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July 13, 2026

U.S. Departments of Labor, Health and Human Services, and Treasury
C/O 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: Department of the Treasury, Internal Revenue Service, 26 CFR Part 54, [REG-118484-25] RIN 1545-BS02;
Department of Labor, Employee Benefits Security Administration, 29 CFR Part 2590, RIN 1210-AC40;
Department of Health and Human Services, 45 CFR Part 146 [CMS-9879-P] RIN 0938-AV94

Dear Secretaries:

The National Catholic Bioethics Center, the Catholic Medical Association, and the National Association of Catholic Nurses, USA write in response to the Call for Comment on the Proposed Rule, *Excepted Fertility Benefits*.[1]

The National Catholic Bioethics Center (NCBC) is a non-profit research and educational institute committed to applying the moral teachings of the Catholic Church to ethical issues arising in health care and the life sciences. NCBC provides consultations to institutions and individuals seeking its opinion on the appropriate application of Catholic moral teachings to these ethical issues. NCBC has a membership of over five hundred members, a number of whom are institutions representing thousands of healthcare professionals. Increasingly, with the documented increase in infertility as cited in the Proposed Rule, NCBC through its consultation service hears of the tragedy of unsuccessful infertility treatments. Many current interventions, rather than focusing on Restorative Reproductive Medicine (RRM) and treating the preexisting causative pathology, focus on expensive, and often unsuccessful "work arounds" such as

[1] 45 CFR Part 146 [CMS-9879-P] RIN 0938-AV94; 29 CFR Part 2590, RIN 1210-AC40; 26 CFR Part 54, [REG-118484-25] RIN 1545-BS02.

invitro fertilization (IVF), which itself can cause pathology in both the mother and child.[2] NCBC wishes to advocate for true health care provided by RRM.

The Catholic Medical Association (CMA) is a national, physician-led community that includes as members about 2500 physicians and healthcare professionals nationwide in all fields of practice. CMA represents faithful Catholics in the healthcare field so that its members can grow in faith, maintain ethical integrity, and provide excellent healthcare in accordance with the teachings of the Catholic Church.

The National Association of Catholic Nurses, USA (NACN-USA) is a non-profit organization of nurses from diverse backgrounds and specialties. NACN-USA shares the ministry of Catholic Nursing which advocates for human rights of vulnerable populations, including vulnerable couples seeking to participate in our Creator's sacred plan of engendering new life, as well as the child who is a sacred gift to those parents, not a commodity engineered into being at great personal risk.

A number of CMA physicians are board certified in obstetrics and gynecology, and a number of NACN-USA nurses including nurse scientists, maternal-child health epidemiologists, advanced practice nurses, and nurses are certified across the spectrum of women's health. These physicians and nurses witness firsthand the suffering caused by infertility. Increasingly these professionals are relying on the scientifically defensible benefits of RRM in treating infertility at its root causes. CMA and NACN-USA can attest that RRM is a highly successful, and cost-effective means of treating infertility,[3] and treats infertility without creating new pathologies to the mother and the child, which do occur with in vitro fertilization.[4]

Definition of Infertility - NCBC, CMA, NACN-USA Support the Following

The Proposed Rule does not define "infertility," leaving benefit eligibility ambiguous. Thus, we propose:

Infertility means a symptom of an underlying disease or condition within a person's body that makes it difficult or impossible to successfully conceive and carry a live child to term where it should otherwise be possible through intercourse with a person of the other sex. A diagnosis of infertility often occurs after 12 months of targeted intercourse (without the use of a chemical, barrier, or other contraceptive method) for women under 35, or after six months of targeted intercourse for women 35 and older (without the use of a chemical, barrier, or other contraceptive method).[5]

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[2] Mayo Clinic, "In vitro Fertilization: Risks" (Sept. 1, 2023). https://www.mayoclinic.org/tests-procedures/in-vitro-fertilization/about/pac-20384716. Also, Roswell Park Comprehensive Cancer Center, "Ovarian Cancer Risk Factors" (Accessed January 25, 2024). https://www.roswellpark.org/cancer/ovarian/what-ovarian-cancer/risk-factors#:~:text=Some%20studies%20found%20that%20women,to%20infertility%20or%20the%20drug. Also, Secretariate of Pro-Life Activities, "In vitro Fertilization: the Human Cost," U.S. Conference of Catholic Bishops (2025). IVF_Human_Cost_2025.pdf.

[3] PC Boyle, *et al*, "Healthy Singleton Pregnancies From Restorative Reproductive Medicine (RRM) After Failed IVF," *Front Med: Lausanne* 5 (July 31, 2018) 210. doi:10.3389/fmed.2018.00210; JB Stanford, *et al,* "Outcomes from treatment of infertility with natural procreative technology in an Irish general practice," *J Am Board Fam Med* 6 (Nov-Dec 21, 2008) 583.

[4] Mayo and Roswell Park, Supra note 2.

[5] Adapted from, Department of Labor/HHS/Treasury Tri-Agency Proposed Rule, *Federal Comment Strategy Guide*: *Excepted Fertility Benefits* (May 10, 2026). Supra note,1.

Benefits of Restorative Reproductive Medicine (RRM)

In referencing both the Arkansas[6] and federal *Reproductive Empowerment and Support through Optimal Restoration Act (RESTORE)* Acts,[7] the Departments indicate awareness of approaches to reproductive health that increasingly are collectively referred to as "restorative reproductive medicine." Since RRM utilizes an individualized approach, it helps each person address their unique underlying causes of infertility. Infertility is not an isolated disease, but a symptom of underlying reproductive health conditions. By focusing on the whole person, RRM improves overall health and increases fertility potential. RRM seeks to identify, diagnose, and treat the root causes of infertility, restoring normal reproductive function where possible. Research-backed benefits of RRM include: optimizing an individual's overall health and longevity; removing barriers to successful implantation and pregnancy; reducing risk of miscarriage and adverse pregnancy outcomes; empowering of individuals with better knowledge about their reproductive health; and strengthening an individual's agency in their family planning decisions.[8]

RRM works prior to and alongside other efforts to improve a couple's chances of conceiving. Treatments may include ultrasounds, blood tests, hormone panels, laparoscopic and exploratory surgeries, examining overall health and lifestyle, eliminating environmental endocrine disruptors, and assessing the health and fertility of the individual's partner.[9] Natural Procreative Technology (NPT), including fertility education (e.g., fertilization awareness methods), has been shown to be effective. There has been a demonstrated association with "…a notably high take-home baby rate in an infertile population with unfavorable prognostic factors, including advanced maternal age, prolonged duration of infertility, or previous failed attempts at conventional ART procedures."[10] RRM also treats other difficult symptoms: hormonal acne, weight gain, mood/depression, painful periods, bloating, inflammation, heavy/irregular periods, nerve pain, bowel symptoms, pain during intercourse, and back pain.[11]

NCBC, CMA, and NACN-USA support the health enhancing provisions within the Proposed Rule. The following are examples of conditions that can cause infertility which can be treated when the root causes are addressed, as referenced in each of the respective footnotes: endometriosis,[12] Polycystic Ovary

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[6] Arkansas State Legislature, 859: *To Create the Reproductive Empowerment and Support Through Optimal Restoration (Restore) Act*.

[7] 91 F.R. 27144.

[8] American Society for Reproductive Medicine, "New Research Examines Range of Restorative Reproductive Medicine Practices from Evidenced - Based Perspective," *ASRM* (May 7, 2026). https://www.asrm.org/news-and-events/asrm-news/press-releasesbulletins/new-research-examines-range-of-restorative-reproductive-medicine-practices-from-evidence-based-perspective/; Fertility Answers, "What is Restorative Reproductive Medicine?" (October 27, 2025) *Fertilityanswers.* https://www.fertilityanswers.com/what-is-restorative-reproductive-medicine/; Dr. Naomi Whitaker, MD, "Restorative Reproductive Medicine: A Field Guide to Root-Cause Care," *RRM Academy* (Last updated June 18, 2026). https://rrmacademy.org/what-is-rrm/; RRM Academy, "What is Restorative Reproductive Medicine (RRM)?" *RRMAcademy* (Last updated May 2026). https://rrmacademy.org/faqs/what-is-restorative-reproductive-medicine-rrm/.

[9] H.R.3589 - *RESTORE Act*, 119th Congress (2025-2026).

[10] José Ignacio Sánchez-Méndez, *et al.,* "Natural procreative technology (NaProTechnology) for infertility: take-home baby rate and clinical outcomes in a 5-year single-center cohort of 1,310 couples," *Front Reprod Health* (2025 Nov 14) 7.1696679. doi: 10.3389/frph.2025.1696679.

[11] 119th Congress, Supra Note, 9.

[12] Dr. Patrick Yeung, "Restorative Reproductive Medicine," *Restore Center for Endometriosis* (July 30, 2025). https://www.restoreendo.com/endo-blog/restorative-reproductive-medicine: Restorative Reproductive Medicine (RRM) seeks to treat endometriosis-related infertility by addressing the root causes of pelvic inflammation, ovulatory dysfunction, and scarring. Rather than bypassing the disease, RRM uses surgical excision, hormonal support, and dietary modifications to heal pelvic anatomy and restore natural fertility.

Syndrome,[13] fibroids,[14] thyroid disorders,[15] adenomyosis,[16] blocked fallopian tubes,[17] environmental endocrine disruptors,[18] and hormonal imbalances in women.[19] Male factor infertility is often initially ignored as a contributing factor. It can include low sperm count and low sperm motility,[20] varicoceles,[21] erectile dysfunction,[22] and diet, lifestyle, and environmental factors.[23] Addressing these conditions requires

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[13] World Health Organization, "Polycystic ovary syndrome" (January 22, 2026). https://www.who.int/news-room/fact-sheets/detail/polycystic-ovary-syndrome: Polycystic ovary syndrome (PCOS)—often called polycystic ovary disease—is a common hormonal disorder characterized by high androgens, irregular periods, and ovarian cysts. "Reparative reproductive health" refers to restoring ovulatory function, fertility, and hormonal balance. Managing this requires a multidisciplinary approach combining metabolic optimization, medications, and lifestyle changes.

[14] Dr. Rodeen Rahbar, "The Impact of Uterine Fibroids on Reproductive Health and Fertility," *Surgical Associates* (Last viewed July 1, 2026). https://sacmd.com/uterine-fibroids-effect-reproductive-health-fertility/: Uterine fibroids (benign growths in the uterus) can disrupt the uterine cavity, impacting fertility, embryo implantation, and pregnancy. Reparative reproductive health focuses on restoring uterine function through targeted interventions like myomectomy (fibroid removal), hormone therapies, and minimally invasive procedures to preserve or enhance your reproductive capacity.

[15] Amanda Jefferys, "Thyroid Dysfunction and Reproductive Health," *TOG: The Obstetrician and Gynecologist* (23 January 2015). https://obgyn.onlinelibrary.wiley.com/doi/10.1111/tog.12161: Thyroid hormones directly interact with your reproductive hormones to regulate ovulation, embryo implantation, and fetal development. Both hypothyroidism (underactive thyroid) and hyperthyroidism (overactive thyroid) can disrupt menstrual cycles, hinder conception, and increase the risk of miscarriage.

[16] Christina Anna Stratopoulou, *et al.,* "Conservative Management of Uterine Adenomyosis: Medical vs. Surgical Approach," *Clin Med.*10:21 (2021 Oct 22) 4878. doi: 10.3390/jcm10214878: Managing adenomyosis through reparative reproductive care focuses on uterine preservation. Treatment utilizes hormonal suppression and conservative surgeries—such as targeted ablation or adenomyomectomy—to restore the uterine environment, reduce pelvic pain, and improve your chances of carrying a successful pregnancy.

[17] Neveda Center for Reproductive Medicine, "Fallopian Tube Blockage Treatment," *Neveda Infertility* (Oct 17, 2024). https://nevadafertility.com/post/fallopian-tube-blockage-treatment#:~:text=When%20it%20comes%20to%20fertility%2C,long%2Dterm%20impact%20on%20one's%20fertility: The following treatments are identified with in vitro fertilization (IVF) listed last if both tubes are removed; but other surgeries are identified: fallopian tube recanalization; laparoscopic surgery; hysteroscopic surgery; salpingectomy.

[18] Xiaoyan Han and Xiaolong Jin, "The impact, mechanisms and prevention strategies of environmental endocrine disruptors on male reproductive health," *Front. Endocrinol.*Vol. 16 (30 September 2025) Sec. Reproduction. https://www.frontiersin.org/journals/endocrinology/articles/10.3389/fendo.2025.1573526/full: Environmental Endocrine Disruptors (EDCs) are synthetic chemicals in plastics, pesticides, and consumer products that mimic or block natural hormones, severely disrupting the hypothalamic-pituitary-gonadal axis. They are linked to diminished ovarian reserve, endometriosis, and lower IVF success rates. Restorative reproductive medicine (RRM) mitigates this via targeted lifestyle, nutritional, and detoxification protocols.

[19] Cleveland Clinic, "Hormonal Imbalance," *My Cleveland Clinic* (April 4, 2022). https://my.clevelandclinic.org/health/diseases/22673-hormonal-imbalance: "If you have lower-than-normal hormone levels, the main treatment is hormone replacement therapy. Depending on which hormone is deficient, you may take oral medication (pills) or injection medication."

[20] Texas Fertility Center, "Restorative Reproductive Medicine – IVF Alternatives" (October 3, 2025). https://txfertility.com/blog/restorative-reproductive-medicine/: To restore low sperm count and quality, restorative reproductive medicine identifies underlying causes—like hormonal imbalances, infections, or varicocele. Treatments often include hormone-stimulating medications (e.g., Clomid or hCG), antioxidant supplements, and minimally invasive surgeries. While this article also includes IVF as an alternative it contains comparative results to RRM methods.

[21] Dr. Naomi Whitaker, MD, "Restorative Reproductive Medicine: A Field Guide to Root-Cause Care," *RRM Academy* (Last updated June 18, 2026). https://rrmacademy.org/what-is-rrm/: Restorative Reproductive Medicine (RRM) seeks to restore natural fertility by identifying and treating underlying medical conditions. In varicoceles (enlarged scrotal veins), RRM approaches this by repairing the veins surgically to restore healthy sperm parameters and testosterone levels.

[22] Jeffrey D Campbell, *et al*., "The good, bad, and the ugly of regenerative therapies for erectile dysfunction," *Transl Androl Urol.* 9: Suppl 2 (2020 Mar) S252–S261. doi: 10.21037/tau.2019.10.06: Reparative and reproductive medicine uses regenerative therapies to repair damaged penile tissue and blood vessels, attempting to cure the root causes of erectile dysfunction (ED) rather than just masking the symptoms. These treatments are most often pursued by men seeking long-term solutions or those whose ED is caused by diabetes, surgery, or vascular disease.

[23] Anett Szabó, *et al.,* "Impact of lifestyle and environmental factors on fertility," *Curr Opin Urol.*35:6 (2025 Sep 15) 685–690. doi: 10.1097/MOU.0000000000001339: "Lifestyle and environmental factors significantly impair male reproductive health

adequate diagnosis not only of the root causes but also the mitigating factors of the infertility-related reproductive health conditions: such as severe tubal blockage, advanced age, and extreme male-factor infertility.

The NCBC, CMA, and NACN-USA take no position of preference on the various Fertility Awareness-based Methods (FABMs), and there are a number of options from which couples can choose.[24] Education and use of FABMs and pre-conception care[25] are critical to these processes. FABMs combine multiple physiological signs—like basal body temperature, cervical mucus, and urinary hormone testing to accurately identify the fertile window. These evidence-based protocols yield typical-use efficacy rates to avoid pregnancy exceeding 98% when followed meticulously.[26] Furthermore, when FABMs were used correctly, studies show a more than 90% success rate for both conception and contraception purposes.[27] Some examples of these effective systems include:

- **Symptothermal Method:** Combines daily Basal Body Temperature (BBT) readings to confirm ovulation has occurred with cervical mucus observations to identify the onset of the fertile window.[28]
- **Marquette Model:** Utilizes home urine monitors (such as the ClearBlue Fertility Monitor) to measure estrogen and luteinizing hormone (LH) levels, eliminating subjective interpretation of mucus.[29]
- **Creighton Model:** Standardized system heavily focused on the observation and charting of cervical mucus patterns.[30]

In addition to FABM there is a need to address the full spectrum of holistic physio-psychosocial implications of infertility, involving a number of healthcare professions, not just medicine and nursing. Infertility triggers a complex, interconnected web of physiological, psychological, and social burdens. The relentless physical demands of treatments (like hormone injections) exacerbate emotional distress, which is further compounded by social isolation, marital strain, and stigma. Addressing these combined factors is vital for comprehensive care.[31] The federal government must engage in robust educational campaigns to this end, and with employers prioritize root-cause diagnostic care before invoking ART. In our discussion of ART, we are referencing the bypassing of the very human nature of reproduction, turning that sacred gift into a laboratory procedure: "Assisted reproductive technology (ART) is any treatment or procedure that involves a laboratory to help you get pregnant. There are different types of ART. IVF (in vitro fertilization) is the most common. They all involve eggs, sperm or embryos being handled outside your

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through hormonal disruption, oxidative stress, and direct germ cell damage. These risks are common and often reversible. Identifying and modifying such exposures is essential for improving fertility outcomes and reducing long-term health burdens."

[24] FACTS About Fertility, "Educate - Engage – Empower: Fertility Appreciation Collaborative to Teach The Science," *Factsaboutfertility.org* (Last viewed July 8, 2026). Patient Educational Materials - FACTS About Fertility. Also, Marguerite Duane, "Fertility Awareness-Based Methods: for Women's Health and Family Planning," *Frontiers* 9:2022 (May 24, 2022).

[25] Stephen R. Pallone and George R. Bergus, "Fertility Awareness-Based Methods: Another Option for Family Planning," *The Journal of the American Board of Family Medicine* 22:2 (March 2009) 147-157. https://www.jabfm.org/content/22/2/147.short.

[26] Ashley Underwood, "Switching from Creighton to Marquette NFP? Here's what to expect," *Vita Fertility Education* (Copyright 2026). https://www.vitaefertility.com/switching-from-creighton-to-marquette-nfp/#:~:text=Switching%20from%20Creighton%20to%20Marquette,%7C%20Getting%20Started%20with%20NFP&text=The%20yearly%20follow%2Dup%20renewal%20is,work%20with%20Vitae%20Fertility%20Education.

[27] Rasha A Bassas, *et al.,* "Fertility Awareness-Based Methods for Family Planning: A Systematic Review," Mohammad Saleh Alharbi & Shatha S Al Harbi, Eds. *Cureus* 17:6 (2025 Jun 17). https://pmc.ncbi.nlm.nih.gov/articles/PMC12270466/.

[28] A Thijssen, *et al.,* "Fertility Awareness-Based Methods' and subfertility: a systematic review," *Facts Views Vis Obgyn* 6:3 (2014) 113–123. https://pmc.ncbi.nlm.nih.gov/articles/PMC4216977/.

[29] McKenna J. Coatney, DO, MA, "Counseling Women on FABMs: Lessons from a Patient Interview," *FACTS About Fertility* (May 28, 2026). https://www.factsaboutfertility.org/counseling-women-on-fabms-lessons-from-a-patient-interview/.

[30] Adair Boudreaux, "The Creighton Model Offers Hope to a Couple with Infertility," *FACTS About Fertility* (April 29, 2020). *https://www.factsaboutfertility.org/the-creighton-model-offers-hope-to-a-couple-with-infertility/.*

[31] Aanchal Sharma and Deepti Shrivastava, "Psychological Problems Related to Infertility," *Cureus* 14:10 (2022 Oct 15).14(10):e30320. doi: 10.7759/cureus.30320.

body."[32] While not every ART procedure involves the manipulation of human life and procreation, the methods we reference are those that separate the engendering of human life from the conjugal act. Unlike ART as referenced here, which bypasses rather than treating the underlying reproductive pathology, RRM, which includes FABMs, works to improve overall health, increase fertility potential, and support natural conception. RRM not only provides evidence of success in addressing infertility but is more cost effective[33] and safer for both mothers and the children they conceive. "The European Society of Human Reproduction and Embryology, reporting annually on IVF clinics across Europe that provide preimplantation genetic testing (PGT) to screen for genetically impaired embryos, concluded that in 2018, out of 5,191 embryos tested, there were 2,942 embryo transfers to a womb (57%), of which 1,673 produced a clinical pregnancy, and only 1,380 children were born alive (27% of those tested as embryos)."[34] Furthermore, IVF carries significant risks for both mother and child, including the possibility of ectopic pregnancy, preterm delivery, severe hemorrhage or seizures in the mother, and higher rates of birth defects and perinatal mortality.[35]

Danger of Creating Further Pathologies to Women and their Babies

While RRM is effective, it clearly is safer for the well-being of both mother and baby. FABM avoid the risks and side effects, not only to women but also to the children engendered, especially by IVF.[36] NCBC, CMA, and NACN-USA are very concerned about the evidenced-based consequences of certain methods of ART, including the risks and side effects, not only to women but also to the children engendered, especially by IVF. While we oppose methods that separate the sacred unity of a husband and wife in achieving procreation, we wish to comment on the need for rigorous regulation when such manipulation of human reproduction occurs.

- **Danger to Women of IVF:** The risks to which women are subjected by IVF is well documented. For example, follicle stimulating hormones (FSH) are used to stimulate oocyte production for ART, particularly IVF. Side effects of ovarian stimulation include ovarian hyperstimulation syndrome: OHSS (swollen and painful ovaries). OHSS is a potentially life-threatening complication of fertility treatments. The primary risks include dangerous fluid shifts causing severe abdominal and chest swelling, blood clots, kidney failure, ovarian torsion (twisting of the ovary), and even death.[37] And while earlier studies found a link of FSHs to a specific type of ovarian tumor, more recent studies do not support these findings.

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[32] Cleveland Clinic, "Assisted Reproductive Technology," *ClevelandClinic.org* (08/25/2025). https://my.clevelandclinic.org/health/treatments/assisted-reproductive-technology.

[33] "IVF costs $15,000 to $30,000 per cycle, with most couples spending $40,000 to $60,000 total. A prospective cohort study found IVF costs on average 20 times more than medication-based fertility treatments." See RRM Academy, "How much does RRM or NaProTechnology treatment cost compared to IVF?" *RRMAcademy.org* (Last updated April 2026). https://rrmacademy.org/faqs/how-much-does-rrm-or-naprotechnology-treatment-cost-compared-to-ivf/. Also, "One study found the average cost of IVF is 20 times greater than fertility treatments that use only medications, making IVF inaccessible to many couples." See Dr. Marguerite Duane and Dr. Tucker Brown, "Restorative Reproductive Medicine for Infertility: A Safe, Effective, Affordable Alternative," *Facts About Fertility* (Feb. 27, 2025) citing Patricia Katz, *et al*., "Costs of infertility treatment: results from an 18-month prospective cohort study," *Fertility and sterility* 95.3 (2011): 915-921.

[34] Secretariate of Pro-Life Activities, "In Vitro Fertilization: The Human Cost," U.S. Conference of Catholic Bishops (March 2025). Citing F. Spinella, *et al*., "ESHRE PGT Consortium data collection XXI: PGT analyses in 2018," *Human Reproduction Open* 2023:2 (2023) 6 (Table II), at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10121336/pdf/hoad010.pdf.

[35] S Bewley, *et al.,* "Adverse outcomes from IVF," *BMJ* (2011) 342: d436. Also, C. G. Vergouw, "The influence of the type of embryo culture medium on neonatal birthweight after single embryo transfer in IVF," *Hum Reprod* 27 (2012) 2619–26.

[36] Facts about Fertility, "FACTS, Re-vitalizing Women's Health Care Together" (Last viewed January 25, 2024). https://www.factsaboutfertility.org/.

[37] Mayo Clinic, "Ovarian Hyperstimulation Syndrome," *Mayoclinic.org* (Last viewed July 4, 2026). https://www.mayoclinic.org/diseases-conditions/ovarian-hyperstimulation-syndrome-ohss/symptoms-causes/syc-20354697.

However, some studies have found that the use of clomiphene citrate (Clomid) for at least a year may increase risk for ovarian tumors. The risk was highest among women who did not get pregnant, so it remains unclear if the risk is due to infertility or the drug.[38] However, this remains a significant concern since ovarian cancer grows quickly and can progress from early stages to advanced stages within a year.[39]

There needs to be strong regulation to protect the health of women. Limitations on the number of cycles of FSH drugs should be mandated by regulation. Engendering multiple embryos beyond those who can be safely implanted, not only is dangerous to the unborn children, but also to their mothers. Regulations must limit the number of embryos being engendered to the number of embryos that can safely be implanted. Clearly, very specific provisions for informed consent addressing these dangers must be mandated. Furthermore, regulations should prevent the abuse of women as "gestational carriers," which is an afront to the women and the children who are considered a commodity by these very procedures.

- **Danger to the Baby:** The goal of infertility treatment is to treat a pathology (RRM), not to guarantee a couple the sacred gift of a baby, which treats the baby as a commodity to be engineered and manipulated by some methods of ART. Such procedures put the baby at great risk. The risks of IVF to the wellbeing of the baby are documented: ectopic pregnancy; multiple births; a slightly higher risk of a baby being born with heart issues, digestive problems, or other conditions; and the risk that the baby will be born early or with a low birth weight.[40] Research is validating these risks to babies. "'The risk of congenital malformations is approximately one-third higher in children conceived with the aid of IVF technology than in other children.' Included are malformations of the cardiac, musculo-skeletal, and genitourinary systems. The authors suggest that IVF techniques themselves, not only paternal and maternal factors, are partly responsible. Even IVF singleton pregnancies are 1.7 times more likely to result in preterm births, and 1.5 times more likely to result in low birth weight, than non-IVF pregnancies."[41] Clearly, very specific provisions for informed consent, addressing these dangers must be mandated.

Most significantly IVF is a violation of the dignity of the human person, who is the embryo, and who is treated as a commodity to be frozen for an uncertain fate. Methods may be used to label some of these young human beings as "unworthy" of implantation and thus relegate them for research and/or destruction. Already the embryo is subject to procedures that commodify the embryo through preimplantation genetic diagnosis and other manipulations that are dangerous to the embryo. The results often relegate the embryo to research and/or destruction, which would be an unethical fate, violating the very purposes of reproductive technology. This is especially true if the ART involves research. The same is true for research involving recent technologies such as "three person embryos" by mitochondrial donation.[42] And although the implantation of such engendered embryos is not permitted in the United States, they are engendered in the U.S. and implanted in a foreign country.[43] Thus, such research processes should be prohibited, and if done at all need to be well regulated. There are significant risks to the embryos

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[38] Roswell Park Comprehensive Cancer Center, "Ovarian Cancer Risk Factors" (Accessed January 25, 2024). https://www.roswellpark.org/cancer/ovarian/what-ovarian-cancer/risk-factors#:~:text=Some%20studies%20found%20that%20women,to%20infertility%20or%20the%20drug.

[39] The University of Kansas Cancer Center, "What Is Ovarian Cancer: Symptoms, Detection and Treatment" (Accessed January 25, 2024). https://www.kucancercenter.org/news-room/blog/2020/08/what-is-ovarian-cancer-symptoms-treatment#:~:text=Ovarian%20cancer%20grows%20quickly%20and,spread%20in%20weeks%20or%20months.

[40] Mayo Clinic, "In vitro Fertilization: Risks" (Sept. 1, 2023). https://www.mayoclinic.org/tests-procedures/in-vitro-fertilization/about/pac-20384716.

[41] Secretariate of Pro-Life Activities, Supra note, 34 citing M. von Wolff and T. Haaf, "In Vitro Fertilization Technology and Child Health," Deutsches Ärzteblatt International 117:3 (2020) 23-30, p. 23, at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7026576/pdf/Dtsch_Arztebl_Int-117_0023.pdf.

[42] Hana Carolina Moreira Farnezi, "Three-parent babies: Mitochondrial replacement therapies," *JBRA Assist Reprod.* 24:2 (2020 Apr-Jun) 189–196. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7169912/.

[43] Emily Mullin, "U.S. researcher says he's ready to start four pregnancies with 'three-parent' embryos,'" *STAT* (April 18, 2019). https://www.statnews.com/2019/04/18/new-york-researcher-ready-to-start-pregnancies-with-three-parent-embryos/.

engendered, and potentially to the egg or embryo donor, and the potential negative effects to the gene pool.[44] Furthermore, the whole area of uterus transplants raises ethical questions concerning the wellbeing of the mother and the risks to which the embryo/fetus is subjected. The transplant is regulated by the Organ Procurement and Transplantation Network, which addresses issues of transplantation, but involves ART.[45]

Engendering embryos with the intent to provide "spares" for eugenic or research purposes is afront to humanity and should be prohibited; and current practices of selective reduction, especially after there has been a deliberate engendering of more embryos than can safely be gestated is an egregious afront to human life and should be prohibited. Some consider a solution to this ART-created problem is to provide for embryo adoption, especially as a treatment for the infertility of others. This constitutes the ultimate commodification of the embryos abandoned by their own parents. Others have promoted embryo adoption for the purpose of rescuing the abandoned embryos. The Catholic Church has spoken on this issue,[46] with mixed interpretations by reputable canonists, moral theologians, and ethicists. All are clear that using "spare" embryos as a treatment for infertility of others is morally unacceptable. However, less consensus exists concerning embryo rescue.[47] This demonstrates the moral implications of the manipulation of human life through a number of methods of ART and specifically IVF.

Conscience Protections

There is no mandate to cover IVF, nor does the proposal require self-insured employers, Medicaid programs, or uninsured coverage arrangements to provide fertility benefits. In fact, the preamble of the Proposed Rule, 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…."[48] However, the conscience protections for persons and agencies/institutions that have a religious character/belief, and those that do not, who wish to provide employees with fertility care benefits, must be safeguarded as protected by the U.S. Constitution's First Amendment[49] and the *Religious Freedom Restoration Act* (RFRA). RFRA was enacted specifically to protect against government actions that substantially burden religious liberty.[50] An integral aspect of the RFRA is the belief that individuals and institutions should not be forced to choose between their own religious beliefs and participation in public life. Furthermore, federal law (Church Amendments) dictates that "[n]o individual shall be required to perform or assist in the performance of any part of a health service program or research activity funded in whole or in part under a program administered by the Secretary of Health and Human Services if his performance or assistance in the performance of such part of such program or activity would be contrary to his religious beliefs or moral convictions."[51] Government policies should not place religious institutions and individuals, as well as non-religious persons of conscience in an impossible position of either materially participating in what they

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[44] Vicente Javier Clemente-Suárez, et al., "Mitochondrial Transfer as a Novel Therapeutic Approach in Disease Diagnosis and Treatment," *Int J Mol Sci.* 24:10 (2023 May) 8848. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10218908/#:~:text=Mitochondrial%20transfer%20involves%20the%20exchange,types%20%5B1%2C13%5D.

[45] Health Resources and Services Administration, *Guidance on Optimizing VCA Recovery (2023 Version)*. (Dec. 4, 2023). 2023dec_vca_guidance_language PDF (optn.transplant.hrsa.gov).

[46] Congregation for the Doctrine of the Faith, "Instruction *Dignitas Personae* on Certain Bioethical Questions" (December 8, 2008), sec. 19, Vatican Website.

[47] Trent Horn & Kent Lasnoski, Eds., *Human Embryo Adoption Vol 2: Catholic Arguments for and Against* (Broomall, PA: National Catholic Bioethics Center, June 27, 2025).

[48] 91 FR at 27146.

[49] U.S. Const. amend. I.

[50] 42 U.S.C. § 2000bb (3).

[51] 42 U.S.C. § 300a-7 (d)

view as grave evils or withdrawing from participating in public programs that help to serve their community. Even though participating in the elements provided by the Proposed Rule is voluntary, the Final Rule should explicitly clarify, as suggested in its Preamble, that employers who offer coverage of fertility services as an excepted benefit are free to exclude any fertility service from that coverage, including IVF. Furthermore, children have a right to both a mother and a father, and manipulating the engendering of life in a manner that denies a child that right is an injustice. Thus, 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 U.S. Supreme Court has affirmed both the right under 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.[52]

While NCBC, CMA, and NACN-USA recognize and support the justice enhancing provisions for the employer within the Proposed Rule, such as the voluntary nature of the proposal, and the provision for employer flexibility, there is the need to secure conscience protections not only for the employer but also for the employee, especially if there is an objection to providing premiums that will contribute to specific methods of ART, e.g., IVF while providing for the desirable RRM. Similar objections under the *Affordable Care Act* led to provisions to isolate costs in premiums for objectionable procedures.[53] 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 insurer should be required to identify the actuarial value of that coverage and ensure that this amount is excluded from the premiums of those who object. This would allow objecting employees to participate in a fertility benefits plan without violating their consciences.

Conclusions

NCBC, CMA, and NACN-USA support the health enhancing provisions within the Proposed Rule, which represent a valuable opportunity to advance real solutions to infertility that respects the God-given dignity of parents and of children, born and pre-born. However, there is a need for a clear definition of infertility that determines infertility by reference to an inability to conceive, based on a pathology, through intercourse with a spouse of the opposite sex. We have provided a definition herein.

The very definition of ART as referenced here bypasses the very human nature of reproduction, turning that sacred gift into a laboratory procedure. Therefore, 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, therapeutically, and morally, and does nothing to address the underlying pathology. We also urge the Departments to engage in robust educational campaigns to this end, and with employers prioritize root-cause diagnostic care before invoking ART.

There needs to be strong regulation to protect the health of women. Clearly, very specific provisions for informed consent addressing these dangers of ART, including IVF if part of the Final Rule, with limitations on the number of cycles of FSH drugs should be mandated by regulation. Furthermore, regulations should prevent the abuse of women as "gestational carriers," which is an afront to the women and the children who are considered a commodity by these very procedures.

Engendering multiple embryos during IVF beyond those who can be safely implanted, not only is dangerous to the unborn child, but also to their mothers. If IVF is included in the Final Rule, regulations must limit the number of embryos being engendered by the number of embryos that can safely be implanted and gestated unto birth. Engendering embryos with the intent to provide "spares" for eugenic or

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[52] *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).

[53] ACA § 1303, 42 U.S.C. § 18023(b)(2)(B)–(C), and 45 C.F.R. § 156.280(e)(2)–(3).

research purposes is an afront to humanity and should be prohibited; and current practices of selective reduction, especially after there has been a deliberate engendering of more embryos than can safely be gestated is an egregious afront to human life and should be prohibited. Embryo adoption does not resolve the quandary of embryos abandoned by their parents.

The Proposed Rule does not mandate IVF coverage, nor does it mandate RRM coverage. However, the Final Rule should proactively protect the religious liberty and conscience rights of employers and employees by explicitly clarifying that employers who offer coverage of fertility services as an excepted benefit are free to exclude any fertility service from that coverage, including IVF. Children have a right to both a mother and a father and manipulating the engendering of life in a manner that denies a child that right should be prohibited. Thus, 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).

There is the need to secure conscience protections for not only the employer but also the employee, especially if there is an objection to providing premiums that will contribute to specific methods of ART while providing for the desirable RRM. Similar objections under the *Affordable Care Act* led to provisions to isolate costs in premiums for objectionable procedures.[54] 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 insurer should be required to identify the actuarial value of that coverage and ensure that this amount is excluded from the premiums of those who object.

Lastly, we understand that some employers may choose to cover ART, but we urge the Departments to encourage employers and insurers to adopt a sort of sequencing in the design of their benefits making RRM-informed diagnostics and treatments a priority while leaving any costly ART as a last resort (if included at all). Such sequencing is consistent with an accurate understanding that true fertility treatments address, and not bypass, the underlying causative pathology.

[54] ACA Supra note, 53.

Thank you for the opportunity to address this critical issue impacting parents, families, their children, and the very values of society.

Respectfully submitted,

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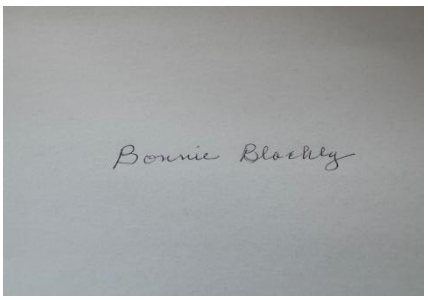

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