ETHICS AND PUBLIC POLICY CENTER

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RE: HHS/DOL/Treasury Proposed Rule, "Excepted Fertility Benefits," RIN 0938–AV94 (HHS), RIN 1210–AC40 (DOL), RIN 1545–BS02 (Treasury)

Dear Secretary Kennedy, Assistant Secretary Aronowitz, and Chief Executive Officer Bisignano:

We are scholars at the Ethics and Public Policy Center (EPPC), and we write to offer public comment in response to the Department of Health and Human Services', the Department of Labor's, and the Department of Treasury's (collectively, "the Departments") proposed rule, "Excepted Fertility Benefits" (Proposed Rule).[1]

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[1] 91 Fed. Reg. 27140 (May 13, 2026), https://www.federalregister.gov/d/2026-09479.

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Our public comment responds to the Departments' request for "comments on the proposal related to the scope of excepted fertility benefits."[2] First, given that the Departments only have "the authority and discretion to specify in regulations additional limited excepted benefits that are similar to" "limited scope dental or vision benefits," the proposed excepted fertility benefits must be limited the treatment of diagnosed infertility. Second, we propose definitions and other specific terms related to the proposed fertility benefits option.

Third, we thank the Departments for proposing to carry out President Trump's Executive Order 14216 through their authority to specify "other similar, limited benefits" and for resisting pressure to use HHS's authority to define essential health benefits, an attempt we believe would have been unlawful and contrary to the President's policy agenda. Fourth, we submit that in the final rule the Departments must undertake and publish a Family Policymaking Assessment as specified in a statutory note to 5 U.S.C. § 601. Finally, we note ways in which this proposal and our recommendations are consistent with the Trump Administration's policy agenda.

I. The proposed excepted fertility benefits must be limited to treatment of diagnosed infertility.

The Proposed Rule anchors the proposed excepted fertility benefits option in the "limited excepted benefits" option outlined in section 9832(c)(2)(A) and (B) of the Internal Revenue Code, section 733(c)(2)(A) and (B) of ERISA, and section 2791(c)(2)(A) and (B) of the PHS Act.[3] As the Departments note, these laws explicitly authorize "limited scope dental or vision benefits" and grant the Departments "the authority and discretion to specify in regulations additional limited excepted benefits that are similar to" the laws' specified benefits plans.[4] Thus, as the Departments recognize, the proposed fertility benefits option must include "a limiting principle that is similar to limited-scope dental and vision excepted benefits for fertility benefits to qualify as … limited excepted benefits."[5]

The Departments have identified the proper legal authority and standard that should govern this proposal. But we do not believe that the fertility benefits option, as proposed, is "similar to" limited-scope dental and vision plans. We therefore do not believe the proposal would, without significant changes, fall under the Departments' delegated authority to create "additional limited excepted benefits."

There are some superficial similarities between the Proposed Rule's "benefits covered" language and the comparable provisions for limited scope dental and vision benefits—

[2] *Id.* at 27147.

[3] *Id.* at 27141.

[4] *Id*.

[5] *Id.* at 27245.

particularly the phrase "substantially all." But it would be shortsighted for the Departments to overlook the history on why the Departments introduced this phrase in 2004.

The "substantially all" language was meant to reassure concerns that limited dental and vision plans were not allowed to cover procedures, even if related to the mouth or eye, that were also covered under typical medical plans. The phrase was meant to clarify that dental and vision plans did not have to exclude such overlap in order to meet the federal definition and qualify for favorable tax treatment.

But the same language here, for a fertility benefits plan, would leave these plans open to abuse. The Departments can and should recognize that the fertility benefits arena is subject to unique political and industry pressures that make it necessary to close the "substantially all" loophole here.

A. "Limited scope" dental and vision plans only cover benefits for treatment of diagnosed medical problems.

We begin with the Departments' own regulatory definitions of limited-scope dental and vision benefits. ***These limited-scope plans are defined not merely by subject matter but by treatment.*** These plans do not cover all "benefits relating to the mouth" or "benefits relating to the eye"; rather, they are limited to "benefits substantially all of which are for ***treatment*** of the mouth"[6] and "benefits substantially all of which are for ***treatment*** of the eye."[7]

The word "treatment" does real legal work. It presupposes that these limited scope plans only cover treatments for diagnosed disorders. A dental plan does not become an "excepted benefit" simply because a service happens to involve the mouth; rather, it must be oriented toward treating a disorder of the mouth. The same is true for vision: a vision plan is not implicated merely because a purchase involves the eyes, it must treat a disorder of the eye. No "limited scope" dental plan would pay for an individual with a properly functioning dental and skeletal structure to get purely cosmetic veneers, because cosmetic enhancement of a healthy mouth is not "treatment" of anything. Likewise, no "limited scope" vision plan covers expensive, non-prescription designer sunglasses for an individual with 20/20 vision. To use the plan, the beneficiary must in every instance have an actual medical problem diagnosed in good faith by a relevant medical professional.

No one is allowed to cheat this "treatment" requirement by failing to participate in the behavior necessary to diagnose a physical issue in need of a treatment. Imagine that someone enrolled in a limited scope vision plan deliberately closed his eyes during a vision exam in order to manufacture a false diagnosis and obtain a covered pair of eyeglasses he did not medically need. No reasonable administrator would consider that a legitimate use of a treatment-based benefit.

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[6] 26 CFR § 54.9831-1(c)(3)(iii)(A) (Treasury); 29 CFR § 2590.732(c)(3)(iii)(A) (DOL); and 45 CFR § 146.145(b)(3)(iii)(A) (HHS) (emphasis added).

[7] 26 CFR § 54.9831-1(c)(3)(iii)(B) (Treasury); 29 CFR § 2590.732(c)(3)(iii)(B) (DOL); and 45 CFR § 146.145(b)(3)(iii)(B) (HHS) (emphasis added).

B. The Departments' "substantially all" threshold was not meant to, and in practice has not, undermined this baseline "treatment" requirement.

Since 2004, the Departments' regulations for limited scope dental and vision plans have stated that "substantially all" benefits in these plans be "for treatment of the mouth (including any organ or structure within the mouth" or "for treatment of the eye."[8] This "substantially all" language also appears in the Departments' proposed definition of scope for excepted fertility benefits, which would be "limited to benefits substantially all of which are for the diagnosis, mitigation, or treatment of infertility or infertility-related reproductive health conditions[.]"[9] As such, we think it is important to remind the Departments of where this "substantially all" phrase comes from and what it does and does not mean in the dental and vision benefits context.

The "substantially all" language in the Departments' "limited scope" definitions was introduced in 2004. Prior to this 2004 final rule, "limited scope dental or vision benefits" had been defined in a 1997 interim final rule as "dental or vision benefits that are sold under a separate policy or rider and that are limited in scope to a narrow range or type of benefits that are generally excluded from hospital/medical/surgical benefits packages."[10]

However, as the Departments recognized in 2004, some raised concerns that this "generally excluded" requirement conflicted with the scope of most existing dental and vision plans:

- Dental plans typically covered "procedures associated with oral cancer or with a mouth injury that results in broken, displaced, or lost teeth," even though coverage for cancer or such injuries was generally covered (and therefore not excluded) by hospital/medical/surgical benefits packages.[11]

- Similarly, vision plans typically covered "benefits for such ophthalmological services as treatment of an eye disease (such as glaucoma or a bacterial eye infection) or an eye injury," even though these treatments were for medical disorders that were generally covered by hospital/medical/surgical benefits packages."[12]

The Departments added this "substantially all" language to their "definitions of limited scope dental … and … vision benefits" to "reflect this market reality."[13] This "substantially all" phrase was not intended as and has not functioned as a limitation on the requirement that all benefits be for "treatment" of a diagnosed medical condition related to the mouth or eye. This language was rather meant to accommodate the reality that procedures for these organs are

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[8] 69 Fed. Reg. 78720, 78734 (Dec. 30, 2004), https://www.federalregister.gov/d/04-28112.

[9] 91 Fed. Reg. at 27145 (emphasis added).

[10] 62 Fed. Reg. 16894 (Apr. 8, 1997), https://www.federalregister.gov/d/97-8275.

[11] 69 Fed. Reg. at 78734.

[12] *Id.*

[13] *Id*.

sometimes the results of broader medical conditions or injuries that are also covered by a general health insurance plan.

In the context of limited scope dental and vision plans, this "substantially all" language appears to have adequately addressed commenters' concerns without destabilizing the insurance market or confusing consumers. Every example the Departments identified in the 1997 preamble is still keyed to an actual diagnosed pathology—cancer, injury, disease, infection. There is no evidence there has been any push from insurers, providers, or beneficiaries to stretch these "limited scope" plans to cover elective, non-diagnostic services as "treatments."

C. Unlike dental and vision benefits, fertility benefits face increased pressure to cover services outside diagnosis.

The same "substantially all" framework, however, would not work for a limited scope fertility benefits plan. That is because the proposed excepted fertility benefits option exists in a wholly different policy environment, one where extending coverage beyond diagnosed pathology is not just a theoretical possibility—it is an explicit and organized goal. It is an active litigation strategy, professional consensus position, and employer benefits trend.

Consider the American Society for Reproductive Medicine (ASRM), the trade and professional association of the fertility industry, which revised its clinical definition of "infertility" in 2023 to include any person who "requires medical intervention … to achieve a successful pregnancy either as an individual or with a partner," regardless of whether that person has any diagnosed reproductive pathology.[14] The ASRM explicitly engineered this redefinition to extend fertility coverage to single people and same-sex couples, whose inability to conceive without medical assistance is rooted first and foremost not in an underlying medical pathology but in their decision not to engage in the act that can lead to pregnancy.[15] The definition is so broad that it would define as "infertile" a married heterosexual couple that wants to become pregnant but is not interested in sexual intercourse with one another, or a single man or woman who wants to have a child.

Some states are already following ASRM's lead. California's SB 729, signed into law in 2024, redefined infertility to include "[a] person's inability to reproduce either as an individual or with their partner without medical intervention" to allow funding of fertility treatments for individuals and same-sex couples.[16] Both the bill's own author and ASRM itself confirmed that

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[14] ASRM Ethics Committee, *Access to Fertility Treatment Irrespective of Marital Status, Sexual Orientation, or Gender Identity*, Fertility & Sterility (2021, rev. 2023), https://www.asrm.org/practice-guidance/ethics-opinions/access-to-fertility-treatment-irrespective-of-marital-status-sexual-orientation-or-gender-identity-an-ethics-committee-opinion-2021/.

[15] *See, e.g.*, ASRM, *Evaluating the Trump Administration's Initiative on IVF* (2025), https://www.asrm.org/advocacy-and-policy/fact-sheets-and-one-pagers/evaluating-the-trump-administrations-initiative-on-ivf/ (urging that fertility benefits "should include single individuals, same-sex couples, diverse racial and ethnic groups, and low-income populations").

[16] S.B. 729, 2025–2026 Reg. Sess. (Cal. 2024).

this change was designed to align California law with ASRM's 2023 definition and extend IVF coverage to single people and same-sex couples.[17]

This is not merely an academic debate. Activists have brought lawsuits seeking to force insurers to cover fertility treatments for beneficiaries who cannot meet traditional diagnostic infertility criteria (which generally require a documented history of unsuccessful heterosexual intercourse). Aetna preliminarily approved a nationwide class action settlement in December 2025 requiring it to cover IVF and other fertility treatments for LGBTQ members; similar suits are pending against other insurers and municipal plans.[18] Litigants and advocates in these cases are explicitly seeking to abolish any diagnostic requirement; they are arguing that diagnostic requirements that structurally exclude them are discriminatory and unlawful.[19]

Meanwhile, employers are already offering, and advocacy groups are already pushing employers to offer, fertility benefits that are explicitly non-diagnostic. A growing share of large employers now cover elective egg freezing for employees with no fertility diagnosis required at all, marketed as a career-planning or lifestyle benefit rather than as treatment for any condition.[20] Fertility industry guidance aimed at employers explicitly urges companies to stop treating egg freezing as "elective" and fold it into standard fertility benefits on equity grounds, not diagnostic necessity.[21]

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[17] Office of Senator Caroline Menjivar, *Governor Signs SB 729, A Victory for Reproductive Justice in California* (Sept. 28, 2024), https://sd20.senate.ca.gov/news/governor-signs-sb-729-victory-reproductive-justice-california (quoting the bill's author's statement that SB 729 "ends the exclusion of IVF coverage, along with discrimination against LGBTQ+ folks by aligning the definition of infertility with the American Society for Reproductive Medicine," and ASRM's statement that the law "expands the definition of infertility to include same-sex couples and single Californians").

[18] *Berton v. Aetna Inc.,* No. 4:23-cv-01849 (N.D. Cal. Dec. 2025) (order granting preliminary approval of class settlement); *see also Goidel v. Aetna Life Ins. Co.*, No. 1:21-cv-07619 (S.D.N.Y. Oct. 14, 2025) (final approval of related class settlement); *see, e.g., Murphy v. Health Care Serv. Corp.*, No. 1:22-cv-02656 (N.D. Ill. filed May 19, 2022) (motion to dismiss denied Oct. 17, 2023); *Briskin v. City of New York*, No. 1:24-cv-03557 (S.D.N.Y. filed May 9, 2024); Kristen Hwang, *Aetna to Cover IVF Treatments for Same-Sex Couples in National Settlement*, CalMatters (Dec. 2025), https://calmatters.org/health/2025/12/aetna-lawsuit-lgbtq-ivf-fertility/ (ASRM's 2023 redefinition of infertility was strategically designed to extend fertility coverage to single people and same-sex couples; this redefinition has since been leveraged to support state mandates, including California's SB 729); Sierra Dehmler, *Does Insurance Cover LGBTQ+ Family Building? Here's What to Know*, Illume Fertility (Aug. 29, 2024), https://www.illumefertility.com/fertility-blog/does-insurance-cover-lgbtq-family-building (last updated Apr. 30, 2026); *Fed. Judge Allows Blue Cross Same-Sex Fertility Treatment Discrimination Suit to Proceed*, Hall Benefits L. (2026), https://hallbenefitslaw.com/federal-judge-allows-blue-cross-same-sex-fertility-treatment-discrimination-suit-to-proceed/ (discussing *Murphy v. Health Care Serv. Corp*., No. 1:22-cv-02656 (N.D. Ill.)).

[19] *Cf.* Rachel N. Morrison, *Avoiding Pandora's Box: Why Federal Nondiscrimination Statutes Do Not Prohibit Health Insurance Coverage Exclusions of Sex-Rejecting Procedures*, 75 Catholic U.L. Rev. 718 (2026), *available at* https://ssrn.com/abstract=5141509 (arguing that the legal theory claiming coverage exclusions of procedures associated with a protected basis are discriminatory is "unsupported in law, unlimited in reality, and unworkable in practice").

[20] Cofertility, *What Employers Offer Egg Freezing Benefits?* (2025), https://www.cofertility.com/freeze-learn/what-employers-offer-egg-freezing-benefits.

[21] The Lucky Egg, *How to Ask Your Employer for Egg Freezing Benefits* (2025), https://theluckyegg.com/2025/09/20/how-to-ask-your-employer-for-egg-freezing-benefits-with-a-script-you-can-

These employers are yielding to certain legal pressures, but the Departments are also required to adhere to the limits on their authority Congress set section 9832(c)(2)(A) and (B) of the Internal Revenue Code, section 733(c)(2)(A) and (B) of ERISA, and section 2791(c)(2)(A) and (B) of the PHS Act.[22] Knowingly leaving a fertility benefits plan open to people regardless of any diagnosed condition would arguably make this option wholly dissimilar from "limited scope dental or vision benefits" and therefore outside the Departments' delegated authority from Congress to create "[s]uch other similar, limited benefits."

II. The Departments should adopt a robust definition of "infertility," adopt concrete mechanisms to enforce this diagnostic requirement, and confirm that employers may adopt ethical safeguards.

For the reasons above, we believe that for practical reasons and legal reasons it is critical that the Departments amend the "benefits covered" definition found in the Proposed Rule to make explicit that, as a condition of payment for any excepted fertility benefit, the plan or issuer must document that the individual beneficiary or the beneficiary's opposite sex partner has received a qualifying diagnosis of infertility or an infertility-related reproductive health condition, consistent with a clinically sound, pathology-based definition of infertility, discussed further below. This approach would close the gap between the Departments' stated treatment-based principle and the broad wording found in the Proposed Rule.

Below we outline principles and proposed definitions for the Departments to consider as you finalize the proposed excepted fertility benefits option.

A. The Departments must define the relevant "diagnosed medical problem," infertility, and must define it by pathology, not by outcome.

Excepted fertility benefits, to be genuinely "similar" to limited-scope dental and vision benefits, must be limited to the treatment of a diagnosed disorder. We submit that the best way to articulate and enforce this treatment-based limit is for the Departments to supply a clinically-sound definition of the disorder being treated. But here we note that though the Proposed Rule refers repeatedly to "infertility or infertility-related reproductive health conditions," the Departments nowhere define "infertility" itself.

This is not a minor gap. It is the single most consequential open question in the rule, because it determines who may access the benefit at all. To fix this problem, the Proposed Rule's broad reference to "infertility or infertility-related reproductive health conditions" needs to be supplemented with a clinically sound definition of "infertility."

There are at present two competing definitions of infertility in the medical community, but the choice would lead to sharply different outcomes for the proposed fertility benefit.

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use/ (arguing egg freezing should not be labeled "elective" because that framing implies it is optional like cosmetic surgery).

[22] 91 Fed Reg. at 27141.

One definition, from the **American Society for Reproductive Medicine (ASRM)**, was discussed above. According to the ASRM's 2023 committee opinion,

- Infertility is defined as, among other things, "the inability to achieve a successful pregnancy" based on a variety of factors, or "the need for medical intervention … to achieve a successful pregnancy either as an individual or with a partner."[23]

- The ASRM's definition specifies that "[n]othing in this definition shall be used to deny or delay treatment to any individual, regardless of relationship status or sexual orientation."[24]

- This definition does not ask whether a couple has engaged in the reproductive act and failed; it asks only whether an individual desires a pregnancy and requires technology to obtain one.

The leading alternative comes from the **International Institute for Restorative Reproductive Medicine (IIRRM)**, "the leading voice in uniting providers and researchers who share a common belief that patients deserve scientifically-based and well researched reproductive health care services that cooperate with and restore reproductive function."[25]

- The IIRRM defines infertility as "a clinical condition that is recognized by the symptom of an inability to conceive through sexual intercourse or to sustain a pregnancy, with that symptom indicating underlying male and/or female pathology."[26]

- Under this definition, a clinical diagnosis of infertility requires that a couple has engaged in fertility-focused intercourse—intercourse timed to the fertile window—for a defined period (six months for women 35 or older, or twelve months of untimed intercourse, or six months of timed intercourse, for women under 35) without achieving pregnancy.

- This definition roots infertility in a demonstrated bodily malfunction: a couple must actually attempt conception through the natural reproductive act before a failure to conceive can be attributed to pathology rather than to the simple absence of the act itself.

Though each definition may have merits for other purposes, **only the IIRRM's definition would render the proposed fertility benefit plan "similar" to existing limited-benefit plans.** As noted above, limited-benefit dental plans are defined not merely by *subject matter* but by *treatment.* The critical threshold question is not whether a beneficiary wants

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[23] Practice Committee, ASRM, *Definition of Infertility: A Committee Opinion* (2023), 120 Fertility & Sterility 1170 (2023), https://www.fertstert.org/article/S0015-0282(23)01971-4/fulltext.

[24] *Id.*

[25] Int'l Inst. for Restorative Reprod. Med., https://iirrm.org/ (last visited July 13, 2026).

[26] Monica Minjeur, et al., *Definition of Infertility and Indications for Fertility Evaluation: Consensus Document*, 2 J. Restorative Reprod. Med. (2026), https://rrmjournal.org/index.php/jrrm/article/view/37.

something included under the plan (veneers, designer sunglasses, or a successful pregnancy), but whether the beneficiary requires treatment for a diagnosed medical disorder.

But the ASRM definition does not identify infertility as the cause of a need for intervention; it defines infertility as the fact of needing intervention to reach a desired outcome. This reverses the ordinary logic of medical diagnosis, under which a disorder is identified by its underlying pathology, and treatment options then follow from that diagnosis. But the ASRM's approach skips this step entirely. According to the ASRM, if a person needs IVF to have a child, even if only because that person does not have a sexual partner, that need alone establishes that the person has "infertility," regardless of whether any bodily malfunction exists.

This so-called "need" has a name: **"social infertility."** The Center for Reproductive Rights defines "social infertility" as **"the inability to reproduce via sexual intercourse due to social factors such as a person's lack of a partner or because of a person's sexual orientation."**[27] But however helpful the term "social infertility" might be in a sociological context, it does not denote any biological dysfunction.

Consider a farmer who seeks a refund from a nursery because his apple tree is barren of fruit, though neither he nor anyone has attempted to pollinate it. Common sense dictates that the obvious absence of the necessary precondition for fruit-bearing is not evidence that the tree itself is diseased.

The same is true for human fertility. The fact that a sexual relationship between two men or two women does not produce a child does not mean that either of their bodies is malfunctioning. Likewise, the fact that a married couple does not become pregnant during one spouse's extended business trip does not signify a medical pathology. Rather, in each case, the couples involved are not using the human reproductive system in a way that would be necessary to test whether it functions properly.

The same logic applies to visual impairment: as with the untested tree, a person who keeps his eyes shut during an exam is not thereby diagnosed as blind. A fertility benefit that is genuinely "similar" to limited scope vision benefits should apply the same diagnostic threshold.

Should the Departments adopt or implicitly incorporate "social infertility" and the ASRM definition as the operative standard for excepted fertility benefits, the consequences would be significant. A single man with no diagnosed reproductive pathology whatsoever would qualify as "infertile" and would be entitled to access expensive, invasive fertility technology—which, given his circumstances, would necessarily include third-party gamete donation and gestational surrogacy to produce a child.

Neither outcome reflects the treatment of a disease or condition; both reflect the use of the benefit to purchase a desired outcome by technological means, a use that would be

[27] Infertility and IVF Access in the United States: A Human Rights-Based Policy Approach (Feb. 2020), Center for Reproductive Rights, https://reproductiverights.org/wp-content/uploads/2020/02/64785006_Infertility-and-IVF-Access-in-the-U.S.-Fact-Sheet_2.5.2020_Final.pdf.

inconsistent with how limited excepted benefits are defined and administered in every other context, including dental and vision care.

To prevent this outcome and preserve the "similar" benefit structure the Departments intend, the Departments should not leave "infertility" undefined, and should not permit plans to rely on ASRM's circumstance-based definition to satisfy the Proposed Rule's "diagnosis, mitigation, or treatment of infertility" standard. Instead, the Departments should reference the IIRRM definition or a substantially similar, pathology-based definition of "infertility" that requires a demonstrated failure to conceive following an adequate period of fertility-focused intercourse between a man and a woman. Doing so would ensure that the benefit is genuinely limited to the treatment of diagnosed pathology, consistent with the Departments' own stated reliance on the dental and vision analogy, and not function as an open-ended subsidy for any individual's preferred path to parenthood.

B. The Departments should adopt concrete mechanisms to enforce the diagnostic requirement.

We have argued that the Departments should anchor the excepted fertility benefit in a pathology-based definition of infertility rather than ASRM's circumstance-based definition. To help enforce this pathology-based definition, the Departments should specify in the final rule how plans and issuers are to apply that definition in practice.

This section proposes four concrete mechanisms the Departments should incorporate into the final rule to achieve this end and ensure that an excepted fertility benefits option qualifies under federal law as a "limited benefits" arrangement" that is "similar" to "limited scope dental or vision benefits."

Taken together, these four mechanisms would convert the diagnostic principle articulated earlier in this comment into administrable regulatory tools. Without such carefully worded, easily enforceable safeguards, we believe that the Departments will not be able to accomplish their goal of limiting excepted fertility benefits to the treatment of diagnosed infertility.

1. Require documented diagnostic fertility testing as a condition of eligibility for ART-level benefits.

The Proposed Rule mentions "diagnostic fertility testing" and notes that nearly one in three respondents to the 2022-23 National Survey of Family Growth indicated that none of the associated costs were covered by their insurance.[28] The Departments should address this gap by encouraging coverage of diagnostic testing. But the final rule should also make such testing a prerequisite before the plan would cover assisted reproductive technology (ART). The final rule should state that, as a condition of coverage for ART—including IVF—the plan or issuer must document that the beneficiary has undergone a diagnostic fertility evaluation consistent with a pathology-based definition of infertility, such as the IIRRM definition discussed above. This requirement would translate the "diagnosis, mitigation, or treatment" language in the proposed

[28] 91 Fed. Reg. at 27154.

benefit definition into an actual, auditable precondition for individual claims, rather than a description that a plan's overall service menu must satisfy in the aggregate.

2. Establish an optional safe harbor that, where clinically appropriate, requires a trial of restorative treatment before any ART referral.

Many disorders underlying infertility—endometriosis, hormonal imbalance, structural abnormalities, male-factor conditions—are treatable through medical or surgical intervention that can restore natural fertility, rather than bypass it. Sequencing patients through diagnosis and, where clinically indicated, a trial of restorative or curative treatment before referring them to ART is not a novel or untested concept; it mirrors standard clinical practice for conditions such as endometriosis, where guidelines generally counsel treating the underlying condition before escalating to more invasive or costly interventions. We recommend that the Departments establish an optional safe harbor under which a plan satisfies the excepted fertility benefit's diagnostic and treatment requirements if it requires (a) a documented diagnostic evaluation, and (b) where clinically appropriate, a trial of restorative or curative treatment, before the plan will cover ART referral. Such sequencing would reduce unnecessary and costly ART utilization, preserve limited lifetime benefit dollars for the full course of a patient's care, and advance the Administration's own stated goal of reducing the number of individuals who ultimately need to resort to IVF by identifying and addressing underlying conditions earlier in the process.

3. Include an illustrative model plan design in the preamble confirming that a restorative-focused benefit qualifies as an excepted fertility benefit.

As described in the Proposed Rule, the anticipated excepted fertility benefits option could cover a wide range of services, "from preventive care to initial treatments to more intensive care." Given this broad definition, plan sponsors may reasonably wonder whether a benefit design that emphasizes restorative and root-cause care, while excluding or tightly limiting IVF, would fit within the Departments' definition. To prevent any such confusion, and the risk that some actors would fail to develop fertility benefit options that the market would welcome, we recommend that the Departments include in the preamble to the final rule at least one illustrative example of a compliant plan design that is restorative in nature, and which excludes IVF or limits it tightly, and confirming expressly that such a plan fully qualifies as an excepted fertility benefit under the final rule. This would signal that restorative, diagnosis-driven care is a paradigm model for the excepted fertility benefit—not merely a peripheral option overshadowed by IVF and other assisted reproductive technologies—and would give risk-averse or ethically motivated employers a clear, administratively simple template to follow.

4. Confirm that plans may adopt differentiated sub-limits within the overall benefit's lifetime dollar cap.

Employer-sponsored dental plans commonly distinguish routine, preventive care from more extensive interventions such as orthodontics, often subjecting the latter to separate, lower sub-limits within an overall plan maximum. We recommend that the Departments confirm, either in the regulatory text or the preamble, that plan sponsors offering excepted fertility benefits may adopt a comparable structure. For example, a plan might establish generous sub-limit for

diagnostic evaluation and restorative or curative treatment, paired with a separate, more constrained sub-limit or a defined number of covered cycles for ART. This approach would preserve the flexibility the Departments have rightly sought to protect for plan sponsors, while ensuring that the overall benefit design remains oriented toward the treatment of diagnosed pathology rather than functioning as an open-ended subsidy for costly, elective technological intervention.

C. The Departments should confirm that plan sponsors may adopt ethical guardrails on assisted reproductive technology.

Above we have offered suggestions on how the Department can explicitly require that access to benefits under an excepted fertility benefits plan access should be conditioned on a diagnosed reproductive pathology rather than mere desire for a child. Here we address a related but distinct question: even for beneficiaries who satisfy that diagnostic threshold, what specific practices may a plan sponsor exclude from coverage? IVF and other assisted reproductive technologies encompass a range of practices that raise serious, well-documented ethical concerns—concerns shared by many physicians, scientists, employers, and ordinary Americans. Many of these objections are rooted in religious convictions, but other moral objections are not religious in nature. All such objections should be honored. The Departments should make clear that plan sponsors remain free to exclude these specific practices from coverage, and that doing so is fully consistent with, not contrary to, the purposes of the excepted fertility benefit.

Several distinct practices commonly associated with assisted reproductive technology warrant particular attention:

- **Creation and destruction of excess embryos.** Standard IVF protocols often involve creating more embryos than will be transferred, with the remainder frozen indefinitely, donated, used for research, or discarded. Many Americans, including many prospective parents, object to protocols that treat human embryos as a byproduct to be created in surplus and disposed of rather than as ends in themselves.

- **Preimplantation genetic testing for eugenic selection.** Genetic screening of embryos is increasingly used not merely to detect serious, life-limiting conditions, but to select or discard embryos based on sex, predicted disability, or non-medical traits such as height, eye color, or predicted intelligence. This raises the same concerns about the instrumentalization of human life and various forms of unjust discrimination that have long animated federal and state policy against sex-selective and disability-selective practices in other contexts.

- **Selective fetal reduction.** Protocols that result in multiple gestation are sometimes followed by abortion procedures to reduce the number of fetuses carried to term, a practice that raises independent ethical concerns distinct from those associated with embryo creation and selection.

- **Commercial surrogacy.** Gestational surrogacy arrangements, particularly commercial arrangements, remain legally unsettled and ethically contested in many states, and plan

sponsors should not be required to underwrite arrangements that conflict with their own convictions or with the law of the states in which they operate.

- **Emerging or experimental technologies, including in vitro gametogenesis.** Emerging technologies that would derive functional gametes from stem cells rather than from a man and a woman's own reproductive cells remain unproven, medically untested in humans, and ethically fraught. Nothing in the final rule should be read to require or encourage plans to cover such experimental technologies.

- **Gamete freezing.** In the Society for Assisted Reproductive Technology (SART) & ASRM's 2012 joint practice guideline, their practice committees cautioned against the use of egg freezing as a solution for age-related fertility decline.[29] Despite this, the use of social egg freezing has exponentially increased, from 4,153 patients in 2014, to 16,436 in 2021.[30] Meanwhile, commercial egg freezing companies such as Cofertility, Genesis Group, and egg banks target young women via emotional social media ads to manipulate them to either donate or preserve their eggs for future use. Companies are also already offering egg freezing as a benefit to attract top female talent, enticing women to bypass their most productive fertile years by giving them a false sense of security that they'll be able to conceive later in life. Despite this, a 2022 study showed most women who tried to become pregnant from cryopreserved eggs did not succeed.[31] It is also an expensive procedure ($10,000-$20,000 per cycle, plus another $5,000-$7,000 to thaw and fertilize the eggs), and carries the serious physical risk of ovarian hyperstimulation. In many of these cases, egg freezing is not used to address current or anticipated reproductive pathologies that may contribute to infertility, but is instead used for social reasons to attempt pregnancy after the age of a woman's natural fertility.

Absent clear guidance, plan sponsors that wish to exclude one or more of these practices—whether for religious, ethical, or business reasons—may face uncertainty about whether doing so jeopardizes the plan's status as a compliant excepted fertility benefit, or exposes the sponsor to claims of discrimination. This uncertainty could discourage sponsors from offering fertility benefits at all, or could pressure sponsors toward broader coverage than they find acceptable simply to avoid regulatory or legal risk. The Departments can resolve this uncertainty at little cost by stating plainly, in the text of the final rule or its preamble, that a plan does not fail to qualify as an excepted fertility benefit merely because it excludes coverage for any of the practices identified above. Such exclusions are no different in kind from exclusions already common in employer-sponsored health plans for other categories of ethically contested, cosmetic, or experimental treatment, and plan sponsors should retain the same latitude here that they exercise elsewhere in benefit design.

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[29] Practice Comms., ASRM & SART, *Mature Oocyte Cryopreservation: A Guideline*, 99 Fertility & Sterility 37 (2013).

[30] Mabel B. Lee, et al., *Elective Fertility Preservation: A National Database Study on Trends in Oocyte Cryopreservation and Oocyte Utilization over a 5- to 7-Year Follow-Up Period*, 234 Am. J. Obstetrics & Gynecology 432, 434 (2025), https://pubmed.ncbi.nlm.nih.gov/40886784/.

[31] Sarah Druckenmiller Cascante, et al., *Fifteen Years of Autologous Oocyte Thaw Outcomes from a Large University-Based Fertility Center*, 118 Fertility & Sterility 158 (2022), https://pubmed.ncbi.nlm.nih.gov/35597614/.

Beyond simply permitting exclusions, the Departments should explicitly allow and even encourage plan designs that favor IVF protocols structured to minimize excess embryo creation, avoid embryo discard, and reduce the risks associated with multiple gestation. Plans that structure their fertility benefits to favor such protocols are not discriminating against beneficiaries or against IVF as a modality; they are making the same kind of considered, values-based coverage decisions that plan sponsors routinely make across every category of health benefit. The Departments should confirm that this kind of ethical benefit design is consistent with, and does not undermine, the purposes of the excepted fertility benefit—and, consistent with the Administration's own stated interest in expanding responsible access to IVF,[32] should treat plans that adopt life-sparing protocols as a model rather than an outlier.

We recognize that one of our recommendations above proposes that the Departments include an illustrative model plan design that limits or excludes IVF coverage, to confirm that a restorative-focused benefit qualifies as an excepted fertility benefit. That recommendation and this section are not in tension: a plan that excludes IVF entirely is one legitimate option that would be consistent with and fit within the Departments' final rule. Just as an employer is free to offer or decline to offer limited fertility benefits, an employer is free to offer such a limited scope plan that excludes IVF altogether in favor of purely restorative care. The Departments can, through the final rule's preamble and regulatory text, clarify that plan sponsors retain maximum flexibility to design a benefit consistent with their own ethical and clinical judgments, while remaining anchored to the diagnostic principle described earlier in this comment.

III. We thank the Departments for resisting pressure to create an IVF mandate through the EHB package.

As we comment on the Proposed Rule, we want to thank the Departments for resisting pressure to declare IVF an "Essential Health Benefit" (EHB) under the Affordable Care Act. In February 2025, President Trump issued his executive order calling on executive agencies to help develop proposals on "Expanding Access to In Vitro Fertilization."[33] A few months later, an article in the New York Times claimed that the Administration was considering declaring IVF to be an EHB and thereby creating an IVF mandate through the Affordable Care Act.[34] However, this would a been a grave mistake, as it would have conflicted with President Trump's caution that his executive order "be implemented consistent with applicable law."

In section 1302 of the ACA, 42 U.S.C. § 18022, Congress gave the Secretary of HHS the authority to define what counts as an "essential health benefit." But Congress also placed important limits on this authority. It said that the "Secretary shall ensure that the scope of essential health benefits … is equal to the scope of benefits provided under a typical employer plan, as determined by the Secretary." 42 U.S.C. § 18022(b)(2)(A).

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[32] Exec. Order 14216, Expanding Access to In Vitro Fertilization, 90 Fed. Reg. 10451 (Feb. 18, 2025), https://www.federalregister.gov/d/2025-03064.

[33] *Id.*

[34] Carline Kitchener, *Inside the I.V.F. Deliberations at the White House as Key Report Nears*, N.Y. Times (May 17, 2025), https://www.nytimes.com/2025/05/17/us/politics/ivf-policy-white-house.html.

This same statutory limitation was a focus of a 2025 HHS proposed rule that rejected suggestions that HHS declare sex-rejecting procedures to be an EHB.[35] HHS noted that "the fact that [sex-rejecting procedures are] typically included in employer-sponsored plans is an independent, sufficient, and legally compelled reason for this rule."[36] As we detailed in our public comment on this proposal,[37] we agree with HHS's legal analysis. We showed in our public comment that Secretary Kennedy has strong grounds to conclude that the typical employer plan does not cover sex-rejecting procedures.[38]

First, according to Kaiser Family Foundation's 2024 Employer Health Benefits Survey, not even the typical *large* employer plan covers sex-rejecting procedures.[39,] Among "firms with 200 or more workers that offer health benefits, 24% cover gender affirming hormone therapy in their health plan with the largest enrollment."[40] Second, the large employer plans covered in KFF's 2024 survey look nothing like the "typical employer plan." According to the Small Business & Entrepreneurship Council, drawing on U.S. Census data, 98.1% of employers have less than 100 employees and 89% of employers have less than 20 employees.[41] The median U.S. employer has between 4 and 5 employees, and we estimate that the "typical employer plan" is likely held by an employer with between 10 and 20 employees.

Our analysis in that April 2025 public comment applies to the IVF context as well. KFF's 2024 survey also shows that the "typical employer plan" does not cover IVF: "Among firms with 200 or more employees that offer health benefits, … 27% provide coverage for in-vitro fertilization (IVF)[.]"[42] Any effort to create an IVF mandate under Secretary Kennedy's authority to define "essential health benefits" would be unlawful under 42 U.S.C. § 18022(b)(2)(A). Moreover, any attempt to designate IVF as an EHB would undercut HHS's argument for clarifying that sex-rejecting procedures may not be included as an essential health benefit. If HHS finalized its Proposed Rule and (as seems likely) is sued on the theory that excluding sex-rejecting procedures is unlawful sex discrimination, it would be hard for HHS to argue that it was required under 42 U.S.C. § 18022(b)(2)(A) to exclude procedures that are

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[35] 90 Fed. Reg. 12942 (Mar. 19, 2025), https://www.federalregister.gov/d/2025-04083.

[36] *Id*. at 12986.

[37] EPPC Scholars' Public Comment on HHS CMS Proposed Rule: "Patient Protection and Affordable Care Act; Marketplace Integrity and Affordability" RIN 0938-AV61, CMS-9884-P (Apr. 11, 2025), https://eppc.org/wp-content/uploads/2025/04/EPPC-Comment-HHS-PPACA-Markeplace-Integrity.pdf.

[38] Consistent with our proposal, we use in this letter "sex-rejecting procedures" instead of the term "sex-trait modifications" used in the Proposed Rule. *See* Eric Kniffin, Mary Rice Hasson & Rachel N. Morrison, *Terminology and Definition: Replacing "Gender-Affirming Care" with "Sex-Rejecting Procedures,"* EPPC (May 9, 2025), https://eppc.org/publication/terminology-and-definition-replacing-gender-affirming-carewith-sex-rejecting-procedures/.

[39] These arguments are made in greater detail on pages 3-6 of our April 11, 2025, public comment, *supra*, note 37.

[40] KFF, *2024 Employer Health Benefits Survey* at 210 (Oct. 8, 2024), https://files.kff.org/attachment/Employer-Health-Benefits-Survey-2024-Annual-Survey.pdf.

[41] Small Business and Entrepreneurship Council, *Facts & Data on Small Business and Entrepreneurship*, https://sbecouncil.org/about-us/facts-and-data/ (last visited April 10, 2025).

[42] KFF, *2024 Employer Health Benefits Survey* at 17.

covered in 24% of large employer plans if it has claimed that EHB plans must include procedures that are covered in 27% of large employer plans.

For all these reasons, we thank the Departments for resisting public pressure to designate IVF as an "essential health benefit" under the Affordable Care Act.

IV. The Departments should conduct and publish a Family Policymaking Assessment.

Beyond the substantive concerns raised above, the Proposed Rule appears to be subject to the Family Policymaking Assessment ("FPA"), a statutory note to 5 U.S.C. § 601 that requires agencies to answer certain questions "[b]efore implementing policies and regulations that may affect family well-being."[43]

The Proposed Rule does not include any assessment addressing these considerations, despite the fact that a rule governing fertility benefits plainly implicates each of them. Few policy areas touch the family more directly than the manner in which children are conceived and brought into the world, and few proposed rules are more squarely aimed at family formation than this one, which invokes President Trump's call to "make it easier for loving and longing mothers and fathers to have children" and "support[] American families in achieving their family formation goals."[44]

The FPA directs agencies to consider, among other things:

- whether a proposed rule "strengthens or erodes the stability or safety of the family and, particularly, the marital commitment";
- whether the rule "helps the family perform its functions, or substitutes governmental [or, here, employer-facilitated] activity for the function";
- whether "the proposed benefits … justify the financial impact on the family";
- whether the action could "be carried out by State or local government or by the family" itself; and
- whether the rule "establishes an implicit or explicit policy concerning … personal responsibility... and the norms of society."[45]

The considerations the FPA identifies are not merely procedural formalities; they bear directly on the substantive arguments raised throughout this comment. Restorative reproductive medicine, unlike IVF, treats infertility by restoring a couple's own capacity to conceive and sustain a pregnancy—helping the family perform its own procreative function rather than substituting an external, technological process for that function. A benefit structure that treats

[43] Treasury and General Government Appropriations Act, 1999, Pub. L. No. 105-277, § 654, 112 Stat. 2681, 2681-528 (1998) (codified as amended at 5 U.S.C. § 601 note).

[44] 91 Fed. Reg. at 27142.

[45] 5 U.S.C. § 601 note (Assessment of Federal Regulations and Policies on Families).

IVF as the default or primary intervention, rather than as one option among several to be pursued after diagnosis and, where appropriate, restorative treatment, risks encouraging exactly the kind of substitution of technological intervention for the family's own function that the FPA directs agencies to consider. Likewise, the financial impact of the benefit on families and on the broader health insurance risk pool—and whether that impact is justified by the benefit's actual contribution to family formation and stability, as opposed to its facilitation of embryo creation and destruction—is precisely the kind of tradeoff the FPA requires the Departments to assess and has not yet assessed.

We recognize that the Proposed Rule notes that states already take varying approaches to fertility coverage. But this observation, if anything, underscores the FPA's relevance rather than diminishes it: the FPA specifically asks whether an action addressed by a federal rule could instead "be carried out by State or local government or by the family," a question the Proposed Rule acknowledges is live but does not answer.

We recommend that the Departments conduct and publish a Family Policymaking Assessment before finalizing this rule, addressing at minimum: (1) whether and how the rule's benefit design affects marital stability and family formation; (2) whether the rule helps families perform their own procreative functions or substitutes technological intervention for those functions; (3) whether the financial impact of the benefit—both on covered families and on the broader risk pool—is justified by its expected effects on family well-being; and (4) whether the goals underlying the rule could be achieved through means that rely more heavily on the family's own capacities, such as the diagnostic and restorative-care mechanisms described in Section IV. Conducting this assessment would not only satisfy the Departments' statutory obligations, but would also sharpen the final rule's benefit design in ways consistent with the diagnostic and ethical principles set out earlier in this comment.

V. These recommendations are consistent with President Trump's agenda.

While the legal and clinical arguments above stand on their own, we highlight below how each of our recommendations also advances the President's stated policy priorities.

The Final Rule should honor President Trump's commitment to following federal law and reining in the administrative state. In Executive Order 14219, President Trump stated, "It is the policy of my Administration to focus the executive branch's limited enforcement resources on regulations squarely authorized by constitutional Federal statutes, and to commence the deconstruction of the overbearing and burdensome administrative state. Ending Federal overreach and restoring the constitutional separation of powers is a priority of my Administration."[46] Consistent with that commitment, the Departments should ensure the excepted fertility benefit regulation is squarely authorized by, and faithfully implements, the

[46] Exec. Order No. 14219, Ensuring Lawful Governance and Implementing the President's "Department of Government Efficiency" Deregulatory Initiative, 90 Fed. Reg. 10583 (Feb. 25, 2025), https://www.federalregister.gov/documents/2025/02/25/2025-03138/ensuring-lawful-governance-and-implementing-the-presidents-department-of-government-efficiency.

statutory text Congress enacted, rather than expanding agency discretion beyond what the "similar" limiting principle permits.

The Final Rule should honor President Trump's commitment to "biological truth." The first day of his term, President Trump issued Executive Order 14168, which promoted "restoring biological truth to the federal government." Pursuant to this executive order, HHS issued a guidance document, "Defining Sex," which sets out "Guidance for Federal Agencies."[47] In that guidance, HHS recognizes that "[r]ecognizing the immutable and biological nature of sex is essential" and "[r]estoring biological truth to the Federal government is critical to scientific inquiry, public safety, morale, and trust in government itself."

There is no more basic biological truth than that it takes a man and a woman to conceive a child. There is nothing more basic than that a relationship between two men or two women, no matter how healthy they are, will not produce child. The same goes for a man or a woman who is not in a sexual relationship, or even a married couple that is not relating sexually. Something more beyond the mere failure to conceive a child is necessary to indicate a medical disorder. This is common sense. It is consistent with President Trump's commitment to "biological truth" to say so in the Departments' final rule.

The Final Rule should reflect President Trump's and Secretary Kennedy's MAHA Agenda. The "Make America Health Again" initiative is a central pillar of President Trump's domestic agenda. Secretary Kennedy likewise has said,

> We must ensure our healthcare system addresses the root causes of disease rather than just managing its symptoms. HHS investments focus on strengthening prevention, expanding timely access to care, and shifting from crisis-driven interventions toward more effective, community-based solutions. This approach improves outcomes, supports recovery, and reduces long-term costs to federal health programs.[48]

This proposal is an ideal opportunity to do just that. Helping Americans understand and restore their fertility is an excellent way to advance the President's and Secretary Kennedy's agenda. At the very least, the Departments' plan should incentivize Americans and our health care system to explore restorative medicine before resorting to expensive, uncertain technologies that raise important moral and ethical concerns.

The Final Rule should reflect President Trump's and Secretary Kennedy's efforts to reduce health care costs. One of the primary goals of President Trump's MAHA agenda is to

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[47] HHS, Defining Sex: Guidance for Federal Agencies, External Partners, and the Public Implementing Executive Order 14168, *Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government* (Feb. 19, 2025), https://womenshealth.gov/sites/default/files/_images/2025/2.19.25%20Defining%20Sex%20Guidance%20for%20Federal%20Agencies%2C%20External%20Partners%2C%20and%20the%20Public%20FINAL.pdf.

[48] Robert F. Kennedy, Jr., Sec'y, U.S. Dep't of Health & Human Servs., Statement Before the H. Comm. on Ways and Means on the President's Fiscal Year 2027 Budget (Apr. 16, 2026), https://waysandmeans.house.gov/wp-content/uploads/2026/04/HHS-Secretary-FY-2027-Budget-TestimonyWays.pdf.

lower healthcare costs.[49] Secretary Kennedy has likewise recognized that "preventing disease costs less and delivers better outcomes than treating it."[50] Requiring a documented diagnostic evaluation before a beneficiary may access assisted reproductive technology, as we recommend above, would reduce unnecessary and costly ART utilization by identifying and treating underlying conditions before beneficiaries incur the substantially higher costs of IVF and related procedures. This and other more technical recommendations outlined in this comment reflect the same principle animating the MAHA agenda: addressing the root cause of a condition is more effective, and less costly, than immediately turning to drugs or surgery.

CONCLUSION

Thank you for the opportunity to provide public comment and for the Departments' careful consideration on these matters.

Sincerely,

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[49] *See, e.g.*, White House, MAHA, https://www.whitehouse.gov/maha/; E.O. 14212, Establishing the President's Make America Healthy Again Commission, 90 Fed. Reg. 9833 (Feb. 13, 2025), https://www.federalregister.gov/d/2025-02871; MAHA Commission, The MAHA Report: Make Our Children Healthy Again: Assessment (May 22, 2025), https://www.whitehouse.gov/wp-content/uploads/2025/05/MAHA-Report-The-White-House.pdf; MAHA Commission, Strategy Report: Make Our Children Healthy Again (Sept. 2025), https://www.whitehouse.gov/wp-content/uploads/2025/09/The-MAHA-Strategy-WH.pdf.

[50] Celine Castronuovo, *RFK Jr. Spars With Democrats Over Fraud, Vaccine Policy (2)*, Bloomberg Gov't (Apr. 15, 2026), https://news.bgov.com/bloomberg-government-news/rfk-jr-touts-preventive-care-to-lower-health-costs-cut-budget.