A M.R.S. § 1832.

9. "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.

10. "Experimental fertility procedure" has the same meaning as defined in 24-A M.R.S. § 4320-U.

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

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

13. "Fertility diagnostic care" has the same meaning as defined in 24-A M.R.S. § 4320-U.

14. "Fertility patient" has the same meaning as defined in 24-A M.R.S. § 4320-U.

15. "Fertility preservation services" has the same meaning as defined in 24-A M.R.S. § 4320-U.

16. "Fertility treatment" has the same meaning as defined in 24-A M.R.S. § 4320-U.

17. "Fertilization" means the penetration of the egg by the sperm.

18. "Gamete" has the same meaning as defined in 24-A M.R.S. § 4320-U.

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

20. "Gestational carrier" has the same meaning as defined in 19A M.R.S. § 1832.

21. "Infertility" has the same meaning as defined in 24-A M.R.S. § 4320-U.

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

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

Commented [PC5]: The law requires coverage of cryopreservation for 5 years. This should be clear in the regulations.

Commented [KK6]: ASRM reiterates that a clearly defined time limit for the term of cryopreservation is critical to enable clinics to appropriately handle embryos and gametes patients may abandon.

Deleted: in liquid nitrogen until such time as required for a frozen embryo transfer, or the freezing of eggs and sperm

Commented [KK8]: To the extent possible, ASRM would suggest aligning clinical definitions such as this one with clinical practice terminology.

Deleted: means a procedure by which eggs are collected from a woman's ovarian follicles.

Deleted: means a fertilized egg that has begun cell division.

Commented [KK9]: ASRM suggests that specific technology such as ZIFT and GIFT be avoided; these technologies are no longer standard of care. Enumerating specific technology may result in regulations that are out of date.

Commented [PC10]: Should these references be more specific to the statute subsections for clarity?

Commented [KK11]: ASRM suggests that specific technology such as ZIFT and GIFT be avoided; these technologies are no longer standard of care. Enumerating specific technology may result in regulations that are out of date.

Commented [PC12]: This definition should be consistent with Maine law, which is found in the Maine Parentage Act. The definition of gestational carrier in the MPA is as follows:

"Gestational carrier" means an adult woman who is not an intended parent and who enters into a gestational carrier agreement to bear a child conceived using the gametes of other persons and not her own, except that a woman who carries a child for a family member using her own gametes and who fulfills the requirements of subchapter 8 is a gestational carrier.

Deleted: means a woman who has become pregnant with an embryo or embryos that are not part of her genetic or biologic entity, and who intends to give the child to one or both of the biological parents after birth

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"Iatrogenic infertility" means an impairment of fertility caused by surgery, radiation, chemotherapy, or other medical treatment affecting reproductive organs or processes.¶

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

25. "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.

26. "Ovulation induction" means the use of drugs (oral or injected) to stimulate the ovaries to develop follicles and eggs.

27. "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.

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. 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 appropriate candidates for fertility treatment including without limitation enrollees:

      (1) with infertility,

      (2) who is at increased risk of transmitting a serious heritable genetic or chromosomal abnormality to a child including, at a minimum, all those specified by the standard-setting organization, and

      (3) who, as an individual or with a partner, is unable to conceive because the individual or couple does not have the necessary gametes for conception

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 [PC13]: The statute references ASRM and its successor organizations. ACOG and SART should not be listed in the regulations.

Deleted: <#>"Surrogate" means a woman who carries an embryo that was formed from her own egg inseminated by the sperm of a fertility patient.¶

Commented [PC14]: I understand that this is no longer standard of care and might not be necessary in the regulations.

Commented [PC15]: These should be consistent with the definitions in the statute of fertility patient and infertility. The statute is explicitly inclusive of fertility healthcare for LGBTQ people, and the regulations must be as well.

Deleted: iatrogenic

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Deleted: been diagnosed by a physician as having a genetic trait associated with certain conditions that include

Commented [PC16]: There is only one standard-setting organization per the statute – ASRM – and the carrier does not have a choice.

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Commented [PC17]: What is the basis of this limitation?

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 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.

Deleted: carrier's designated

Section 5. Required Benefits

Fertility coverage shall include, at a minimum, payment of benefits for the following services for fertility patients:

Commented [PC18]: This seems in tension with the language of the statute which is drafted broadly to be evergreen as technology changes.

1. Insemination;

Deleted: and procedures when recognized as medically appropriate, in light of the fertility patient's medical history, under guidelines adopted in compliance with this rule

2. Assisted hatching;

Deleted: Artificial insemination

Commented [PC19]: I understand that assisted hatching is an outdated procedure that is no longer standard of care.

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:

Commented [PC20]: What is the origin of this limit?

(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;

(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;

Commented [PC21]: See notes above.

7. Intracytoplasmic sperm injections;

8. In vitro fertilization, including in vitro fertilization using donor eggs and in vitro fertilization where the embryo is transferred to a gestational carrier;

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

10. Ovulation induction;

11. Surgery, including microsurgical sperm aspiration; and

12. Costs associated with cryopreservation and storage of gametes and embryos for five years.

13. Fertility preservation services.

Section 6. Permissible Benefit Limitations and Exclusions

1. Benefits for insemination may be limited to three 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 cycles;

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

   (A) Reversal of voluntary sterilization;

   (B) Medical services rendered to a surrogate 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 donor;

   (D) Experimental fertility procedures; and

   (E) Ovulation kits and sperm testing kits and supplies.

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.

Deleted: or surrogate

Deleted: sperm, eggs,

Commented [PC22]: This limit seems to be arbitrary and not, as envisioned by the law, based on an individual's medical history. To the extent limits are included, they should be no less than six cycles of insemination, and the use of the word "lifetime" should be avoided as the statute is clear that previous treatment and diagnosis cannot be a basis for limiting coverage and that language may also conflict with the ACA.

Deleted: intrauterine

Deleted: lifetime

Commented [PC23]: Where does a two-cycle limit come from?

Deleted: two lifetime

Commented [PC24]: What does this mean? Pre-natal costs?

Deleted: surrogate

Commented [PC25]: Subsection (F) conflicts with the statute.

Deleted: ;

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Deleted: <#>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.¶

Section 7. Benefit Mandate Defrayal

Commented [PC26]: This should be rewritten to avoid default language but instead be written as a trigger if required.

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 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].