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Office of Health Plan Standards and Compliance Assistance
Employee Benefits Security Administration
Room N–5653
U.S. Department of Labor
200 Constitution Avenue NW
Washington, DC 20210
Attention: 1210–AC40

Re: Excepted Fertility Benefits, RIN 1210–AC40

To Whom It May Concern:

I. Introduction

On behalf of the United States Conference of Catholic Bishops (the "USCCB"), thank you for the opportunity to comment on "Excepted Fertility Benefits," a proposed rule by the Internal Revenue Service, the Employee Benefits Security Administration, and the U.S. Department of Health and Human Services (the "Departments").

The USCCB appreciates the Departments' recognition of infertility as a serious matter and their intent to support family formation. The Church affirms the deep desire of spouses to welcome children and supports medical efforts to address infertility. At the same time, public policy should not promote practices that undermine the dignity of human life or sever the connection between procreation and the marital act. The USCCB therefore evaluates the proposed rule both positively and critically. These comments focus on ethical integrity, statutory coherence, and administrability.

II. What the Church teaches about infertility.

The profound desire of couples to have children is both good and natural. At its core, it comes from the generative nature of God's love and His first command given to creatures, including humans even before the fall, to "Be fertile and multiply."[1] Experiences of infertility, then, have been a source of profound grief throughout human history. As the Catechism of the Catholic Church notes, "Couples who discover that they are sterile suffer greatly. 'What will you give me,' asks Abraham of God, 'for I continue childless?' and Rachel cries to her husband Jacob, 'Give me children, or I shall die!'"[2]

As pastors, bishops and priests see the pain of so many of their parishioners struggling with infertility. For this reason, the Church supports appropriate pastoral ministries to couples living this experience. "The Church has compassion for couples suffering from infertility and wants to be of real help to them."[3] Though never easy, it seeks their genuine encouragement and consolation. As Pope St. John Paul II reflected on such families, "You are no less loved by God; your love for each other is

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[1] Gen. 1:28.
[2] Catechism of the Catholic Church ("CCC") no. 2374 (quoting Gen. 15:2, 30:1).
[3] United States Conference of Catholic Bishops ("USCCB"), Life-Giving Love in an Age of Technology, 2009.

complete and fruitful when it is open to others, to the needs of the apostolate, to the needs of the poor, to the needs of orphans, to the needs of the world."[4]

The answer, to be sure, is not only spiritual. The bishops support science and medicine to investigate and treat infertility, so long as it does not attempt to do so by ways that violate the dignity of the human person, such as by violating the right to life or the exclusivity of marriage. "Research aimed at reducing human sterility is to be encouraged, on condition that it is placed 'at the service of the human person, of his inalienable rights, and his true and integral good according to the design and will of God.'"[5] "Some solutions offer real hope for restoring a couple's natural, healthy ability to have children. Others pose serious moral problems by failing to respect the dignity of the couple's marital relationship, of their sexuality, or of the child."[6]

III. What infertility is.

Infertility is perhaps best understood not as a condition itself but as a symptom of underlying disease or medical conditions. It is also not simply the inability to have the exact child one wants through one's preferred means.

We recommend that infertility be defined as follows:

> A symptom of an underlying disease or condition within a person's body that makes it difficult or impossible to successfully conceive and/or (in the case of a woman) carry a live child to term where it should otherwise be possible through intercourse with a person of the opposite sex. A diagnosis of infertility often occurs after 12 months of targeted intercourse for women under 35, or after six months for women 35 and older, without the use of a chemical, barrier, or other contraceptive method.

To help establish reasonable limits on the costs, circumstances, and applications of fertility benefits coverage, this definition should be operative in the final rule. The rule should allow coverage of costs of diagnostic services for all plan participants and beneficiaries, but should require demonstration of a diagnosis of infertility (as defined) as a condition of eligibility for coverage of any other services.

IV. The rule should promote coverage of RRM.

We are grateful that the Departments acknowledge that "care options that address the root causes of infertility, allow those who experience infertility a potential path to expand their families"[7] and accordingly, therefore, "clarify that this provision would include benefits for items and services to address underlying medical causes of infertility."[8] As the Departments repeatedly emphasize that employers would have the flexibility under the proposed rule to choose the scope of their benefits and the items and services included,[9] it is important to ensure that employers – and ultimately

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[4] Pope St. John Paul II, Homily at Mass for the Families, Onitsha, Nigeria, Feb. 13, 1982.
[5] CCC 2375 (quoting Congregation for the Doctrine of the Faith, *Donum vitae*, intro., 2, 1987).
[6] USCCB, Life-Giving Love.
[7] 91 F.R. 27143.
[8] 91 F.R. 27145.
[9] *E.g.*, 91 F.R. 27146, 27147, 27159.

beneficiaries – can make meaningful use of that flexibility by affording them the opportunity to know of the full range of possible fertility care that can identify and heal a patient's underlying conditions while safeguarding human life and dignity. Moreover, as the preamble recounts the Departments' commitment in their 2025 FAQs on Affordable Care Act Implementation Part 72 to "encourage" employers' adoption of benefits "including treatments to restore fertility by addressing root causes of infertility... ," the final rule should positively and explicitly include such encouragement and protect pertinent access.[10]

In referencing both the Arkansas and federal Reproductive Empowerment and Support through Optimal Restoration ("RESTORE") Acts,[11] the Departments indicate awareness of approaches to reproductive health that, increasingly, are collectively referred to as "restorative reproductive medicine" ("RRM"). RRM approaches generally recognize that infertility is a symptom of an underlying condition, not a disease in and of itself; and they therefore seek to restore normal reproductive function by identifying and treating its root causes. RRM is not a monolith, and not all who could be considered practitioners subscribe to the nomenclature. Further, its approaches each involve a wide array of possible diagnostics and interventions, depending on the individual patient. Amid this, the definition enacted in the Arkansas law can provide a helpful, if not perfect, point of reference: "'Restorative reproductive medicine' means a scientific approach to reproductive medicine that seeks to cooperate with or restore the normal physiology and anatomy of the human reproductive system without the use of methods that are inherently suppressive, circumventive, or destructive to natural human functions." The law goes on to say that RRM "includes: (i) Ultrasounds; (ii) Blood tests; (iii) Hormone panels; (iv) Laparoscopic and exploratory surgeries; (v) Examinations of a patient's overall health and lifestyle; (vi) Elimination of environmental endocrine disruptors; (vii) Assessment of the health and fertility of a patient's partner; (viii) Natural procreative technology; (ix) Fertility awareness-based methods; and (x) Fertility education and medical management."[12]

We are grateful to see a number of these same services included as examples of those for which benefits may be offered under the proposed rule for the diagnosis, mitigation, or treatment of infertility and infertility-related conditions, and the inclusion of "medically appropriate items or services targeted to address such conditions."[13] We are likewise grateful for a number of conditions that the NPRM recognizes as frequently underlying infertility and requiring treatment that RRM can provide, such as endometriosis (which too often goes undiagnosed), polycystic ovary syndrome (increasingly named polyendocrine metabolic ovarian syndrome), and hormonal imbalances.[14] Though we note the absence of others in that list, such as fallopian tube blockage (which the proposed rule unfortunately only referenced with respect to in vitro fertilization and not actual treatment of the blockage[15]).

RRM is in part distinguished by its being in contrast to approaches that are inclined toward assisted reproductive technologies ("ART"). Curiously, critics of RRM from interested sectors of the medical community sometimes claim that it is not different from what they already do before referring to ART and that it is more-or-less pseudoscience. Presumably, however, both cannot be true

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[10] 91 F.R. 27144.
[11] 91 F.R. 27144.
[12] Ark. Code Sec. 20-16-2603(8), 23-85-137(a)(4).
[13] 91 F.R. 27146-47.
[14] 91 F.R. 27146.
[15] 91 F.R. 27147.

at the same time, betraying the weakness of such critiques. To be sure, much of what an RRM provider does is what other OB/GYNs or, in particular, reproductive endocrinologists should do and may do to a limited extent. Yet in practice, the RRM approaches involve more in-depth, comprehensive, holistic, and individualized diagnostic work (empowered in part by highly detailed cycle charting) than patients typically experience.[16] This in turn informs treatment. Often, that treatment is more cost-effective than other approaches, as the NPRM appears to recognize,[17] though at times surgeries are required.[18] Importantly, RRM does not claim to be a cure-all. Reported success rates vary but are at least as good as ART,[19] and are about one-third for patients for whom multiple rounds of in vitro fertilization ("IVF") have already failed.[20] Even when RRM may not result in a live birth, patients are often healthier and more empowered with respect to their health.

In light of the foregoing, we again applaud the apparent, if somewhat implicit, inclusion of restorative reproductive medicine practices in the proposed fertility benefits. We offer the following suggestions for the final rule to make the benefits even stronger in this regard:

1. The final rule should make explicit that comprehensive, restorative reproductive medicine approaches to identify and heal root causes of infertility can be included as benefits. The proposed triplicate regulatory text describing benefits "for the diagnosis, mitigation, or treatment of infertility or infertility-related reproductive health conditions..., which may include medically appropriate items or services targeted to address such conditions" is a commendable start, but would benefit from more explicit detail as to what the latter would include, in line with the preamble, the RESTORE Acts, and the above analysis.

2. Relatedly, the final rule and the Departments should promote awareness among insurers, employers, and employees about RRM to help them realize access to a range of benefits, as envisioned by the Administration.[21]

3. The final regulations should ensure that patients seeking RRM approaches are able to get them, including across state lines on account of the relatively smaller number of RRM providers. That is to say, if an employer offers a fertility benefit, insurers should not be permitted to define or limit the eligible use of that benefit in ways that would effectively discriminate against RRM approaches, protocols, or providers (such as by covering only shorter consultations or not accommodating a need to find a provider out-of-state).

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[16] *E.g.*, A. Vega, "Woman Finds 'Unexplained Infertility' Caused by 4 Hidden Conditions After Doctors Told Her Nothing Was Wrong," People, May 1, 2026, https://people.com/woman-finds-4-hidden-conditions-causing-her-unexplained-infertillity-exclusive-11962312; M. Kearns, "What I Went Through to Meet My Daughter," The Free Press, July 19, 2025, https://www.thefp.com/p/what-i-went-through-to-meet-my-daughter-ivf-fertility.
[17] 91 F.R. 27143 ("Often, less invasive fertility treatments are more affordable than ART").
[18] M. Duane, MD, and T. Brown, MD, "Restorative Reproductive Medicine for Infertility: A Safe, Effective, Affordable Alternative," FACTS About Fertility, Feb. 27, 2025, https://www factsaboutfertility.org/restorative-reproductive-medicine-for-infertility-a-safe-effective-affordable-alternative/.
[19] *Id. See also* N. Whittaker, MD, "Restorative Reproductive Medicine: A Field Guide to Root-Cause Care," RRM Academy, updated Jun. 18, 2026, https://rrmacademy.org/what-is-rrm/.
[20] Boyle PC, de Groot T, Andralojc KM and Parnell TA, "Healthy Singleton Pregnancies From Restorative Reproductive Medicine ("RRM") After Failed IVF," Front. Med., 5:210 (2018), doi: 10.3389/fmed.2018.00210.
[21] 91 F.R. 27144.

4. Moreover, though we appreciate the flexibility envisioned for employers under the rule, the NPRM also acknowledges that benefits' functionality may be fundamentally at risk on account of likely enrollment patterns and expense.[22] We urge the Departments to consider that this might be partially resolved by encouraging employers and insurers to adopt a sort of sequencing (akin perhaps to step-up therapy) in the design of their benefits, making costly ART a last resort (if included at all) after RRM-informed diagnostics and treatments are tried.

5. The NPRM's appearing to refer to non-ART approaches as "less invasive" and "pre-conception"[23] should be clarified to not exclude exploratory or restorative surgeries, or care to prevent or address recurrent miscarriage that might be considered post-conception, from the available benefits.

V. The rule should exclude coverage of IVF and other non-therapeutic interventions.

a. IVF kills countless children and violates others' rights and dignity.

In contrast to restorative reproductive medicine, in vitro fertilization does not aim to treat the underlying causes of infertility but seeks to bypass them – in a sense, overriding the symptom. The steps of IVF – hyperstimulation of a woman's ovaries, retrieval of eggs, fertilization in a laboratory, and transfer of some of the resulting embryos to her womb – do nothing for the conditions making her or her husband infertile, or for their health.[24] This ought to raise doubt as to whether IVF should be included as an actual "fertility treatment" or "treatment for infertility" in the coverage proposed in the rule at all;[25] and it may be even arbitrary to do so. Of course, there are drugs or procedures in the field of medicine that partially relieve a symptom rather than remedy the cause. Yet even at producing a child who survives, despite great cost, IVF is not particularly effective, with a live birth in only a little over a third of attempts ("cycles").[26] Insofar as Departments indicate that our nation's fertility rate is partly what animates this proposal,[27] it ought to be recognized that IVF coverage does not appear correlated to more births in states that mandate it.[28] This further suggests that the inclusion of IVF may be arbitrary. There are a number of additional considerations with respect to IVF and similar

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[22] 91 F.R. 27162.
[23] 91 F.R. 27143, 27147.
[24] Note, except where otherwise indicated, we use the term "embryo" broadly to include also the human developmental stages of zygote and blastocyst.
[25] *See* 91 F.R. 27147 ("Treatment of infertility may also include IVF ... . IVF is the most commonly used ART procedure and one of the most effective for treating infertility"). *But see* id. and *infra* note 26 on effectiveness.
[26] 91 F.R. 27147 ("In a national report on ART looking at the chance of a live birth, the data showed a 41.7 percent chance of live birth with an intended egg retrieval for women under the age of 35. Between 2004 and 2013, among women ages 18 to 43 using autologous oocytes (i.e. the individual's own eggs), the live birth rate per IVF cycle was 35.5 percent."); Centers for Disease Control and Prevention, "National ART Summary," Assisted Reproductive Technology (ART), December 10, 2024, https://www.cdc.gov/art/php/national-summary/index.html?cove-tab=0 (37.5% of non-"banking" cycles); see also C. Wilson, "IVF success rates peak as only one in four attempts achieve pregnancy," New Scientist, June 25, 2019, at https://www.newscientist.com/article/2207514-ivf-success-rates-peak-as-only-one-in-four-attempts-achieve-pregnancy/.
[27] 91 F.R. 27142, 27153-54, 27160, 27165.
[28] *Compare* state map at Centers for Disease Control, Nat. Ctr. for Health Statistics, "Fertility Rate," Apr. 8, 2026, https://www.cdc.gov/nchs/state-stats/births/fertility-rate.html *with* state map at Resolve: The National Fertility and Family Building Association, "Insurance Coverage by State," https://resolve.org/learn/financial-resources/insurance-coverage/insurance-coverage-by-state/.

technologies that further counsel against its being included as a covered procedure in the proposed excepted fertility benefits. These include the massive toll on embryonic human beings, the commodification of people, and the sanctity of marriage and its import for society.

First, IVF, especially as practiced in the U.S., kills or freezes at least as many preborn children as abortion – at a magnitude of hundreds of thousands or perhaps over a million per year. Because national data on IVF is based on egg retrieval cycles, not numbers of embryos created, the exact toll is unknown. Still, typically multiple fertilized eggs or zygotes – *human beings* – are produced per cycle. A majority stop developing and/or die around this stage.[29] Some surviving "normal" blastocysts are then selected for attempted implantation in a womb and others destroyed or put in inhumane cryopreservation. This selection regularly involves genetic screening for "quality," "grade," or even traits like sex – a dystopian form of modern eugenics that kills those children deemed genetically inferior. It is also increasingly based on artificial intelligence ("AI")-assisted polygenic tests for mere predispositions rather than even actual conditions. If more than one embryo takes in a woman's uterus, "selective reduction" abortion is common. All told, according to the Centers for Disease Control, of 435,426 cycles (again, with most of those cycles each representing multiple human beings created) fewer than 22% resulted in a live birth in 2022 (or 37.5% for non-"banking" cycles).[30] One IVF clinic suggests that someone in their mid-thirties will need about 11 or 12 eggs, 80% of which are mature for fertilization, to achieve one live birth.[31] In consideration of these numbers, promoting IVF thus stands in glaring contrast to this Administration's other pro-life statements and actions.

In a footnote in the preamble, the NPRM clarifies that the scope of fertility benefits that may be offered excludes abortion.[32] This of course makes sense, as abortion is the opposite of fertility care. But this exclusion highlights the core moral problem of including IVF within the scope of benefits: IVF, in practice, involves a form of abortion on a massive scale.

While not the same as death, freezing embryonic human beings is also a profound and terrible violation of their dignity and rights. "*The freezing of embryos ... constitutes an offence against the respect due to human beings*..."[33] "Cryopreservation is *incompatible with the respect owed to human embryos*; it presupposes their production *in vitro*; it exposes them to the serious risk of death or physical harm, since a high percentage does not survive the process of freezing and thawing; it deprives them at least temporarily of maternal reception and gestation; it places them in a situation in which they are susceptible to further offense and manipulation."[34] It may also, in a sense, be likened to putting innocent children in a prison, often abandoned and with no end in sight. And at least

[29] C. Wilson, "Why two-thirds of IVF embryos suddenly stop developing," New Scientist, June 30, 2022, at https://www.newscientist.com/article/2326772-why-two-thirds-of-ivf-embryos-suddenly-stop-developing/.
[30] Centers for Disease Control and Prevention, "National ART Summary," Assisted Reproductive Technology ("ART"), December 10, 2024, https://www.cdc.gov/art/php/national-summary/index.html?cove-tab=0.
[31] BostonIVF, "Understanding IVF Attrition Rates: How Many Eggs Does It Take to Make a Baby?," https://www.bostonivf.com/resources/fertility-support/how-many-eggs-do-i-need-to-retrieve-to-have-a-baby."
[32] 91 FR at 27145.
[33] *Donum vitae*, I.6.
[34] Congregation for the Doctrine ("CDF") of the Faith, *Dignitas personae*, no. 18, 2008 (citing also CDF, *Donum vitae*, I.6).

hundreds of thousands of our smallest brothers and sisters in the U.S. are experiencing this fate right now.[35]

A second fundamental problem with IVF and related technologies thus becomes apparent – regardless of outcome, it commodifies our fellow human beings and treats them like products and property. This is neither cognizant with dignity nor with our nation's principles. To be sure, parents have special rights and responsibilities over their children. Yet a child is still an individual human being. And the nature that places parents over their children is the same nature that informs what the corresponding rights of a child, as a new member of the human family, are. "A child is not something *owed* to one, but is a *gift*. The 'supreme gift of marriage' is a human person. A child may not be considered a piece of property, an idea to which an alleged 'right to a child' would lead. In this area, only the child possesses genuine rights: the right 'to be the fruit of the specific act of the conjugal love of his parents,' and 'the right to be respected as a person from the moment of his conception."[36] Assisted reproductive technology violates that right of human children to come about through the conjugal act, and instead – no matter how sincerely they are loved and desired by the parents – manufactures them through a third-party technological intervention and a financial transaction. It must be said that being conceived by IVF does not make a person have any less dignity than anyone else. All people bear the image and likeness of God and have equal, infinite dignity as a result. It is precisely for that reason that we advocate to protect them and their dignity in all circumstances and stages of life.

The problem of commodification of human beings is compounded in cases involving gamete donation or surrogacy. Here too, the natural rights of the child are violated, including by "infring[ing] the child's right to be born of a father and mother known to him and bound to each other by marriage"[37] and treating him or her like "an object of trafficking."[38] It seems insufficiently considered that, in case of surrogacy in particular, a newborn is created only to be deliberately torn away from the mother whose warmth, voice, and presence was the only bond and life he or she had ever known and grew to depend upon. Surrogacy also objectifies and exploits the gestational mother, "based on the exploitation of situations of [her] material needs."[39] "For, in this practice, the woman is detached from the child growing in her and becomes a mere means subservient to the arbitrary gain or desire of others. This contrasts in every way with the fundamental dignity of every human being and with each person's right to be recognized always individually and never as an instrument for another."[40]

The increasingly global nature of the surrogacy industry further illustrates these concerns. Commercial surrogacy arrangements are regularly marketed across national borders, with foreign

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[35] Mary Pflum, "Nation's fertility clinics struggle with a growing number of abandoned embryos," NBC News, August 12, 2019, https://www nbcnews.com/health/features/nation-s-fertility-clinics-struggle-growing-number-abandoned-embryos-n1040806.
[36] CCC 2378. See also Dicastery for the Doctrine of the Faith, *Dignitas infinita*, no. 48, 2024 ("A child is always a gift and never the basis of a commercial contract.") (quoting Pope Francis, Address to Members of the Diplomatic Corps Accredited to the Holy See, Jan. 8, 2024).
[37] CCC 2376.
[38] *Dignitas infinita*, no. 48 (quoting Pope Francis, Address to Members of the Diplomatic Corps Accredited to the Holy See, Jan. 8, 2024).
[39] *Id*.
[40] *Dignitas infinita*, no. 50. See also nos. 48-49; Pope Francis, Address to Members of the Diplomatic Corps Accredited to the Holy See, Jan. 8, 2024; and Pope Leo XIV, Address to Members of the Diplomatic Corps Accredited to the Holy See, Jan. 9, 2026.

clients seeking gestational services in the United States through specialized agencies and intermediaries, demonstrating how children and reproduction can become objects of international commerce.[41] Thus, as we urge the exclusion of IVF as a "treatment" for infertility in the forthcoming regulations, we necessarily also call for the exclusion of gestational surrogacy and related costs.

The third inherent error in IVF and similar technologies follows. By introducing a third-party into the very act of conception, these practices violate the exclusivity of the marriage bond in its most unique context and unnaturally separate the procreative aspect from the unitive aspect (that is, regarding the unity of the spouses) of the marital act. "Techniques that entail the dissociation of husband and wife, by the intrusion of a person other than the couple (donation of sperm or ovum, surrogate uterus), are gravely immoral. . . They betray the spouses' right to become a father and a mother only through each other. Techniques involving only the married couple (homologous artificial insemination and fertilization) are perhaps less reprehensible, yet remain morally unacceptable. They dissociate the sexual act from the procreative act. The act which brings the child into existence is no longer an act by which two persons give themselves to one another, but one that entrusts the life and identity of the embryo into the power of doctors and biologists and establishes the domination of technology over the origin and destiny of the human person. Such a relationship of domination is in itself contrary to the dignity and equality that must be common to parents and children. Under the moral aspect procreation is deprived of its proper perfection when it is not willed as the fruit of the conjugal act, that is to say, of the specific act of the spouses' union. Only respect for the link between the meanings of the conjugal act and respect for the unity of the human being make possible procreation in conformity with the dignity of the person."[42]

The importance of the integrity between the procreative and unitive purposes of the marital act, and of marriage itself, in the context of assisted reproduction may appear abstract, but is deeply consequential for society. Many social ills, with impacts on families, communities, and even the economy, appear to be exacerbated by our present culture's three-way separation of marriage, sexual relations, and procreation (such as through ubiquitous contraception and no-fault divorce). Over the decades, how we see each other and treat our relationships in this space has degraded, and contributed to widespread fatherlessness and single parenthood, and all its resulting difficulties.[43] To be sure, assisted reproductive technology is distinct in several respects. Yet it still involves the disassociation of procreating children from both sexual relations and the unique, exclusive relationship between the spouses. On top of the aforementioned commodification of children (and donors and surrogates) and treating them like products to be ordered (no matter how well intended) or even discarded, all of this entrenches a problematic public mindset that misconstrues what our closest fellow human beings *are* and what they are *for*, namely that they may be for our own enjoyment (however well-intended) rather than their own inherent good. This in turn weakens family bonds at a conceptual and cultural level (if not necessarily in every practical instance), which are indispensable to a thriving society.

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[41] "Chinese couples come to U.S. to have children through surrogacy," Los Angeles Times, Feb. 19, 2012: https://www.latimes.com/business/la-xpm-2012-feb-19-la-fi-china-surrogate-20120219-story.html; "A mysterious surrogacy mansion, A drug-plagued property. And a criminal known as 'Dragon,'" Los Angeles Times, Oct. 2, 2025: https://www.latimes.com/california/story/2025-10-02/arcadia-surrogacy-case.
[42] CCC 2376-2377 (quoting CDF, *Donum vitae*) (internal quotation marks omitted).
[43] *See generally, e.g.,* Helen M. Alvaré, Putting Children's Interests First in U.S. Family Law and Policy, Cambridge University Press, 2017.

It is worth stressing that couples who turn to IVF usually do so with the most sincere and loving intentions. And we reiterate the bishops' pastoral compassion for, and desire to support, those hurting with experiences of infertility. This includes not just pastoral support but support for medical solutions that authentically heal patients or otherwise assist their ability to conceive with their spouse. Interventions like IVF that violate human life and dignity by killing countless preborn children and involving third-parties in the very act of conception, however, cannot be the answer.

b. Including IVF risks inclusion of other objectionable services.

Including IVF deprives the administration of its best argument for excluding other morally and ethically objectionable procedures. The proposed rule could have drawn a principled line at including therapeutic treatments like RRM and excluding non-therapeutic services like IVF. Instead, the Departments will now have to attempt to distinguish between IVF and other services that, like IVF, simply facilitate reproduction: surrogacy, in vitro gametogenesis ("IVG"), embryo adoption, and so on. Exclusion of costs associated with the services that same-sex couples must use to obtain a child – surrogacy, sperm donation, IUI – will expose the rule to claims that it is unconstitutional or unlawfully discriminates on the basis of sexual orientation.[44]

While it is of course true that the Affordable Care Act ("ACA") does not, as a rule, exclude coverage of non-therapeutic services, fertility benefits present distinct concerns that warrant drawing that line here.

To illustrate, consider coverage of pain management. By its very nature, pain management does not treat the underlying condition causing a patient's pain. It may be covered under the ACA through several Essential Health Benefit categories, including ambulatory patient services, prescription drugs, preventive and wellness services, and chronic disease management.[45] Yet federal law also explicitly distinguishes between pain management and assisted suicide, even though both may involve similar clinicians, medications, and end-of-life services. Congress expressly protected services furnished "for the purpose of alleviating pain or discomfort" while separately prohibiting the use of federal funds for services furnished "for the purpose of causing, or assisting in causing," death.[46] In the ACA exchange context, that restriction may operate where federal premium tax credits, cost-sharing-reduction funds, or other ACA financial assistance would otherwise subsidize assisted suicide. More importantly, the distinction that federal law draws between pain management and assisted suicide demonstrates that, even within a category of services that may otherwise look continuous, moral concerns can define a boundary. Here, the most readily defensible boundary excludes IVF.

c. Inclusion of IVF exposes the entire rule to the argument that it exceeds the Departments' statutory authority.

The statutory provision establishing the category of limited, excepted benefits describes such benefits as follows:

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[44] *See, e.g., Murphy v. Health Care Serv. Corp*., No. 22-cv-2656, 2023 WL 6847105, at *3–4 (N.D. Ill. Oct. 17, 2023); *Berton v. Aetna Inc.*, No. 4:23-cv-01849-HSG, 2024 WL 869651, at *4 (N.D. Cal. Feb. 29, 2024); *Briskin v. City of New York*, No. 1:24-cv-03557 (S.D.N.Y. filed May 9, 2024).
[45] 42 U.S.C. § 18022(b)(1)(A), (F), (G), (I); 45 C.F.R. 156.110(a)(1), (6), (7), (9).
[46] *See* 42 U.S.C. §§ 14402, 18113.

(A) Limited scope dental or vision benefits.

(B) Benefits for long-term care, nursing home care, home health care, community-based care, or any combination thereof.

(C) Such other similar, limited benefits as are specified in regulations.[47]

The residual clause in paragraph (C) does not confer a general authority to exempt any health benefit the Departments regard as socially valuable or insufficiently available in the market. It requires a limiting principle.

Under the familiar canon of *ejusdem generis*, the residual phrase "such other similar, limited benefits" must be interpreted in light of the specific benefits Congress identified: limited-scope dental benefits, vision benefits, long-term care, nursing-home care, home-health care, and community-based care. Each of those categories is both medically discrete and narrow in scope. None is a broad social-policy benefit directed toward facilitating a major life objective. The residual clause therefore authorizes only benefits of a similarly confined character.

A properly confined fertility benefit may be capable of satisfying that standard. A benefit limited to the diagnosis, mitigation, treatment, restoration, or preservation of reproductive function would be bounded by both medical condition and therapeutic purpose. Such a benefit would cover ordinary medical care for reproductive pathology: evaluation of infertility, laboratory testing, imaging, treatment of endometriosis and other infertility-related reproductive health conditions, and so on. That kind of benefit could plausibly be understood as "limited" in the same general sense as other limited excepted benefits: it is confined to a defined class of medical conditions and services.

A benefit directed toward diagnosis and treatment of reproductive dysfunction remains anchored to a medical condition. IVF coverage is different because eligibility turns not on treatment of pathology but on achievement of a desired reproductive outcome. It is an assisted reproductive technology that may bypass, rather than treat, restore, or mitigate, the underlying reproductive dysfunction. Including IVF therefore transforms the proposed benefit from a therapeutic reproductive-health benefit into a broader family-formation benefit directed at producing a child. The Departments themselves repeatedly describe the purpose of the proposal as supporting family formation. But family formation is not a medical condition and treatment for family formation is not a recognized category of healthcare benefit. To the extent the proposed benefit is justified as facilitating family formation rather than treating reproductive pathology, the rule moves beyond the statutory concept of a limited health benefit and into social-policy territory that Congress did not identify in § 300gg-91(c)(2). Further, a rule seeking to facilitate family formation would seem to intrude into areas, such as those implicating parentage and domestic relations, typically governed by state law. Congress would not ordinarily delegate such a policy choice through a residual clause vaguely authorizing "similar, limited benefits."

The proposed $120,000 lifetime cap illustrates the problem of the rule moving beyond the statutory concept of a limited health benefit. The Departments have not identified that amount because it reflects an independent understanding of what qualifies as a "limited" benefit under §

[47] 42 U.S.C. 300gg-91(c)(2).

300gg-91(c)(2)(C). Rather, the cap is driven by the economics of IVF. IVF is expensive, so the Departments have proposed a cap high enough to accommodate IVF. But that reverses the statutory analysis. The statute requires the Departments first to identify a benefit that is similar and limited. It does not allow the Departments to define the benefit broadly, include high-cost ART procedures, and then adopt a very large cap because the chosen services are expensive.

The $120,000 cap is therefore not evidence that the proposed benefit is limited, but rather that the proposed benefit has been defined too broadly. If the Departments confined the benefit to RRM and other therapeutic services directed to reproductive pathology, they could adopt a lower or redesigned cap (such as an annual cap with a rollover) that would more plausibly resemble the modest economic limitations used for other residual-clause excepted benefits. But by including IVF, the Departments have obligated themselves to adopt a cap that approximates the cost of major medical infertility treatment. That undermines, rather than supports, their claim of statutory authority.

The Departments may possess authority to recognize narrow fertility benefits directed toward diagnosis, mitigation, treatment, or restoration of reproductive function. What they may not do is transform that narrow category into a federally sanctioned family-formation benefit encompassing IVF and other assisted reproductive technologies that neither diagnose nor treat reproductive pathology. The residual clause authorizing "similar, limited benefits" cannot bear that weight. The final rule should therefore exclude IVF and other non-therapeutic ART services.

d. The proposed rule's inclusion of IVF is arbitrary and capricious.

The explanation in III.L.1 of the NPRM for how the Departments considered excluding IVF as an excepted benefit, and decided not to, is unpersuasive as it bears certain contradictions that make the decision appear arbitrary.[48] The heading says that the Departments considered including "Only Diagnostic Procedures," but then they go on to describe that option as excluding IVF cycles and covering only "pre-IVF items and services." These are not synonymous, and either ignore or are contrary to other, aforementioned parts of the preamble that recognize non-IVF interventions to treat root causes of infertility after diagnosis. If the Departments, per the header of III.L.1, thought only about diagnostic procedures when considering whether to exclude IVF, then they forgot to include an array of treatments in their considerations.

Further, referring to what would have been included absent IVF as "pre-IVF items and services" either substantially narrows or misunderstands the range of non-ART procedures that should have been considered. "Pre-IVF" erroneously sounds as though IVF is always the best and final option that everything else is oriented toward. But that is not true. As discussed above, RRM approaches to diagnosis and treatment are not oriented toward IVF, are not "pre-IVF," and in fact have at times been used successfully *after* IVF has failed.[49]

Our foregoing recommendation to encourage coverage designs that require a sequence of tests and procedures, along the lines of RRM, before reaching IVF (if IVF is included at all) reflects simply that IVF should never be anyone's first option. To refer to non-IVF items and services as "pre-IVF" is erroneous and/or underinclusive, and suggests that the decision to include IVF in the proposed benefits did not consider all the other options that III.L.1 would otherwise portend. To the

[48] *See* 91 F.R. 27163.
[49] *See* Boyle, *supra* note 20.

extent that this (in addition to other issues noted earlier in our letter) may indicate that the decision to include IVF was made arbitrarily, it is not saved by the fact that Executive Order 14216 specifically called for expanding access to IVF. We are not aware of any precedent that allows an internally arbitrary rulemaking to bootstrap itself into non-arbitrariness solely by invoking the executive order that inspired it, as that would seem to empower presidents to generate and immunize otherwise unlawful regulations.[50]

e. If the final rule includes IVF, it must at least establish guardrails.

The final rule should not include IVF, for the reasons described above. If it does, however, then for the same reasons, especially those in V.a, it must at least establish strict conditions on the circumstances under which IVF (or similar ART) will be covered. We would strongly urge these conditions to at least include the following:

1. Coverage should limit the number of embryos produced per egg retrieval cycle to the number that will be imminently transferred to their mother's womb. These numbers should be kept as low as possible. Limitations like this are not unheard of and have existed, for example, in countries like Germany and Italy.[51]

2. Destruction or disposal of embryos must not be covered.

3. Reduction (i.e. abortion) of embryos that have implanted must not be covered.

4. Genetic screening to be used in the selection of embryos before or after implantation must not be covered.

5. Informed consent requirements must be in place to communicate clearly IVF's low success rates; health risks both to children, including those who are born alive as a result of it, and to mothers; and existence of alternatives like restorative reproductive medicine. This could be one of the appropriate ways to implement our recommendation #2 in section IV of this letter, about promoting awareness of RRM.

6. Per our recommendation #4 in section IV of this letter, coverage of IVF or ART could be subject to an encouragement on employers to require the use of RRM-informed diagnostics and treatments first. This could also include the provision of information on charting and fertility awareness-based methods to assist and empower patients and their spouses in the diagnostic process.

7. Lastly, IVF itself must only be covered when the plan participant or his or her spouse has received a medical diagnosis of infertility, as described in section III of this letter, and not

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[50] Further, as noted above, the NPRM excludes abortion from the scope of benefits that may be offered, but includes IVF, which involves abortion. The agencies do not explain why the rule excludes abortion of children in utero but permits abortion of children in vitro. At least from a moral perspective, this is arbitrary and capricious at the most basic level – a fundamental, unexplained inconsistency in the rule.

[51] Amanda Mansfield, "The Treatment of Human Embryos Created through IVF: The U.S. and 15 Selected Countries' Regulations," Charlotte Lozier Inst., November 22, 2024, https://lozierinstitute.org/the-treatment-of-human-embryos-created-through-ivf-the-u-s-and-15-selected-countries-regulations/.

> for selective screening or other purposes. IVF is the platform on which the newly available service of polygenic embryo screening has been built, creating an incentive to use IVF even when natural conception is possible.[52] Polygenic embryo screening promises parents the ability to choose an embryo not only on factors like genetic disposition to certain diseases or conditions, but also on traits like height, eye color, and intelligence. Of course, another way to say this is that it promises parents the ability to abort or freeze embryos based on the traits that they don't want. The Departments should at least ensure that IVF is only used when a couple cannot conceive naturally, understood in accord with the definition offered in section III of this letter.

To the extent possible, all of the foregoing conditions and limitations on coverage should not just limit what expenses are covered within a cycle, but should prevent coverage for part of any cycle where the proscribed aspects of procedures are used (even if those non-covered aspects are paid for by other means).

f. The rule should explicitly exclude coverage of other non-therapeutic services.

The NPRM describes the scope of permissible coverage as follows:

> [F]ertility benefits would be recognized as limited excepted benefits when coverage is limited to benefits substantially all of which are for the diagnosis, mitigation, or treatment of infertility or infertility-related reproductive health conditions and substantially all of which are provided by medical professionals authorized to practice under applicable law.[53]

It then suggests that the scope should be construed broadly: "These proposed rules are generally intended to provide employers and health insurance issuers with flexibility to cover a broad spectrum of treatments and interventions for fertility-related and pre-conception care as part of the excepted fertility benefit."[54]

Besides abortion, the NPRM does not explicitly exclude coverage of any service that might plausibly be characterized as fertility-related. Especially in light of the preamble's suggestion that the benefits are intended to be broad in scope, such exclusions are essential. Current and near-future services and technologies in the fertility industry pose grave threats to human dignity. The rule should, at a minimum, explicitly exclude surrogacy, donor gamete and embryo procurement, embryo selection, preimplantation genetic testing ("PGT"), sex selection, elective fertility preservation, IVG, mitochondrial replacement, germline editing, reproductive cloning, artificial womb services, embryo adoption and all services ancillary to those excluded services.

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[52] Anna Louie Sussman, *Should Human Life Be Optimized?*, N.Y. Times (Apr. 1, 2025), https://www.nytimes.com/interactive/2025/04/01/opinion/ivf-gene-selection-fertility.html ("Today [polygenic embryo screening] is an expensive procedure offered to patients undergoing in vitro fertilization, *who are often but not always infertile couples seeking treatment*. But Ms. Siddiqui…envisions such comprehensive screening eventually replacing the old-fashioned way of having children altogether. 'Sex is for fun, and embryo screening is for babies,' she said in a video she shared on X. 'It's going to become insane not to screen for these things.'") (emphasis added).
[53] 91 FR at 27145.
[54] 91 FR at 27147.

Recent investigations into commercial surrogacy arrangements highlight the practical risks inherent in treating reproductive services primarily as market transactions. Allegations involving large-scale surrogacy operations, the recruitment of women to carry children for others, and questions concerning the welfare and legal status of resulting children, underscore the wisdom of drawing clear regulatory boundaries around surrogacy-related services and refusing to characterize them as treatment for infertility.[55]

g. The rule should exclude embryo adoption as a treatment for infertility.

As mentioned above, the inclusion of IVF in this rule would further promote an unavoidable consequence: the indeterminate freezing of preborn lives. Many are aware "that a grave injustice has been perpetrated and wonder how best to respond to the duty of resolving it."[56] The Church has not offered a definite solution, and we do not attempt to provide one here.[57] The rights the family, however, must be acknowledged because they flow from natural law governing the order (and proper ends) of marriage, sexual relations, and procreation, the practical importance of which we have discussed above. The question of embryo adoption cannot be separated from this reality, nor the profound ethical and legal implications that it entails.

By transferring an embryo into the womb of a woman, to whom that child is not genetically related to, nor naturally conceived by the marital act, the right of the married couple to become a mother and father only through each other (the unity of marriage) is violated.[58] Too, the nature of embryo adoption fails to fulfill the moral requirement "that the procreation of a human person be brought about as the fruit of the conjugal act specific to the love between spouses," a right that is owed to the child.[59] The infertility experienced by a married couple, which understandably can be a source of great pain and sorrow, "does not confer upon the spouses the right to have a child, but only the right to perform those natural acts which are *per se* ordered to procreation."[60]

The Church affirms that "[t]he proposal that these embryos could be put at the disposal of infertile couples as a *treatment for infertility is not ethically acceptable* for the same reasons which make artificial heterologous procreation illicit as well as any form of surrogate motherhood; this practice would also lead to other problems of a medical, psychological and legal nature."[61] (emphasis added).

Embryo adoption has been sought by couples who struggle with infertility and/or intend to give an embryo a chance to be born, who would otherwise be destroyed. Yet, "[t]his proposal, praiseworthy with regard to the intention of respecting and defending human life, presents however various problems not dissimilar to those mentioned above."[62] Still, though similar, serious concerns

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[55] "21 children removed from Arcadia home after couple accused of tricking women into surrogacy," Los Angeles Times, July 17, 2025: https://www.latimes.com/california/story/2025-07-17/arcadia-babies-taken-surrogate-mothers-investigation.
[56] *Dignitas personae*, no. 19.
[57] *Id*. ("All things considered, it needs to be recognized that the thousands of abandoned embryos represent a situation of injustice which in fact cannot be resolved.").
[58] *Id*., no. 12.
[59] *Id*. On the rights of the child, see *Donum vitae*, II. A. 1, 8, 1987.
[60] *Donum vitae*, II.A.8.
[61] *Dignitas personae*, no. 19.
[62] *Id*.

may continue to be discerned in that scenario, embryo adoption as a "treatment for infertility" is wholly unacceptable, as, among other things, it makes a child a means to an end for adults. It should, therefore, be excluded from the fertility benefits.

Embryo adoption is at times also utilized by same-sex couples. In the case of a male couple, a surrogacy agreement is contracted with a third party, whereas a female couple may choose to function as surrogate between themselves. In either case, the procedure necessitates the use of surrogacy to bring forth the child into the world, who is consequently deprived of having both a mother and father. This raises grave legal, ethical, and social concerns, some of which have been discussed elsewhere in this comment.

Additionally, embryo donation or embryo "adoption," as it is commonly referred to, in the United States is generally governed by contract and property law, not family law. In this context, preborn children are legally considered property, not human beings. Children then become the basis of a commercial transaction, which fails to consider their best interests over the desires of the contracting parties.

Thirty years ago, Pope St. John Paul II appealed for an end to the production of human embryos, "taking into account that there seems to be no morally licit solution regarding the human destiny of the thousands and thousands of 'frozen' embryos which are and remain the subjects of essential rights and should therefore be protected by law as human persons."[63] On behalf of the bishops of the United States, we reiterate that same appeal today. We also urge you to explicitly exclude the further commodification of children through embryo adoption as a "treatment" for infertility.

VI. The rule should facilitate the conception of children within the context of marriage.

Reflecting on "the 'indispensable' contribution of marriage to society," Pope Francis more than once affirmed that "[c]hildren have a right to grow up in a family with a father and a mother capable of creating a suitable environment for the child's growth and emotional development."[64] The presence of both a mother and a father is crucial to persons' "[c]ontinuing to grow up and mature in a correct relationship represented by the masculinity and femininity of a father and a mother and thus preparing for affective maturity,"[65] as is their being "bound to each other by marriage."[66] These principles arise not only from revelation but from nature, wherein the union of a man and woman is the only way that a child comes into being, and all children are born with such radical (and lengthy) dependency that sustained support both in addition to and *for* a mother are needed. Thus the family, itself founded on marriage, becomes the first and vital cell or building block of civilization.[67] Even today, the practical importance of marriage is apparent as it, on average, is a powerful factor in the strength of a family's (and ultimately even a community's) socioeconomic prospects and outcomes.

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[63] *Id*. *See also* John Paul II, Address to the participants in the Symposium on "Evangelium vitae and Law" and the Eleventh International Colloquium on Roman and Canon Law, no. 6. 1996.
[64] Pope Francis, Address to Participants in the International Colloquium on the Complementarity Between Man and Woman," Rome, no. 3, Nov. 17, 2014. See also Pope Francis, Address to Members of the International Catholic Child Bureau, Apr. 11, 2014.
[65] Pope Francis, Address to Members of the International Catholic Child Bureau, Apr. 11, 2014.
[66] CCC 2376.
[67] Pope St. John Paul II, *Familiaris consortio*, no. 42, 1981 (citing Second Vatican Council, *Apostolicam actuositatem*, no. 11).

All of this being the case, then, the proposed fertility coverage should both define infertility with respect to the inability to procreate with someone of the opposite sex, such as described above in section III of this letter, in recognition of its medical and biological bases, and not extend benefits beyond oneself and a dependent spouse.

VII. The rule should protect religious liberty and conscience rights.

We appreciate that the NPRM appears to indicate that employers can exclude IVF (or any other particular service) from the benefits they offer. For instance, the preamble emphasizes that a goal of the Departments is "preserving flexibility for employers to design and offer their benefits in a way that is tailored towards their workforce…".[68] And the rule text offers an example of a compliant plan that appears to cover only fertility counseling, not IVF.[69] However, the final rule should explicitly clarify that employers who offer coverage of fertility services as an excepted benefit are free to exclude any fertility service from that coverage, including IVF.

The final rule should also expressly recognize the right of religious and mission-oriented employers to limit benefits to married couples (that is, a married man and woman). The Supreme Court has affirmed both the right under the Religious Freedom Restoration Act ("RFRA") for religious employers to exclude coverage that would substantially burden their religious exercise and also the ability of federal agencies to proactively accommodate that right.[70]

Finally, the final rule should provide a mechanism for employees of organizations that include IVF, or any other objectionable service, to avoid subsidizing that service through their participation in the plan. The Departments could adopt a mechanism modeled on ACA § 1303, 42 U.S.C. § 18023(b)(2)(B)–(C), and 45 C.F.R. § 156.280(e)(2)–(3).[71] If a fertility excepted-benefit plan covers IVF or other excluded ART services, the issuer should be required to identify the actuarial value of that coverage, collect a separate premium amount only from enrollees who elect that coverage, and deposit those amounts into a segregated account used exclusively to pay claims for those services. This would allow objecting employees to participate in a fertility benefits plan without violating their conscience.

VIII. Recommendations and conclusion

In summary, we respectfully offer the following observations and recommendations:

1. The final rule should adopt, as a limiting principle, the requirement that covered services must be therapeutic/restorative in nature. This would entail an exclusion of non-therapeutic interventions like IVF, surrogacy, and other forms of ART.

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[68] 91 FR at 27146.
[69] 91 FR at 27172.
[70] *Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682 (2014); *Little Sisters of the Poor Saints Peter and Paul Home v. Pennsylvania*, 591 U.S. 657 (2020).
[71] Reference to the ACA's separate payment and segregated funding model for comparison, however, should not be taken as support for that model in its own context of abortion and qualified health plans, where it circumvents the Hyde Amendment, which would not apply to the proposed limited excepted benefits because they are not subsidized by federal taxpayer funding.

2. The final rule should adopt a definition of infertility that determines infertility by reference to ability to conceive through intercourse with a person of the opposite sex.

3. Benefits should be limited to the plan participant and his or her beneficiary spouse.

4. Non-diagnostic services should be available only after a medical diagnosis of infertility for the plan participant or his or her beneficiary spouse.

5. The final rule should promote benefit design that favors restorative care.

6. The lifetime cap on benefits should be recalibrated or redesigned based on therapeutic/restorative treatment costs, not on the costs of IVF or other ART.

7. The final rule should clarify that no employer, having chosen to offer fertility benefits, must cover any particular service, and should proactively protect the religious liberty and conscience rights of employers and employees.

The proposed rule represents a valuable opportunity to advance real solutions to infertility that respect the God-given dignity of parents and of children, born and preborn. We urge the Departments to refocus the rule on therapeutic, restorative treatments, and to abandon its inclusion of IVF, which is profoundly flawed both legally and morally.

Thank you for your consideration of these comments.

Respectfully submitted,

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