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Mr. Timothy Schott, Acting Superintendent
c/o Karma Lombard
Maine Bureau of Insurance
34 State House Station
Augusta, Maine 04333-0034

Re: Bureau of Insurance Proposed Rule Chapter 865, Standards for Fertility Coverage

Dear Acting Superintendent Schott:

On behalf of Anthem Health Plans of Maine, Inc., d/b/a Anthem Blue Cross and Blue Shield, I would like to submit the following comments with respect to Bureau of Insurance Proposed Rule Chapter 865, Standards for Fertility Coverage.

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.

➢ SECTION 4, COVERAGE REQUIREMENTS

- ***Section 4(1)(A) (p. 3).*** As proposed, this paragraph of the rule limits a carrier's ability to adopt guidelines for experimental fertility procedures to those procedures and treatments related to the diagnosis and treatment of infertility; however, the underlying statute (24-A M.R.S.A. § 4320-U) does not contain such a limitation. The statute defines "experimental fertility procedure" as "a procedure for which the published medical evidence is not sufficient for the American Society for Reproductive Medicine, its successor organization or a comparable organization to regard the procedure as established medical practice." Under the statutory definition, experimental fertility procedures could also include fertility preservation services.
- ***Section 4(1)(B) (p. 3).*** This appears to establish requirements that go beyond the scope of the underlying statute. As proposed, this paragraph requires carriers to look to American Society for Reproductive Medicine (ASRM) or other standard setting organizations to determine who could be credentialed as a participating provider or which out-of-network providers could provide fertility services. Nothing in section 4320-U establishes or contemplates such a requirement; accordingly, we believe that this paragraph should be stricken from the proposed rule. Carriers should be free to determine the criteria for network participation.
- ***Section 4(2) (pp. 3-4).*** As proposed, this subsection provides that a carrier cannot require higher copayments for fertility coverage than the plan specifies for other comparable

specialty services. It further provides that the carrier must pay at least 80% of the cost of the fertility coverage, or the percentage of specified in the plan for other comparable specialty services, whichever is less. We have three concerns with respect to this subsection:

1. It is not clear what constitutes a "comparable specialty service". For example, plans may have cost sharing based upon the type of service or based on the place of service (*e.g.*, office visit, in patient facility, outpatient facility, etc.). As a result, we would suggest that it refer to the highest coinsurance required under the plan, rather than "comparable
2. In addition, this subsection requires that the "carrier must pay at least 80% <u>of the cost of fertility coverage</u>" (*emphasis added*). Member cost shares are applied to an allowed amount, rather than the "cost" of a service. We suggest that this sentence be revised to read "***the enrollee's coinsurance may not exceed the greater of 20% or the highest coinsurance percentage specified in the plan for other services.***"
3. The last sentence of the subsection requires that carriers comply with any cost sharing requirements required by the Clear Choice program. The "Clear Choice program" is not defined and we note that alternative plans offered in the merged market are not required to comply with Clear Choice plan design requirements. As a result, we would suggest revising this sentence to read as follows: "***A carrier 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 applicable cost shares required for Clear Choice plans."***

- ***Section 4(3) (p. 4).*** This subsection proposes to essentially prohibit prior authorization and utilization management, other than those of general applicability and cites as an example if prior authorization is required for all hospitalizations or all surgeries. We would note:

  1. 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. The proposed subsection goes beyond what is required under the rule and exceeds the grant of authority contained in section 4320-U(5), which authorizes the Bureau of Insurance to adopt rules
  2. 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.

3. 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? Similarly, not all treatments or procedures require prior authorization or are subject to utilization management. Would that mean that no infertility treatments or procedures can be subject to such requirements? As noted above, section 4320-U does not prohibit carriers from utilizing prior authorization. We recommend that the Bureau confirm that prior authorization and utilization management can be applied to fertility treatments and procedures as determined by the issuer's criteria.

➢ SECTION 5, REQUIRED BENEFITS

- The list of required benefits is extremely broad and contains some treatments and procedures of questionable value as reviewed by ASRM. For example, in 2022, ASRM issued an opinion in which it stated that "[t]here 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 made the 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."[1]

  Similarly, the proposed rule would require coverage of intracytoplasmic sperm injections (ICSI). Similarly, the proposed rule would require coverage of intracytoplasmic sperm injections (ICSI). ASRM found that ICSI may be of benefit for select patients undergoing IVF but not for all patients.[2]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.

- We would note 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. We would suggest an alternate approach by looking at what is commonly covered today and using that as the basis for

[1] **The role of assisted hatching in in vitro fertilization: a guideline (2022) | American Society for Reproductive Medicine | ASRM,** https://www.asrm.org/practice-guidance/practice-committee-documents/the-role-of-assisted-hatching-in-in-vitro-fertilization-a-guideline-2022/?_t_tags=siteid%3a01216f06-3dc9-4ac9-96da-555740dd020c%2clanguage%3aen&_t_hit.id=ASRM_Models_Pages_ContentPage/_a76a8816-664d-4816-9d70-c18ab72bfda2_en&_t_hit.pos=3, accessed June 29, 2023.

[2] **Intracytoplasmic sperm injection (ICSI) for non–male factor indications: a committee opinion (2020) |American Society for Reproductive Medicine | ASRM,** https://www.asrm.org/practice-guidance/practice-committee-documents/intracytoplasmic-sperm-injection-icsi-for-nonmale-factor-indications-a-committee-opinion-2020/?_t_tags=siteid%3a01216f06-3dc9-4ac9-96da-555740dd020c%2clanguage%3aen&_t_hit.id=ASRM_Models_Pages_ContentPage/_0963e9e3-3584-458b-a45f-c554c77723ba_en&_t_hit.pos=7, accessed June 29, 2023.

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. For example, our small group plans that currently include infertility coverage provide coverage as follows:

- Benefits are available for up to six complete in-vitro fertilization cycles before each live birth, which includes:
  - any combination of standard in-vitro fertilization, such as Al (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.

➢ SECTION 7, BENEFIT MANDATE DEFRAYAL

First and foremost, we would strongly urge the Bureau 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. With respect to the provisions of Section 7 as proposed, we offer the following comments:

- Benefit defrayals must not be subject to availability of funding. Federal guidance clearly states that states must defray the full cost of benefits, not partially as described in 45 CFR 155.170
- Without a full defrayal, carriers cannot accurately price plans amidst uncertainty over whether a benefit will be defrayed due to funding concerns. Furthermore, if carriers are not reimbursed as required, those unreimbursed costs must either be built into the costs of plans purchased by members receiving advanced premium tax credits (APTC) or be borne by those individuals who do not receive APTC and small groups purchasing coverage in the merged market, thereby increasing health insurance costs even further.
- We note that the Affordable Care Act requires defrayal of the premium, rather than costs to the carrier. CMS guidance provides that the calculations should 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 purposes of the premium tax credit and identifying benefits subject to reduced cost-sharing.[3]
- As noted at the public hearing, reimbursement based solely on the claims costs for

[3] Clearance Round 1 FAQ on Defrayal of State Additional Required Benefits 9.19 (cms.gov), https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQ-Defrayal-State-Benefits.pdf

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.

- 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.

Thank you again for the opportunity to provide these comments, and I would be happy to respond to any questions you may have.

Sincerely,

Kristine M. Ossenfort, Esq.
Senior Government Relations Director