BUREAU OF INSURANCE
BASIS STATEMENT AND SUMMARY OF COMMENTS
02-031 C.M.R. CHAPTER 865
STANDARDS FOR FERTILITY COVERAGE

Superintendent of Insurance Robert L. Carey hereby adopts Rule Chapter 865, "Standards for Fertility Coverage," pursuant to 24-A M.R.S. §§ 212 and 4320-U. The purpose of the Proposed Rule is 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. On October 31, 2023, after determining that the adopted rule would be substantially different from the original Proposed Rule, the Bureau issued a Request for Additional Comments, with a supplemental comment period closed at 4:30 p.m. on December 15, 2023. The Request for Additional Comments included a Revised Proposed Rule and advised interested persons that the Bureau would find comments on the following points particularly helpful:

- 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?
- 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.

The rule is hereby adopted with the changes discussed below that have been made in response to the initial and additional comments, and with a few additional non-substantive editorial

corrections. Revisions made in the Revised Proposed Rule are depicted in red type, and further revisions made in the Adopted Rule in response to the additional comments are depicted in blue type.

Comments

The following persons commented at the hearing:

Dan Demeritt, Executive Director
Maine Association of Health Plans (MeAHP)

Kristine Ossenfort, Esq., Senior Government Relations Director
Anthem Health Plans of Maine, Inc. (Anthem)

Kate Weldon LeBlanc, Executive Director
Resolve New England (RNE)

Mr. Demeritt on behalf of MeAHP, Ms. Ossenfort on behalf of Anthem, and Ms. LeBlanc (jointly with Catherine Tucker, Esq., Vice Chair, RNE Advocacy Committee) on behalf of RNE also submitted timely written comments on the original proposal, as did:

In a joint letter:
Patience Crozier, Esq., Director
Mary L. Bonauto, Esq., Senior Director of Civil Rights and Legal Strategies
GLBTQ Legal Advocates & Defenders (GLAD)
and
Dr. Michael Thomas, President
American Society of Reproductive Medicine (ASRM)

Gia Drew
Executive Director
EqualityMaine (EQME)[1]

Davina Fankhauser
Co-Founder and Executive Director
Fertility Within Reach

unsigned letter submitted by Community Health Options (CHO)

unsigned letter submitted by Harvard Pilgrim Health Care

CHO, Harvard Pilgrim, Ms. Ossenfort on behalf of Anthem, and Ms. LeBlanc on behalf of RNE also submitted timely written comments in response to the Request for Additional Comments, as did:

Dr. Lis Regula
Advocacy Associate
Men Having Babies (MHB)

[1] EQME's letter "also support[ed] comments that have previously been submitted jointly by GLBTQ Legal Advocates and Defenders (GLAD) and the American Society for Reproductive Medicine."

Janene Oleaga, Esq.
Oleaga Law LLC

Katherine Pregel
Director, Government Relations & Public Policy
Laboratory Corporation of America Holdings (Labcorp)

Julia MacDonald
Maine Government Relations Director
American Cancer Society Cancer Action Network (ACS CAN)
jointly on behalf of ACS CAN and the following additional organizations:
Alliance for Fertility Preservation
Association for Clinical Oncology (ASCO)
Leukemia & Lymphoma Society
Northern New England Clinical Oncology Society (NNECOS)
Resolve: The National Infertility Association

Summary of Comments and Bureau of Insurance Responses

General Comments

Comments: Several comments provided background on the work that went into the bill. RNE "is grateful to the legislature and to Governor Mills for making this pro-family law a reality, and to the Department of Professional and Financial Regulation for the work to date on these proposed rules." Ms. Fankhauser, on behalf of Fertility Within Reach, explained: "Last legislative session, I had the honor of testifying before this committee, in favor of LD 1539, An Act to Provide Access to Fertility Care. I also served as an expert for the actuary reports related to the bill." 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 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." RNE added that "It was approved in this way so that all those of reproductive age including individuals and LGBTQ couples would have equitable access to care. Other states who have older fertility insurance laws are now doing this retroactively ... but fortunately, Maine is able to do this proactively now." Ms. Oleaga wrote "to voice my support of the intentions behind LD 1539: to address inequity in family building. As I have testified before [on LD 1539], the average Mainer simply cannot afford to pursue fertility treatments. Having a family should not be cost prohibitive. The implementation of this

statute on January 1, 2024, will mean the difference between having a child and not for countless hopeful parents in Maine."

Bureau Response: In developing this rule, we have worked to make the vision of this legislation a meaningful reality.

Comments: Anthem "We appreciate the Bureau's efforts to develop a rule to provide clarity and consistency as well as appropriate parameters around this new benefit, which also will have a significant impact on premiums." MeAHP described the process as an opportunity to "learn more through today's hearing and through conversations with our carriers. RNE commented: "we know that we at Resolve New England and many other advocates share the Bureau of Insurance's desire to ensure that these regulations align with the authorizing statute." They were "very proud to be one of the strong advocates for the passage of this legislation and we're so grateful that it's become a reality and we're grateful to all of you for working on the regulations to date to get to the point where they are now and for the opportunity to testify today." GLAD and ASRM "thank the Department for the work to date on these proposed regulations." Fertility Within Reach wrote "to ask you to take action to implement the law after considering the Maine Bureau of Insurance's report. We are grateful to see potential insurance regulations constructed .... After a thorough review, I would like to share some concerns we would appreciate you addressing before finalizing these important regulations." EQME "was a proud supporter of the fertility insurance legislation last session, and we appreciate the opportunity to provide our feedback on the draft rules. We also support comments that have previously been submitted jointly by GLBTQ Legal Advocates and Defenders (GLAD) and the American Society for Reproductive Medicine."

Bureau Response: We appreciate the support and constructive feedback the stakeholders have shared with us.

Comments: RNE, GLAD, and ASRM included extensive markups of the rule in its written comments, showing their requested revisions. The GLAD/ASRM joint letter explained that the goal of their requested revisions was 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.

Bureau Response: We appreciate their furnishing specific revisions for our consideration.[2]

Comments: RNE explained that they are "a nonprofit organization that provides emotional support, resources and advocacy for all those in New England that are dealing with fertility and family building challenges," and Ms. LeBlanc, their Executive Director, added that "I personally did IVF to become a parent, so this is very close to my heart." Ms. Fankhauser explained that she was the Co-Founder of Fertility Within Reach, a national nonprofit advocating for fertility healthcare and currently serve as President of the New England Fertility Society. Ms. Oleaga shared her perspective as an assisted reproduction and adoption attorney. MeAHP explained that "Our association represents carriers providing coverage or administering health care coverage for about 600,000 Maine people." Labcorp described itself as "a global leader of innovative and comprehensive laboratory services that helps doctors, hospitals, pharmaceutical companies, researchers, and patients make clear and confident decisions.... Labcorp offers a broad complement of testing services related to fertility and pregnancy and would be impacted by the proposed revisions." The joint letter submitted by ACS CAN and five other organizations said they "applaud the goal of expanding access to fertility services" and that their purpose in participating was to "ensure that Mainers can access the care they need to reduce the burden of cancer, including fertility preservation services." EQME "is the oldest and largest statewide organization dedicated to creating a fair and just society for lesbian, gay, bisexual, transgender, and queer Mainers." 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." 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. MHB explained that their "primary advocacy goal is to broaden equitable access to biological parenting by removing barriers for the LGBTQ+ community," and that this rulemaking project provides an opportunity to make significant progress in eliminating financial barriers to parenting in Maine. "MHB believes that the anguish and yearning that many feel when they are expanding their family is worthy of the same forms of health insurance coverage that an otherwise healthy cis and straight couple would receive and that the access to building a biological family should not be constrained only to people privileged enough to have that status."

Bureau Response: Our work has been assisted greatly by the involvement of stakeholders representing diverse patient perspectives, diverse clinical perspectives, policy experts, and

[2] Where these requested revisions are quoted below, minor technical changes have been made to conform to Bureau redlining and citation conventions, to correct missing or duplicated punctuation, and to conform requested deletions to the precise language of the Proposed Rule.

the insurance carriers that have been given the responsibility of financing and delivering fertility care benefit.

Comment: In Harvard Pilgrim's additional comments, they asked for "clearer direction as to who each section of the rule (egg donors, surrogates, gestational carriers, etc) is intended to cover, member/non-member."

Bureau Response: Unfortunately, Harvard Pilgrim failed to identify the specific provisions of the Revised Proposed Rule where they found clearer direction to be necessary, or why they found those provisions unclear. We received several comments on the original Proposed Rule that called our attention to unclear or ambiguous language, including scope-of-coverage issues similar to those raised by Harvard Pilgrim. As a general matter, what the statute mandates is coverage for fertility patients who are enrolled in health plans subject to the Maine Health Plan Improvement Act. Some fertility services for covered enrollees involve third parties who are not fertility patients and might not be enrollees, but who serve as donors, surrogates, or gestational carriers for covered fertility patients. Section 5(8) and Section 5(11) require limited coverage for the costs of certain specific services rendered to a donor, gestational carrier or surrogate, while Section 6(5)(B) and Section 6(5)(C) specify other expenses that need not be covered. While we had hoped that the clarifications made in the Revised Proposed Rule and the further clarifications made in the Adopted Rule would address the concerns raised, we recognize that no rule can fully resolve all possible contingencies. If unforeseen issues arise in the course of implementing this rule, we will work with all affected parties to address them.

Comments: Many commenters, in both rounds of comments, expressed their interest in providing whatever assistance they can.

Bureau Response: We appreciate the involvement of a wide range of stakeholders and the assistance they have provided through their comments, and we look forward to working with them on implementation. We agree with the importance of inclusivity and the removal of financial barriers, which means the overriding goal must be simultaneously maximizing affordability and equity.

Section 2, applicability and scope

In the course of our review of the comment on Section 9, the effective date of the rule, we realized that there was a conflict between Sections 2 and 9 of the Revised Proposed Rule. Because the rule does not affect policies already approved for issuance in 2024, which are already in force for most enrollees, the applicability date should be 2025 rather than 2024, except for the limited purpose of determining whether defrayal will be required for coverage issued in 2024, and implementing that process if necessary. Section 2 has therefore been revised as follows:

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, ~~2024~~ 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 generally

Comment: In response to the initial comments, the Revised Proposed Rule modified a number of definitions for reasons discussed in more detail below. In the Request for Additional Comments, we specifically solicited feedback on whether those changes were accurate, and on whether they were worded in ways that might have unintended consequence. We received no objections to any of our proposed revisions to the definitions, and Ms. Oleaga responded generally to the revised definitions as follows: "I appreciate and agree with many of the changes to the definitions provided in Section 3 as they are consistent with definitions provided by leading organizations in reproductive medicine, including the American Society for Reproductive Medicine (ASRM)."

Bureau Response: We appreciate receiving confirmation that the proposed revisions were useful.

Comment: RNE objected to the inclusion of provisions for "several specific procedures ... that are no longer widely used." And, so, in my opinion they should not be referenced directly in the Rule. Those include assisted hatching, GIFT, and ZIFT which I will, again, outline in the written procedures." RNE renewed this objection when they submitted their additional comments.

Bureau Response: We have retained these definitions because we determined that it was appropriate to retain the references to the underlying procedures for the reasons discussed in response to the comments to Section 5.

Comment: In her comments on the Revised Proposed Rule, Ms. Oleaga also requested additional provisions "indicating that the intention is for these definitions to be consistent with Maine law and with the definitions provided by the 'standard-setting organizations' as defined in the statute. Any discrepancies between the definitions listed in the statute and the definitions provided by the standard-setting organizations should be resolved in favor of the latter," and provisions "stating that any future advances in reproductive technology replacing or improving upon the definitions listed in Section 3 should be incorporated into the statute and covered accordingly." She noted that newer technology is not necessarily more costly and that any such expansion would be subject to the general right carriers have under the statute and the rule to exclude coverage for experimental procedures.

Bureau Response: For purposes of Maine law, any discrepancies between the statute and other sources must be resolved in favor of the statute. However, the purpose of definitions is simply to make sure we are understood when we use certain terms. If the clinical guidelines use similar language to mean different things, it does not change what the rule does or does not require, because the standard-setting organization does not have the power to change the law, only to develop guidelines for clarifying and implementing the law. If

the definitions truly conflict, rather than complementing one another, the documents can only be reconciled by looking to the substance of what each document says rather than the inconsistent terminology the authors have used. Likewise, the rule cannot serve as a platform to enable the statute to amend itself to address future technological advances. Instead, as RNE explained in its responses to our request for comments on that topic, "The statute was drafted with the intention of being able to adapt to advances in fertility care without needing to be amended," and through the clinical guideline approach, "as advances in reproductive technology are generally accepted as a standard of care, they should be covered." And as Anthem noted in its response to that request, if some technological advances nevertheless cannot be accommodated within the framework of the rule, the answer will be to amend the rule.

Proposed Section 3(1), definition of artificial insemination

Because the term has been changed, in response to the comments, this subsection was renumbered as Section 3(20) in the Revised Proposed Rule, and the comments are summarized and discussed below under that heading.

Section 3(1) (Proposed Section 3(2)), definition of assisted hatching

Comment: Although we received no objections to the accuracy or the wording of this definition, this was one of the terms RNE characterized as obsolete at the hearing, and has requested that we remove from the rule.

Bureau Response: Because we have retained the assisted hatching benefit, for the reasons discussed in response to the comments on Section 5(2), the definition has likewise been retained.

Proposed Section 3(4), definition of completed egg retrieval

Comment: This was one of the definitions RNE requested that we delete, stating that the term does not need to be separately defined, GLAD and ASRM suggested that the following definition would likely be simpler:

[3.] "Completed egg retrieval" means ~~all office visits, procedures and laboratory and radiological tests performed in preparation for~~ an egg retrieval~~; the attempted or successful retrieval of the egg(s); and, if the retrieval is successful, culture and fertilization of the egg(s)~~ in which the retrieval procedure occurs.

Bureau Response: We agree with RNE. Although we received no objections to this definition when it was retained in the Revised Proposed Rule, it was apparent as we reviewed the comments that this proposed definition addresses the scope of coverage for egg retrievals, not the standard for determining when an egg retrieval is "completed" within the meaning of this rule. Although GLAD and ASRM had attempted to propose such a standard, their suggested language is circular and does not provide meaningful guidance. This subsection is therefore deleted, and its content has been moved into the new definition of "egg retrieval," which has been renumbered as Subsection 4:

~~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).~~

Section 3(3) (Proposed Section 3(5)), definition of cryopreservation

Comments: GLAD/ASRM offered the following definition:

[3.] "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.

RNE offered the same definition at the hearing, and their initial comment letter provided the following more expansive definition:

[3.] "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~~, gametes, ovarian tissue, or testicular tissue.

GLAD and ASRM also requested that a timeframe for cryopreservation be included.

Bureau Response: The time frame for cryopreservation relates to the appropriate scope of a cryopreservation benefit, not how to define what is or is not "cryopreservation," so those issues have been addressed in our revisions to the cryopreservation benefit requirement at Section 5(12). Likewise, we agree that liquid nitrogen is not a definitional element, and that gonadal tissue could also be cryopreserved for purposes of fertility preservation, consistent with the inclusion of "reproductive material" in 24-A M.R.S. § 4320-U(1)(D). For reasons discussed elsewhere, we have retained references to eggs, ovaries, sperm, and testicles in this rule. Accordingly, the Revised Proposed Rule proposed the following modifications to this definition:

~~5.~~ ~~4.~~ 3. "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.

Comment: Although we received no additional comments directly addressing the revised definition, Harvard Pilgrim expressed concern "that cryopreservation of ovarian and/or testicular tissue is not currently covered by any payer in the country."

Bureau Response: Strictly speaking, this is a comment on the coverage requirement, at Section 5(15), and not on the definition itself, but the two are obviously related. For the reasons discussed in our analysis of Section 5(15), we have adopted both the definition and the coverage requirement as proposed in the Revised Proposed Rule.

To follow Section 3(3), requested new definition of donor

Comments: For purposes of compatibility with the Maine Parentage Act, RNE, GLAD, and ASRM all proposed adding the following definition:

[4.] "Donor" has the same meaning as defined in 19-A M.R.S. §§ 1832 & 1922.

Bureau Response: Section 1832(5) defines "Donor" to mean "a person who contributes a gamete or gametes or an embryo or embryos to another person for assisted reproduction or gestation, whether or not for consideration." Although 19-A M.R.S. § 1922 was referenced in the requested definition of "donor," that section is not definitional – instead, it establishes a general rule that a donor is not legally a parent, while enumerating two specific exceptions. Otherwise, the definition is not incorrect, but it is not necessary, and it incorporates terminology not used in the rule. The purpose of the statutory definition is to clarify that it is irrelevant to parental rights whether or not the donor has been paid, and that question is not at issue in the context of this rule – what is important for purposes of identifying the specific fertility treatments that might require coverage in a particular case is whether the gametes were contributed by a fertility patient or by a third party, and the meaning of "donor" is self-evident and unambiguous for that purpose. Therefore, the requested subsection has not been added.

Section 3(4) (Proposed Section 3(6)), definition of egg retrieval

Comments: RNE requested modifying this definition as follows:

[4.] "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).

The letter from GLAD and ASRM requested a similar revision, commenting that "To the extent possible, ASRM would suggest aligning clinical definitions such as this one with clinical practice terminology":

[4.] "Egg retrieval" means ~~a procedure by which eggs are collected from a woman's ovarian follicles~~ 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).

Bureau Response: While reviewing the definitions after receiving the additional comments, we realized that the proposed definitions of "completed egg retrieval" and "egg retrieval" were misaligned. Although the egg retrieval definition is clinically accurate, the language proposed in the definition of "completed egg retrieval" completes the egg retrieval definition by identifying the specific services that must be included within the egg retrieval benefit. We then realized that this reorganization was precisely what the commenters had proposed, without explanation, in the initial round of comments. RNE's proposed revision also removes some unnecessary gendered language. We therefore adopt RNE's proposal with a punctuation change to conform to Bureau style:

~~6.~~ ~~5.~~ 4. "Egg retrieval" means a procedure by which eggs are collected from ~~a woman's~~ 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).

Section 3(5) (Proposed Section 3(7)), definition of embryo

Comments: RNE, GLAD, and ASRM all proposed redefining "embryo" as follows:

[5.] "Embryo" ~~means a fertilized egg that has begun cell division~~ has the same meaning as defined in 19-A M.R.S. § 1832.

Bureau Response: The Maine Parentage Act, at 19-A M.R.S. § 1832(6), defines "embryo" to mean "a cell or group of cells containing a diploid complement of chromosomes or a group of such cells, not including a gamete, that has the potential to develop into a live born human being if transferred into the body of a woman under conditions in which gestation may be reasonably expected to occur. Although the terminology used in this definition is unnecessarily opaque to the ordinary reader, and the syntax is confusing, this definition is the one that is consistent with the way the term is used in this rule. The definitions of cryopreservation and embryo transfer recognize that a fertilized egg is regarded as an embryo for fertility treatment purposes whether or not cell division has begun. Therefore, the original proposed definition was replaced in the Revised Proposed Rule with a definition based on the Maine Parentage Act definition. We received no comments on that revised definition and it is therefore adopted as follows:

~~7.~~ ~~6.~~ 5. "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.

Section 3(6) (Proposed Section 3(8)), definition of embryo transfer

Comments: ASRM questioned the reference to ZIFT, asserting that it is "no longer standard of care" and warning that "Enumerating specific technology may result in regulations that are out of date." RNE found the phrase "transfer of cryopreserved embryos and donor embryos" confusing, noting that these are not separate categories because donor embryos are also cryopreserved. RNE proposed the following revised definition:

[6.] "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~~.

Bureau Response: We agree that the final sentence is confusing, and it addresses points that are not in doubt.[3] Furthermore, the substantive provisions of the rule expressly provide that both "fresh and frozen" embryo transfers must be covered, and that the required coverage for IVF includes "in vitro fertilization using donor eggs." Therefore, the Revised Proposed Rule proposed deleting that sentence. However, we proposed retaining the language including placement in the fallopian tube, because even if ZIFT is no longer widely used, it is still necessary to clarify that when it does occur, it is considered

[3] Although comments have indicated a need for clarification that donor embryo transfer is within the scope of the coverage requirement, it is unquestionably an embryo transfer.

an "embryo transfer." Finally, we proposed deleting the specific reference to ZIFT and the phrase "through the cervix" because they are standards of practice that are properly addressed in the clinical guidelines, not elements that define whether or not an embryo has been transferred. We received no comments on the definition in the Revised Proposed Rule, which is therefore adopted as follows:

~~8.~~ ~~7.~~ 6. "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~~.

Section 3(7) (Proposed Section 3(9)), definition of experimental fertility procedure

Comment: The Proposed Rule references the statutory definition, but only cites the section number. GLAD and ASRM suggested that it might be clearer for the various references to Section 4320-U to include pinpoint citations to the subsection and paragraph numbers.

Bureau Response: This subsection has been revised as follows, as proposed in the Revised Proposed Rule:

~~9.~~ ~~8.~~ 7. "Experimental fertility procedure" has the same meaning as defined in 24-A M.R.S. § 4320-U(1)(A).

Section 3(10) (Proposed Section 3(12)), definition of fertility diagnostic care

Comment: This is one of the additional definitions for which GLAD and ASRM suggested a more precise reference in their comment on Section 3(7).

Bureau Response: This subsection has been revised as follows, as proposed in the Revised Proposed Rule:

~~12.~~ ~~11.~~ 10. "Fertility diagnostic care" has the same meaning as defined in 24-A M.R.S. § 4320-U(1)(B).

Section 3(11) (Proposed Section 3(13)), definition of fertility patient

Comment: This is one of the additional definitions for which GLAD and ASRM suggested a more precise reference in their comment on Section 3(7).

Bureau Response: This subsection has been revised as follows, as proposed in the Revised Proposed Rule:

~~13.~~ ~~12.~~ 11. "Fertility patient" has the same meaning as defined in 24-A M.R.S. § 4320-U(1)(C).

Section 3(12) (Proposed Section 3(14)), definition of fertility preservation services

Comment: This is one of the additional definitions for which GLAD and ASRM suggested a more precise reference in their comment on Section 3(7).

Bureau Response: This subsection has been revised as follows: , as proposed in the Revised Proposed Rule

~~14.~~ ~~13.~~ 12. "Fertility preservation services" has the same meaning as defined in 24-A M.R.S. § 4320-U(1)(D).

Section 3(13) (Proposed Section 3(15)), definition of fertility treatment

Comment: This is one of the additional definitions for which GLAD and ASRM suggested a more precise reference in their comment on Section 3(7).

Bureau Response: This subsection has been revised as follows, as proposed in the Revised Proposed Rule:

~~15.~~ ~~14.~~ 13. "Fertility treatment" has the same meaning as defined in 24-A M.R.S. § 4320-U(1)(E).

To follow Section 3(14), requested new definition of "gamete"

Comments: RNE, GLAD, and ASRM all requested adding the following definition, in connection with their proposal to use the term "gametes" to replace most or all references to "eggs" and "sperm.":

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

Bureau Response: RNE at hearing simply proposed using "the statutory definition," but there are two statutory definitions. The Maine Parentage Act, which other comments requested that we follow, makes explicit the possibility that a gamete could take the form of "Deoxyribonucleic acid from one human being combined with the cytoplasm, including without limitation cytoplasmic deoxyribonucleic acid, of another human being." 19-A M.R.S. § 1832(7)(C). The definition at 24-A M.R.S. § 4320-U(1)(F), is "a cell containing a haploid complement of deoxyribonucleic acid that has the potential to form an embryo when combined with another gamete. 'Gamete' includes sperm and eggs." Both definitions were designed to encompass the possibility that future reproductive technology might include the ability to create gametes that are not "sperm" or "egg" cells as those terms are generally understood, and could, among other possibilities, enable same-sex couples to have children with the DNA of both parents. However, the creation of so-called "artificial gametes" through DNA replacement has not yet been successfully accomplished in humans, and even the recombinant gametes currently envisioned by experimenters still take the form of eggs and sperm. The terms "eggs" and "sperm" are clearer to a more general audience, and some provisions of this rule make it necessary to distinguish between them. Therefore, it is not appropriate at this time to subsume them both within a single definition that "includes," but is not limited to, eggs and sperm.

Section 3(15) (Proposed Section 3(17)), definition of gamete intrafallopian tube transfer

Comments: GLAD and ASRM repeated their comment on what is now Subsection 6, which had characterized those technologies as "no longer standard of care" and warned

that "Enumerating specific technology may result in regulations that are out of date." This was also one of the definitions RNE requested that we delete, commenting at hearing that this is a procedure that is "no longer widely used," and in both their initial written markup and their additional comment letter that GIFT and ZIFT are no longer performed and therefore do not need to be referenced in the rule.

Bureau Response: We received no objections to the accuracy or the wording of this definition. Because the benefit has been retained at Section 5(9), when the procedure is within the scope of applicable clinical guidelines and coverage is consistent with the other limitations permitted by this rule, the definition has likewise been retained.

Section 3(16) (Proposed Section 3(18)), definition of gestational carrier

Comments: As proposed, the rule distinguishes between "surrogates," who are the biological parents of the children they carry, and "gestational carriers," who are not. RNE, GLAD, and ASRM all proposed combining them into the single term "gestational carrier" and defining it by reference to the Maine Parentage Act. According to RNE, the proposed definition "is legally inaccurate. Gestational Carriers do not 'give' the child to the Intended Parents." They all requested a substantially similar revision:

[16.] "Gestational carrier" ~~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~~ has the same meaning as defined in 19-A M.R.S. §[§] 1832[& 1922].[4]

Bureau Response: The definition they ask us to incorporate by reference reads 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." The Proposed Rule, by contrast, defines "gestational carrier" as someone who is not the biological parent of the child who is being carried, in contrast to a "surrogate." The purpose of the Maine Parentage Act definition is to establish whether or not the person carrying the child has any parental rights, while the definition in the Proposed Rule is clinical in nature: a gestational carrier has necessarily been impregnated by some sort of advanced reproductive technology. At a high level, therefore the proposed definition is more appropriate for purposes of this rule than the definition requested by the comments. In the Revised Proposed Rule we proposed eliminating the objectionable verb "give" and making additional revisions to mirror the terminology used in the definition of "surrogate" and to reflect, as noted in several comments on other provisions, that a gestational carrier might be a transgender man or a nonbinary person. We have also made one further change, in response to the additional comments by Ms. Oleaga and RNE on embryo donations, to recognize that a gestational carrier is not necessarily the genetic parent of the embryo. As adopted, this subsection reads as follows:

[4] An additional cross-reference proposed by RNE is shown in brackets. 19-A M.R.S. § 1922, however, is not a definitional provision, as discussed above in response to the comments asking us to add a definition of "donor," and furthermore is not directly relevant because it governs the legal rights of donors and a gestational carrier is not a donor.

~~18.~~ ~~17.~~ 16. "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~~ a fertility patient, and not the gestational carrier, will be a parent of the child after birth.

Section 3(17) (Proposed Section 3(19)), definition of iatrogenic infertility

Comments: RNE, GLAD, and ASRM requested that we delete this definition. RNE stated that "this definition is not needed"; the revisions requested by these commenters all delete the only use of the term in the body of the rule. RNE renewed this objection in their additional comments.

Bureau Response: We received no objections to the accuracy or the wording of this definition. Because references to iatrogenic infertility have been retained in Section 4(2)(C)(1)), this definition is adopted as proposed.

Section 3(18) (Proposed Section 3(20)), definition of infertility

Comment: This is one of the additional definitions for which GLAD and ASRM suggested a more precise reference in their comment on Section 3(7).

Bureau Response: This subsection has been revised as follows, as proposed in the Revised Proposed Rule:

~~20.~~ ~~19.~~ 18. "Infertility" has the same meaning as defined in 24-A M.R.S. § 4320-U(1)(G).

Comment: MHB and Harvard Pilgrim both noted in their additional comments that ASRM has updated its definition of infertility, which now reads as follows: "The inability to achieve a successful pregnancy based on a patient's medical, sexual, and reproductive history, age, physical findings, diagnostic testing, or any combination of those factors." Both comments urged consistency with the new ASRM definition, with MHB adding that its importance is that it recognizes "infertility as being not just a medical condition, and also an individual or couples' status that present challenges to biological parenting, such as singleness or being in a relationship that does not follow cisgender and heteronormative standards. This definition of infertility is also in line with the social model of disability and the U.S. Equal Employment Opportunity Commission's view of infertility as a disability."

Bureau Response: This subsection incorporates the statutory definition of infertility by reference, and the statutory definition is controlling. We agree with the principles discussed in the comments and we find the statutory definition to be consistent with those principles. We do not read either comment as asking us to strike the reference to the statutory definition and replace it with the ASRM language.

Section 3(19) (Proposed Section 3(21)), definition of intracytoplasmic sperm injection

Comment: RNE's markup included a change in punctuation.

Bureau Response: The new punctuation appears to be an error created by markup software. There was no substantive comment suggesting that any change was intended. This subsection is therefore adopted as proposed.

Section 3(20) (Proposed Section 3(1)), definition of intrauterine or vaginal insemination

Comments: RNE commented: "'Artificial insemination' is really not the ideal term and should be replaced with the current definition of 'insemination' as determined by the American Society of Reproductive Medicine." Their proposed revision deletes the adjectives "artificial" insemination and "woman's" vagina.

[19.] "~~Artificial insemination~~ Insemination" means the introduction of sperm into a ~~woman's~~ vagina or uterus by noncoital methods for the purpose of conception, including intrauterine insemination.

GLAD and ASRM proposed substituting the term "assisted reproduction" as used in the Maine Parentage Act and defined at 19-A M.R.S. § 1832(3), saying "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."

[2.] "~~Artificial insemination~~ Assisted reproduction" means ~~the introduction of sperm into a woman's vagina or uterus by noncoital methods for the purpose of conception, including intrauterine~~ 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.

Alternatively, they suggested that "A definition of insemination could be adapted from ASRM instead or in addition to a definition of assisted reproduction":

[20.] "~~Artificial insemination~~ Insemination" means the ~~introduction~~ placement of sperm via a syringe into a ~~woman's~~ vagina ~~or~~, uterus ~~by noncoital methods~~, or cervix for the purpose of ~~conception, including intrauterine insemination~~ producing a pregnancy.

Bureau Response: Although the Parentage Act definition of "assisted reproduction" enumerates a few illustrative examples, the term itself is defined to mean is any "method of causing pregnancy other than sexual intercourse." Specific methods of assisted reproduction are not defined there because they are not relevant for purposes of determining who is the legal parent or parent of the child. Conversely, this catch-all term is not relevant for purposes of this rule, which needs to define specific methods to which

specific provisions of this rule and the applicable policy provisions and clinical guidelines apply. In particular, the purpose of this particular definition is to distinguish this particular procedure from other fertility treatment procedures. Indeed, GLAD and ASRM's suggested revisions did not add any language using the new term they proposed defining. We agree, however, with the requests to eliminate the gendered term "woman" and to add cervical insemination to the scope of the definition. To replace the objectionable adjective "artificial," the Revised Proposed Rule proposed substituting the phrase "intrauterine or vaginal insemination" used in the Maine Parentage Act at 19-A M.R.S. § 1832(3)(A), which is more precise and is also useful for reconciling the conflict between Section 5(1) and Section 6(1) as originally proposed. Other requested changes were not made because no substantive reason was given for the requests. We received no comments on that revised terminology and definition, and this subsection is therefore adopted as follows:

~~1.~~ ~~21.~~ 20. "~~Artificial~~ Intrauterine or vaginal insemination" means the introduction of sperm into ~~a woman's vagina or~~ the uterus ~~by noncoital methods~~, cervix, or vagina for the purpose of conception~~, including intrauterine insemination~~.

Section 3(21) (Proposed Section 3(22)), definition of in vitro fertilization

Comment: RNE at hearing explained that: "There's also a very simple way to avoid gender language in the definition of in vitro fertilization," and suggested the following revision. GLAD and ASRM proposed a substantially similar revision:

[21.] "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~~ uterus.

Bureau Response: The requested modification was made in the Revised Proposed Rule, with one further nonsubstantive revision. We received no comments on that revised definition, which is therefore adopted as follows:

~~22.~~ 21. "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.

Section 3(23) (Proposed Section 3(24)), definition of microsurgical sperm aspiration or extraction

Comment: As proposed, the definition of microsurgical sperm extraction describes techniques used to obtain sperm for use with intracytoplasmic sperm injection "in cases of obstructive azoospermia." RNE stated that they had consulted with a urologist who specializes in fertility, and they requested revising the surgery benefit, now numbered as Section 5(14), to address nonobstructive azoospermia by adding a requirement to cover "microsurgical testicular sperm extraction." Their requested definition of that new term reads as follows:

[23]. "Microsurgical Testicular Sperm Extraction" (mTESE) means the techniques used to obtain sperm for use with intracytoplasmic sperm injection (ICSI) in cases of nonobstructive 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.

Bureau Response: We agree that coverage for both microsurgical aspiration and microsurgical testicular extraction should be available when indicated by the applicable clinical guidelines. However, we have reviewed the proposed definition of "microsurgical sperm aspiration," and it was already worded broadly enough to include testicular sperm extraction, but only when used for patients with obstructive azoospermia." Therefore, in the Revised Proposed Rule, we revised the existing definition to remove that limitation and to provide a more accurate description of the range of procedures that are included. We received no comments on that revised terminology and definition, and this subsection is therefore adopted as follows:

~~24.~~ 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.

Section 3(25) (Proposed Section 3(26)), definition of standard-setting organization

Comments: GLAD, ASRM, and RNE all requested deletion of the references to the American College of Obstetrics and Gynecology and the Society for Assisted Reproductive Technology. GLAD and ASRM wrote: "The statute references ASRM and its successor organizations. ACOG and SART should not be listed in the regulations," adding in a marginal comment to their requested revision to what is now Section 4(2)(C)(2) that "There is only one standard-setting organization per the statute – ASRM – and the carrier does not have a choice." RNE proposed the following revision:

[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~~ its respective successor organizations.

Bureau Response: The statute, as RNE acknowledged in its letter, refers to "a comparable organization," 24-A M.R.S. § 4320-U(3)(E). This expressly contemplates the possibility that there could be more than one standard-setting organization. Because GLAD and ASRM provide no basis for their assertion that ACOG and SART do not qualify to be designated as comparable organizations, this definition is adopted as proposed.

Section 3(26) (Proposed Section 3(27)), definition of surrogate

Comments: In their initial comments, RNE, GLAD, and ASRM all requested that we delete this definition. RNE explains that it "is referenced in 'gestational carrier' definition from the Maine Parentage Act." Their markups deleted the substantive uses of this term, replacing it with "gestational carrier."

Bureau Response: This definition has been retained for the reasons discussed above in response to the comments on the definition of "gestational carrier," now at Subsection 16. It should be noted that both GLAD and ASRM's own comments and the text of 24-A

M.R.S. §§ 4320-U(3)(C) & (4)(B) use the word "surrogacy." However, as was done with the definition of "gestational carrier," the Revised Proposed Rule removed gendered language. We received no comments on that revised definition, and this subsection is therefore adopted as follows:

~~27.~~ 26. "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.

To follow Section 3(26), requested new definition of voluntary sterilization

Comment: RNE requested making "voluntary sterilization" a defined term, in order to incorporate an exception in order "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." Their proposed definition reads as follows:

[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.

Bureau Response: If an exception were necessary, a better location might be in Section 6(3)(A), which allows carriers to exclude coverage for the reversal of a voluntary sterilization. However, the examples provided do not indicate any need for an exception. A hysterectomy is not reversible, and the use of a surrogate or gestational carrier is not a reversal of the patient's sterilization.

Section 3(27) (Proposed Section 3(28)), definition of zygote intrafallopian tube transfer

Comments: RNE, GLAD, and ASRM have all requested the deletion of this definition, Consistent with their comments on Section 3(15) and Section 5(9).

Bureau Response: We received no objections to the accuracy or the wording of this definition. Because the benefit has been retained at Section 5(9), when the procedure is within the scope of applicable clinical guidelines and coverage is consistent with the other limitations permitted by this rule, the definition has likewise been retained.

Section 4, coverage requirements generally

Comment: I commented: "The coverage requirements outlined in Section 4 should be amended to improve alignment with 24-A M.R.SA. 4320-U."

Bureau Response: As discussed below in response to the comments on specific provisions, we do not agree that Section 4 as proposed is inconsistent with the statute. However, the Revised Proposed Rule corrected a drafting error, called to our attention by IMeAHP and Anthem. in the phrasing of what are now Paragraphs (A) and (B) of Section 4(2), which require any experimental procedure exclusions or fertility care provider standards to be supported by clinical guidelines. We also made further corrections in response to comments received on the Revised Proposed Rule.

New Section 4(1), nondiscrimination

Comments: In their comments on Proposed Section 4(1)(C) (now 4(2)(C)), EQME, RNE, GLAD, and ASRM all emphasized the legislative intent to be inclusive, and to make fertility care available to all who need it. EQME commented that they "particularly want to highlight that the definition of 'fertility patient' in the Maine statute was carefully drafted, with input from various experts, to be inclusive of various people who need fertility treatment to try to achieve their dream of having a healthy baby. This includes LGBTQ+ couples, those pursuing solo parenthood, and those who need to seek in vitro fertilization to prevent severe genetic conditions in their offspring." Similarly, RNE noted the "intentionally inclusive definition of fertility patient, which ... was approved in this way so that all those of reproductive age, including individuals and LGBTQ couples, would have equitable access to care," and GLAD and ASRM praised the statute's "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," adding in their marginal notes: "The statute is explicitly inclusive of fertility healthcare for LGBTQ people, and the regulations must be as well."

In response to those comments, the Revised Proposed Rule added this subsection. Ms. Oleaga "applaud[s] the addition of Section 4.1 that was clearly drafted with the same spirit of inclusivity and equity that was a touchstone of the bill as initially proposed. Coverage should be provided to all Mainers, regardless of gender-identity, sexual orientation, or marital status." As noted in the analysis of the definition of infertility at Section 3(18), MHB and Harvard Pilgrim both urged consistency with the ASRM definition of infertility, with MHB specifically characterizing nondiscrimination as the touchstone of that definition; MHB "ask[s] that these rules maintain the spirit of the law and the newly adopted definition of infertility as adopted by the American Society for Reproductive Medicine." In addition, Anthem's additional comments called our attention to a citation error in this subsection.

Bureau Response: These principles were already implicit in the rule as originally proposed, and are explicitly set forth in the governing statute at 24-A M.R.S. § 4320-U(3)(D). We agree that they are so fundamental to the purposes of the statute and the rule that an explicit codification in the rule is also appropriate. Therefore, this subsection has been adopted as proposed in the Revised Proposed Rule, with the correction of the citation error that Anthem had identified:

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~~ 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.

Section 4(2), clinical guidelines generally

Comments: Unlike MHB, Harvard Pilgrim did not identify a specific rationale for recommending consistency with the ASRM definition; however, one salient difference between the ASRM definition and the statutory definition is ASRM's focus on each

patient's circumstances: "a patient's medical, sexual, and reproductive history, age, physical findings, diagnostic testing."

Bureau Response: Although the Maine statute does not use these factors to define infertility, the same intent is embodied in 24-A M.R.S. § 4320-U(4)(E), which requires that "Any limitations imposed by a carrier must be based on a' enrollee's medical history and clinical guidelines adopted by the carrier." The importance of clinical judgment applied to the circumstances of specific cases has been a recurring thread in comments from carriers and fertility patients alike, and we have endeavored to respond fully to all comments identifying additional steps we might take to implement this principle.

Section 4(2)(A) (Proposed Section 4(1)(A)), guidelines for identifying experimental and excluded treatments

Comments: As originally proposed, this paragraph directed carriers to include provisions in their clinical guidelines "identifying experimental fertility procedures and treatments not covered for the diagnosis and treatment of infertility." AI and MeAHP both read the phrase "for the diagnosis and treatment of infertility" as words of limitation and objected to that perceived limitation. Anthem specifically requested authorization to identify and exclude experimental fertility preservation procedures.

Bureau Response: There was no intent to exclude fertility preservation from the scope of this paragraph or Paragraphs B and C. All three paragraphs have been clarified to reflect that they apply to the entire range of fertility care. We received no additional comments on Paragraph A, which is therefore adopted with the following revisions, as proposed in the Revised Proposed Rule:

(A) identifying experimental fertility procedures and treatments not covered for the diagnosis and treatment of infertility or for fertility preservation;

Section 4(2)(B) (Proposed Section 4(1)(B)), guidelines for fertility care provider standards and qualifications

Comment: Fertility Within Reach expressed concern that the language providing for the guidelines to include "standards for health care providers to provide procedures and treatments to diagnose and treat infertility" was an inappropriate limitation on coverage. They recommended replacing "treat infertility" with "offer fertility healthcare treatment" so that fertility preservation can be included.

Bureau Response: Excluding fertility preservation from the scope of this paragraph would not have the effect if excluding it from coverage, and the suggested "offer treatment" language would not address fertility preservation. However, as with Paragraph A above, there was no intent to exclude fertility preservation from the scope of this paragraph, which is therefore adopted with the following revisions, as proposed in the Revised Proposed Rule:

(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;

Comments: MeAHP and Anthem both objected to the language directing carriers to address "the required training, experience, and other standards for health care providers to provide" covered services in their clinical guidelines. They asserted that this provision goes beyond the scope of the statute, that it interferes with the credentialing process, and that "Carriers should be free to determine the criteria for network participation." Anthem renewed their objections in their additional comments,[5]

Bureau Response: This paragraph does not say the carrier's clinical guidelines must be the sole determinant of network participation or approval of out-of-network services. As revised above, the paragraph refers specifically to "the required training, experience, and other standards for health care providers to provide fertility diagnostic care, fertility treatment, and fertility preservation services." Only the carrier's fertility-specific standards need to be included within its clinical guidelines, which do not replace the carrier's general credentialing standards or its statutory right under 24-A M.R.S. § 2672 to contract selectively with providers, nor do they replace or modify the carrier's duty to maintain an adequate network.

Comment: In their additional comments, Anthem added a specific request to be allowed "to apply additional criteria such as malpractice insurance, disciplinary record requirements, licensure, board certification." In the alternative, they requested that "If this provision is retained, it should be modified to provide that carriers should consider the standards, rather than 'shall adopt and use,'" the general standard set forth in the introductory paragraph of Section 4(2)

Bureau Response: As explained in our response to Anthem's initial comments, the use of such criteria is not subject to the clinical guideline requirement unless the criteria are applied specifically or more stringently to fertility care providers. Where the guidelines are applicable, the statute mandates that the carrier must base its guidelines on current guidelines developed by a standard-setting organization, not merely "consider" them.

Section 4(2)(C) (Proposed Section 4(1)(C)), determination of appropriate candidates for fertility care

Comments: As proposed, this paragraph directs carriers to include provisions in their clinical guidelines for "determining appropriate candidates for fertility treatment." RNE commented that they "are very proud that the statute has an intentionally inclusive definition of fertility patient," which they urged us to substitute in place of "appropriate candidates for fertility treatment." They commented further that the statutory definition "was approved in this way so that all those of reproductive age, including individuals and LGBTQ couples, would have equitable access to care," and that "Other states who have older fertility insurance laws are now doing this retroactively including New York, but fortunately, Maine is able to do this proactively now." Their requested revision reads as follows:

[5] MeAHP did not participate in the additional comments.

(C) determining ~~appropriate candidates for fertility treatment 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~~ those that are fertility patients in accordance with the requirements of 24-A M.R.S. § [4320-U].

GLAD, ASRM, and EQME offered similar comments. The revision proposed by GLAD and ASRM took a different but substantively similar approach, tracking the language of the statutory definition of "fertility patient" rather than using the term directly:

(C) determining appropriate candidates for fertility treatment 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~~ 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 ~~designated by the carrier~~; 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.

Bureau Response: We agree that the definition of "fertility patient," at 24-A M.R.S. § 4320-U(1)(C), is broad and inclusive. As discussed above, we have added Section 4(1) to reinforce the principle that all fertility patients with state-regulated health plans are entitled to coverage for medically necessary fertility care. The purpose of the clinical guidelines, however, is not to identify which individuals are entitled to medically necessary care, but to identify what care is medically necessary. 24-A M.R.S. § 4320-U(3) expressly permits carriers to "include reasonable limitations" on fertility coverage in their health plan, consistent with clinical guidelines adopted by the carrier consistent with this rule. As RNE's own comment letters acknowledged: "We do not expect unlimited fertility coverage for all and recognize that the carriers will develop clinical guidelines."[6]

Comments: Fertility Within Reach requested changing the phrase "with iatrogenic infertility" to "with a medical need for fertility preservation," to avoid excluding patients with other medical needs, such as Diminished Ovarian Reserve, from accessing fertility preservation services. RNE proposed a similar revision to what is now Section 4(2)(C)(1) in their supplemental comments.

Bureau Response: The paragraph, as proposed, was already open-ended, "including without limitation" enrollees with iatrogenic infertility. However, because of the concerns raised, the Revised Proposed Rule adopted the suggestion to clarify explicitly that all

[6] The version of this comment quoted here is from their additional comment letter.

patients "with a medical need for fertility preservation" are within scope. Nevertheless, we have retained the specific reference to iatrogenic infertility because it raises unique concerns; the need for fertility preservation services often arises while the patient might have no current fertility impairment at all. This has led in the past to denials of coverage for lack of medical necessity, and this is why states have adopted explicit requirements in this area. We also made further editorial revisions to clarify that the "and" is inclusive rather than exclusive, and that the issue is not actually patients who already have iatrogenic infertility, but those who are about to undergo procedures that are likely to cause iatrogenic infertility. A number of states have laws expressly referring to prospective iatrogenic infertility. Montana, for example, adopted legislation this year mandating coverage for "medically necessary costs for standard fertility preservation services when an insured member is diagnosed with cancer and the standard of care involves medical treatment that may directly or indirectly cause iatrogenic infertility." And even though 24-A M.R.S. § 4320-U(1)(D) does not use the word "iatrogenic," it recognizes the concept by defining "fertility preservation services" to include services for a patient "who is expected to undergo treatment that may directly or indirectly cause a risk of impairment of fertility." Finally, in reviewing this paragraph of the Revised Proposed Rule in response to the additional comments, we noticed that like Paragraphs A and B, it referred specifically to fertility "treatment" although its intended scope was the full range of fertility "care." We also made an editorial revision to conform with the statute's use of the phrase "fertility preservation services." Accordingly, this paragraph has been further revised to read as follows:

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

(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.

Section 4(2)(C)(2) (Proposed Section 4(1)(C)(2)) and Section 4(5) (Proposed Section 4(4)), designation of standard-setting organization by carrier

Comments: RNE, GLAD, and ASRM, as noted earlier, requested that we revise both of these provisions to eliminate language authorizing carriers to choose a standard-setting organization, asserting that ASRM is the only eligible organization.

Bureau Response: The carrier's ability to designate a standard-setting organization is part of its responsibility to adopt clinical guidelines under 24-A M.R.S. § 4320-U(3)(E). The potential to choose from among multiple standard-setting organizations- has been retained as proposed for the reasons discussed when we considered the definition of standard-setting organization, now at Section 3(25).

Section 4(3) (Proposed Section 4(2)), parity between fertility coverage and other benefits

Comment: With limited exceptions, this subsection prohibits carriers from imposing requirements for fertility coverage that are more restrictive than comparable requirements for other coverage, including a general prohibition against imposing "a separate visit maximum or procedure maximum on any fertility treatment." As originally proposed, it contained an exception allowing carriers to limit coverage for egg retrievals to the first four completed egg retrievals over the lifetime of the egg retrieval patient, as described more fully in Proposed Section 5(5) (now Section 5(8)). We received several comments on the egg retrieval limit, which has been moved to a new Section 6(2) for the reasons discussed below.

Bureau Response: The proposed language of this subsection conflicted with Proposed Section 6(1) and Proposed Section 6(2) (now Section 6(3)), because egg retrievals were not the only benefit subject to a proposed lifetime limit. The Revised Proposed Rule addressed this conflict by proposing to replace the specific reference to egg retrievals in Section 4(3) with a general reference to Section 6, the section governing exclusions and limitations in general, and by moving the provisions permitting a lifetime limit on egg retrievals to a new Section 6(2). Accordingly, comments on this subsection relating to lifetime limits in general are addressed in the beginning of our analysis of Section 6, and comments on this subsection relating specifically to egg retrievals are addressed in our analysis of new Section 6(2).

Comment: Anthem objected to the underlying parity requirement, asserting at the hearing that prohibiting a separate visit maximum or procedure maximum exceeds the Superintendent's rulemaking authority because "The only thing that's prohibited by the statute is differences based on a person's status in a protected class."

Bureau Response: As noted above in our response to comments on the previous subsection, 24-A M.R.S. § 4320-U(3) allows carriers to impose "reasonable" limitations, but only to the extent "not inconsistent with ... rules adopted by the bureau." A general requirement for parity with other benefits, with the specific exceptions enumerated in Section 6, is a reasonable restriction on carrier's benefit design.

Comment: In addition to its general objection to this subsection, Anthem raised three specific concerns with respect to its content: First, Anthem said the term "comparable specialty service" is unclear, noting that cost sharing for specialty services could vary based upon the type or setting of the service, and suggest that the rule permit applying the highest coinsurance required under the plan rather than a "comparable" coinsurance. Second, they objected to requiring payment of at least 80% of the "cost" of fertility coverage because cost sharing is based on the allowed amount, which is not necessarily the full cost of the service. Finally, Anthem found the reference to Clear Choice confusing because we did not define "Clear Choice program" and because alternative plans offered in the merged individual/ small group market are not required to comply with Clear Choice plan design requirements.

Accordingly, Anthem requested the following revisions to this subsection:

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, or the percentage specified in the plan for other comparable specialty services, whichever is less~~ the enrollee's coinsurance may not exceed the greater of 20% or the highest coinsurance percentage specified in the plan for other services. A carrier ~~shall~~ offering Clear Choice plan designs in the pooled market pursuant to Title 24-A, chapter 34-B and Bureau of Insurance Rule chapter 851 must comply with any ~~other restrictions on cost sharing~~ applicable cost shares required ~~by the~~ for Clear Choice ~~program or other applicable law~~ plans.

Bureau Response: The Revised Proposed Rule retained the provisions calling for comparison to "comparable specialty services"; we felt that if material questions arise as to which services are comparable, they can be resolved during the form approval process. We agree, however, that specifying a maximum coinsurance percentage is clearer and more accurate than specifying a minimum share the carrier must pay. We also agree that the reference to Clear Choice was confusing, and have concluded that it is also unnecessary, because for Clear Choice plans, compliance with the applicable design parameters established by the Superintendent is one of the "restrictions on cost sharing required by ... applicable law." Therefore, the Revised Proposed Rule incorporated those two changes and the change discussed earlier in response to the comments about lifetime limits.

Comment: In their additional comments, Anthem observed that as published, this subsection of the Revised Proposed Rule was unclear; they assumed that the sentence on coinsurance was intended to read: "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."

Bureau Response: We appreciate the correction. As published, the Revised Proposed Rule inadvertently displayed the highlighted language below in underlined test. This was language we have deleted from the original proposal, so it should have been in strikeout text. We appreciate receiving comments that spoke cogently to the following proposal, notwithstanding the typographical error that made it more difficult to follow:

~~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.

Comment: Anthem's additional comments renewed their request to replace the "comparable specialty services" standard with "the highest coinsurance percentage specified in the plan for other services." They offered new justifications for this request by citing three of the questions we posed in our Request for Additional Comments, asserting that the proposed limits on coverage do not reflect the best allocation of the funding resources the Legislature has provided for benefit defrayal because the limits on coinsurance significantly increase the costs defrayal by increasing the underlying benefit costs; that these limits could also have the unintended consequence of increasing cost sharing for other services in order to mitigate the impact on premiums; and finally, that increased cost sharing for this "extremely generous" benefit would reduce the risk that legislatively budgeted defrayal funds might not be sufficient to provide full cost defrayal.

Bureau Response: While Anthem's concerns are noted, we do not consider it overly generous to require coverage that is generally equivalent to other comparable specialty services, with the specific exceptions expressly permitted in the rule.

Comment: CHO's additional comments observed that the language of this subsection, as proposed in the Revised Proposed Rule, appeared to be drafted with medical coverage in mind, even though what is now Section 5(12) requires plans with prescription drug coverage to include fertility drugs within the drug coverage rather than the medical coverage. CHO observed that Section 4(3) does not have any express exclusion for drug coverage, but the term "comparable specialty services" does not make sense in the prescription drug context, and cost sharing is described in terms that reflect the typical cost sharing parameters for medical coverage, not drug coverage. CHO "does not believe it's the Bureau's intent to create a separate pharmacy drug tier for fertility coverage," and recommended that drug tiering placement should be "consistent with how other drugs are placed into tiers (e.g., generic drugs used to treat infertility are placed in the generic tier, specialty drugs used to treat infertility are placed in the specialty tier)."

Bureau Response: We agree. We did not intend to limit the scope of this subsection to the medical side of the plan. We intended to require the same type of parity for drug benefits as we do for medical benefits, and requiring (or even permitting) a separate tier for fertility drugs would have been inconsistent with that intent. Accordingly, we have adopted this subsection with the following further revisions:

~~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~~ 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 ~~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~~.

(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 ~~the Clear Choice program or other~~ applicable law.

Section 4(4) (Proposed Section 4(3)), utilization management

Comments: This subsection prohibits preauthorization requirements and other utilization management requirements that are directed to fertility treatment, allowing only requirements of general applicability that do not have the purpose or effect of defeating the prohibition against fertility-specific restrictions. Anthem and MeAHP both object to this subsection. Anthem asserted, in both its initial and additional comments, that the proposal exceeds the Superintendent's statutory authority because "Prior authorization and utilization management are important tools used by carriers to help control costs. 24-A M.R.S.A. § 4320-U does not prohibit carriers from using prior authorization or utilization management; it merely (1) prohibits the imposition of different limitations, benefits or requirements on persons who are members of a protected class under the Maine Human Rights Act and (2) requires that any limitations imposed must be based on the enrollee's medical history and clinical guidelines adopted by the carrier. Neither of these provisions impose any additional restrictions on a carrier's ability to use prior authorization or utilization management.... It is important to note that not all treatments and procedures will be appropriate for all fertility patients, and the carrier's ability to manage utilization of these services is important to help ensure that our members are receiving appropriate care.... It is not clear what is meant by 'of general application.' For example, while most surgeries require prior authorization, there are some that do not. Would that mean that prior authorization cannot be applied to surgical fertility procedures?" MeAHP offered substantially similar objections, and added that the term "general applicability" is not defined.

Bureau Response: This subsection is adopted as proposed. It does not prohibit prior authorization and utilization management. It only requires the carrier to apply these tools equitably, consistent with the manner in which it uses them for other services. This principle of parity is appropriate and consistent with the statute for the reasons discussed in response to prior comments. If actual rather than hypothetical questions arise regarding its implementation in particular cases, they will be resolved in the form approval process.

Comment: CHO noted that this section does not specifically address utilization management for prescription benefits, and asked whether it would be permissible to implement utilization management strategies such as step therapy, prior authorization, quantity limits (*e.g.,* 30-day supply) or non-formulary drug exclusions. In their additional

comments, they paraphrased this section (in a manner similar to Anthem) as "stat[ing that] preauthorization (PA) requirements may not be imposed," and asserted that carriers need to be able to use step therapy "to ensure we are being good stewards of financial resources." They asked whether they correctly understand that it is not "the Bureau's intent to allow carte blanche access without regard to cost" and that step therapy is not categorically prohibited by this subsection.

Bureau Response: As noted in response to the previous comment, the rule does not say requirements such as prior authorization "may not be imposed." These techniques are permitted, as applied to the management of prescription claims, if they are consistent with the policy's general provisions for prescription benefits and comply with the relevant provisions of the Insurance Code.

Section 5, enumeration of specific required benefits

Comments: In the initial round of comments, stakeholders from diverse perspectives questioned the list of benefits enumerated in this section. MeAHP asserted that "The benefits enumerated in Section 5 may include treatments and procedures that are experimental or are of undetermined value.... In its rulemaking, the Bureau could establish an expectation for commonly covered fertility services that could be expanded to include advancements in treatment that are proven in the future to be effective and valuable." In particular, they cited two ASRM practice guidelines evaluating assisted hatching and intracytoplasmic sperm injections, the benefits enumerated at Section 5(2) and Section 5(10), and their comments hyperlinked both guidelines, which are hereby incorporated into the rulemaking record. The same two papers were also cited by Anthem, GLAD, and ASRM. Anthem stated that "the intent of 24-A M.R.S.A. 4320-U is to provide coverage for fertility services but not necessarily to require unfettered coverage of all fertility services. The list of required benefits is extremely broad and contains some treatments and procedures of questionable value as reviewed by ASRM." GLAD and ASRM requested that we "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 they emphasized that the fertility coverage statute "is drafted broadly to be evergreen as technology changes."

Bureau Response: Although the version of Section 5 exposed for comment in the Revised Proposed Rule followed the same general approach as the original proposal, and proposed retaining all of the benefits initially enumerated, our Request for Additional Comments specifically asked stakeholders for feedback on possible alternative approaches: "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?" We received only three responses to that question, and none of them requested any fundamental restructuring. Section 5 is therefore adopted as proposed in the Revised Proposed Rule, with one clarifying revision to Section 5(7). That revision and other issues relating to specific benefits are discussed in the subsection-by-subsection analysis below. As discussed in

response to the general comments, these provisions are open to further reconsideration as experience with coverage develops and clinical standards for fertility care evolve further.

Comments: Anthem responded as follows to the question in the Request for Additional Comments: "We do not believe the rule should attempt to address future advances in technology, the efficacy and cost of which are unknown. The appropriate course of action would be to amend the rule if needed to address advances in technology. If the rule attempts to address future technologies, it should also contemplate the fact that technologies covered under the rule today may become outdated and no longer appropriate due to advances in technology." RNE responded that "The statute was drafted with the intention of being able to adapt to advances in fertility care without needing to be amended, in part by referencing the standard setting organizations in our field and by excluding procedures that are still deemed experimental by those organizations. Thus, as advances in reproductive technology are generally accepted as a standard of care, they should be covered by providers." The third response, from Ms. Oleaga, suggested provisions "stating that any future advances in reproductive technology replacing or improving upon the definitions listed in Section 3 should be incorporated into the statute and covered accordingly," and is discussed above in our general analysis of Section 3.

Bureau Response: As discussed in our response to Ms. Oleaga's comment on Section 3, the RNE and Anthem comments are complementary rather than conflicting. The clinical guideline framework provides substantial room to accommodate advances in technology, especially if carriers' clinical guidelines and policy terms keep pace with evolving standards of practice without the need for new legal requirements. However, when the rule nevertheless ceases to be a good fit with the practice of fertility care, then the rule (and possibly the statute) will need to be amended.

Comment: In both its initial and additional comments, Anthem asked us to use "what is commonly covered today ... as the basis for what should be required coverage. The required coverage could then be amended over time to reflect changes in medical technology. In other words, we would suggest starting with a core set of covered services and expanding those covered services in the future as warranted." Anthem explained that some of their small group plans already include fertility coverage consisting of "up to six complete in-vitro fertilization cycles before each live birth, which includes:

- "any combination of standard in-vitro fertilization, such as *[sic]* AI (intracervical or intrauterine artificial insemination)
- "any Assisted Reproductive Technology (ART) such as IVF-ET (in-vitro fertilization and embryo transfer), GIFT (gamete intrafallopian transfer), or (ZIFT zygote intra-fallopian transfer)
- "if a live birth does not occur after six complete in-vitro fertilization cycles, no further benefits are available. Incomplete cycles do not count towards the six-cycle limit."

Bureau Response: Products already on the market and benefit requirements that had already been implemented in other states were factors that had been considered during the development of both the original Proposed Rule and the Revised Proposed Rule.

Comments: RNE's initial comments proposed the following change to the introductory paragraph to Section 5:

> Fertility coverage shall include, at a minimum, payment of benefits for the following services and procedures ~~when recognized as medically appropriate, in light of the fertility patient's medical history~~ for fertility patients, under guidelines adopted in compliance with this rule:

GLAD and ASRM requested a similar but more extensive revision:

> Fertility coverage shall include, at a minimum, payment of benefits for the following services and procedures ~~when recognized as medically appropriate, in light of the fertility patient's medical history, under guidelines adopted in compliance with this rule for~~ fertility patients:

Bureau Response: In their comments on other provisions of the rule, all of these organizations highlighted the importance of 24-A M.R.S. § 4320-U(3)(E), which not only allows but requires consideration of the "enrollee's medical history and clinical guidelines adopted by the carrier." We therefore decline to make the requested deletion. It is not clear that it is necessary to specify that fertility care benefits are for fertility patients, but it is not inaccurate, so the Revised Proposed Rule added that phrase as requested. Finally, as discussed above in response to the comments on what is now Section 4(3), all benefits enumerated in this section are subject to any applicable limitations in Section 6, so the Revised Proposed Rule added language to clarify this point. We received no comments on the revised introduction to Section 5, which is therefore adopted as follows:

> 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:

Section 5(1), insemination benefit

Comment: RNE, GLAD, and ASRM request that we delete the word "artificial," consistent with their comments on the definition.

Bureau Response: The Revised Proposed Rule made the requested change to the terminology, as discussed in our response to the comments on Section 3(20) (Proposed Section 3(1)), and made a conforming change to this subsection. We received no comments on the revised language, which is therefore adopted as follows:

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

Section 5(2), assisted hatching benefit

Comments: This procedure is the subject of one of the ASRM practice guidelines referenced in comments by MeAHP, Anthem, GLAD, and ASRM, as noted above in the general comments on Section 5. GLAD and ASRM did not specifically request deletion of this subsection, but flagged it with a marginal note asserting "that assisted hatching is an outdated procedure that is no longer standard of care." Similarly, RNE did not expressly include a deletion in their markup, but they had also included assisted hatching in the list they provided at the hearing identifying technologies they characterized as obsolete. Anthem and MeAHP likewise questioned the need for this benefit, each citing the ASRM practice guideline. This is one of the procedures MeAHP identified as possibly being "experimental or ... of undetermined value." and Anthem's initial comment on this subsection quoted ASRM's finding that there is "moderate evidence that assisted hatching does not significantly improve live birth rates in fresh assisted reproductive technology cycles and insufficient evidence for the benefit of assisted hatching in patients with poor prognosis or undergoing frozen embryo transfer cycles," and the resulting recommendation that "Laser-AH should not be routinely recommended for all patients undergoing IVF. There are insufficient data to make a recommendation for selected groups, such as patients with poor prognosis." Noting the ASRM practice paper's conclusion "that assisted hatching is not appropriate in all instances," Anthem suggested at the hearing, citing 24-A M.R.S. § 4320-U(3)(E) and echoing their comments on Section 4(4), "that some form of medical management be permitted to determine appropriateness of the procedure for the individual."

Bureau Response: We agree with Anthem that medical management is appropriate for this procedure, especially in light of evidence that the procedure appears to have been overused. On the other hand, the ASRM paper did not conclude that the procedure is never appropriate. Because this indicated that the development and application of clinical guidelines was the best way to address the problem, the Revised Proposed Rule proposed retaining this subsection, subject to the general condition that like all benefits enumerated in Section 5, it is required only "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." We received no additional comments on this subsection, other than Anthem's renewal of their previous comments. The subsection is therefore adopted as proposed.

New Sections 5(4) through 5(6), laboratory testing, imaging, and physical exam benefits

Comment: In their initial comments, RNE requested the addition of three new subsections requiring additional enumerated benefits, to read as follows:

[4.] Laboratory testing;

[5.] Ultrasounds and other imaging procedures;

[6.]: Physical examinations;

Bureau Response: When we reviewed this comment, we noted that "laboratory assessments and imaging studies" are expressly included within the statutory definition of "fertility diagnostic care," 24-A M.R.S. § 4320-U(1)(B), which is incorporated by

reference at Section 3(10). Accordingly, we understood this comment more as a request for clarification than as a request to expand the scope of required coverage, and we included these subsections in the Revised Proposed Rule.

Comment: Labcorp expressed concern that Section 5(4) creates "a potential ambiguity" because it "requires coverage for laboratory testing but does not elaborate on the types of testing that must be covered." Focusing on a hypothetical stillbirth, they noted that a failed pregnancy does not reset the 12-month clock that gives rise to a statutory presumption of infertility under 24-A M.R.S. § 4320-U(1)(G), which they cited as legislative recognition that there can be a connection between failed pregnancies and infertility. Despite this connection, Labcorp speculated that an insurer might deny coverage to test for the cause of the fetal death because "an insurance carrier might only permit testing for the etiology of the infertility itself, not the etiology of a failed pregnancy."

Bureau Response: It is not clear what scenarios might lead a carrier to deny a claim for coverage on the basis that the etiology of a particular failed pregnancy had no relevance to "the etiology of the infertility itself," and if the carrier's rationale was credible, it is questionable why such a test would necessarily be within the scope of a fertility mandate. This scenario, if it ever arose in practice, ought to be resolved by clinical guidelines and the standard claim appeal process, not by adding more detailed and prescriptive language to the text of the rule. Furthermore, the comment did not suggest any language that would address their concerns.

Comment: The only other comment we received on these subsections was from Anthem, which objected: "These services are already covered when medically necessary but inclusion of them in this rule may mean that those services are subject are subject to the cost sharing applicable under this rule, rather than the cost sharing that would ordinarily apply to those services."

Bureau Response: Anthem's statement that these services are already covered when medically necessary, together with the lack of comment from any other stakeholders, corroborates our understanding that these subsections represent a clarification rather than an expansion of coverage. Their objection based on cost sharing requirements is not persuasive, because Section 4(3) expressly permits carriers to apply the cost sharing that would ordinarily apply, with a further provision allowing them to impose coinsurance or increase the coinsurance percentage if the normal coinsurance does not already equal or exceed 20%. These subsections are therefore adopted as proposed in the Revised Proposed Rule.

Section 5(7) (Proposed Section 5(4)), embryo transfer benefit

Comment: In their initial comments, Harvard Pilgrim asked for additional guidance on the benefit for fresh and frozen embryo transfers, specifically how this benefit differs from the benefit for in vitro fertilization required by Section 5(8), and who is covered for this benefit.

Bureau Response: Embryo transfers are covered consistent with clinical guidelines, subject to the conditions and limitations permitted by this rule, when the embryo is transferred into a covered fertility patient or into a covered fertility patient's gestational carrier or surrogate. Although embryo transfer is defined in this rule as part of the in vitro fertilization process, the fertilization and the subsequent embryo transfer are separate clinical procedures occurring at different times. Embryo transfers are covered separately under this subsection even if the fertilization procedure took place before the policy was in force, and one round of fertilization (whether or not covered under the policy) could enable more than one embryo transfer procedure.

Comment: Ms. Oleaga expressed concern that this subsection fails to mention donated embryos and requested "Listing embryo transfers with donated embryos as a required benefit." She noted that this is an important option for some fertility patients, that the number of cryopreserved embryos is growing exponentially, and that there is no financial downside to the carrier if a fertility patient uses a donated embryo rather than a new round of covered IVF. RNE's additional comments likewise requested the following amendment to this subsection:

~~4.~~ 7. Fresh and frozen embryo transfer, including donor embryos;

Bureau Response: It was never our intent to exclude donated embryos from the scope of coverage. The only reason this subsection failed to mention donated embryos explicitly was because we were unaware that there was a question. The transfer of a donated embryo is unquestionably an embryo transfer, and 24-A M.R.S. § 4320-U(3)(C) expressly prohibits "any limitations on coverage for any fertility services based on an enrollee's use of ... donor embryos." However, when we received two separate comments on this issue, we reviewed the Revised Proposed Rule to see whether we had left any ambiguity. Although three separate provisions mention donor eggs, the only provision of the original Proposed Rule that had mentioned donor embryos has been removed. Although it was removed from the definition of embryo transfer because it was part of superfluous and confusing sentence, we agree that the simplification of the definition should have been accompanied by a clarification of the corresponding substantive provision. This subsection has therefore been revised as requested, with a nonsubstantive editorial clarification:

~~4.~~ 7. Fresh and frozen embryo transfer, including the transfer of donor embryos;

Proposed language in Section 5(8) (Proposed Section 5(5)) relating to lifetime limits

Language relating to the lifetime limit on egg retrievals was moved to new Section 6(2) and new Section 6(4) in the Revised Proposed Rule. Accordingly, as with the comments on Section 4(3), comments on this subsection relating specifically to egg retrievals are addressed in our analysis of Section 6(2), while comments on this subsection relating to lifetime limits in general are addressed in the beginning of our analysis of Section 6, and where relevant, in our analysis of Section 6(4).

Section 5(8) (Proposed Section 5(5)), egg retrieval benefit

Comments: Fertility Within Reach requested we add "monitoring" follicle development and "egg retrieval" to the list of examples of covered donor medical costs, explaining that "These would be the same CPT Codes used on the intended parent (enrollee) if they were to experience the egg retrieval themselves. It is the same cost to the carrier whether monitoring and egg retrieval are with the intended parent or the live donor. The Enrollee is paying premiums for this benefit, so why limit access to the treatment they need just because they are working with a donor?" They noted further that although carriers have objected to providing benefits to non-enrollees, the medical costs of live organ donation are covered even if the donor is a non-enrollee and they said the same standard should apply for live egg donors. RNE also proposed adding additional requirements for covered donor costs. Their requested revision reads as follows:

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

~~(A) Where~~ 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;~~

Bureau Response: In response to this comment, the Revised Proposed Rule proposed making the requested revisions,[7] with some editorial changes. We also replaced the phrase "donor medical costs" with "covered medical costs," because this subsection describes the scope of the egg retrieval benefit generally, and the requirement to include donor expenses is in addition to the underlying requirement to cover the retrieval of the fertility patient's own eggs. With those revisions, Section 5(8) of the Revised Proposed Rule reads as follows:

~~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;

[7] However, as discussed above, the material relating to lifetime limits, which was the subject of a separate comment, was moved to Section 6(2) and Section 6(4) rather than being deleted entirely.

~~(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;~~

Comment: The only additional comment we received on this subsection was from Anthem. They expressed concern that the changes significantly broaden the required coverage and they "suggest that the language originally proposed is more appropriate." Their objection is that the original language made it clear that the costs must be related to the egg retrieval, while they characterize the revised language as "broader and could be read to require coverage of all medical costs of the donor, not just those related to the egg retrieval," which would be inappropriate when the donor is not covered under the policy.

Bureau Response: We agree that general coverage of a donor's medical costs would be inappropriate when the donor is not insured under the policy. However, that is not what this subsection requires. We retained the limitation that donor coverage applies only to the donor's "associated" medical costs, and gave specific examples of the types of medical costs that are associated with the egg retrieval procedure. This subsection is therefore adopted as proposed in the Revised Proposed Rule.

Section 5(9) (Proposed Section 5(6)), intrafallopian tube transfer benefit

Comments: RNE commented at hearing that these procedures are "no longer widely used," and their subsequently-submitted markup deleted this subsection. They renewed that request in their additional comments, stating that "These procedures are no longer done. GLAD and ASRM did not delete it, but they flagged it with a marginal note "See notes above," and those notes had asserted that "ZIFT and GIFT ... are no longer standard of care."

Bureau Response: As with assisted hatching (Section 5(2)), the Revised Proposed Rule proposed retaining this subsection, subject to the general condition that like all benefits enumerated in Section 5, it is required only "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." The categorical assertion that these procedures are no longer used may be an overstatement, and both ZIFT and GIFT are specifically mentioned in the benefit package Anthem described in their general comments to Section 5. Therefore, as discussed in our response to the comments on Section 5(2), we believe the clinical guideline requirement provides adequate protection against overutilization, and we have adopted this subsection as proposed. Another disincentive for overutilization of these procedures is that under Section 6(3), they are subject to the same combined two-cycle limit that also includes fresh and frozen embryo transfers. Furthermore, even if further experience demonstrates that these procedures will soon be entirely obsolete, or perhaps already are entirely obsolete, that would merely make this requirement irrelevant. A requirement to cover the procedures when medically appropriate becomes moot if there are no medically appropriate cases, and if we confirm at some later date that such a requirement is no longer necessary, it can be repealed at that time.

Section 5(10) (Proposed Section 5(7)), intracytoplasmic sperm injection benefit

Comment: This procedure is the subject of one of the ASRM pIce guidelines referenced in comments by MeAHP, Anthem, GLAD, and ASRM, as noted above in the general comments on Section 5. Anthem's additional comment renewed their initial comment, which summarized the ASRM finding "that ICSI may be of benefit for select patients undergoing IVF but not for all patients," and then concluded: "The ASRM opinion demonstrates (1) that broad coverage of ICSI should not be required as it is not always appropriate treatment and (2) reinforces the need for carriers to have the ability to require prior authorization for covered services."

Bureau Response: While there is evidence that this procedure has been overutilized, and, in Anthem's words, "is not always appropriate treatment," the balance of considerations weighs even more strongly in favor of retaining coverage for ICSI than it did for assisted hatching, GIFT, and ZIFT, discussed above. As Anthem expressly acknowledged, the ASRM practice guideline included a finding "that ICSI may be of benefit for select patients." If clinical guidelines identify other groups of fertility patients who will not benefit from this procedure, it will not need to be covered for those patients. As discussed earlier, both the statute and the rule permit prior authorization and other medical management when applied in a reasonable and nondiscriminatory manner. This subsection is therefore adopted as proposed.

Section 5(11) (Proposed Section 5(8)), in vitro fertilization benefit

Comment: RNE requested the following revision. GLAD and ASRM requested a similar revision, deleting the phrase "or surrogate" but retaining the term "eggs":

[11.] In vitro fertilization, including in vitro fertilization using donor ~~eggs~~ gametes and in vitro fertilization where the embryo is transferred to a gestational carrier ~~or surrogate~~;

Bureau Response: Because we have retained the terms "eggs" and "surrogate" for the reasons discussed in response to the comments to the definitions in Section 3, this subsection is adopted as proposed.

Comment and Bureau Response: Harvard Pilgrim's question about the relationship between the IVF benefit and the embryo transfer benefit is summarized and addressed at Section 5(7), above.

Section 5(12) (Proposed Section 5(9)), medication benefit

Comment: RNE requested the following revision to this subsection:

[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;

Bureau Response: We agree, and we included the requested revision in the Revised Proposed Rule. There were no new comments on this subsection, which is adopted with the proposed revision.

Comment: Fertility Within Reach requested a different revision, due to concerns that the phrase "infertility drugs" could limit the reasons medications can be provided and how they are used, noting that infertility might not be the first indication of use for some necessary medications. They recommended substituting the phrase "drugs used to treat fertility health care."

Bureau Response: This revision is not necessary. The subsection requires a general benefit for medications used in fertility care, and the term "fertility" medications is used in an inclusionary clause, not a limiting clause; the purpose of the clause is to clarify that injectable medications are within the scope of this benefit and that it applies even if the policy provides no other prescription benefit. Furthermore, the language requested would not be appropriate because "fertility health care" is not the condition being treated.

Comment: CHO asked, in both its initial and additional comments: "Does this mean that a provider can't buy and bill under the medical benefit, and means the provider must obtain the medication from a pharmacy that is contracted with the carrier, or the Member obtains the medication and self-injects or brings the medication to the practice?"

Bureau Response: Nothing in this subsection prohibits carriers from providing this benefit to enrollees in the most convenient and efficient way possible.

Section 5(14) (Proposed Section 5(11)), surgery benefit

Comment: RNE, as discussed above in connection with their proposal to revise Section 3 to add "microsurgical testicular sperm extraction" as a new defined term, requested the following revision:

[14.] Surgery, including but not limited to microsurgical sperm aspiration and microsurgical testicular sperm extraction; and

Bureau Response: As discussed in response to their requested definition in Section 3, we agree that coverage for microsurgical testicular sperm extraction should be available when this procedure is medically appropriate. We have revised the terminology in what is now Section 3(23) to clarify this point, and the Revised Proposed Rule makes a conforming revision to this subsection. Although the phrase "not limited to" is not strictly necessary, the Revised Proposed Rule also made that clarification as requested. We received no comments on the language in the Revised Proposed Rule, which is therefore adopted as follows:

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

Section 5(15) (Proposed Section 5(12)), cryopreservation benefit

Comment: GLAD and ASRM commented "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." They noted that "The law requires coverage of cryopreservation for 5 years," and requested that we make this point clear in the rule, proposing the following revision:

[15.] Costs associated with cryopreservation and storage of ~~sperm, eggs,~~ gametes and embryos for five years.

Bureau Response: The five-year requirement is expressly specified in the statute at 24-A M.R.S. § 4320-U(1)(D). Although it does not, strictly speaking, set a "time limit for the term of cryopreservation," it does limit the term for which carriers are required to provide coverage. Therefore, the Revised Proposed Rule proposed including the requested addition of the five-year coverage period, with an additional revision to this subsection to track the revised language in the definition of "cryopreservation," now at Section 3(3):

~~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.

Comment: As noted in our analysis of Section 3(3), Harvard Pilgrim expressed concern "that cryopreservation of ovarian and/or testicular tissue is not currently covered by any payer in the country."

Bureau Response: The purpose of any mandated benefit is to require coverage for health care services that where coverage might not be provided in the absence of the mandate. Given the lack of a similar objection from any other carrier, it is possible that the statement that this procedure is currently never covered might not be entirely accurate, or that mandated coverage might not be perceived by other carriers as a material burden. The submission of a comment requesting the inclusion of gonadal tissue within the definition of cryopreservation, and two comments describing specific procedures that might involve that form of cryopreservation, indicate that it is already part of current medical practice, and 24-A M.R.S. § 4320-U(D) defines fertility preservation services to include "cryopreservation of gametes, embryos and reproductive material." As noted in our analysis of Section 3(3), we received no comments questioning the inclusion of ovarian and testicular tissue as reproductive material that might be cryopreserved. This does not necessarily mean that such cryopreservation should be covered, but in cases where the procedure is still experimental, or where the applicable clinical guidelines identify it as not being medically necessary, coverage is not required. If there are cases where it is medically necessary, it ought to be required, even if prevailing terms of coverage have not yet kept pace with prevailing standards of practice.

To follow Section 5(15), requested new fertility preservation benefit

Comments: GLAD, ASRM, RNE, and EQME all stressed the importance of fertility preservation services. EQME commented that "It is also critical that 'fertility preservation services' continue to be included under Required Coverage," and RNE noted that the term

"is included in the definition section of the proposed rules but not under Required Coverage, as indicated in the statute. I believe this was an unintentional oversight and should be fixed. This is a core part of the law." GLAD, ASRM, and RNE proposed adding a new subsection at the end of Section 5, to read:

[16.] Fertility preservation services.

We did not include this in the Revised Proposed Rule, for the reasons discussed below, and RNE renewed this request in their additional comments, joined by MHB and the six organizations participating in the ACS CAN joint letter. MHB noted that fertility preservation is not just an LGBTQ+ issue but also of particular importance for cancer patients. Their comment addressed both the importance of fertility preservation in general and the need to provide coverage for "some crucial services like the collection and analysis of sperm specimens and the surgical extraction of an ovary (or a portion thereof) for ovarian tissue cryopreservation." The joint letter acknowledged that coverage for egg retrieval was already required but characterized that as an overlap between fertility preservation services and the services required for IVF, and asserted that "some necessary services, such as collection and analysis of sperm specimens and surgical removal of an ovary (or part of an ovary) for ovarian tissue cryopreservation are not listed." RNE also acknowledged "overlap in some procedures," but said "medically necessary fertility preservation care is distinct from fertility treatment for the direct purpose of conception, and thus must be referenced separately."

Bureau Response: As discussed earlier in response to several comments on what is now Section 4(2), we agree that fertility preservation is an important component of fertility care. As such, it is specifically protected by the statute, and we have added language to clarify this point. However, the failure to include a separate line item for "fertility preservation services" in Section 5 was not unintentional and was not an oversight. Coverage of "fertility preservation services" is not a specific benefit. It is a class of benefits, like "fertility treatment," and neither fertility treatment nor fertility preservation needs to be enumerated separately within section 5. Furthermore, as the comments acknowledge, the high-level categories overlap. Egg retrievals, for example, need not be enumerated separately as "egg retrievals when the immediate purpose is fertility preservation" and "egg retrievals when the immediate purpose is fertility treatment." Where comments have addressed specific fertility preservation services, or language that might be read as inadvertently excluding them, we have responded to those comments and added or corrected language as needed. Finally, we note that contrary to the concern expressed in the joint letter, Section 5(15) does require coverage for cryopreservation of both testicular and ovarian tissue when medically necessary.

Section 6, comments on lifetime limits generally

Comments: In Section 6 of the Revised Proposed Rule, Subsections 1 through 3 proposed permitting lifetime limits on intrauterine or vaginal insemination, egg retrievals, and embryo transfers, while Subsection 4 excludes procedures from being charged toward those limits if the cost was paid out of pocket by the patient. This incorporates language that was originally placed in Proposed Section 4(2) (now Section 4(3)) and in Section 5(5)

(now Section 5(8)). As explained earlier, all comments addressing lifetime limits in general have been consolidated here for purposes of discussion.

RNE objected in their initial and additional comments that the lifetime limits authorized by the rule are "arbitrary," "not based on medical standards," and violate the statutory principle that coverage decisions, "should be grounded in the individual patient's 'medical history' in consultation with their medical provider." RNE urged that "Clinical decisions should be based on the medical expertise of the treating physician in consultation with the patient." As additional bases for their contention that lifetime limits violate applicable statutes, RNE also asserted:

- That lifetime limits are prohibited by Section 4320-U because previous treatment and diagnosis cannot be a basis for limiting coverage;
- That limiting egg retrievals differently from other fertility care is also prohibited by Section 4320-U because it provides different coverage based on sex;
- That lifetime limits on fertility benefits are not allowed under the federal Affordable Care Act (ACA) because this treats infertility as a pre-existing condition; and
- That the ACA generally prohibits lifetime limits.

GLAD and ASRM likewise remarked that lifetime limits "may conflict with the ACA."

Bureau Response: Though it cannot be denied that the proposed lifetime limits interfere to a degree with provider discretion and the availability of care, the same is true of any limits on coverage. As noted earlier, RNE acknowledged in both their initial and additional comment letters that unlimited fertility coverage is not realistic. Lifetime limits are one mechanism for limiting coverage that is sometimes used both in insurance policies and in laws of other states requiring fertility coverage. For the following reasons, we are not persuaded by the comments arguing that lifetime limits should be prohibited.

24-A M.R.S. § 4320-U(3) specifically authorizes "reasonable limitations" on fertility benefits, which may not be inconsistent with rules adopted by the Bureau. The rule we have adopted further clarifies which lifetime limitations are considered reasonable. Although Paragraph E of that subsection further provides that "Any limitations imposed by a carrier must be based on an enrollee's medical history and clinical guidelines adopted by the carrier," the requirement to consider each enrollee's medical history does not mean each enrollee is entitled to individualized contract terms, something that is expressly prohibited by federal and state law. Likewise, it does not mean that the contract terms and the terms of this rule must be open-ended, without specific numerical limitations. In that regard, it should be noted that the statute itself specifies a five-year limit on cryopreservation, at 24-A M.R.S. § 4320-U(1)(D), and a one-year threshold for identifying infertility, at 24-A M.R.S. § 4320-U(1)(G).

While both the ACA and the Maine Insurance Code specifically prohibit certain types of lifetime limits, neither prohibition is applicable here. The ACA provision, Public Health Service Act (PHSA) § 2711, only applies to essential health benefits, and fertility care has not been designated as an essential health benefit for Maine at this time. This does mean, however, that in order for any of the benefits currently subject to lifetime limits to be

eligible for addition to Maine's essential benefit package at any point in the future, one necessary condition would be the repeal of the lifetime limit. The state law provision, 24-A M.R.S. § 4320(1), pre-dates the ACA and is not limited to essential health benefits, but both the state and federal provisions apply only to limits on the dollar value of benefits and do not prohibit per-service limits such as those allowed by this rule.

Both the ACA and the Maine Insurance Code also prohibit preexisting condition exclusions, PHSA § 2704 & 24-A M.R.S. § 2850(2), but a coverage limit is not a preexisting condition exclusion. Under both state and federal law, the prohibition against lifetime limits is separate from the treatment of preexisting condition exclusions. Fertility coverage is available to the full extent provided by this rule to all fertility patients, regardless of whether they knew of their infertility at the time they first enrolled in coverage. For the same reason, we interpret 24-A M.R.S. § 4320-U(3)(B) as addressing preexisting conditions, not lifetime limits. That provision prohibits carriers from using "any prior diagnosis or prior fertility treatment as a basis for excluding, limiting or otherwise restricting the availability of" the required fertility coverage. "Prior diagnosis or treatment" is the most common criterion for identifying excludable preexisting conditions in cases where exclusions are permitted, and "prior diagnosis" is not even relevant to the application of a lifetime limit. In one of the states that currently permits lifetime limits, the currently pending Connecticut House Bill 6617 would enact "prior diagnosis or fertility treatment" language substantially similar to Maine's, but would retain language expressly permitting lifetime limits on intrauterine insemination, and the accompanying legislative analysis interprets the bill as implicitly permitting some other lifetime limits as well.[8]

Finally, 24-A M.R.S. § 4320-U(3)(D) provides that "A carrier may not impose different limitations on coverage for, provide different benefits to or impose different requirements on a class of persons protected under Title 5, chapter 337 than those of other enrollees," and a person's sex, sexual orientation, and gender identity are all protected classes under 5 M.R.S. §§ 4552 and 4553(8-F). However, the distinctions drawn in this rule between different types of reproductive organs and different types of gametes are clinically based and nondiscriminatory; for example, egg retrieval is covered on exactly the same terms whether the eggs are retrieved from a woman, a transgender man, or a nonbinary person. Specific references to reproductive biology are necessary for fertility care, and we expect them to be an inevitable part of the clinical guidelines that are required by 24-A M.R.S. § 4320-U(3)(E).

Section 6(1), limits on intrauterine or vaginal insemination

Comments: The Revised Proposed Rule changed the term from "intrauterine insemination" to "intrauterine or vaginal insemination," consistent with the change in terminology made in Section 3(20) and Section 5(1), but proposed retaining the three-cycle limit. RNE requested deletion of this provision. In addition to their general objections to lifetime limits, as discussed earlier, RNE asserted that the limit on intrauterine or vaginal

insemination was "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?" They noted that insemination is a lower cost than IVF and objected to limiting coverage in cases where "that is a course of treatment that is likely to be successful for an individual patient," while adding that "patients should also not be arbitrarily required to do inseminations if it is not clinically indicated." Ms. Oleaga submitted similar comments, finding it "problematic to limit the number of intrauterine or vaginal inseminations, or to require a specific number of inseminations or less expensive fertility treatments before providing coverage for in vitro fertilization." GLAD and ASRM also questioned this subsection, asserting that "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." Six cycles was also the applicable limit in the plan Anthem had proposed as a model, but that was a combined limit for various types of assisted reproductive technologies. GLAD and ASRM proposed the following revision:

1. Benefits for ~~intrauterine~~ insemination may be limited to three ~~lifetime~~ cycles.

Bureau Response: The question that needs to be addressed is the three-cycle limit, not the word "lifetime." If lifetime limits are a problem, deleting the word "lifetime" does not solve the problem – it adds a new problem by failing to specify whether three cycles is a lifetime limit or is measured in some other manner. While we recognize the concerns with each of the lifetime limits we have proposed, there need to be some limits on coverage in order to maintain its affordability. The savings projected to result from each of these three limits were important components of the cost estimates we provided to the Legislature, when the legislation was being considered, and upon which the Legislature relied when they evaluated the potential need for cost defrayal and appropriated what they determined to be the necessary funds if defrayal is required. In the Request for Additional Comments, we asked stakeholders for their views on whether the proposed limits on coverage reflect the best allocation of the funding resources the Legislature has provided. Anthem was the only stakeholder that responded to this question, and their response was: "We do not believe that the proposed limits on coverage do so. The proposed limit on coinsurance to a maximum of 20% significantly increases the cost of the mandate, thereby increasing the defrayal costs that must be borne by the State." The lifetime limits give each covered fertility patient the opportunity to have access to each of these treatments if medically indicated, and to have full coverage for a limited number of these procedures on the same terms as any other comparable health care service. We do not believe Anthem's proposed resources would be a fairer way to implement the necessary cost controls, even if the resulting savings were sufficient to allow material changes to the lifetime limits. This subsection is therefore adopted with the modifications proposed in the Revised Proposed Rule. As with the benefit requirements enumerated in Section 5, this subsection and the other limitations permitted in Section 6 are open to further reconsideration as clinical standards for fertility care evolve further and experience develops on the actual cost of services, utilization rates, and demand for services that are not currently covered.

New Section 6(2), limits on egg retrievals (contains material from Proposed Section 4(2) (now 4(3)) and Proposed Section 5(5) (now 5(8))

Comments: This provision of the Revised Proposed Rule, permitting carriers to impose a lifetime limit of four completed egg retrievals, was located in Sections 4(2) and Section 5(5) of the original Proposed Rule, but was moved to Section 6 for consistency with the other provisions permitting coverage limitations and exclusions, as discussed in our analysis of what are now Section 4(3) and Section 5(8). Comments on those provisions of the original proposal that addressed the limit on egg retrievals have been consolidated here, for purposes of discussion, with additional comments on this subsection of the Revised Proposed Rule, which reads as follows:

2. Benefits for egg retrieval may be subject to a lifetime limit of four completed egg retrievals.

The only objections to this limitation were part of the objections raised by several stakeholders to lifetime limits in general in both the initial and additional round of comments. It should be noted, however, that some stakeholders expressed concern, in their comments on Section 6(3), that permitting carriers to limit embryo transfers to two cycles undercuts the value of coverage for four egg retrievals.

Bureau Response: The comments on compatibility between this subsection and Subsection 3 are directed primarily toward the two-cycle limit for embryo transfers, and therefore are addressed below. The general objections to lifetime limits are discussed above, in our response to the general discussion of lifetime limits. While we recognize and appreciate the concerns that are raised by any limitations on coverage, we have adopted this subsection as proposed in the Revised Proposed Rule for the reasons discussed more fully in our response to comments on Section 6(1), above.

Section 6(3) (Proposed Section 6(2)), limits on gamete and embryo transfer

Comment: The Revised Proposed Rule retained this subsection as originally proposed, with the correction of a punctuation error. As proposed, it permitted carriers to limit "any combination of" GIFT, ZIFT, or fresh or frozen embryo transfer (FET) to two lifetime cycles." CHO asked: "Does an IVF procedure include the embryo transfer or is it separate from that and an additional charge? The way written may lead to additional confusion for our Members and the Provider community." Fertility Within Reach commented that "Most IVF cycles include fresh embryo transfers. This can optimize patient outcomes. This permissible limitation, where an egg retrieval and transfer combination is limited to two-lifetime cycles, directly conflicts with the required benefits. As written, the insurance department is regulating that patients must avoid an embryo transfer at the time of their egg retrieval if they want access to the required benefit of four egg retrievals."

Bureau Response: The comments have alerted us to a problem with including IVF in the same category as gamete and embryo transfers. This subsection was not intended to reduce the availability of covered embryo transfers to one or none. The intent was that an IVF procedure and one subsequent embryo transfer constitute a single cycle, but that provision was not clearly worded. It is even less clear in cases where more than one IVF procedure becomes necessary in order to obtain an embryo that is suitable for transfer. The nature of

IVF is that it is always undertaken with subsequent embryo transfer in mind, even when the immediate purpose is fertility preservation and no specific plans have been made beyond the fertilization and cryopreservation. Therefore, IVF already indirectly triggers the two-cycle limit on embryo transfers, even without including it expressly in this subsection. The intent of including IVF within this subsection was simply to clarify that IVF need not be covered if the coverage limit for embryo transfer(s) has already been exhausted, and that clarification belongs in Section 6(5), alongside the existing limit on coverage after the egg retrieval limit has been exhausted. Therefore, this subsection has been revised as follows:

~~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~~;~~.

Comments: RNE, Fertility Within Reach, and CHO all questioned the consistency of the two-cycle limit with the limit of four completed egg retrievals. RNE and Fertility Within Reach both requested deletion of the entire subsection. In addition to their general objection on lifetime limits of any form, RNE commented that "transfers are not one of the higher expenses as part of the IVF process," and that they "strongly recommend that carriers provide unlimited coverage for embryo transfers. This encourages patients to do single embryo transfer when clinically indicated and ensures that patients will not have embryos that they cannot afford to transfer if they wish to do so." In their additional comments, they added that if the limit on egg retrievals is retained, notwithstanding their objections to that limit, they "particularly recommend that there be NO *(emphasis in original)* limit on embryo transfers and that the reference to two lifetime IVF cycles in Section 6 should be removed." Similarly, Ms. Oleaga subsequently commented that limits on embryo transfers "will lead to misguided decisions regarding the number of embryos transferred during any single embryo transfer procedure," with increased risks both to the enrollee or gestational carrier and to the fetuses. She noted further that in her opinion, rather than saving money, it also adds to the insurance carrier's overall expected financial costs.

Bureau Response: If carriers determine that covering unlimited embryo transfers will save more money in the long run than the direct cost of the additional benefits provided, the rule does not prohibit them from providing that coverage. This provision is only relevant if carriers evaluate the costs and benefits of the limitation and anticipate that unlimited embryo transfers will result in a net cost. Because resources are not unlimited, some limitations on coverage are necessary, and a two-cycle limit provides all fertility patients with the opportunity to have fertility treatment covered for two potential pregnancies. Therefore, we have retained the limitation on embryo transfers for the reasons discussed more fully in our response to comments on Section 6(1), above.

Comment: In their additional comments, CHO renewed their concern about the compatibility between this subsection and Subsection 2, asking for clarification whether "we as the carrier would pay for 4 egg retrievals, but not all of the procedures to fertilize and put the embryos back, is this a correct assumption?"

Bureau Response: While it is often the case that an assisted reproductive cycle will begin with a covered egg retrieval, continue with a covered IVF procedures, and culminate in a pregnancy resulting from a covered embryo transfer, there are many reasons why there is not necessarily a one-to-one correspondence in all cases between egg retrievals and IVF procedures, nor between IVF procedures and embryo transfers, and also reasons why one or more of the procedures involved might be out of the scope of the applicable limits.

Comment: Fertility Within Reach objected to including GIFT and ZIFT in this subsection, asserting that these procedures are no longer performed. Other stakeholders have generally requested removing references to these procedures from this rule.

Bureau Response: Even if these procedures were no longer performed or covered going forward, it would still be necessary to clarify that covered procedures performed in the past are within the scope of the applicable lifetime limit.

Comment: GLAD and ASRM asked "Where does a two-cycle limit come from?" and their requested revision to the initial proposal deletes the phrase "two lifetime":

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;

Bureau Response: It is not clear what GLAD and ASRM intended. The deletion of the phrase "two lifetime" is either a clerical error or an unfinished thought – it is not clear whether they simply intended to delete the entire paragraph or were contemplating some substitute language that they did not complete.

New Section 6(4), exemption of non-covered services from charging against lifetime limits

Comment: In the original Proposed Rule, Section 5(5)(B) proposed excluding procedures "where the cost was not covered by any carrier, self-insured health plan, or governmental program" from the provision allowing carriers to exclude coverage for egg retrievals if the patient four has already undergone four completed egg retrievals. Proposed Section 5(5), the general coverage requirement for egg retrievals, has been renumbered as Section 5(8), and as explained in our analysis of Section 5(8), the exemption for prior uncovered egg retrievals has been reallocated to Section 6(4) of the Revised Proposed Rule. Because the concept is not specific to egg retrievals, the Revised Proposed Rule removed the reference to egg retrievals and made this subsection applicable to all lifetime limits. Although we received no comments directly addressing either Section 5(5)(B) of the original Proposed Rule or Section 6(4) of the Revised Proposed Rule, CHO noted in both its initial comments and its additional comments that as used in what are now Sections 6(1) and 6(3). the term "lifetime" is undefined, and they asked whether it refers to life of the policy or the enrollee.

Bureau Response: In the original Proposed Rule, it explicit for egg retrievals, and implicit for the other benefits subject to lifetime limits, that "lifetime" referred to the life of the patient. The Revised Proposed Rule added language clarifying both that "lifetime" has the same meaning for all benefits subject to lifetime limits and that the individual fertility

patient filing the claim is the measuring life for each of those benefits. As proposed in the Revised Proposed Rule, this subsection addresses the ambiguities that were identified and is therefore adopted as follows:

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.

Section 6(5)(B) (Proposed Section 6(3)(C)), excluded egg and sperm donor expenses

Comment: RNE requested that this paragraph be rewritten as follows, to eliminate references to eggs and sperm:

(C) Nonmedical costs of ~~an egg or sperm~~ a gamete donor;

Bureau Response: We have retained the terms "eggs" and "sperm" for the reasons discussed in response to the comments to the definitions in Section 3.

Comment: Harvard Pilgrim asked whether the cost of procurement of donor eggs and sperm must be covered.

Bureau Response: In their letter, they headed this question "Section 4: Coverage Requirements" but then cited this paragraph, which distinguishes between medical and nonmedical costs, in the body of the comment, so we are addressing it here. In general, "procurement" of donor gametes is expressly included in the definition of fertility preservation services at 24-A M.R.S. § 4320-U(1)(D), so reasonable egg or sperm procurement costs must be covered except to the extent that they directly or indirectly pay the nonmedical costs of the donor. That exclusion is expressly permitted by statute, 24-A M.R.S. § 4320-U(4)(B), which excludes "Any nonmedical costs related to donor gametes, donor embryos or surrogacy." To conform to the statute, the Revised Proposed Rule revised this paragraph as follows, and it has also been renumbered because logically, the limited exception for certain medical costs should follow the general exception for nonmedical costs. As adopted, it reads as follows:

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

Section 6(5)(C) (Proposed Section 6(3)(B)), excluded gestational carrier and surrogate expenses

Comments: RNE said the meaning of this paragraph and Paragraph E were unclear and noted that neither exclusion was explicitly permitted by the statute." Harvard Pilgrim, CHO, GLAD, and ASRM also found the proposed wording unclear. Harvard Pilgrim asked whether this exclusion was intended to apply to gestational carriers as well as surrogates. RNE added that an exclusion for "medical" expenses was overbroad "because IVF with a gestational carrier or traditional surrogate IS a covered benefit." *(Emphasis in original)* RNE requested the following revision:

(B) ~~Medical~~ Maternity care services rendered to a ~~surrogate for purposes of childbearing~~ gestational carrier where the ~~surrogate~~ gestational carrier is not covered by the carrier's policy or contract;

GLAD and ASRM requested the following revision:

(B) Medical services rendered to a surrogate for purposes of childbearing where the ~~surrogate~~ gestational carrier is not covered by the carrier's policy or contract;

Bureau Response: We agree that the intent was for the exclusion to apply to both surrogates and gestational carriers, as the terms are defined in this rule, but to apply only to prenatal and maternity care subsequent to a successful fertility procedure. Therefore, the Revised Proposed Rule revised this paragraph and renumbered it as discussed earlier to follow the exclusion for nonmedical expenses. We received no additional comments on this paragraph, which is adopted as proposed in the Revised Proposed Rule:

~~(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;

Section 6(5)(E) (Proposed Section 6(3)(E)), excluded testing kit expenses

Comment: RNE commented at the hearing that this exclusion was unclear as written, and suggested the following revision in the markup they subsequently submitted.

(E) Ovulation kits and sperm testing kits and supplies designed for at home use; and

Bureau Response: The Revised Proposed Rule made the requested revision, with a nonsubstantive stylistic change. We received no additional comments on this paragraph, which is adopted as proposed in the Revised Proposed Rule:

(E) Ovulation kits and sperm testing kits and supplies designed for home use;

Section 6(5)(F) (Proposed Section 6(3)(F)), requirement to try less expensive treatments when medically appropriate

As proposed, this paragraph would have allowed exclusion of IVF, GIFT, and ZIFT if the patient has not used all reasonable less expensive and medically appropriate treatments, or if the patient has exceeded four covered egg retrievals. As we have reviewed the comments on this paragraph and Section 6(3), we realized that different assisted reproductive technologies raise different concerns, and that provisions governing the effect of prior egg retrievals and subsequent embryo transfers are more appropriately placed in their own separate paragraphs. Accordingly, comments on the requirement to try alternative treatments are discussed here in Paragraph F of this subsection, while issues relating to prior egg retrievals are discussed below at new Paragraph G and issues relating to subsequent embryo transfers are discussed below at new Paragraph H.

Comments: RNE, GLAD, and ASRM all requested deletion of this paragraph. GLAD and ASRM said this paragraph conflicts with the statute, but did not articulate the precise nature of the perceived conflict. RNE said in their initial comments that it was not clear how "reasonable" or "medically appropriate" would be decided or by whom, and any limits should be based on current clinical guidelines and the individual patient's medical history. In their additional comments, they urged that this paragraph be revised or removed because "For some individuals, inseminations and other 'less expensive and medically appropriate treatments" are medically indicated, and for others, they are not.'" Ms. Oleaga raised similar concerns, and added that such decisions "should be based exclusively on the medical opinion of the treating physician." Fertility Within Reach likewise asserted that "reasonable less expensive and medically appropriate treatments" should only be determined by the treating physician and "must be based on current medical findings (less than five years old)." They also cited the "FASST" trial as evidence that "certain patients who went straight to IVF and were followed through birth saved medical costs" compared to other patients who began with procedures that are initially less expensive. They proposed the following revision to this paragraph:

(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, excluding frozen embryo transfers."

Bureau Response: General objections to the lifetime limit concept have already been discussed at length and need not be addressed further here. There is no conflict between a requirement to try "reasonable less expensive and medically appropriate treatments" when they are available and a requirement to consider "current clinical guidelines and the individual patient's medical history." Those are precisely how one decides what is reasonable or medically appropriate, and if there are disputes between the carrier and the treating physician over the application of these principles, they can be resolved through the internal appeal and external review processes that are already required by existing law. Making the treating physician the sole arbiter of the reasonableness of the treating physician's recommendations would remove essential checks and balances that are essential to the fair implementation of those procedures. The determination of which medically appropriate alternative is expected to be less expensive in the long run can be a complex calculation involving the varying probabilities of success, and those probabilities of success are appropriately considered in the development of clinical guidelines. In cases where it is clear that the costlier procedure will actually save money in the long run, the carrier has little incentive to waste money on a cheaper procedure with a low probability of success. Therefore, the first part of this paragraph is adopted as proposed, and the remainder is addressed separately below:

(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~~;

Comment: Echoing their comments on what is now Section 6(3), Fertility Within Reach objected that GIFT and ZIFT are no longer performed by reproductive endocrinologists.

As noted earlier, other comments have generally objected to referencing GIFT or ZIFT in the rule.

Bureau Response: For the reasons discussed in response to the comments on Section 5(9) and Section 6(3), the underlying coverage requirement has been retained, when the procedure is within the scope of applicable clinical guidelines and coverage is consistent with the other limitations permitted by this rule. Therefore, we have kept these procedures within the scope of this paragraph.

Section 6(5)(G), exclusion of related procedures after four egg retrievals

Comment: Fertility Within Reach requested continued coverage for frozen embryo transfers after the limit of four egg retrievals is exhausted, explaining that "It is not recommended to transfer poorly graded embryos before moving forward with another egg retrieval. This disrupts timely and appropriate care and potentially placing the patient at risk of miscarriage."

Bureau Response: In the Revised Proposed Rule, we proposed language clarifying that the limit of four egg retrievals should only be considered for procedures "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." However, we realize that this revision was not fully responsive to the comment questioning incentives to transfer poorly graded embryos. If an egg retrieval is not covered because the lifetime limit has been exhausted, there is a fundamental difference between permitting carriers to exclude a subsequent IVF or GIFT procedure using those eggs and permitting them to exclude a subsequent embryo transfer (including ZIFT). The embryo transfer occurs at a different phase in the cycle, it is not inherently linked to a specific egg retrieval, and is subject to its own independent lifetime coverage limit. If a fertility patient still has one or both covered embryo transfers available, and the patient has already undergone one or more IVF procedures, the best outcome for both the patient and the carrier is to permit the use of the most promising available embryo(s), whether the prior IVF procedure was paid for by the current carrier, by a different carrier, or by the patient out of pocket. Therefore, the limitation on prior egg retrievals should only be controlling for coverage of IVF and GIFT procedures, and the limitation on subsequent embryo transfers should be addressed in a different paragraph. Accordingly, the portion of Section 6(5)(F) of the Revised Proposed Rule relating to procedures following ineligible egg retrievals has been renumbered as Section 6(5)(G) and further revised as follows:

(G) In vitro fertilization or gamete intrafallopian tube transfer involving eggs ~~or the resulting embryos when the eggs~~ that were collected ~~after the~~ from a fertility patient ~~has~~ who had exceeded the limit of four covered completed egg retrievals~~.~~; and

New Section 6(5)(H), IVF for patients who have exhausted the limit for covered embryo transfers

As discussed above in response to comments on Section 6(3) and Section 6(5)(F), there should not be a separate limit on IVF "cycles" because IVF is by its nature part of a cycle that includes one or two other lifetime limits, so those limits should be controlling. Cases

where the egg retrieval limit is controlling have been addressed by new Section 6(5)(G), and cases where the embryo transfer limit is controlling are addressed by new Section 6(5)(H), which applies only to IVF because the other procedures enumerated in Section 6(5)(F) remain within the scope of Section 6(3) and as such are already directly subject to the two-cycle limit. As adopted, this paragraph reads as follows:

(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.

Section 6(6) (Proposed Section 6(4)), minimum content of clinical guidelines

Comments: RNE noted that 24-A M.R.S. § 4320-U(3)(E) requires a carrier's clinical guidelines to "cite with specificity any data or scientific reference relied upon." As they interpret this requirement, it "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." They requested the following revision:

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[al] 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.

Fertility Within Reach expressed similar concerns, and urged that "To expedite access to care, patients need to understand why they are denied coverage immediately so they can properly advocate for their access to health care." They requested the following revision:

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, citing current research for each guideline, and make them available to any enrollee upon request.

Bureau Response: We agree that this subsection should be strengthened to reflect the statutory requirement to cite data and scientific references with specificity, but do not believe it is necessary at this time to mandate specific details that go beyond what the statute requires; we will revisit that decision if we discover that carriers are using guidelines written in a manner that has an adverse impact on consumers. The Revised Proposed Rule made the following revisions to this subsection. We received no additional comments on that proposal, which has been adopted as follows:

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, citing with specificity any data or scientific reference relied upon, and make them available to any enrollee upon request.

Section 7, cost defrayal generally

Comments: RNE asserted in their initial comments that "defrayal is not a requirement. It is an ACA provision, but the cost defrayal language is that they 'may be subject to,' not that it is necessary or required." They expressed concern, which they renewed in their additional comments, "that Maine would set a troubling precedent if the state made cost defrayal payments voluntarily." GLAD and ASRM also urged that Section 7 should not be phrased as "default language."

Bureau Response: Defrayal, when it applies, is a requirement, not an option. The title of the governing statute is "STATE MUST ASSUME COST," and it reads as follows *(emphasis added)*:

> A State **shall** make payments--
>
> > (I) to an individual enrolled in a qualified health plan offered in such State; or
> >
> > (II) on behalf of an individual described in subclause (I) directly to the qualified health plan in which such individual is enrolled;
>
> to defray the cost of any additional benefits described in clause (i).[9]

The only discretion the ACA grants the states under this section is how the defrayal payments will be made – to the enrollee or directly to the carrier – and whether or not the state triggers the defrayal requirement at all by choosing to mandate "any additional benefits described in clause (i)"; *i.e.*, mandated benefits that are determined by the federal Centers for Medicare and Medicaid Services (CMS) to be subject to the defrayal requirement because they exceed the requirement to provide coverage for essential health benefits (EHB). We agree, of course, that defrayal payments should only be made when they are actually required, as discussed more fully below in response to comments on Section 7(1).

Comments: Anthem asked us in both their initial and additional comments "to strike Section 7 from Rule chapter 865 and adopt a separate rule to address benefit mandate defrayal. Other mandates may also be subject to defrayal, now or in the future. As a result, the provisions for defrayal should be the subject of separate rulemaking and consistent across all mandated benefits subject to defrayal." MeAHP made a similar comment.

Bureau Response: We will consider whether a separate rule with broader scope than fertility might be needed going forward, but unless and until such a general defrayal rule is adopted, repealing or refraining from adopting Section 7 would be premature.

[9] ACA § 1311(d)(3)(B)(ii), *codified at* 42 USC § 18031(d)(3)(B)(ii).

Section 7(1), contingency of defrayal requirement

Comments: This subsection provides that Section 7 applies "if some or all of the benefits required by this rule are subject to cost defrayal under the federal Affordable Care Act." MeAHP expressed concern that this standard is unclear and creates ambiguity. GLAD and ASRM requested that Section 7 "should be rewritten to avoid default language but instead be written as a trigger if required," and RNE said the rule "should be clear that the cost defrayal outlined in Section 7 would only be done if the federal government *specifically* acts on or enforces the language that is in the ACA. To our knowledge, specific regulations about how these should be calculated or paid have not been promulgated. *(Emphasis in original)* They included a substantially similar comment in their additional comments, and also added: "RNE is grateful that Maine approved funding *in case* cost defrayal is needed, but we feel this should be set aside and cost defrayal should *[sic]* be done proactively until there is more clarity from the federal government about this. This would also enable the state to review actual data of a period of time (ideally at least one full year) rather than using projections." *(Emphasis in original)* Likewise, MHB said they "strongly advise the state not to act unless explicit guidance is received from CMS indicating the necessity of defrayal or outlining the specific requirements of federal law. According to federal law, it is the carrier's responsibility to determine the defrayal cost, and this calculation must be based on an actuarial analysis conducted by a member of the American Academy of Actuaries, with the results reported to the state." And Ms. Oleaga commented: "I urge you to reconsider any inclination to voluntarily repay defrayal costs under the provisions of the ACA as set forth in Section 7. To my knowledge, this is simply not done by any legislature. Perhaps guidance from the legislatures in Massachusetts and New York is advisable on this topic. I am primarily concerned with setting poor precedent in this area."

In the markup submitted with their initial comments, RNE requested the following revision:

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.

Bureau Response: The rule does not call for voluntary cost defrayal. It already contains a clear and precise trigger mechanism in the Proposed Rule at Section 7(2)(D), which requires a determination by the Superintendent, after consultation with CMS, that some or all of the benefits required by this rule are subject to cost defrayal. It would not be appropriate for the State, as a matter of state law, to purport to require the federal government to conduct further rulemaking as a precondition for the State's compliance with its defrayal obligation under federal law, once the State has determined that the obligation exists. We agree that consultation with other states is appropriate, and we have done so. Finally, waiting until the exact payment amount is known before acting to appropriate the funds would increase uncertainty rather than reducing it. As provided in Section 7(3), defrayal payments when required are already based on the carrier's actual cost, not on projections. However, in order to have certainty that funds will be available

when needed, the initial appropriation must rely on projections. This subsection is therefore adopted as proposed.

Comment: MHB directed our attention to a Notice of Proposed Rulemaking that CMS published during our additional comment period,[10] which proposes to give states more flexibility in establishing new EHBs. MHB noted that some relevant provisions of the federal rule are proposed to take effect as early as Plan Year 2025. Accordingly, they "**recommend that the Commissioner defer discussions on the defrayal policy until the final federal rule is released.**" *(emphasis in original)* The relevant paragraphs of the ACS CAN joint letter had some nonsubstantive editorial differences but were the same in substance, and included the same closing recommendation in boldface.

Bureau Response: Even if the risk of cost defrayal went away after the current plan year, Section 7 would still be necessary. Furthermore, the portion of the rule scheduled to take effect in Plan Year 2025 would not put the defrayal question to rest. It is true that beginning next year, CMS proposes repealing the regulation that requires defrayal of all benefits mandated by post-2011 state laws – even if those benefits are included in the State's EHB benchmark plan. However, fertility care is not currently part of Maine's EHB benchmark. Even with the more flexible standards CMS is proposing, it is not clear that it will be feasible to make fertility care an EHB in Maine, and those new standards will not go into effect until Plan Year 2027.

Section 7(1), timing of defrayal

Comments: Anthem, in their additional comments, and MeAHP objected to the language in Section 7(1) which provides that defrayal involves "payment of reimbursement" to carriers, as set forth in more detail in Section 7(3). They both cited CMS guidance calling for defrayal calculations to "be done prospectively to allow for the offset of an enrollee's share of premium and for purposes of calculating the portion of the premium attributable to EHB for the purposes of the premium tax credit and identifying benefits subject to reduced cost-sharing." MeAHP interprets this guidance "to mean that defrayal transfers to carriers should come prospectively based on anticipated premium impact rather than as reimbursement for benefits," and Anthem asserted "that the Affordable Care Act requires defrayal of the premium, rather than costs to the carrier." Although the Revised Proposed Rule proposed no changes to this subsection, the Request for Additional Comments specifically solicited comments about alternatives, including how to structure and implement a prospective reimbursement methodology if we decided to replace the proposed retrospective methodology. The only response we received was from Anthem, which withdrew their earlier comment on this subsection. Anthem acknowledged that the federal regulations were silent about whether reimbursement must be prospective or retrospective, and concluded that the Proposed Rule's approach "does serve to reduce premium and has the advantage of covering actual costs, rather than estimated costs, and we are supportive of the approach."

[10] HHS Notice of Benefit and Payment Parameters for 2025, 88 FR 82510, November 24, 2023.

Bureau Response: The statute, quoted above in response to the general comments on Section 7, requires states "to defray the cost of any additional benefits," not to defray the cost of insurance coverage. It gives states two options: to pay enrollees or to pay carriers. We agree that if a state elects the option to pay enrollees, the natural mechanism for those payments would be premium reimbursement, we have elected the option of making defrayal payments directly to carriers. As CMS has advised, prospective calculations are necessary in order to ensure that defrayable benefits are excluded from premium payments, federal premium subsidies, and federal cost-sharing subsidies. In Maine, those calculations are done through the ratemaking process in accordance with Section 7(4), to ensure that if some or all of the fertility benefits required by this rule are determined to be subject to defrayal, the anticipated cost of those benefits will not be included in the premiums charged for qualified health plans offered on the Marketplace. It should be noted that in Utah, a state that has adopted a general defrayal regulation, that regulation has included a provision that defrayal payments "are paid in arrears" since the regulation was first adopted in 2019. This subsection is therefore adopted as proposed.

New Section 7(2)(D), scope of defrayal

In the course of considering the comments on the defrayal process generally, and ensuring that we do not make payments in cases where no payments are required, we realized that the Proposed Rule and Revised Proposed Rule had omitted one important criterion for benefit defrayability. To the extent that there is overlap between the benefits required by this rule and benefits that were historically part of Maine's EHB package, those benefits are not newly mandated and therefore are not subject to defrayal. We have therefore added a new Section 7(2)(D), which reads as follows:

(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

Section 7(3)(A), calculation of incurred costs

Comments: Anthem requested in both their initial and additional comments that an allowance for indirect costs be included within the reported cost of benefits subject to defrayal, asserting that "reimbursement based solely on the claims costs for covered infertility services will not properly account for additional costs associated with the fertility mandate, such as an increase in multiple births, and the complications associated with such cases, including any increase in neonatal intensive care cases." They also made the same proposal as part of their response to our request to provide comments on how to structure and implement the reimbursement methodology. Fertility Within Reach responded to Anthem's initial comment as follows: "During last week's hearing, Anthem Insurance shared its belief that costs associated with maternity care should be added to the premium costs for fertility healthcare. Insurers calculate maternal care, and they do not subtract the population facing fertility healthcare issues. Therefore, to add maternity to the fertility premium would be to count this population twice." RNE offered a similar response, and also asserted that fertility treatment no longer presents a higher risk of multiple births.

Bureau Response: It is speculative whether the increased utilization of fertility care will result in any material increase in claims costs for other medical services provided to fertility patients, and any such indirect costs would be fully covered under the ACA with federal subsidies available for eligible enrollees. Any indirect costs are appropriately addressed through the ratemaking process in the same manner as any indirect costs that already arise from fertility care currently received by enrollees, or from the medical complications and more complex effects of services that are already within the scope of coverage. There is no federal guidance that would suggest that these types of indirect costs are subject to the defrayal requirement. This subsection is therefore adopted as proposed.

Section 7(3)(A)(2), reporting of claims subject to defrayal

Comment: In both their initial and additional comments, Anthem requested: "In order to ensure the appropriate scope of defrayals under the approach proposed in Rule Chapter 865, we would suggest that the Bureau of Insurance work with carriers and other stakeholders to identify the specific CPT codes and costs that may be include in defrayal calculations." Anthem also made a similar comment in response to our question about the best ways to structure the reimbursement methodology.

Bureau Response: This suggestion is helpful, although the correlation between CPT codes and the requirements of the rule will not always provide definitive answers. If it is determined to be useful, the appropriate place for a list of fertility-related CPT codes would be the reporting instructions, not the text of this rule, especially since any revisions to the list would then require further rulemaking.

Section 7(3)(C), availability of funding

Comments: MeAHP and Anthem both objected to this paragraph, which establishes a contingency process "if legislative funding is less than the aggregate amount of valid reimbursement requests." Anthem noted that federal law clearly requires states to defray the full cost of benefits. Both comments warned of the uncertainty that would be created by making reimbursement contingent on the availability of funds and the harm that would result for both carriers and consumers. MeAHP warned that at the time the comments were submitted. "we are awaiting budget language subject to very recent votes in the Appropriations Committee that may impact defrayal."

Bureau Response: The Revised Proposed Rule would have kept this paragraph in place, with a revision to Subparagraph (3) to clarify that it was intended to place restrictions on compensatory rate increases, not to authorize them. However, in light of legislative action to ensure that defrayal is funded if necessary, we agree that the rule should proceed from the premise that the State keeps its obligations, and not suggest that there might be any alternative to cost defrayal in cases where it is required. Therefore, we have deleted this paragraph as requested:

~~(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~~[11] 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.~~

Section 9, effective date

Comment: Anthem requested postponing the effective date of the Rule until January 1, 2025, and permitting carriers to continue following the interim guidance under Bulletin 467 for Plan Year 2024.

Bureau Response: We agree with the substance of the comment. Although the statute is already in effect for 2024, the carriers' 2024 plan portfolios are already in place and are not governed by this rule. However, the timing issues are better addressed by the approach taken in the Clear Choice rule, Chapter 851, to make the rule effective at the earliest possible date but to defer the applicability date. That was the intent of the additional language in included in the Revised Proposed Rule, but our evaluation of Anthem's comment made us realize that this language is more appropriately placed in Section 2 rather than Section 9, as discussed above in our analysis of Section 2. With the immediate effective date, both the substantive and procedural provisions of the rule will apply to the filings carriers make in 2024 for Plan Year 2025, and the preparations for potential defrayal will also be in effect immediately. Therefore, we have reverted to the original proposed language for Section 9:

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~~.

[11] This language was inadvertently displayed as underlined rather than strikeout text in the published version of the Revised Proposed Rule.