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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

Excepted Fertility Benefits

AGENCY: Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; Centers for Medicare & Medicaid Services, Department of Health and Human Services.

ACTION: Proposed rules.

SUMMARY: This document contains proposed rules that would amend the regulations regarding excepted benefits under the Employee Retirement Income Security Act of 1974, the Internal Revenue Code, and the Public Health Service Act to establish certain fertility benefits as a new category of limited excepted benefits. Excepted benefits are generally exempt from the market requirements that were added to those laws by the Health Insurance Portability and

Accountability Act, the Patient Protection and Affordable Care Act, the No Surprises Act, and certain other Federal laws specifically related to group health plans and group and individual health insurance coverage.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than [Insert date 60 days after date of publication in the **Federal Register**].

ADDRESSES: Written comments may be submitted to the address specified below. Any comment that is submitted will be shared with Treasury, Internal Revenue Service (IRS), and the Department of Health and Human Services (HHS). Please do not submit duplicates.

Comments will be made available to the public. Warning: Do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. All comments are posted on the internet exactly as received and can be retrieved by most internet search engines. No deletions, modifications, or redactions will be made to the comments received, as they are public records. Comments may be submitted anonymously.

In commenting, please refer to file code 1210-AC40. The Departments cannot accept comments by facsimile (FAX) transmission.

Comments must be submitted in one of the following two ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to *https://www.regulations.gov.* Follow the "Submit a comment" instructions.

2. By mail. You may mail written comments to the following address ONLY: 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.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. The comments are posted on the following website as soon as possible after they have been received: *https://www.regulations.gov*. Follow the search instructions on that website to view public comments. The Departments encourage commenters to include supporting facts, research, and evidence in their comments. When doing so, commenters are encouraged to provide citations to the materials referenced, including active hyperlinks. Likewise, commenters who reference materials that have not been published are encouraged to upload relevant data collection instruments, data sets, and detailed findings as a part of their comment. Providing such citations and documentation will assist the Departments in analyzing the comments.

Plain Language Summary: In accordance with 5 U.S.C. 553(b)(4), a summary of not more than 100 words in length of this proposed rule, in plain language may be found at https://www.regulations.gov/.

FOR FURTHER INFORMATION CONTACT: Alexander Krupnick, Internal Revenue Service, Department of the Treasury, at 202-317-5500; Rebecca Miller and David Sydlik, Employee Benefits Security Administration, Department of Labor, at 202-693-8335; David Mlawsky, Centers for Medicare & Medicaid Services, Department of Health and Human Services, at 410-786-6851.

Customer Service Information: Individuals interested in obtaining information from DOL concerning private employment-based health coverage laws may call the Employee Benefits

Security Administration (EBSA) Toll-Free Hotline at 1-866-444-EBSA (3272) or visit the DOL's website (*https://www.dol.gov/agencies/ebsa*).

In addition, information from HHS on private health insurance coverage and coverage provided by self-funded, non-Federal governmental group health plans can be found on the Centers for Medicare & Medicaid Services (CMS) website (https://www.cms.gov/marketplace/about/oversight), and information on health care reform can be found at *https://www.healthcare.gov/* or *https://www.hhs.gov/healthcare/index.html*.

SUPPLEMENTARY INFORMATION:

I. Background

A. Introduction

1. Statutory Provisions

The Health Insurance Portability and Accountability Act of 1996 (HIPAA)[1] added chapter 100 to the Internal Revenue Code (Code), part 7 to the Employee Retirement Income Security Act (ERISA), and title XXVII to the Public Health Service Act (PHS Act), which set forth portability and nondiscrimination rules with respect to health coverage. These provisions of the Code, ERISA, and the PHS Act were later augmented by other laws, including the Mental Health Parity Act of 1996[2]; the Newborns' and Mothers' Health Protection Act[3]; the Women's Health and Cancer Rights Act[4]; the Genetic Information Nondiscrimination Act of 2008[5]; the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA)[6]; the Children's Health Insurance Program Reauthorization Act of 2009[7]; Michelle's Law[8]; the Patient Protection and Affordable Care Act[9], as amended by the Health Care and

[1] Pub. L. 104-191 (Aug. 21, 1996).
[2] Pub. L. 104-204 (Sept. 26, 1996).
[3] Pub. L. 104-204 (Sept. 26, 1996).
[4] Pub. L. 105-277 (Oct. 21, 1998).
[5] Pub. L. 110-233 (May 21, 2008).
[6] Pub. L. 110-343 (Oct. 3, 2008).
[7] Pub. L. 111-3 (Feb. 4, 2009).
[8] Pub. L. 110-381 (Oct. 9, 2008).
[9] Pub. L. 111-148 (Mar. 23, 2010).

Education Reconciliation Act of 2010 (collectively known as the Affordable Care Act or ACA)[10]; Division BB of the Consolidated Appropriations Act, 2021, which includes the No Surprises Act[11]; and Division J of the Consolidated Appropriations Act, 2026.[12]

The ACA reorganized, amended, and added to the provisions of part A of title XXVII of the PHS Act relating to health coverage requirements for group health plans and health insurance issuers in the group and individual markets. The term "group health plan" includes both insured and self-insured group health plans. The ACA also added section 715 to ERISA and section 9815 to the Code to incorporate the provisions of part A of title XXVII of the PHS Act into ERISA and the Code, making them applicable to group health plans and health insurance issuers providing health insurance coverage in connection with group health plans. The provisions of the PHS Act incorporated into ERISA and the Code, as amended or added by the ACA, are sections 2701 through 2728 (market requirements).

In accordance with Code section 9831(b) and (c), ERISA section 732(b) and (c), and PHS Act sections 2722(b) and (c) and 2763, the market requirements of chapter 100 of the Code, part 7 of ERISA, and title XXVII of the PHS Act do not apply to a group health plan or a health insurance issuer in the group or individual market in relation to the provision of excepted benefits described in Code section 9832(c), ERISA section 733(c), and PHS Act section 2791(c).[13] There are four statutory categories of excepted benefits: benefits that are excepted in all circumstances; limited excepted benefits, which are the subject of this rulemaking; independent, noncoordinated excepted benefits; and supplemental excepted benefits.

The first category, under section 9832(c)(1) of the Code, section 733(c)(1) of ERISA, and section 2791(c)(1) of the PHS Act, includes benefits that are generally not health coverage (such

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[10] Pub. L. 111-152 (Mar. 30, 2010).
[11] Pub. L. 116-260 (Dec. 27, 2020).
[12] Pub. L. 119-75 (Feb. 3, 2026).
[13] HHS does not interpret the ACA amendments to PHS Act section 2722(b) and (c) (formerly PHS Act section 2721(c) and (d)) as restricting the exemption for excepted benefits so it applies only with respect to subpart 2 of part A of title XXVII of the PHS Act, and it does not intend to use its resources to enforce the market requirements with respect to excepted benefits offered by non-federal governmental plan sponsors and encourages States to adopt a similar approach with respect to issuers of excepted benefits. *See* 75 Fed. Reg. 34538, 34539-40 (Jun. 17, 2010).

as automobile insurance, liability insurance, workers' compensation, and accidental death and dismemberment coverage). The benefits in this category are excepted in all circumstances. In contrast, the benefits in the second, third, and fourth categories are types of health coverage that are excepted only if certain conditions are met.

The second category of excepted benefits is limited excepted benefits. Under section 9832(c)(2)(A) and (B) of the Code, section 733(c)(2)(A) and (B) of ERISA, and section 2791(c)(2)(A) and (B) of the PHS Act, limited excepted benefits include limited-scope dental or vision benefits, and benefits for long-term care, nursing home care, home health care, or community-based care that are offered separately, or any combination thereof. Section 9832(c)(2)(C) of the Code, section 733(c)(2)(C) of ERISA, and section 2791(c)(2)(C) of the PHS Act further provide that limited excepted benefits also include such other, similar limited benefits as are specified in regulations.[14] To be a limited excepted benefit, the benefits must either: (1) be provided under a separate policy, certificate, or contract of insurance; or (2) otherwise not be an integral part of the plan.[15]

The third category of excepted benefits, referred to as "noncoordinated excepted benefits," includes both coverage for only a specified disease or illness (such as cancer-only policies), and hospital indemnity or other fixed indemnity insurance. These benefits are excepted under section 9831(c)(2) of the Code, section 732(c)(2) of ERISA, and section 2722(c)(2) of the PHS Act only if all of the following conditions are met: (1) the benefits are provided under a separate policy, certificate, or contract of insurance; (2) there is no coordination between the provision of such benefits and any exclusion of benefits under any group health plan maintained by the same plan sponsor; and (3) the benefits are paid with respect to any event without regard

[14] Moreover, section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act authorize the Secretaries of Treasury, Labor, and HHS (collectively, the Secretaries) to promulgate such regulations as may be necessary or appropriate to carry out the provisions of chapter 100 of the Code, part 7 of ERISA, and title XXVII of the PHS Act.

[15] *See* Code section 9831(c)(1), ERISA section 732(c)(1), and PHS Act section 2722(c)(1) and 2763(b); *see also* 79 Fed. Reg. 59130, 59131-59134 (Oct. 1, 2014) (discussing the application of these requirements to benefits such as limited-scope dental and vision benefits and employee assistance programs).

to whether benefits are provided under any group health plan maintained by the same plan sponsor or, with respect to individual coverage, under any health insurance coverage maintained by the same health insurance issuer.

The fourth category, under section 9832(c)(4) of the Code, section 733(c)(4) of ERISA, and section 2791(c)(4) of the PHS Act, is supplemental excepted benefits. These benefits are excepted only if they are provided under a separate policy, certificate, or contract of insurance and are Medicare supplemental health insurance (also known as Medigap), TRICARE supplemental programs, or "similar supplemental coverage provided to coverage under a group health plan."[16]

2. Limited Excepted Benefit Regulations

As stated in section I.A.1 of this preamble, under section 9832(c)(2) of the Code, section 733(c)(2) of ERISA, and section 2791(c)(2) of the PHS Act, limited excepted benefits include limited scope vision or dental benefits, benefits for long-term care, nursing home care, home health care, or community-based care that are offered separately, or any combination thereof. Under section 9832(c)(2)(C) of the Code, section 733(c)(2)(C) of ERISA, and section 2791(c)(2)(C) of the PHS Act, the Departments have the authority and discretion to specify in regulations additional limited excepted benefits that are similar to the limited benefits specified in section 9832(c)(2)(A) and (B) of the Code, section 733(c)(2)(A) and (B) of ERISA, and section 2791(c)(2)(A) and (B) of the PHS Act and that either are provided under a separate policy, certificate, or contract of insurance, or are otherwise not an integral part of a plan.

In 1997, the Departments published interim final regulations defining limited-scope dental and vision benefits, as well as long-term care benefits.[17] The 1997 interim final rules did not define the terms limited-scope dental and limited-scope vision benefits. The preamble to the

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[16] To be considered "similar supplemental coverage" and thus a supplemental excepted benefit, the coverage, whether offered in the group or individual market, must supplement coverage provided under a group health plan. This category does not include coverage that supplements individual health insurance coverage. *See* 89 Fed. Reg. 23338, 23342 fn. 36 (Apr. 3, 2024).

[17] 62 Fed. Reg. 16894 (Apr. 8, 1997).

1997 interim final rules stated that limited-scope dental and vision benefits typically do not include medical services, such as procedures associated with oral cancer or mouth injury or ophthalmological services treating an eye disease or eye injury.[18] Following these interim final regulations, the Departments also published a notice clarifying the conditions under which it is appropriate to treat benefits under a health flexible spending arrangement (health FSA) as limited excepted benefits.[19] In 2004, the Departments published final regulations defining the conditions under which limited-scope dental and vision benefits, long-term care benefits, and health FSAs would be considered limited excepted benefits.[20] In contrast with the scope of services covered by limited-scope dental and vision benefits contemplated in the preamble of the 1997 interim final rules, the 2004 final rules defined limited-scope dental and vision benefits more broadly. Under the 2004 final rules, limited-scope dental benefits are benefits substantially all of which are for treatment of the mouth (including any organ or structure within the mouth). Limited-scope vision benefits are benefits substantially all of which are for treatment of the eye.

In 2014, the Departments amended the excepted benefit regulations for limited-scope dental and vision benefits, as well as for certain employee assistance programs (EAPs).[21] Under the 2014 final rules, the Departments removed the requirement that participants pay an additional premium or contribution for limited-scope dental or vision benefits to qualify as benefits that are not an integral part of the plan in order to qualify as excepted benefits. The 2014 final rules also established four requirements that an EAP must meet in order to be an excepted benefit. The first requirement is that the EAP does not provide significant benefits in the nature of medical care. The second requirement is that the EAP cannot be coordinated with the benefits under another group health plan. To satisfy this requirement, participants in the other group health plan must not be required to use and exhaust benefits under the EAP before an individual is eligible for

[18] *Id.* at 16903.
[19] 62 Fed. Reg. 67688 (Dec. 29, 1997).
[20] 69 Fed. Reg. 78720 (Dec. 30, 2004).
[21] 79 Fed. Reg. 59130 (Oct. 1, 2014).

benefits under the other group health plan, and participant eligibility for the EAP must not be dependent on participation in another group health plan. The third requirement that an EAP must satisfy in order to be an excepted benefit is that no employee premiums or contributions may be required as a condition of participation in the EAP. The fourth requirement is that an EAP may not impose any cost-sharing requirements. Following the 2014 final rules, the Departments also finalized rules for a pilot program for limited wraparound benefits as limited excepted benefits in the group market if five conditions were satisfied.[22] This pilot program was available for a limited time and has since sunset. Most recently, in 2019, the Departments finalized rules establishing an excepted benefit Health Reimbursement Arrangement (HRA) as a limited excepted benefit, which can be used to reimburse certain medical care expenses, subject to the requirements at 26 CFR 54.9831-1(c)(3)(viii), 29 CFR 2590.732(c)(3)(viii), and 45 CFR 146.145(b)(3)(viii).[23]

3. Recent Executive Orders and Access to Fertility Benefits and Services

On February 18, 2025, President Trump issued Executive Order 14216, "Expanding Access to In Vitro Fertilization" (Executive Order 14216).[24] In Executive Order 14216, President Trump highlighted the importance of family formation, and emphasized that "as a Nation, our public policy must make it easier for loving and longing mothers and fathers to have children." Executive Order 14216 seeks to ensure reliable access to in vitro fertilization (IVF) and provide more affordable treatment options, recognizing both the medical necessity of infertility treatment for affected individuals and the broader importance of supporting American families in achieving their family formation goals. As part of the Executive Order, President Trump made it the policy of the Administration to ensure reliable access to IVF treatment, including by easing unnecessary statutory or regulatory burdens to make IVF treatment drastically more affordable. Separately, on January 31, 2025, President Trump issued Executive Order 14192 "Unleashing Prosperity

[22] 80 Fed. Reg. 13995 (Mar. 18, 2015).
[23] 84 Fed. Reg. 28888 (Jun. 20, 2019).
[24] Exec. Order No. 14216, 90 Fed. Reg. 10451 (Feb. 18, 2025).

Through Deregulation" (Executive Order 14192). In Executive Order 14192, President Trump emphasized that the application of complicated Federal regulation imposes massive costs on the lives of millions of Americans, creates a substantial restraint on our economic growth and ability to build and innovate, and hampers our global competitiveness.[25] Therefore, President Trump emphasized that it was the policy of the government to alleviate unnecessary regulatory burdens placed on the American people.

The Departments recognize that family formation is a longstanding priority for millions of Americans in the United States, and access to fertility benefits and services plays a role in supporting their ability to build families. However, the United States is currently experiencing a declining fertility rate. Between 2014 and 2024 the number of births declined by 9 percent and the general fertility rate declined by 14 percent, from 62.9 births per 1,000 females ages 15 to 44 to 53.8.[26] The total fertility rate has remained below replacement level for over a decade. Since 1990, the U.S. total fertility rate declined from about the replacement level of 2.1 births per woman—the fertility level needed for a population to replace itself from one generation to the next—to 1.6 births per woman in 2023.[27] Even as the birth rate has fallen, however, Americans continue to report that their ideal family size includes an average of 2.7 children.[28]

Infertility is a common problem in the United States, with recent CDC data highlighting that one in five Americans suffer from infertility.[29] While infertility stems from a variety of factors affecting both men and women, including, but not limited to, age, ovulation, uterine, and ejaculation disorders, chronic reproductive health conditions, medications, and genetic disorders,

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[25] Exec. Order No. 14192, 90 Fed. Reg. 9065 (Feb. 6, 2025).
[26] *See* Joyce Martin, M.P.H., Brady Hamilton, Ph.D., and Michelle Osterman, M.H.S, *National Vital Statistics System*, Data Brief Number 535 (Jul. 2025), https://www.cdc.gov/nchs/data/databriefs/db535.pdf; *see also* Michelle J.K. Osterman, M.H.S, et. al., *Births: Final Data for 2023,* National Vital Statistics Report, Volume 74, No. 1 (Mar. 18, 2025), https://www.cdc.gov/nchs/data/nvsr/nvsr74/nvsr74-1.pdf.
[27] *See* Anne Driscoll, Ph.D., and Brady Hamilton, Ph.D, *Effects of Age-specific Fertility Trends on Overall Fertility Trends: United States, 1990–2023*, National Vital Statistics Reports, Vol. 74, No. 3 (Mar. 6, 2025), https://www.cdc.gov/nchs/data/nvsr/nvsr74/nvsr74-3.pdf.
[28] Megan Brenan, *Americans' Ideal Family Size Remains Above Two Children*, Gallup (Sept. 4, 2025), https://news.gallup.com/poll/694640/americans-ideal-family-size-remains-above-two-children.aspx.
[29] *Infertility: Frequently Asked Questions* (May 15, 2024), https://www.cdc.gov/reproductive-health/infertility-faq/index.html.

it can also be unexplained after medical tests reveal no obvious fertility problems. Possible reasons for unexplained infertility include an undiagnosed underlying condition, sperm and egg quality,[30] or environmental factors.[31]

Fertility treatments, including medication, surgery, intrauterine insemination (IUI), and assisted reproductive technology (ART) procedures such as IVF, as well as less invasive pre-conception care options that address the root causes of infertility, allow those who experience infertility a potential path to expand their families.[32] In 2022, 98,289 infants born (or about 2.7% of all infants born) in the United States were conceived through the use of ART.[33] While ART has been available for more than three decades, families seeking to avail themselves of these technologies often face access challenges related to cost.[34] IVF is the most commonly used form of ART and more than 99% of ART procedures performed are IVF.[35] A single cycle of IVF has recently been estimated to cost between $15,000 and $20,000.[36] However, given that the average number of cycles that are needed to become pregnant from IVF is 2.5, the average cost of IVF to

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[30] Cleveland Clinic, *Unexplained Infertility* (June 6, 2022), https://my.clevelandclinic.org/health/diseases/23187-unexplained-infertility.

[31] *See* Jie Lin, et. al., *Association between heavy metals exposure and infertility among American women aged 20-44: A cross-sectional analysis from 2013 to 2018 NHANES data* (Feb. 13, 2023), https://pmc.ncbi.nlm.nih.gov/articles/PMC9971928/; Amran, N. H., Zaid, S. S. M., Mokhtar, M. H., Manaf, L. A. & Othman, S., *Exposure to Microplastics during Early Developmental Stage: Review of Current Evidence*, Toxics 10, 597 (Oct. 10, 2022), https://pmc.ncbi.nlm.nih.gov/articles/PMC9611505/.

[32] U.S. Department of Health and Human Services, *Use Across the United States* (Mar. 13, 2024), https://us.pagefreezer.com/en-US/wa/browse/0a7f82bb-be6e-448a-ae11-373d22c37842?find-by-timestamp=2025-01-02T05:49:59Z&url=https:%2F%2Fwww.hhs.gov%2Fabout%2Fnews%2F2024%2F03%2F13%2Ffact-sheet-in-vitro-fertilization-ivf-use-across-united-states.html&timestamp=2025-01-02T07:03:02Z.

[33] U.S. Centers for Disease Control and Prevention, *National ART Summary* (Dec. 10, 2024), https://www.cdc.gov/art/php/national-summary/index.html?cove-tab=2.

[34] *See* World Health Organization, *Infertility* (Nov. 28, 2025), https://www.who.int/news-room/fact-sheets/detail/infertility (These proposed rules contains links to non-United States Government websites. The Departments are providing these links because they contain additional information relevant to the topic(s) discussed in this proposed rule or that otherwise may be useful to the reader. The Departments cannot attest to the accuracy of information provided on the cited third-party websites or any other linked third-party site. The Departments are providing these links for reference only; linking to a non-United States Government website does not constitute an endorsement by the Departments or any of their employees of the sponsors or the information and/or any products presented on the website. Also, the privacy protections generally provided by United States Government websites do not apply to third-party sites).

[35] Saswati Sunderam, PhD et. al., *Assisted Reproductive Technology Surveillance — United States, 2018*, Morbidity and Mortality Weekly Report (Feb. 18, 2024).

[36] U.S. Department of Health and Human Services, *Fact Sheet: In Vitro Fertilization (IVF) Use Across the United States* (Mar. 13, 2024), https://us.pagefreezer.com/en-US/wa/browse/0a7f82bb-be6e-448a-ae11-373d22c37842?find-by-timestamp=2025-01-02T05:49:59Z&url=https:%2F%2Fwww.hhs.gov%2Fabout%2Fnews%2F2024%2F03%2F13%2Ffact-sheet-in-vitro-fertilization-ivf-use-across-united-states.html&timestamp=2025-01-02T07:03:02Z.

conceive successfully can exceed $40,000.[37] Often, less invasive fertility treatments are more affordable than ART for a wide variety of reasons, but may still present significant cost barriers to patients depending on which treatments are most clinically appropriate for each specific patient.

4. Coverage of Fertility Benefits (EHBs, State Insurance Laws, and Employer Sponsored Plans)

Historically, employer-sponsored group health plans have not covered most fertility treatments, including prescription fertility medications as well as IVF and non-IVF treatments.[38] Though coverage is now increasing, the majority of employer-sponsored group health plans do not offer coverage of many fertility benefits, with some estimates indicating that approximately 60 percent of employers do not offer fertility benefits.[39] Of those that do offer fertility benefits, many have claims for such benefits administered under a separate contract from their major medical coverage, with many employers offering their fertility benefits through specialty vendors.[40] Accordingly, even where fertility benefits are offered by an employer, they are often treated as a separate offering from the main group health plan, with separate claims processes, provider networks, and other plan administration features. Further, while insured plans may be required to cover fertility benefits, including IVF, as an Essential Health Benefit (EHB) or by applicable State law, such requirements generally do not apply to self-insured group health plans,

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[37] *Id.; see also* Society for Assisted Reproductive Technology, *Preliminary National Summary Report 2024, Final Primary Outcome Per Egg Retrieval Cycle, Patient's Own Eggs, First IVF*, https://www.sartcorsonline.com/Csr/Public?ClinicPKID=0&reportingYear=2024&newReport=True (last accessed Apr. 16, 2026) (finding that a preliminary national summary report for 2024 from the Society for Assisted Reproductive Technology reported that the rate of live births following first-use IVF for women under the age of 35 using their own oocytes is only 13.8%).

[38] Cara McMullin, *Organizations Adding More Fertility and Adoption Support*, International Foundation of Employee Benefits Plans (Aug. 22, 2024), https://blog.ifebp.org/organizations-adding-more-fertility-and-adoption-support/; Mercer, *Mercer National Survey of Employer-Sponsored Health Plans* (2024).

[39] Cara McMullin, *Organizations Adding More Fertility and Adoption Support*, International Foundation of Employee Benefits Plans (Aug. 22, 2024), https://blog.ifebp.org/organizations-adding-more-fertility-and-adoption-support/.

[40] Ron Shinkman, *Compared: Progyny, Kindbody, Carrot, and Maven as fertility benefit coverage increases 33% in two years* (Apr. 20, 2023), https://www.fertilitybridge.com/news-articles/fertility-benefit-coverage-progyny-kindbody-carrot-maven.

which cover more than half of the people covered by private-sector employer-sponsored health coverage.[41]

Coverage of fertility benefits as an EHB varies by State and issuer. EHBs are defined under ACA section 1302 and 45 CFR 156 subpart B. Non-grandfathered health insurance coverage offered in the individual or small group market is required to cover 10 categories of EHBs.[42] Under ACA section 1302(b)(2)(A) and 45 CFR 156.111, States select an EHB-benchmark plan for their State, which must provide a scope of benefits that is equal to the scope of benefits provided under a typical employer plan. Where benefits are not EHBs, they are not required to be covered (unless a separate Federal or State insurance law applies) and are not subject to certain protections that apply to EHBs, such as PHS Act section 2707(b)'s maximum out-of-pocket requirements and section 2711's prohibition on annual and lifetime dollar limits.[43] While large group health insurance plans and self-insured group health plans are not required to cover EHBs under the ACA, they must comply with the requirements of PHS Act section 2707(b) and section 2711 for those EHBs that they cover.[44]

Other insurance laws requiring coverage of fertility benefits vary at the State level.[45] Currently, 15 States and the District of Columbia require that health insurance coverage include

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[41] KFF, *Share of Private-Sector Enrollees Enrolled in Self-Insured Plans* (2024), https://www.kff.org/state-health-policy-data/state-indicator/share-of-private-sector-enrollees-enrolled-in-self-insured-plans/.

[42] PHS Act section 2707(a); ACA section 1302(a)-(b). The 10 categories of essential health benefits are ambulatory patient services; emergency services; hospitalization; maternity and newborn care; mental health and substance use disorder services, including behavioral health treatment; prescription drugs; rehabilitative and habilitative services and devices; laboratory services; preventive and wellness services and chronic disease management; and pediatric services, including oral and vision care.

[43] PHS Act sections 2707(b) and 2711; *see also* 26 CFR 54.9815-2711, 29 CFR 2590.715-2711, and 45 CFR 147.126.

[44] PHS Act sections 2707(b) and 2711. Final regulations implementing PHS Act section 2711 provide that, for plan years beginning on or after January 1, 2020, a group health plan or health insurance issuer that is not required to provide EHB under section 1302(b) of the ACA must define EHB, for purposes of the prohibition on lifetime and annual limits, in a manner consistent with an EHB-benchmark plan selected by a State in accordance with 45 CFR 156.111, including coverage of any additional required benefits that are considered EHB consistent with 45 CFR 155.170(a)(2). 26 CFR 54.9815-2711(c)(2); 29 CFR 2590.715-2711(c)(2); 45 CFR 147.126(c)(2).

[45] *See* KFF, *Mandated Coverage of Infertility Treatment*, https://www.kff.org/state-health-policy-data/state-indicator/infertility-coverage/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D (last accessed Apr. 16, 2026) (finding 23 States and the District of Columbia have required various levels of fertility-related care coverage for private insurance, while 15 States and the District of Columbia have required various levels of IVF coverage); *see also* RESOLVE, *Insurance Coverage by State* (2024),

IVF benefits.[46] State IVF coverage requirements often include procedural limitations on coverage, such as establishing a benefit-specific waiting period before coverage is provided. For example, some of these waiting periods require a participant or beneficiary to fail to get pregnant or fail to carry a baby to full term for a specified period of time prior to being eligible for IVF coverage. The length of this waiting period may vary depending on the age of the person attempting to get pregnant. Under some State laws, a diagnosis of infertility by a licensed physician allows a covered individual to access fertility benefits before the waiting period requirement has been satisfied. Some State laws also contain coverage limitations based on dollar amount or other quantitative limitations, or both, but coverage limitations are present in all State IVF coverage requirements.[47] For example, a limit on the total number of IVF treatment cycles or oocyte retrievals is common, with limits ranging from one cycle of IVF treatment to three, the latter of which is more common.[48] In contrast, some State laws include explicit dollar-amount lifetime caps as low as $15,000 and as high as $100,000.[49] Some States also require coverage of other ART procedures in addition to IVF, such as gamete intrafallopian transfer (GIFT) and zygote intra-fallopian transfer (ZIFT).[50]

A few States also recently enacted legislation that addresses coverage for other fertility treatments in an attempt to address the root causes of infertility and give couples more information about their reproductive health. For example, in 2025, Arkansas enacted the

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https://resolve.org/learn/financial-resources/insurance-coverage/insurance-coverage-by-state/ (last accessed Apr. 16, 2026) (finding that 25 States have infertility insurance laws, 21 States have laws requiring coverage of fertility preservation treatments, and only 15 States have IVF coverage requirements).

[46] *See id.* (Some States require coverage of other ART procedures in addition to IVF, such as gamete intrafallopian transfer (GIFT), Zygote intra-fallopian transfer (ZIFT), and pronuclear stage tubal transfer (PROST)); *see also* OPM*, 2025 FEHB IVF Information* (Oct. 1, 2024), https://www.opm.gov/healthcare-insurance/healthcare/reference-materials/reference/2025-fehb-ivf-information.pdf (Additionally, for plan year 2025 all Federal Employees Health Benefits (FEHB) Program carriers are required to cover three cycles of IVF-related drugs).

[47] *See* RESOLVE, *Insurance Coverage by State*, https://resolve.org/learn/financial-resources/insurance-coverage/insurance-coverage-by-state/ (last accessed Apr. 16, 2026).

[48] Arkansas sets the maximum lifetime coverage amount at $15,000. *See* Ark. Code § 23-85-137(d); 054-00.1-6 Ark. Code. R. (2025). Maryland and Rhode Island set their respective lifetime maximum coverage limitations at $100,000. Md. Ins. Code Ann. §15–810(e) (2021); 27 R.I. Gen. Laws § 27-18-30(g) (2017).

[49] *See* RESOLVE, *Insurance Coverage by State*, https://resolve.org/learn/financial-resources/insurance-coverage/insurance-coverage-by-state/ (last accessed Apr. 16, 2026).

[50] *See, e.g.,* Ark. Code § 20-16-2603(1)(D), (E); D.C. Code § 31-3834.06(i)(3).

Reproductive Empowerment and Support Through Optimal Restoration Act (RESTORE Act), which amended State law[51] to require that fertility treatment coverage also include fertility treatments that address reproductive health conditions and male factor infertility.[52] The RESTORE Act, among other things, attempts to address the gap in research and care for female reproductive health and treat the underlying reproductive health conditions causing infertility.[53] The RESTORE Act requires coverage for medical treatments including ultrasounds; blood tests; hormone panel tests; laparoscopic or exploratory surgery; examination of a patient's overall health and lifestyle; eliminating environmental endocrine disruptors; assessing the health and fertility health of a patient's partner; natural procreative technology; fertility awareness-based methods; and fertility education and medical management.[54]

5. FAQs Part 72

On October 15, 2025, President Trump announced that the Departments would clarify the existing categories of excepted benefits employers can use to offer fertility benefits, including the categories of independent, noncoordinated excepted benefits and limited excepted benefits. The Departments then contemporaneously issued FAQs about Affordable Care Act Implementation Part 72 (FAQs Part 72)[55] highlighting their commitment to exploring ways to leverage their existing authority to protect IVF access, reduce costs for IVF, and encourage the adoption of a full range of fertility benefits by employers, including treatments to restore fertility by addressing root causes of infertility, in accordance with Executive Order 14216.

FAQs Part 72 clarifies the existing categories of excepted benefits employers can use to offer fertility benefits, including the categories of independent, noncoordinated excepted benefits

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[51] Ark. Code § 23-85-137.
[52] Reproductive Empowerment and Support Through Optimal Restoration (RESTORE) Act, H.B. 1142 (2025).
[53] *Cf.* Chuck Grassley, *Grassley, Hyde-Smith, Lankford Introduce Bill to Help Address Infertility* (Jun. 14, 2024) (introducing similar legislation in the U.S. Senate), https://www.grassley.senate.gov/news/news-releases/grassley-hyde-smith-lankford-introduce-bill-to-help-address-infertility
[54] Ark. Code § 20-16-2603(8).
[55] *FAQs about Affordable Care Act Implementation Part 72* (Oct. 16, 2025), https://www.dol.gov/agencies/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-72 and https://www.cms.gov/files/document/faqs-part-72.pdf.

and limited excepted benefits. Additionally, in FAQs Part 72, the Departments announced their intention to undertake notice and comment rulemaking to provide additional ways that certain fertility benefits may be offered as a limited excepted benefit, if certain conditions are met. In accordance with the directives in Executive Order 14216 and Executive Order 14192 and the commitment expressed in FAQs Part 72, in consideration of the concerns highlighted in this section of the preamble, the Departments are now issuing these proposed rules to reduce the regulatory burden for employers seeking to offer fertility benefits to their employees. As discussed later in section II.A.6 of this preamble, HHS is considering and soliciting comments on whether similar approaches would be appropriate to reduce regulatory burden and improve access to fertility benefits for individuals in the individual market.

II. Overview of the Proposed Rules – Departments of the Treasury, Labor, and HHS

A. Proposed Standards

Many employers, for a variety of reasons, do not cover fertility benefits as part of their major medical coverage. Additionally, there may be scenarios in which an employer wants to offer fertility benefits without regard to whether their employees have other coverage at all, or without regard to whether their employees have coverage that is subject to and satisfies the market requirements. The Departments wish to support and encourage employers in their offering of fertility benefits and to ensure that employees are able to afford a range of fertility treatments to make it easier to have children. Therefore, the Departments propose to utilize the Departments' statutory authority under Code section 9832(c)(2)(C), ERISA section 733(c)(2)(C), and PHS Act section 2791(c)(2)(C) to recognize fertility benefits as other similar limited excepted benefits, if specific conditions are satisfied.

Under proposed paragraph (c)(3)(i) of 26 CFR 54.9831-1 and 29 CFR 2590.732 and proposed paragraph (b)(3)(i) of 45 CFR 146.145, fertility benefits would be excepted benefits if they satisfy the requirements of proposed paragraph (c)(3)(ix) of 26 CFR 54.9831-1 and 29 CFR 2590.732 and proposed paragraph (b)(3)(ix) of 45 CFR 146.145. Under proposed paragraph

(c)(3)(ix) of 26 CFR 54.9831-1 and 29 CFR 2590.732 and proposed paragraph (b)(3)(ix) of 45 CFR 146.145, fertility benefits would be a new type of limited excepted benefit if they are provided under a separate policy, certificate, or contract of insurance or are otherwise not an integral part of the plan as described in proposed paragraph (c)(3)(ix)(C) of 26 CFR 54.9831-1 and 29 CFR 2590.732, and proposed paragraph (b)(3)(ix)(C) of 45 CFR 146.145, and satisfy the requirements of proposed paragraph (c)(3)(ix)(A), (B), and (D) of 26 CFR 54.9831-1 and 29 CFR 2590.732, and proposed paragraph (b)(3)(ix)(A), (B), and (D) of 45 CFR 146.145.

As explained in section I.A.1 of this preamble, the Departments have statutory authority to create additional categories of limited excepted benefits that are similar to the limited excepted benefits specified in statute, and that are provided under a separate policy, certificate, or contract of insurance, or are otherwise not an integral part of a plan.[56] Similar to adult dental and vision coverage, fertility benefits are often not considered EHBs, are often not covered by self-funded group health plans at all or solely to a limited extent, and are often not administered under the same contract as benefits offered through an employer's major medical plan. The Departments' proposal to specify in regulations excepted fertility benefits as a new additional category of other similar limited excepted benefits is consistent with the market reality that fertility benefits are often not covered or, in the minority of cases in which such benefits are covered, are administered under a separate contract from a plan sponsor's major medical plan, along with the statutory framework applicable to limited excepted benefits. This proposal also aligns with the priorities of the Trump Administration expressed in Executive Order 14216 to protect IVF access and reduce out-of-pocket and health plan costs for IVF treatment.

Additionally, the ability to offer a separate excepted fertility benefit that is not subject to the market requirements captured in chapter 100 of the Code, part 7 of ERISA, and title XXVII of the PHS Act is consistent with Executive Order 14192's goals of reducing regulatory burden, as excepted benefits are not subject to certain market requirements imposed on other group

[56] *See* Code section 9831(c)(1), ERISA section 732(c)(1), and PHS Act section 2722(c)(1).

health plans and group health insurance coverage. The Departments are soliciting comments on the proposal to establish excepted fertility benefits as a new category of limited excepted benefits, the limits of the category itself, and the associated proposed conditions for such benefits to qualify as a limited excepted benefit set forth below.

1. Benefits Covered

As stated in section I.A.1 of this preamble, under the Code, ERISA, and the PHS Act, limited excepted benefits include limited-scope dental or vision benefits, benefits for long-term care, nursing home care, home health care, or community-based care that are offered separately, or any combination thereof, and may include "such other similar, limited benefits as are specified in regulations" by the Departments.[57] Thus, in proposing to create excepted fertility benefits as a new category of limited excepted benefits, the Departments determined that fertility benefits are similar to the limited excepted benefits identified in section 9832(c)(2) of the Code, section 733(c)(2) of ERISA, and section 2791(c)(2) of the PHS Act because they are benefits that are often excluded from major medical coverage offered by employers and are often administered under a separate contract. In developing this proposal, the Departments considered in what manner a fertility benefit would be sufficiently limited to be similar to the other categories of limited excepted benefits.

The Departments have consistently applied limiting principles in prior rulemakings when exercising their statutory authority to specify in regulations additional categories of limited excepted benefits.[58] For example, a health FSA is a limited excepted benefit only if the arrangement is structured so that the maximum benefit payable to any participant in the class for a year does not exceed two times the participant's salary reduction election under the arrangement for the year (or, if greater, $500 plus the amount of the participant's salary reduction election).[59] Additionally, limited wraparound coverage was recognized as a limited

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[57] Code section 9832(c)(2)(C), ERISA section 733(c)(2)(C), and PHS Act section 2791(c)(2)(C).
[58] *See* 83 Fed. Reg. 54420, 54437 (Oct. 29, 2018).
[59] 26 CFR 54.9831-1(c)(3)(v); 29 CFR 2590.732(c)(3)(v); 45 CFR 146.145(b)(3)(v).

excepted benefit during a temporary pilot program only if it was limited in amount, such that the cost of coverage per employee (and any covered dependents) under the limited wraparound coverage did not exceed the greater of the maximum permitted annual salary reduction contribution toward a health FSA or 15 percent of the cost of coverage under the primary plan.[60] As stated earlier in this preamble, the statutorily identified dental and vision excepted benefits are limited by implementing regulations in the scope of coverage provided instead of dollar amount, such that substantially all of the benefits thereunder are for the treatment of the mouth (including any organ or structure within the mouth) and treatment of the eye, respectively.[61]

The Departments propose to apply a limiting principle that is similar to limited-scope dental and vision excepted benefits for fertility benefits to qualify as a limited excepted benefit, in addition to proposing to apply a lifetime dollar limit. Under these proposed rules, the Departments propose to add paragraph (c)(3)(ix)(A) to 26 CFR 54.9831-1 and 29 CFR 2590.732 and paragraph (b)(3)(ix)(A) to 45 CFR 146.145, to specify that fertility 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.[62]

The Departments also propose to specify that such benefits may include medically appropriate items or services targeted to address infertility-related reproductive health conditions, in order to clarify that this provision would include benefits for items and services to address underlying medical causes of the infertility. Similar to limited-scope dental and vision benefits, and benefits for long term care, nursing care, and home care and community-based care, this proposed excepted fertility benefit is for targeted, limited benefits that are not typically

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[60] 26 CFR 54.9831-1(c)(3)(vii)(B), 29 CFR 2590.732(c)(3)(vii)(B), and 45 CFR 146.145(b)(3)(vii)(B).
[61] 26 CFR 54.9831-1(c)(3)(iii), 29 CFR 2590.732(c)(3)(iii), and 45 CFR 146.145(b)(3)(iii).
[62] The Departments do not intend for this excepted fertility benefit to include coverage for abortion or abortion-related services. As proposed, this excepted fertility benefit would be for the diagnosis, mitigation, or treatment of infertility or infertility-related reproductive health conditions.

covered under an employer's major medical plan and are often administered under a separate contract. The definition of limited-scope dental and vision benefits under 26 CFR 54.9831-1(c)(3)(iii), 29 CFR 2590.732(c)(3)(iii), and 45 CFR 146.145(b)(3)(iii) allows for coverage of a range of services from preventive care visits through more intensive care such as major restorative care, orthodontics, and ophthalmological services. The Departments propose to allow for a similar scope of coverage for the excepted fertility benefit in order to provide meaningful coverage for individuals facing challenges with infertility or infertility-related reproductive health conditions. As detailed further below, under these proposed rules, fertility benefits that provide coverage for some or all of a similar range of items and services – from preventive care to initial treatments to more intensive care – would fall within the scope of coverage necessary to qualify as limited excepted benefits.

Consistent with the Departments' goal of preserving flexibility for employers to design and offer their benefits in a way that is tailored towards their workforce, the Departments intend that excepted fertility benefits could provide coverage for the services of fertility counselors and general education on fertility, provided that substantially all of the fertility benefits are still at the direction of a medical professional authorized to practice under applicable law. This is also consistent with many families' desire to pursue non-IVF fertility treatment options.[63] As such, the Departments are proposing language to codify that excepted fertility benefits must be for items and services, substantially all of which are provided by medical professionals authorized to practice under applicable law.

Additionally, the Departments recognize that the causes of infertility and infertility-related conditions may vary by individual based on their overall health, specific health

[63] A recent survey of 1,010 adults in the United States, United Kingdom, Ireland, and Canada, who are trying to conceive, have tried to achieve pregnancy in the last five years, or plan to try to achieve pregnancy in the next five years revealed that 89% of women preferred to use a less invasive fertility treatment if supported by evidence before trying IVF. Furthermore, the survey showed that 78% of respondents said that having a better understanding of non-IVF options would make them more likely to pursue other fertility options first. Carrot, *Beyond IVF: What people really want from fertility care* (March 2026), https://content.get-carrot.com/rs/418-PQJ-171/images/2026-Beyond-IVF-Report.pdf?version=0 (last accessed Apr. 16, 2026).

conditions, age, and environmental and socioeconomic factors. For example, maintaining a healthy weight and eating a healthy diet can help men and women address infertility.[64] Common reproductive health conditions, such as polycystic ovary syndrome, endometriosis, or uterine fibroids also can cause infertility for women.[65] Furthermore, there are many underlying endocrinopathies that cause infertility including thyroid disorders, hyperprolactinemia, acromegaly, Cushing's disease, hypogonadotropic hypogonadism, and primary ovarian disorders.[66] For men, fertility can be impacted by conditions such as varicoceles, obstruction in the vas deferens, and male hypogonadism.[67] Therefore, under these proposed rules, excepted fertility benefits may include coverage to diagnose, mitigate and treat infertility and infertility-related conditions and may include medically appropriate items or services targeted to address such conditions.

The Departments note that fertility benefits that may be excepted fertility benefits under these proposed rules may include benefits that are typically covered by major medical plans, including as an EHB. To the extent the group health plan or health insurance issuer of group health insurance coverage offers a major medical plan that both covers any such benefits as an EHB as well as under an excepted fertility benefit, there may be overlapping coverage. Nothing in these proposed rules would prevent such overlapping coverage and coordination-of-benefits provisions under the terms of the plan or coverage, and applicable State and Federal law would continue to apply.[68]

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[64] American College of Obstetricians & Gynecologists, *Treating Infertility, Frequently Asked Questions, What lifestyle changes may help improve my chances for pregnancy?*, https://www.acog.org/womens-health/faqs/treating-infertility (last accessed Apr. 16, 2026).
[65] U.S. Centers for Disease Control and Prevention, *Common Reproductive Health Concerns for Women* (May 15, 2024), https://www.cdc.gov/reproductive-health/women-health/common-concerns.html.
[66] Unuane D, Tournaye H, Velkeniers B, Poppe K. *Endocrine disorders & female infertility*. Best Pract Res Clin Endocrinol Metab. (2011).
[67] Mayo Clinic, *Diagnosis and Treatment, Male infertility* (Dec. 28, 2022), https://www.mayoclinic.org/diseases-conditions/male-infertility/symptoms-causes/syc-20374773.
[68] *See, e.g.,* 42 CFR 411 (providing Medicare Secondary Payer rules); *see also McGurl v. Trucking Employees of North Jersey Welfare Fund, Inc*., 124 F.3d 471 (3d Cir. 1997) (utilizing ERISA common law authority to determine which plan would take precedence where coordination of benefits provisions conflicted).

As stated earlier in this section of the preamble, under these proposed rules, excepted fertility benefits may include benefits to diagnose infertility. Examples of benefits for the diagnosis of infertility include, but are not limited to, benefits for lab tests, imaging, and diagnostic procedures such as laparoscopies and hysteroscopies. Such benefits may also include, for example, benefits for evaluation with hysteroscopy or laparoscopy for patients with a history of endometriosis, pelvic infections, or ectopic pregnancy,[69] as well as blood tests to measure hormones for both men and women, semen analyses to assess the quality and health of the sperm for men, and urine tests to measure levels of luteinizing hormone for women.[70]

Additionally, under these proposed rules, an excepted fertility benefit may also include benefits to mitigate infertility and address infertility-related reproductive health conditions including, for example, examination of a patient's overall health and lifestyle and elimination of environmental endocrine disruptors.[71] Benefits to mitigate infertility under these proposed rules may also include, but are not limited to, fertility awareness-based methods, fertility education and medical management, surgical procedures, and pre-conception care with a focus on fertility awareness.

Under these proposed rules, benefits to mitigate infertility that would be considered excepted fertility benefits may furthermore include assessment of the health and fertility of a patient's partner (where the partner is also a participant or a beneficiary under the plan or coverage). Male-factor infertility treatments are also a component of infertility mitigation.[72]

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[69] Tammy Lindsay, MD, and Kirsten Vitrikas, MD, *Evaluation and Treatment of Infertility*, Am Fam Physician, March 1, 2015; 91(5), https://www.aafp.org/pubs/afp/issues/2015/0301/p308.pdf (During a hysteroscopy, a licensed medical professional inserts a hysteroscope (a thin, lighted tube) through the cervix into the uterus and checks for any irregular signs. During a laparoscopy, a licensed medical professional makes a small cut beneath the navel and places a thin viewing device through the cut to check the fallopian tubes, ovaries, and uterus); Mayo Clinic, *Diagnosis and Treatment*, https://www.mayoclinic.org/diseases-conditions/infertility/diagnosis-treatment/drc-20354322 (last accessed Apr. 16, 2026).

[70] American College of Obstetricians & Gynecologists, *Evaluating Infertility, Frequently Asked Questions, What does the basic testing for women include?*, https://www.acog.org/womens-health/faqs/evaluating-infertility (last accessed Apr. 16, 2026).

[71] *See* Heather Patisaul, *Reproductive Toxicology: Endocrine disruption and reproductive disorders: impacts on sexually dimorphic neuroendocrine pathways*, https://rep.bioscientifica.com/view/journals/rep/162/5/REP-20-0596.xml (Oct. 5, 2021).

[72] *See* Jefferson Health, *Male Factor Infertility* (last accessed Apr. 16, 2026), https://www.jeffersonhealth.org/conditions-and-treatments/male-factor-infertility.

They can include an evaluation of a patient's medical history, a physical examination, analysis of a patient's semen, and surgical approaches, including robotic surgery.[73] Additional methods of mitigation include ultrasound scanning, urinalysis, genetic tests, testicular biopsies, and other tests to determine sperm function.

Another example of a benefit to treat infertility that would be an excepted fertility benefit under these proposed rules is ovulation induction, which includes either oral or injectable medications, that can help improve ovulation patterns or increase the number of eggs released each month.[74] Additionally, although hysteroscopy and laparoscopy are tests that can help diagnose infertility, these tests can also help with the treatment of infertility. For example, a laparoscopy can remove growths called fibroids or endometriosis tissue which can lead to infertility.[75] Treatment of infertility may also include IVF, where egg production is stimulated through medication and eggs are surgically retrieved from the ovaries prior to ovulation and fertilized with sperm in a laboratory environment before being transferred into the uterus.[76] People who have absent or blocked fallopian tubes, endometriosis, ovulatory dysfunction, or low sperm count, among others, are generally considered candidates for IVF.[77]

IVF is the most commonly used ART procedure and one of the most effective for treating infertility.[78] Other types of ART, such as GIFT and ZIFT, are much less common. In a national

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[73] Mourad Assidi, Ph.D., *Infertility in Men: Advances towards a Comprehensive and Integrative Strategy for Precision Theranostics*. Cells (May 22, 2022), https://doi.org/10.3390/cells11101711.
[74] Johns Hopkins Medicine, *Gynecology & Obstetrics Fertility Center, Infertility Services: Ovulation Induction*, https://www.hopkinsmedicine.org/gynecology-obstetrics/specialty-areas/fertility-center/infertility-services/ovulation-induction-intercourse (last accessed Apr. 16, 2026).
[75] Mayo Clinic*, Diagnosis and Treatment*, https://www.mayoclinic.org/diseases-conditions/infertility/diagnosis-treatment/drc-20354322 (last accessed Apr. 16, 2026); *see also* American College of Obstetricians & Gynecologists, *Treating Infertility, Frequently Asked Questions, What are gonadotropins?*, https://www.acog.org/womens-health/faqs/treating-infertility (last accessed Apr. 16, 2026) (Gonadotropins are another drug used to trigger ovulation. Gonadotropins are used if other drugs are not successful or if many eggs are needed for infertility treatments. Gonadotropins are given in a series of shots early in the menstrual cycle.).
[76] Johns Hopkins Medicine, Gynecology & Obstetrics Fertility Center, *Infertility Services: In Vitro Fertilization (IVF)*, https://www.hopkinsmedicine.org/gynecology-obstetrics/specialty-areas/fertility-center/infertility-services/ivf (last accessed Apr. 16, 2026).
[77] Johns Hopkins Medicine, Gynecology & Obstetrics Fertility Center, *Infertility Services: In Vitro Fertilization (IVF)*, https://www.hopkinsmedicine.org/gynecology-obstetrics/specialty-areas/fertility-center/infertility-services/ivf (last accessed Apr. 16, 2026).
[78] U.S. Department of Health and Human Services, *Fact Sheet: In Vitro Fertilization (IVF) Use Across the United States* (Mar. 13, 2024), https://us.pagefreezer.com/en-US/wa/browse/0a7f82bb-be6e-448a-ae11-

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.[79] 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.[80] The Departments recognize that based on the cost of IVF treatment, employers and issuers may choose to limit the benefits available for IVF under an excepted fertility benefit.

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. The Departments believe allowing employers and health insurance issuers this flexibility creates the opportunity for fertility benefits to help individuals address their specific fertility needs, regardless of whether they need pre-conception care related to the underlying cause of infertility or more invasive treatments and procedures, like IVF. Furthermore, to the extent that issuers are assuming financial risk for providing fertility benefits under a separate contract from major medical insurance, the Departments believe the assumption of such risk for a patient's financial exposure and fertility outcome creates a powerful incentive for the issuer to help patients access the highest-quality interventions based on each specific patient's needs at the lowest cost. The Departments solicit comments on the proposals related to the scope of excepted fertility benefits, including the illustrative examples provided in this preamble.

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[79] Society for Assisted Reproductive Technology, *Preliminary National Summary Report for 2024,* National Summary Report (last accessed Apr. 16, 2026), https://www.sartcorsonline.com/CSR/PublicSnapshotReport?ClinicPKID=&reportingYear=2024&fromDisclaimer=true.

[80] Luke, B. et al., *Likelihood of success at each stage of IVF treatment by maternal age and oocyte source: analysis of the 2004-13 cycles in the SART CORS*, Fertility and Sterility (Sept. 2017), https://www.fertstert.org/article/S0015-0282(17)31538-8/fulltext.

2. Lifetime Dollar Amount

In addition to the proposed limitation on the scope of coverage, the Departments are also proposing to establish a lifetime dollar limit for the proposed excepted fertility benefits. Under these proposed rules, at paragraph (c)(3)(ix)(B) of 26 CFR 54.9831-1 and 29 CFR 2590.732 and paragraph (b)(3)(ix)(B) of 45 CFR 146.145, the Departments propose that the total lifetime benefit per participant, together with their beneficiaries (if such beneficiaries are eligible for the excepted fertility benefit), would not exceed $120,000. This proposed maximum lifetime dollar limit would be indexed for medical inflation to keep up with the rising cost of medical items and services. As illustrated in proposed Example 3, to the extent the plan or issuer of the excepted fertility benefits paid $120,000 in benefits (plus the increase due to medical inflation applicable for the plan year) for any participant, together with their beneficiaries if eligible, counting plan payments for both the current plan year to date and any previous plan years, the excepted fertility benefits would be exhausted and no further coverage or additional benefits could be provided by the plan or issuer.[81] Further, a fertility benefit that provides benefits in excess of the maximum lifetime dollar limitation for any participant, together with their beneficiaries if eligible, would fail to meet the requirements of proposed paragraph (c)(3)(ix) of 26 CFR 54.9831-1 and 29 CFR 2590.732 and paragraph (b)(3)(ix) of 45 CFR 146.145.

The Departments are proposing that for plan years beginning after December 31, 2027, the maximum lifetime dollar amount would be increased by an amount equal to $120,000 multiplied by the difference between the overall medical care component of the CPI–U (unadjusted) published by the Department of Labor for December of the previous plan year and 587.144 (the overall medical care component of the CPI-U (unadjusted) for December 2025), divided by 587.144.[82] This method is similar to the method utilized to account for medical

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[81] If consistent with the plan's terms, the excepted fertility benefit plan may, in future years, cover additional benefits for such participant or beneficiary based on the then-applicable lifetime total benefit maximum, as increased by medical inflation.

[82] *See* Bureau of Labor Statistics, *Medical care in U.S. city average, all urban consumers, not seasonally adjusted*, https://data.bls.gov/timeseries/CUUR0000SAM?output_view=data

inflation in the Departments' grandfathered plan regulations.[83] The Departments seek comment regarding whether an alternative method of calculating medical inflation may more accurately reflect the rising costs of fertility treatment.

The Departments have applied limits on other limited excepted benefits specified in regulations, such as the limited health FSA and the excepted benefit HRA. These types of account-based limited excepted benefits can be used to reimburse a wide range of medical care expenses as defined under section 213(d) of the Code. The Departments recognize that certain limited excepted benefits that are not limited in scope by benefit type (as compared to limited-scope dental or limited-scope vision benefits) must be limited in some way to constitute the type of ancillary benefit contemplated within the meaning of "similar, limited benefits" under Code section 9832(c)(2)(C), ERISA section 733(c)(2)(C), and PHS Act section 2791(c)(2)(C). For example, a health FSA is an excepted benefit only if the arrangement is structured so that the maximum benefit payable to any participant in the class for a year does not exceed two times the participant's salary reduction election under the arrangement for the year (or, if greater, $500 plus the amount of the participant's salary reduction election).[84] An excepted benefit HRA may not exceed $1,800, indexed for inflation for plan years beginning after December 31, 2020.[85]

In the context of the proposed excepted fertility benefit, as stated earlier in this preamble, the Departments recognize that the causes of infertility and infertility-related conditions may vary by individual based on various factors such as overall health, specific health conditions, age, and environmental and socioeconomic factors. Given the potential for an expansive understanding of the items and services that may constitute benefits for the diagnosis, mitigation, or treatment of infertility and its causes, the establishment of a total lifetime dollar limit, together with the limit in scope, would ensure the Departments, in the exercise of their statutory authority to specify this new category of limited excepted benefits, give appropriate meaning to the term

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[83] 26 CFR 54.9815-1251(g)(4)(i), 29 CFR 2590.715-1251(g)(4)(i), and 45 CFR 147.140(g)(4)(i).
[84] 26 CFR 54.9831-1(c)(3)(v), 29 CFR 2590. 732(c)(3)(v), and 45 CFR 146.145(b)(3)(v).
[85] 26 CFR 54.9831-1(c)(3)(viii), 29 CFR 2590. 732(c)(3)(viii), and 45 CFR 146.145(b)(3)(viii).

"limited." For excepted fertility benefits, a total lifetime dollar limit, as opposed to the annual dollar limit utilized for other excepted benefits such as excepted benefit HRAs and limited health FSAs, is more appropriate because applying a maximum lifetime dollar limit would be similar to the structure of several States' insurance laws (which impose a lifetime limit on coverage of IVF) as well as the structure of the majority of employer plans that currently offer IVF coverage.[86] The Departments request comment on the proposal to apply a limit on scope of coverage and a lifetime dollar limit and whether fertility benefits that meet both requirements would be sufficiently "similar" and "limited" to constitute the type of benefit contemplated within the meaning of "similar, limited benefits" under Code section 9832(c)(2)(C), ERISA section 733(c)(2)(C), and PHS Act section 2791(c)(2)(C).

In proposing the lifetime dollar amount be limited to $120,000 (plus medical inflation for plan years beginning after December 31, 2027), the Departments considered the main cost drivers of fertility benefits, including IVF. One source estimates the average cost of one IVF cycle in the U.S. ranges from $15,000 to $20,000.[87] Another source suggests that the cost is higher, costing $24,373 to $38,015 for IVF and $61,377 for successful pregnancy via IVF.[88] Even less costly procedures like IUI can be several thousand dollars per treatment.[89] Beyond the cost of the procedures involved, a patient faces other associated costs such as imaging, bloodwork, and medications. Given that the average number of cycles that are needed to achieve a successful pregnancy from IVF is 2.5, the total cost of IVF can exceed $40,000, or even $60,000, depending on the source.[90] The Departments are therefore proposing a $120,000

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[86] *See* 054.00.1 Ark. Admin. Code § 6; *see also* 27 R.I. Gen. Laws § 27-18-30(g); *see also* Md. Code Ann., Ins. § 15–810(e); *see also* Mercer, *National Survey of Employer-Sponsored Health Plans* (2024).

[87] Alina Salganicoff, Brittni Frederiksen, and Usha Ranji, *Will Trump's Announcement Expand Access to IVF?*, KFF (Oct. 27, 2025), https://www.kff.org/womens-health-policy/will-trumps-announcement-expand-access-to-ivf/?spm=a2700.accio_bizSeo.0.0.25a87e47NpdtI2.

[88] Patricia Katz et. al., *Costs of infertility treatment: results from an 18-month prospective cohort study,* Fertil Steril. (March 1, 2011).

[89] Penn Medicine, *Intrauterine insemination (IUI)*, https://www.pennmedicine.org/treatments/intrauterine-insemination (last accessed Apr. 16, 2026).

[90] Patricia Katz et. al., *Costs of infertility treatment: results from an 18-month prospective cohort study*, Fertil Steril. (March 1, 2011); U.S. Department of Health and Human Services, *Fact Sheet: In Vitro Fertilization (IVF) Use Across the United States* (Mar. 13, 2024), https://us.pagefreezer.com/en-US/wa/browse/0a7f82bb-be6e-448a-ae11-

lifetime dollar limit because it would give employers and health insurance issuers the flexibility to offer benefits sufficient to meaningfully provide a benefit that covers the needs of their employees, including successful conceptions via IVF. The Departments do not intend that employers and issuers offering fertility benefits would be unduly constrained in designing a meaningful fertility benefit, and accordingly, the Departments are proposing a dollar limit that reflects the cost of fertility treatment for many individuals and is in line with the lifetime maximum benefits of several State insurance laws (which are currently as high as $100,000).[91] The Departments also believe setting such dollar limit would reduce the amount of disruption for employers who may choose to transition their current fertility benefits to an excepted fertility benefit, as such employers could retain any current dollar limit, as long as it is $120,000 or lower, while adding a limiting principle.

While the Departments considered proposing an alternative, lower lifetime dollar limit (e.g. $50,000), they determined that such a limit may constrain employers and health insurance issuers that want to offer a fertility benefit sufficient to cover multiple fertility treatments, including for those families who wish to have more than one child. While the Departments acknowledge the proposed $120,000 lifetime dollar limit would be a considerable benefit, the Departments are of the view that this limiting principle, in conjunction with the proposed limitation on the scope of benefits covered by the excepted fertility benefit, aligns with the meaning of the term "similar, limited benefits" under Code section 9832(c)(2)(C), ERISA section 733(c)(2)(C), and PHS Act section 2791(c)(2)(C). The fact that the statute sets forth benefits for "long-term care, nursing home care, home health care, community-based care, or any

373d22c37842?find-by-timestamp=2025-01-02T05:49:59Z&url=https:%2F%2Fwww.hhs.gov%2Fabout%2Fnews%2F2024%2F03%2F13%2Ffact-sheet-in-vitro-fertilization-ivf-use-across-united-states.html&timestamp=2025-01-02T07:03:02Z.

[91] *See* Mercer, *National Survey of Employer-Sponsored Health Plans* (2024) (The median lifetime dollar limit for employer-sponsored IVF coverage was $20,000 in 2023); Md. Ins. Code Ann. §15–810(e) (2021); 27 R.I. Gen. Laws § 27-18-30(g) (2017).

combination thereof" as a category of limited benefits, which can cost an average of $120,900,[92] suggests that Congress contemplated that the limited excepted benefits category could include other benefits of comparable value, including the proposed excepted fertility benefit category.

The Departments also note that other States have made fertility benefits an EHB. EHBs are prohibited from having annual or lifetime dollar limits, but may have non-dollar limits, such as limits on the number of IVF cycles covered. Proposing a lifetime dollar limit for the excepted fertility benefits would not undermine these State insurance requirements. Fertility benefits that are EHB in a State must be covered by the non-grandfathered individual and small group major medical health insurance coverage in that State.

The Departments solicit comment on whether a different maximum dollar amount is necessary to achieve the goals of sufficiently limiting the scope of the excepted fertility benefits. The Departments also solicit comment on whether a maximum dollar amount is unnecessary and the Departments should instead rely on the definition of excepted fertility benefits to limit their scope.

The Departments are also considering whether the dollar limit should be a maximum lifetime dollar amount as proposed, or whether the amount should be a maximum annual limit (e.g., up to $15,000) where any unused portion could carry over to the following plan year, similar to what is allowed for excepted benefit HRAs.[93] The advantage of such a cumulative annual amount under the latter arrangement is that it would encourage participants to enroll in the excepted fertility benefit before they may be planning to use the benefit in order to build up the benefit to be used at a later date. [94] Accordingly, the Departments solicit comment on whether

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[92] *See* HHS Office of the Assistance Secretary for Planning and Evaluation, Office of Behavioral Health, Disability, and Aging Policy, *Long-Term Services and Supports for Older Americans: Risks and Financing, 2022* (Aug. 2022), https://aspe.hhs.gov/sites/default/files/documents/08b8b7825f7bc12d2c79261fd7641c88/ltss-risks-financing-2022.pdf.

[93] *See* 26 CFR 54.9831-1(c)(3)(viii)(B)(*2*); 29 CFR 2590.732(c)(3)(viii)(B)(*2*); and 146.145(b)(3)(viii)(B)(*2*).

[94] Under the current proposal, a plan sponsor could similarly design an excepted fertility benefit such that it imposes an annual dollar limitation where any unused portion could carry over to subsequent plan years, up to the lifetime dollar amount at proposed paragraph (c)(3)(ix)(B) of 26 CFR 54.9831-1 and 29 CFR 2590.732 and paragraph (b)(3)(ix)(B) of 45 CFR 146.145.

instead of a lifetime dollar limit, a maximum annual cumulative limit should apply to the excepted fertility benefit, and what the annual dollar amount should be under such an alternative approach.

3. Not an Integral Part of the Plan

To be a limited excepted benefit under Code section 9831(c)(1), ERISA section 732(c)(1), and PHS Act section 2722(c)(1), benefits must: (1) be provided under a separate policy, certificate, or contract of insurance; or (2) otherwise not be an integral part of the plan. While only insured coverage may qualify under the first test, both insured and self-insured coverage may qualify under the second test.[95]

Under these proposed rules, for a fertility benefit in the group market to be considered not an integral part of the plan, the Departments propose that a group health plan that is not limited to excepted benefits and that is not an HRA or other account-based group health plan must be made available by the same plan sponsor for the plan year to the participants offered the fertility benefit. Only individuals eligible to participate in the traditional group health plan would be eligible to participate in the excepted fertility benefit. However, while the plan sponsor would be required to offer a traditional group health plan to all individuals offered the fertility benefit, participants in the fertility benefit (and beneficiaries, if eligible for the fertility benefit) would not be required to enroll in that traditional group health plan in order for the fertility benefit to qualify as a limited excepted benefit. This proposed standard is similar to rules for health FSAs at paragraph (c)(3)(v) of 26 CFR 54.9831-1 and 29 CFR 2590.732, and paragraph (b)(3)(v) of 45 CFR 146.145 and for excepted benefit HRAs at paragraph (c)(3)(viii) of 26 CFR 54.9831-1 and 29 CFR 2590.732, and (b)(3)(viii) of 45 CFR 146.145. Participants (and beneficiaries, if eligible for the fertility benefit) enrolling in the fertility benefit may decline coverage for the other group health plan coverage. For example, a participant may decline the other group health plan

[95] 79 Fed. Reg. 59130, 59131 (Oct. 1, 2014).

coverage if the participant can opt out of that coverage, whether or not there is a contribution required for the coverage.[96] This may be an attractive option for participants who have enrolled in group health plan coverage through another household member, such as a spouse, but would still like to take advantage of this excepted fertility benefit. The Departments solicit comments on this approach.

The Departments are also considering whether additional safeguards are necessary to ensure that such coverage is not an integral part of the plan. For example, the rule for EAPs to qualify as limited excepted benefits requires at paragraph (c)(3)(vi)(C) of 26 CFR 54.9831-1 and 29 CFR 2590.732 and paragraph (b)(3)(vi)(C) of 45 CFR 146.145 that no employee premiums or contributions be required as a condition of participation in the EAP. Additionally, paragraph (c)(3)(vi)(D) of 26 CFR 54.9831-1 and 29 CFR 2590.732 and paragraph (b)(3)(vi)(D) of 45 CFR 146.145 provides that EAPs that qualify as limited excepted benefits have no cost sharing. As compared to EAPs, excepted fertility benefits may provide a broader scope of benefits. Accordingly, the Departments are not proposing to prohibit plans and issuers from charging a premium or contribution or imposing cost sharing for excepted fertility benefits. In addition, there are other categories of limited excepted benefits that are permitted to charge a premium or contribution and/or impose cost-sharing that the Departments believe are more analogous to the proposed excepted fertility benefits (e.g., limited-scope dental or vision benefits and benefits for long-term care). The Departments solicit comments on whether an additional safeguard that no employee premium or contribution be required as a condition of participation in the excepted fertility benefit should be imposed, or whether plans and issuers should have the flexibility to charge premiums or contributions and impose cost sharing, as they do for limited-scope dental, vision, and long-term care coverage.

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[96] This is also consistent with the standard applicable to limited scope dental benefits, limited scope vision benefits, and long-term care benefits that are limited excepted benefits. *See* 26 CFR 54.9831-1(c)(3)(ii)(A), 29 CFR 2590.732(c)(3)(ii)(A), and 45 CFR 146.145(b)(3)(ii)(A).

4. Notice Requirements

In order to ensure that participants and beneficiaries who are eligible to participate in an excepted fertility benefit are informed about its availability and understand the scope of coverage provided, the Departments propose, under their statutory authority in section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act, to require that plans and issuers provide written notice to plan participants and beneficiaries in accordance with proposed paragraph (c)(3)(ix)(D) of 26 CFR 54.9831-1 and 29 CFR 2590.732 and proposed paragraph (b)(3)(ix)(D) of 45 CFR 146.145 for fertility benefits to qualify as limited excepted benefits. Under these proposed rules, if a single notice is provided to a participant and any beneficiaries at the participant's last known address, then the requirement to provide the notice to the participant and any beneficiaries would generally be satisfied. However, if a beneficiary's last known address is different from the participant's last known address, a separate notice provided to the beneficiary at the beneficiary's last known address would be required. In either case, such address could include an electronic address, if otherwise allowed under the relevant disclosure requirements applicable to the plan.[97]

Such a notice requirement would be in addition to any notice requirements otherwise applicable to excepted benefits. For excepted benefits that are ERISA welfare benefit plans, such disclosure requirements would include the Summary Plan Description (SPD) under ERISA section 102 and 29 CFR 2520.102-3(j)(2) and (3) and 2520.104b-2(a). The Departments recognize that SPDs often contain far too much detail for a summary document and intend that participants and beneficiaries have information on the excepted fertility benefits in a shorter, more reader-friendly format.[98] The proposed notice requirement would instead be expected to

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[97] *See* 29 CFR 2520.104b-1.

[98] *See* ERISA Advisory Council, *Mandated Disclosure for Retirement Plans – Enhancing Effectiveness for Participants and Sponsors* (Nov. 2017), https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/about-us/erisa-advisory-council/2017-mandated-disclosure-for-retirement-plans.pdf; *see also* ERISA Advisory Council, *Advisory Council Report of the Working Group on Health and Welfare Benefit Plans' Communications* (2005), https://www.dol.gov/agencies/ebsa/about-ebsa/about-us/erisa-advisory-council/2005-health-and-welfare-benefit-plans-communications.

function as an executive summary or "quick reference guide" for the excepted fertility benefits.[99] While the excepted fertility benefits notice would be a separate notice, it could be provided with other ERISA-required documents. For example, if multiple documents are furnished together as part of an open enrollment packet, the excepted fertility benefits notice could be included as part of the packet. Under these proposed rules, the notice for non-Federal governmental plans would similarly be expected to function as an executive summary and be a separate notice that could be provided with other documents.

Under these proposed rules, the Departments would require issuers and plan sponsors of both insured and self-insured excepted fertility benefits to provide this notice. The Departments require a notice for other types of limited excepted benefits, such as excepted benefit HRAs at paragraph (c)(3)(viii) of 26 CFR 54.9831-1 and 29 CFR 2590.732 and paragraph (b)(3)(viii) of 45 CFR 146.145. The Departments are of the view that participants and beneficiaries should be aware of the availability of any excepted fertility coverage offered, so that they can utilize it expeditiously. Additionally, participants and beneficiaries may be unfamiliar with how benefits for the diagnosis, mitigation, and treatment of infertility generally work under the plan. Therefore, the Departments intend that the proposed notice would be an important educational tool that would help participants and beneficiaries navigate their excepted fertility benefits. It is also important that participants understand what would be covered under their excepted fertility benefits, as opposed to under their traditional group health plan. Therefore, in the Departments' view, it is appropriate to require this additional disclosure.[100] The Departments solicit comments on this approach, and whether there are alternative approaches that may better accomplish the same goal of informing eligible participants and beneficiaries about the availability of excepted fertility benefits and the scope of coverage provided.

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[99] *Id.*

[100] *See* ERISA sections 505 and 734, PHS Act sections 2761 and 2792, ACA section 1321(a)(1) and (c), and Code section 7805 (providing the Secretaries of Labor, HHS, and the Treasury the authority to promulgate regulations as may be necessary or appropriate to carry out provisions of ERISA, the PHS Act, and the Code).

a. Notice Content

The Departments propose in proposed paragraph (c)(3)(ix)(D)(*1*) of 26 CFR 54.9831-1 and 29 CFR 2590.732 and proposed paragraph (b)(3)(ix)(D)(*1*) of 45 CFR 146.145 that this notice would include a description of the coverage. This description would be required to include a summary of benefits and limitations of the coverage, including the lifetime dollar limit established by the plan or issuer that complies with the maximum lifetime dollar limit described in proposed paragraph (c)(3)(ix)(B) (or paragraph (b)(3)(ix)(B), as applicable). As proposed, the notice would also include information on how to identify and utilize a network provider, if applicable, and how to submit a claim for reimbursement. This could include, for example, any electronic and paper filing options, the required information needed for such a claim, and a brief description of the documentation that must be submitted in order for the plan or issuer to be able to process the claim promptly. Finally, the notice would be required to include accurate information on whether the benefit utilizes the same claims procedure as for the sponsor's other group health plans. Participants and beneficiaries would need such information in order to properly utilize their fertility benefits and receive the promised coverage. The Departments solicit comments on this approach, including whether any additional elements should be required for the notice.

Furthermore, the notice would be required to be written and presented in a manner calculated to be understood by the average plan participant. In determining whether this standard has been satisfied, the plan or issuer would be required to take into account such factors as the level of comprehension and education of typical participants and beneficiaries in the plan or coverage and the complexity of the terms of the plan or coverage. Accounting for these factors would likely require limiting or eliminating the use of technical jargon, complex medical terminology except where necessary, and defining any technical terms of art used. This would also generally require eliminating long, complex sentences, and providing information in plain English (i.e., at or below an 8th-grade reading level) so that the information provided would not

have the effect of misleading, misinforming, confusing, or failing to inform participants or beneficiaries. The Departments solicit comments on this approach.

b. Notice Timing

Under proposed paragraph (c)(3)(ix)(D)(*2*) of 26 CFR 54.9831-1 and 29 CFR 2590.732 and proposed paragraph (b)(3)(ix)(D)(*2*) of 45 CFR 146.145, a plan or issuer would be required to provide the notice no later than the first date on which the participant is eligible to enroll in coverage, and annually thereafter. This would allow individuals to be informed about their coverage and generally would align with the timing of disclosures that participants and beneficiaries currently receive from their group health plan, such as the summary of benefits and coverage.[101] Additionally, this notice would be required to be provided upon request of the participant or beneficiary. This would ensure that participants and beneficiaries would have such information available to them when needed. The Departments solicit comments on this approach.

5. Examples

In proposed 26 CFR 54.9831-1(c)(3)(ix)(E), 29 CFR 2590.732(c)(3)(ix)(E), and 45 CFR 146.145(b)(3)(ix)(E), the Departments also propose including several examples in order to illustrate the requirements of these proposed rules and provide clarity. In example 1 of these proposed rules, an employer offers benefits for fertility counseling through a separate policy of insurance that satisfy the requirements of proposed paragraph (c)(3)(ix)(A) and (B) (or paragraph (b)(3)(ix)(A) and (B), as applicable). The issuer of the fertility counseling coverage also provides notice to plan participants and beneficiaries at or before the time individuals are given the opportunity to enroll in the coverage and annually thereafter. The notice is written in a manner calculated to be understood by the average plan participant and includes a description of the coverage, including a summary of benefits and limitations of the coverage, how to identify and utilize a network provider, how to submit a claim for reimbursement, and that the benefit utilizes the same claims procedure as for the sponsor's other group health plans. The fertility counseling

[101] *See* 26 CFR 54.9815-2715(a)(1)(i), 29 CFR 2590.715-2715(a)(1)(i), and 45 CFR 147.200(a)(1)(i).

coverage also has a lifetime dollar limit that complies with proposed 26 CFR 54.9831-1(c)(3)(ix)(B), 29 CFR 2590.732(c)(3)(ix)(B) and 45 CFR 146.145(b)(3)(ix)(B).

In example 1 of these proposed rules, the benefits under the fertility counseling coverage satisfy the requirements to be considered a limited excepted benefit under proposed paragraph (c)(3)(ix) (or paragraph (b)(3)(ix), as applicable). The employer provides fertility benefits that do not exceed the maximum lifetime limit which are limited as required and are provided by the employer through a separate fully insured policy. Additionally, the plan provides written notice in accordance with proposed paragraph (c)(3)(ix)(D) (or paragraph (b)(3)(ix)(D), as applicable). Therefore, the benefits would qualify as an excepted fertility benefit that is a limited excepted benefit.

In example 2 of these proposed rules, an employer sponsors a group health plan that is not limited to excepted benefits, that is not an HRA or other account-based group health plan and also offers fertility benefits for the mitigation or treatment of infertility that satisfy the requirements of proposed paragraph (c)(3)(ix)(A) (or paragraph (b)(3)(ix)(A), as applicable). The fertility benefits are self-funded by the employer. The employer offers both the group health plan and the fertility benefits to participants and permits participants to enroll in either or both benefit options or decline to participate in either or both options for the plan year. The employer also includes a lifetime dollar limit on fertility benefits that satisfies the requirements of proposed paragraph (c)(3)(ix)(B) (or (b)(3)(ix)(B), as applicable) and provides written notice to participants in accordance with the requirements of proposed paragraph (c)(3)(ix)(D) (or paragraph (b)(3)(ix)(D), as applicable).

In example 2 of these proposed rules, the fertility benefits satisfy the conditions in proposed paragraph (c)(3)(ix) (or paragraph (b)(3)(ix), as applicable). Because the fertility benefits are not provided under a separate policy, certificate, or contract of insurance, the requirements under paragraphs (c)(3)(ix)(C) (or paragraph (b)(3)(ix)(C), as applicable) apply. The fertility benefits are not an integral part of the group health plan because the employer

offers, to participants that are offered the fertility benefit, coverage under another group health plan that is not limited to excepted benefits for the plan year, and that is not an HRA or other account-based group health plan and participants may decline coverage for such other group health plan coverage. In addition, the fertility benefit plan offers fertility benefits for the mitigation or treatment of infertility that satisfy the requirements of paragraph (c)(3)(ix)(A) (or paragraph (b)(3)(ix)(A), as applicable), includes a lifetime limit on fertility benefits that complies with paragraph (c)(3)(ix)(B) (or paragraph (b)(3)(ix)(B), as applicable), and provides written notice as required by paragraph (c)(3)(ix)(D) (or paragraph (b)(3)(ix)(D), as applicable).

Example 3 of these proposed rules illustrates the application of the lifetime limit on dollar amounts for the excepted fertility benefit. In example 3, an employer sponsors a fertility benefit plan for the mitigation or treatment of infertility that satisfies the requirements of paragraph (c)(3)(ix)(A), (C) and (D) (or paragraph (b)(3)(ix)(A), (C) and (D), as applicable) in a plan year. The fertility benefits are self-funded by the employer. The fertility benefit plan imposes a lifetime, per participant limitation on benefits of $120,000. During the plan year, the fertility benefit plan covers a given participant's claims for treatment of infertility by medical professionals authorized to practice under applicable law totaling $65,000. In December of the plan year, the overall medical care component of the CPI–U (unadjusted) published by the Department of Labor is 625.522. During the following plan year, the plan again covers $65,000 in claims for the same participant for treatment of infertility by medical professionals authorized to practice under applicable law pursuant to such plan's terms.

In this example, the plan fails to satisfy the conditions to be an excepted fertility benefit because lifetime benefits to the participant in the following plan year exceed $127,843.66, which is the proposed excepted fertility benefit lifetime dollar limit indexed for medical inflation for the relevant plan year. For purposes of calculating the lifetime dollar limit adjusted for medical inflation in this example, medical inflation is calculated by subtracting 587.144 (the overall medical care component of the CPI-U (unadjusted) for December 2025) from 625.522 (the

overall medical care component of the CPI–U (unadjusted) published by the Department of Labor for December of the previous plan year) and dividing that amount by 587.144 ((625.522-587.144)/587.144). This amount is multiplied by $120,000 which determines the dollar amount of medical inflation ($7,843.66). Because the fertility benefit covers benefits beyond the permissible lifetime dollar limit adjusted for medical inflation ($127,843.66)), the plan fails to satisfy the condition that the benefit be limited in amount. The employer may still cover fertility benefits that are in excess of the lifetime limit through its group health plan that is not limited to excepted benefits and that is not an HRA or other account-based group health plan, provided it otherwise complies with the market requirements of chapter 100 of the code, part 7 of ERISA, or title XXVII of the PHS Act, as applicable.

6. Applicability

This proposal to create an excepted fertility benefit as a new category of limited excepted benefits would apply to group health plans and health insurance issuers offering group health insurance coverage for plan years beginning on or after January 1, 2027. The Departments solicit comments on this proposed applicability date, including how long it may take group health plan sponsors and health insurance issuers in the group market to make the necessary amendments for their existing fertility benefits coverage to qualify as limited excepted benefits or to newly offer a limited benefit for excepted fertility benefits, if so desired, and with respect to insurance coverage, for States to review and approve such filings. The Departments also solicit comment on whether these proposed rules, if finalized, should instead be applicable upon the effective date of the final rules in order to grant group health plan sponsors and health insurance issuers flexibility to offer this new category of limited excepted benefits immediately, if desired.

In accordance with the directives in Executive Order 14216 and the commitment expressed in FAQs Part 72, these proposed rules would reduce the regulatory burden for employers with respect to offering fertility benefits to their employees because they would establish a new pathway for plan sponsors to offer fertility benefits as a limited excepted benefit

that generally would not be subject to the parallel market requirements of chapter 100 of the Code, part 7 of ERISA, and title XXVII of the PHS Act.

As proposed, these rules would apply to group health plans and health insurance issuers offering group health insurance coverage. The Departments are generally aware of how employers provide fertility benefits in the group market, including through specialty vendors. The Departments believe that employers would utilize excepted fertility benefits to expand their fertility coverage offerings. The Departments have less information, however, on how excepted fertility benefits might work in the individual market, including whether there would be interest from issuers to offer these benefits on a stand-alone basis in such market.

HHS is considering whether the final rules should adopt similar standards for the individual market to reduce regulatory burden and promote access to fertility coverage for individuals and their dependents. Specifically, HHS is considering an approach under which it would exercise its authority under section 2791(c)(2)(C) of the PHS Act to recognize certain fertility benefits as limited excepted benefits in the individual market under sections 2722(c)(1) and 2763(b) of the PHS Act for policy years beginning on or after January 1, 2027, if certain conditions are met.

Under the approach HHS is considering, the individual market excepted benefit regulations at 45 CFR 148.220(b) would provide that fertility benefits constitute excepted fertility benefits in the individual market, if the benefits are offered under a separate policy, certificate, or contract of insurance and satisfy the conditions in proposed 45 CFR 146.145(b)(3)(ix)(A), (B), and (D) that the benefits be limited in scope, be subject to a maximum lifetime dollar amount, and the issuer provides written notice informing individuals and their dependents of the availability of coverage and describing the coverage.

Under this approach, certain proposed group market standards for excepted fertility benefits would be modified or inapplicable with respect to the individual market. For example, an issuer of excepted fertility benefits in the individual market would be required to provide

notice to individuals and their dependents containing similar content as the group market. The notice would be provided with any application materials provided to individuals or dependents prior to enrollment, and annually thereafter at the time of coverage renewal, as well as upon request of an individual or dependent. This would allow individuals and their dependents to be informed about the fertility benefit coverage before enrolling or reenrolling in coverage and generally would align with the proposed notice timing standard for the group market. Unlike in the group market, the notice in the individual market would not be required to include information on whether the excepted fertility benefit utilizes the same claims procedure as the sponsor's other group health plans, as there is no plan sponsor in the individual market.

Also under the approach HHS is considering, the individual market excepted benefit regulations would not incorporate the proposed group market standard at 45 CFR 146.145(b)(3)(ix)(C) that benefits not be an integral part of a plan, as the reference to "plan" in section 2722(c)(2) of the PHS Act has been interpreted as referring to a group health plan.[102] Furthermore, HHS's individual market excepted benefits regulations at 45 CFR 148.220 provide that individual coverage is excepted only if the benefits are offered under a separate policy, certificate, or contract of insurance. Therefore, the requirement that the benefits not be an integral part of a plan would not apply under the approach HHS is considering for the individual market.

HHS seeks comments on all aspects of this approach, including whether it would be appropriate to create a new category of limited excepted benefits for excepted fertility benefits in the individual market, the standards HHS is considering, and any additional standards or considerations that may be appropriate for the individual market.

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[102] *See, e.g.,* 79 Fed. Reg. 59130, 59131 (Oct. 1, 2014) ("To be excepted under this second category, the statute (specifically, ERISA section 732(c)(1), PHS Act section 2722(c)(1), and section 9831(c)(1) of the Code) provides that limited benefits must either: (1) Be provided under a separate policy, certificate, or contract of insurance; or (2) otherwise not be an integral part of a group health plan, whether insured or self-insured.").

7. Severability

The Departments are proposing amendments to recognize excepted fertility benefits as a new category of limited excepted benefits. The Departments' authority to propose these amendments is well-established in law and practice. However, in the event that any portion of these proposed rules, if finalized, is declared invalid, the Departments intend that the other provisions, which could still function sensibly, would be severable. Overall, the aim of the Departments is to ensure that employers and issuers can offer fertility benefits that qualify as limited excepted benefits. The proposed group market requirements under paragraphs (c)(3)(ix)(A), (B) and (C) of 26 CFR 54.9831-1, and 29 CFR 2590.732 and paragraph (b)(3)(ix)(A), (B) and (C) of 45 CFR 146.145, while part of a comprehensive regulatory scheme, are also separate requirements and can stand independently of each other and the Departments' other group market excepted benefits regulations.

Similarly, the proposed notice requirements at paragraphs (c)(3)(ix)(D) of 26 CFR 54.9831-1, and 29 CFR 2590.732 and paragraph (b)(3)(ix)(D) of 45 CFR 146.145 are separate requirements that can stand independently of the standards under paragraphs (c)(3)(ix)(A), (B), and (C) of 26 CFR 54.9831-1, and 29 CFR 2590.732 and paragraph (b)(3)(ix)(A), (B), and (C) of 45 CFR 146.145. Consequently, following any potential legal challenge, a court's decision to invalidate one standard should not affect any provision that relates to a separate standard. As indicated, this discussion of the application of severability to the provisions in these proposed rules offers examples and is not exhaustive of other potential applications. Therefore, these proposed rules specify that if any provision of paragraph (c)(3)(ix) of 26 CFR 54.9831-1 and 29 CFR 2590.732, and paragraph (b)(3)(ix) of 45 CFR 146.145 is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, the provision would be construed so as to continue to give the maximum effect to the provision permitted by law. For example, if the notice requirement were to be struck down, an employer could still offer an excepted fertility benefit that met the other conditions of

paragraph (c)(3)(ix) of 26 CFR 54.9831-1 and 29 CFR 2590.732, and paragraph (b)(3)(ix) of 45 CFR 146.145. However, if such holding is one of invalidity or unenforceability, these proposed rules specify the provision would be severable from this section and would not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

III. Regulatory Impact Analysis

A. Summary

These proposed rules would establish fertility benefits as a new category of limited excepted benefits, the limits of the category itself, and the associated proposed conditions for such benefits to qualify as a limited excepted benefit. The Departments have examined the impacts of these proposed rules as required by Executive Order 12866,[103] Executive Order 13563,[104] Executive Order 14192,[105] the Paperwork Reduction Act of 1995,[106] the Regulatory Flexibility Act,[107] section 202 of the Unfunded Mandates Reform Act of 1995,[108] and Executive Order 13132.[109]

B. Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects; distributive impacts; and equity). Executive Order 13563 emphasizes the importance of quantifying costs and benefits, reducing costs, harmonizing rules, and promoting flexibility.

Under Executive Order 12866, "significant" regulatory actions are subject to review by the Office of Management and Budget (OMB). Section 3(f) of the Executive Order defines a

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[103] Regulatory Planning and Review, 58 Fed. Reg. 51735 (Oct. 4, 1993).
[104] Improving Regulation and Regulatory Review, 76 Fed. Reg. 3821 (Jan. 18, 2011).
[105] 90 Fed. Reg. 9065 (January 31, 2025).
[106] 44 U.S.C. 3506(c)(2)(A) (1995).
[107] 5 U.S.C. 601 *et seq*. (1980).
[108] 2 U.S.C. 1501 *et seq*. (1995).
[109] Federalism, 64 Fed. Reg. 153 (Aug. 4, 1999).

"significant regulatory action" as any regulatory action that is likely to result in a rule that may:

1) Have an annual effect on the economy of $100 million or more; or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or Tribal governments or communities (also referred to as "economically significant");
2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;
3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or
4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive order.

Based on the Departments' estimates, OMB's Office of Information and Regulatory Affairs (OIRA) has determined this rulemaking is significant per section 3(f). The Departments have provided an assessment of the potential costs, benefits, and transfers, associated with these proposed rules, and OMB has reviewed these proposed rules.

Executive Order 14192, titled "Unleashing Prosperity Through Deregulation," was issued on January 31, 2025. Section 3(a) of Executive Order 14192 requires an agency, unless prohibited by law, to identify at least ten existing regulations to be repealed when the agency issues a new regulation. In furtherance of this requirement, section 3(c) of Executive Order 14192 requires that the new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with prior regulations. A significant regulatory action (as defined in section 3(f) of Executive Order 12866) that would impose total costs greater than zero is considered an Executive Order 14192 regulatory action. These proposed rules, if finalized as proposed, are therefore expected to be regulatory actions under Executive Order 14192.

C. Need for Regulatory Action

Executive Order 14216, "Expanding Access to In Vitro Fertilization," states that the policy of the Trump Administration is to provide support, awareness, and access to affordable fertility treatments, including reliable access to IVF treatment, by easing unnecessary statutory or regulatory burdens to make IVF and fertility treatments drastically more affordable.[110]

These proposed rules would help address the increasing need for fertility services through the addition of a new type of limited excepted benefit that provides coverage for items and services to diagnose, mitigate, or treat infertility or infertility-related reproductive health conditions. By proposing to expand the classification of limited excepted benefits to include this coverage, the Departments anticipate greater coverage for such items and services could help address coverage gaps and prohibitively expensive medical care that limits access to and utilization of such items and services.

1. Background

The decline in fertility rates has been an increasing concern in the United States. Since 1990, the general fertility rate, which is the number of births per 1,000 women aged 15 to 44, has declined by 23 percent in the United States. This has resulted in over half a million fewer births in the United States in 2023 compared to 1990. Across the population, the general fertility rate has broadly declined with the total fertility rate now estimated at 1.6 births per woman, well below the 2.1 births per woman required for population stability (referred to as the "replacement rate").[111]

The decline in births has been driven by women under 30, who had nearly 1.2 million fewer births in 2023 than in 1990, a decline of nearly 40 percent.[112] This has coincided with increasing delays to childbirth, indicated by the age of the mother at their child's first birth,

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[110] 90 Fed. Reg. 10451 (Feb. 18, 2025).
[111] Anne Driscoll and Brady Hamilton, *Effects of Age-Specific Fertility Trends on Overall Fertility Trends: United States, 1990-2023*, Centers for Disease Control and Prevention, National Vital Statistics Reports, Vol. 74, No. 3 (Mar. 6, 2025), https://stacks.cdc.gov/view/cdc/174576.
[112] *Id.*

which has steadily increased from 24.2 years of age in 1990 to 27.5 in 2023.[113, 114] Similarly, the age of the father at their first child's birth has also increased over time.[115] Though individuals may intentionally delay childbirth to later in life, advanced maternal age increases the risks associated with pregnancy complications.[116] This, coupled with the declining natural fertility associated with older age, could result in some intentionally delayed pregnancies not occurring and leading to missed birth opportunities.

While women under 30 have experienced a significant decline in birth rates, women over 30 have experienced growth in their birth rates and now account for 51 percent of all births in the United States.[117] The number of births to women over 40 nearly tripled between 1990 and 2023, while births to women aged 35 to 39 nearly doubled and births to women aged 30 to 34 increased moderately. This resulted in approximately 600,000 additional births to women over 30 in 2023 when compared to 1990, though this growth was not sufficient to offset the considerable decline in births to women under 30.

These changes in reproductive patterns have not been reflected in individuals' stated preferences, as the average ideal number of children reported in surveys has remained between 2.4 and 2.7 for nearly half a century.[118] Distinct from an "ideal," the intended family size has also been stable across a similar time period, indicating most individuals intend to have between

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[113] T.J. Matthew and Brady Hamilton, *Mean Age of Mother, 1970-2000,* Centers for Disease Control and Prevention, National Vital Statistics Reports, Vol. 51, No. 1 (Dec. 11, 2002), https://www.cdc.gov/nchs/data/nvsr/nvsr51/nvsr51_01.pdf.
[114] Andrea Brown, Brady Hamilton, Dmitry Kissin and Joyce Martin, *Trends in Mean Age of Mother: 2016 – 2023* (Jun. 13, 2025), https://pmc.ncbi.nlm.nih.gov/articles/PMC12278045/.
[115] Gladys Martinez and Kimberly Daniels, *Fertility of Men and Women Aged 15-49 in the United States: National Survey of Family Growth, 2015-2019,* Centers for Disease Control and Prevention, National Center for Health Statistics, National Health Statistics Reports, No. 179 (Jan. 10, 2023), https://www.cdc.gov/nchs/data/nhsr/nhsr179.pdf.
[116] Siddharth Zabak, Ashish Varma, Spandan Bansod, and Meera Pohane. *Exploring the Complex Landscape of Delayed Childbearing: Factors, History, and Long-Term Implications* (Sept. 30, 2023), https://pmc.ncbi.nlm.nih.gov/articles/PMC10616531/.
[117] Anne Driscoll and Brady Hamilton, *Effects of Age-Specific Fertility Trends on Overall Fertility Trends: United States, 1990-2023*, Centers for Disease Control and Prevention, National Vital Statistics Reports, Vol. 74, No. 3 (Mar. 6, 2025), https://stacks.cdc.gov/view/cdc/174576.
[118] Gallup News Service, *Americans' Ideal Family Size Remains Above Two Children* (Sept. 4, 2025), https://news.gallup.com/poll/694640/americans-ideal-family-size-remains-above-two-children.aspx.

two and three children.[119] As fertility rates are forecasted to continue declining while both men and women further delay childbirth to later in life, the growing divergence between intended reproduction rates and actual rates suggests that access to medical care that can assist in reproduction will become even more integral to prospective parents.[120]

A 2024 report from the National Center for Health Statistics illustrates that, as women age, fecundity – the ability to produce offspring – declines while fertility issues increase, a health outcome that is similarly observed in men.[121] As such, many medical providers will typically diagnose and treat fertility issues in women aged 35 or older after they have attempted to conceive for at least six months.[122]

Declining fertility in later life, coinciding with intentional delays to reproduction, has generated demand for assistive reproductive medical care. A 2024 survey from KFF indicated that 13 percent of women have reported that they or their partner required fertility treatments to help them become pregnant or prevent a miscarriage.[123] Additionally, data from the 2022-2023 National Survey of Family Growth (NSFG) indicate that among respondents ages 25 to 45, approximately 12 percent of women and 7 percent of men reported having sought medical care to help in having a child.[124] The KFF Women's Health Survey reported that among women of reproductive age who reported that they or their partner have needed fertility services, approximately 22 percent did not receive any services.[125] This suggests a small but significant

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[119] Kellie Hagewen and S. Philip Morgan, *Intended and Ideal Family Size in the United States, 1970-2002*, Population Development and Review, Vol. 31(3) (Sept. 1, 2005), https://pmc.ncbi.nlm.nih.gov/articles/PMC2849141/.
[120] Global Burden of Disease 2021 Fertility and Forecasting Collaborators*, Global Fertility in 204 Countries and Territories, 1950-2021 with Forecasts to 2100: A Comprehensive Demographic Analysis for the Global Burden of Disease Study 2021*, The Lancet Vol. 403, 2057-99 (May, 2024), https://www.sciencedirect.com/science/article/pii/S0140673624005506.
[121] Colleen Nugent and Anjani Chandra, *Infertility and Impaired Fecundity in Women and Men in the United States, 2015-2019,* Centers for Disease Control and Prevention, National Health Statistics Reports, No. 202 (Apr. 24, 2024), https://www.cdc.gov/nchs/data/nhsr/nhsr202.pdf.
[122] *Infertility: Frequently Asked Questions*, Centers for Disease Control and Prevention, Division of Reproductive Health (May 15, 2024), https://www.cdc.gov/reproductive-health/infertility-faq/index.html.
[123] KFF, *Women's Health Survey 2024* (Oct. 21, 2024), https://www.kff.org/womens-health-policy/access-to-fertility-care-findings-from-the-2024-kff-womens-health-survey/.
[124] National Center for Health Statistics, *National Survey of Family Growth, 2022-2023*, Public Use Data File (last accessed April 16, 2026), https://www.cdc.gov/nchs/nsfg/nsfg-2022-2023-puf.htm#nsfg.
[125] KFF, *Women's Health Survey 2024* (Oct. 21, 2024), https://www.kff.org/womens-health-policy/access-to-fertility-care-findings-from-the-2024-kff-womens-health-survey/.

number of reproductive age adults require but do not receive the necessary medical care to conceive. Given the continual rise of average parental age at first birth over the past several decades, reproductive medical treatments are expected to become increasingly important to a greater share of women and men trying to conceive. In 2022 approximately 2.7 percent of all live births in the United States were born with the use of ART, such as IVF.[126, 127]

Given the numerous and complex issues that could potentially contribute to, or accompany, infertility, medical care to resolve infertility can be lengthy, expensive, and multifaceted, addressing numerous potential causes through diagnostics and treatment from a variety of specialists. As such, diagnosing and treating fertility issues can be complex and prohibitively expensive for many people who are hoping to conceive. As infertility is not commonly considered a disease by insurers and benefits for infertility are frequently not included as a covered service by health plans, many of those hoping to utilize medical care for assistance with reproduction struggle to afford such high-cost procedures, as discussed in sections III.C.2 and 3 of this preamble.

2. Lack of Coverage for Fertility Services

The 2022-2023 NSFG indicates that for all female respondents indicating they had ever sought medical care to help conceive, approximately 66 percent had diagnostic fertility testing done on themselves or a male partner.[128] Nearly 1 in 3 of those who had diagnostic fertility testing (33 percent) stated that none of the costs were covered by their insurance. Similarly, 40 percent of female respondents utilizing IVF indicated that none of the costs were covered by their insurance, while 29 percent reported no coverage for commonly prescribed medications to improve ovulation. This is consistent with other research showing a considerable absence of

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[126] Michelle Osterman, Brady Hamilton, Joyce Martin, Anne Driscoll, and Claudia Valenzuela, *Births: Final Data for 2022,* National Center for Health Statistics, National Vital Statistics Reports, Vol 73. No. 2 (Apr. 4, 2024), https://www.cdc.gov/nchs/data/nvsr/nvsr73/nvsr73-02-tables.pdf.
[127] Centers for Disease Control and Prevention, *National ART Summary,* (Dec. 10, 2024), https://www.cdc.gov/art/php/national-summary/index.html?cove-tab=2.
[128] National Center for Health Statistics, *National Survey of Family Growth, 2022-2023*, Public Use Data File (last accessed April 16, 2026), https://www.cdc.gov/nchs/nsfg/nsfg-2022-2023-puf.htm#nsfg.

coverage for fertility-related medical care. A report by the KFF found that in 2024, 37 percent of large firms (200 or more employees) reported providing coverage for fertility medications, while IVF was covered by 27 percent of large firms.[129] Other infertility treatments were covered at even lower rates.

3. Prohibitive Costs of Certain Fertility Services

Access to fertility services can be limited by financial barriers, as is the case with many healthcare services that are not widely covered by health insurance. The 2024 KFF Women's Health Survey indicates that among the approximately 12 percent of reproductive age women that reported needing and not receiving fertility services, cost was the most commonly cited barrier to acquiring the necessary medical care.[130] A 2024 study found that the average cost for preliminary diagnostic fertility testing in the United States was approximately $1,600.[131] A 2010 study of women undergoing infertility treatment reported that median per-person treatment costs, inclusive of out-of-pocket and insurer expenditures, ranged from approximately $1,200 to $38,000 depending on treatment type, while median total costs for those women with successful pregnancy outcomes ranged from approximately $6,000 to $73,000 depending on treatment type.[132] Across all women seeking infertility treatment, the median cost was approximately $15,000. These costs only included fertility treatment expenses and did not include any associated healthcare costs, such as for labor and delivery. A 2014 study, examining the out-of-pocket expenses for common fertility treatments among couples with commercial health insurance, found that the median overall out-of-pocket expense was approximately $5,300 across

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[129] KFF, *2024 Annual Survey of Employer Health Benefits* (Oct. 2024), https://files.kff.org/attachment/Employer-Health-Benefits-Survey-2024-Annual-Survey.pdf.
[130] KFF, *2024 Women's Health Survey* (Oct. 21, 2024), https://www.kff.org/womens-health-policy/access-to-fertility-care-findings-from-the-2024-kff-womens-health-survey/.
[131] Naveena Daram, Malika Day, Rose Maxwell, and Megan Ozcan, *Disparities in Infertility Workup Costs Across the United States,* Fertility and Sterility Reports, Vol. 5 No. 4 (Oct. 5, 2024), https://pmc.ncbi.nlm.nih.gov/articles/PMC11705584/.
[132] Patricia Katz, Jonathan Showstack, James Smith, Robert Nachtigall, Susan Millstein, Holly Wing, Michael Eisenberg, Lauri Pasch, Mary Croughan, and Nancy Adler, *Costs of Infertility Treatment: Results from an 18-month Prospective Cohort Study,* Journal of Fertility & Sterility, Vol. 95 No. 3 (Mar. 1, 2011), https://pmc.ncbi.nlm.nih.gov/articles/PMC3043157/pdf/nihms253376.pdf.

all couples seeking fertility care, while those using IVF had median out-of-pocket expenses exceeding $19,000.[133] More recent data suggests that in 2024, a single cycle of fertility drugs cost over $5,000, and the full cost of an IVF cycle ranged from $15,000 to $20,000, with many individuals requiring multiple cycles.[134]

The NSFG indicates that of the female respondents that had none of their medical costs for fertility-related medical care covered by insurance, approximately 28 percent reported combined family incomes of less than $50,000 in the previous year.[135] For these and many other families already grappling with the costs associated with raising a child, the financial burden of obtaining medical care to assist in reproduction may impose a barrier to accessing care or place undue hardship on individuals intending to have a child.

4. Summary

The previous sections illustrate the growing need for fertility services, the lack of widely available and affordable insurance coverage for such services, and the prohibitive costs associated with obtaining these services out-of-pocket. These proposed rules would establish, as a new limited excepted benefit category, standalone coverage for the diagnostic procedures, mitigation, and treatments for infertility or infertility-related reproductive health conditions. This would allow group health plans and health insurance issuers in the group market to offer fertility-related benefits that generally are not subject to the market requirements of part 7 of ERISA and parallel provisions in title XXVII of the PHS Act and chapter 100 of the Code, thereby providing a more flexible pathway for employers that wish to provide coverage for fertility services to do so and allow employers to provide these benefits for employees, regardless of whether they enroll in their major medical coverage. This, in turn, would potentially reduce out-of-pocket

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[133] Alex Wu, Anobel Odisho, Samuel Washington, Patricia Katz, and James Smith, *Out-of-Pocket Fertility Patient Expense: Data from a Multicenter Prospective Infertility Cohort,* Journal of Urology, Vol. 191, No. 2 (Feb. 1, 2014), https://www.auajournals.org/doi/10.1016/j.juro.2013.08.083.

[134] Alina Salganicoff, Brittni Frederiksen, and Usha Ranji, *Will Trump's Announcement Expand Access to IVF?*, KFF (Oct. 27, 2025), https://www.kff.org/womens-health-policy/will-trumps-announcement-expand-access-to-ivf/?spm=a2700.accio_bizSeo.0.0.25a87e47NpdtI2.

[135] National Center for Health Statistics, *National Survey of Family Growth, 2022-2023*, Public Use Data File (last accessed April 16, 2026), https://www.cdc.gov/nchs/nsfg/nsfg-2022-2023-puf.htm#nsfg.

costs and increase access and utilization for families with fertility issues and unable to bear the full cost of treatments.

D. Regulatory Baseline

While the Departments have exercised their rulemaking authority for limited excepted benefits that are not an integral part of a group health plan,[136] they have not previously included coverage for the diagnosis, mitigation, or treatment of infertility or infertility-related reproductive health conditions. Traditional group health plans may provide coverage for some medical services or care related to fertility issues, though this coverage varies widely and may not include comprehensive coverage that includes medication or treatment for infertility. Separately, as of November 2025, 23 States and the District of Columbia require various levels of fertility-related care coverage for private insurance, though these requirements do not apply to self-insured plans.[137] Fifteen States and the District of Columbia require various levels of IVF coverage as well, though these requirements also do not apply to self-insured plans.[138]

The baseline for these proposed rules reflects the current legal and regulatory framework. Therefore, it accounts for group health insurance coverage already subject to State requirements that would not be eligible to utilize the excepted benefit to meet those requirements. Benefits, costs, and transfers associated with these proposed rules are measured as changes relative to this baseline.

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[136] *See* 26 CFR 54.9831–1(c)(3)(v), (vi), (vii), and (viii); 29 CFR 2590.732(c)(3)(v), (vi), (vii), and (viii); and 45 CFR 146.145(b)(3)(v), (vi), (vii), and (viii).

[137] KFF, *Mandated Coverage of Infertility Treatment* (Nov. 2025), https://www.kff.org/state-health-policy-data/state-indicator/infertility-coverage/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D (The States listed in the KFF report are Arkansas, California, Colorado, Connecticut, Delaware, Georgia, Hawaii, Illinois, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Montana, New Hampshire, New Jersey, New York, Ohio, Oklahoma, Rhode Island, Texas, Utah and West Virginia as well as the District of Columbia).

[138] RESOLVE, *Insurance Coverage by State* (last accessed Apr. 16, 2026), https://resolve.org/learn/financial-resources/insurance-coverage/insurance-coverage-by-state/ (The States listed as requiring IVF treatments are Arkansas, California, Colorado, Connecticut, Delaware, Hawaii, Illinois, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Rhode Island, and Utah as well as the District of Columbia).

E. Summary of Impacts

In accordance with OMB Circular A–4, Table 1 depicts an accounting statement summarizing the Departments' assessment of the benefits, costs, and transfers associated with this proposed regulatory action. These proposed rules would impact individuals who elect to enroll in standalone coverage of fertility-related items and services that could include coverage of diagnostic procedures, medications, and treatments for infertility or infertility-related reproductive health conditions. As such, they would also impact issuers and plan sponsors of such coverage as well as the plans themselves. The Departments are unable to quantify all benefits, costs, and transfers of the rulemaking but have sought, where possible, to describe these non-quantified impacts.

TABLE 1. Accounting Statement

<table>
<tr><td colspan="5">Benefits:</td></tr>
<tr><td colspan="5">Non-Quantified:
Potentially improved access to and utilization of medical care for fertility-related health.
Potentially improved fertility-related health and birth outcomes, including more births, for participants and beneficiaries.
Potential increased tenure and productivity of covered employees</td></tr>
<tr><td>Costs:</td><td>Estimate</td><td>Year Dollar</td><td>Discount</td><td>Period Covered</td></tr>
<tr><td rowspan="2">Annualized Monetized ($million/year)</td><td>$1.49</td><td>2026</td><td>7 percent</td><td>2027-2036</td></tr>
<tr><td>$1.48</td><td>2026</td><td>3 percent</td><td>2027-2036</td></tr>
<tr><td colspan="5">Quantified: $1.88 million (first year), $1.43 million (subsequent years)
Prepare and send notice to eligible participants and beneficiaries. ($1.58 million in the first year; $1.43 in subsequent years)
One time rule familiarization costs for issuers. ($304,000 in the first year)
Non-Quantified:
Increased number of births could lead to increased health care expenditures for employers, plan participants, and government programs.</td></tr>
<tr><td colspan="5">Transfers:</td></tr>
<tr><td colspan="5">Non-Quantified:
Transfer of some financial risk from participants and beneficiaries to plans.
Transfer of financial contributions from low-utilization participants and beneficiaries to high-utilization participants and beneficiaries.
Transfer of Tax Revenue from Government to participants, beneficiaries and employers through Tax-Advantaged Employee Benefits.</td></tr>
</table>

Perpetual Time Horizon Costs:
• Annualized Cost (in 2024 dollars): $1.41 million

F. Affected Entities

These proposed rules would impact group health plans and issuers offering excepted fertility benefits, and the participants and beneficiaries in those plans. The Departments expect that participants and beneficiaries seeking more expansive coverage of benefits for the diagnosis, mitigation, and treatment of infertility or infertility-related reproductive health conditions, particularly those between the ages of 25 and 45 who currently lack, but are seeking, coverage for such services, would be most likely to enroll. The Departments lack data that would allow for the estimation of the number of excepted fertility benefit plans that would arise due to these proposed rules. Table 2 summarizes the number of group health plans, group health insurance issuers, participants, and other entities that could be affected by these proposed rules. These estimates are discussed in greater detail in this section (III.F.1-3) of this preamble.

TABLE 2. Affected Entities

Group Health Insurance Companies	373
Group Health Insurance Issuers	811
Group Health Plans and Sponsoring Employers	522,811
Participants and Eligible Employees[139]	54,411,264
Participants and Eligible Employees Likely to Enroll	743,361

The Departments seek comments on the number of entities that would be affected by these proposed rules. In particular, the Departments seek comments on the number of issuers and plans that might offer coverage of diagnostic procedures, medications, and treatments for infertility as limited excepted benefits as well as the expected number of participants that might enroll in these

[139] The Departments acknowledge that beneficiaries may also be affected by these proposed rules. However, since notices are likely to be sent out at the policy holder level, and the Departments lack sufficient data on the number of beneficiaries, the Departments' calculations will only include affected participants and eligible employees.

plans.

1. Group Health Insurance Issuers

The Departments estimate that these proposed rules could affect up to 373 health insurance companies offering group health insurance coverage (811 group health insurance issuers when considering the total number of subsidiaries licensed to sell health insurance in a specific State).[140] These entities provide insurance coverage to fully insured plans as well as administrative services such as plan management to level-funded and self-insured group health plans.

Issuers in States with a fertility benefit requirement are already providing some level of coverage for the diagnosis, mitigation, or treatment of infertility. Issuers in States without a fertility benefit requirement could also be providing some level of coverage. The Departments are uncertain how many of these issuers currently provide fertility benefits as part of their coverage or how many of these issuers would likely offer excepted fertility benefits in response to these proposed rules. Issuers already providing coverage for fertility benefits voluntarily could be the issuers most likely to elect to offer excepted fertility benefits, but it is unknown how many would do so. There are also service providers that specialize in coverage or benefit management of fertility-related benefits that could be well positioned to provide coverage of an excepted fertility benefit or help design and manage such coverage. The Departments utilize the number of group health insurance issuers (811) as an estimate of the upper bound of the number of issuers that could provide excepted fertility benefit coverage. The Departments request comments on the number of issuers that might provide such coverage.

[140] A health insurance company is a legal entity with subsidiaries that are each licensed to sell health insurance in one specific State, while an issuer is one of those subsidiaries. Data source: Centers for Medicare and Medicaid Services, *2023 Medical Loss Ratio Data*, https://www.cms.gov/marketplace/resources/data/medical-loss-ratio-data-systems-resources.

2. Group Health Plans

These proposed rules would impact non-Federal group health plans[141] and employers that decide to sponsor excepted fertility benefits. Currently, 15 States and the District of Columbia have laws mandating insurance coverage for IVF.[142] However, issuers providing insured coverage to fully insured group health plans in States already requiring IVF coverage would likely not be able to meet State requirements by offering those benefits through excepted benefit plans. As a result, the Departments have excluded fully insured group health plan sponsors in the 15 States and the District of Columbia that currently require IVF benefits in their analysis, while including all self-insured plan sponsors and fully insured plan sponsors in all other States.[143] Additionally, the Departments assume that plan sponsors that already offer fertility benefits as part of their comprehensive health plans would offer excepted fertility benefits on a more limited basis, similar to plans that offer dental and/or vision benefits that also offer these benefits in standalone plans. The Departments relied on dental and vision excepted benefit offer rates as a proxy for excepted fertility benefits offer rates, although because those benefits are substantially less expensive and affect a larger population, this may overstate the actual offer rates for excepted fertility benefits. Finally, the Departments assume that the smallest of plans, those with fewer than 10 participants, would be unlikely to offer such an excepted benefit as the prevalence of infertility among such a small group would likely impact few, if any, participants and the potential costs may be prohibitive for these small groups.

Based on these assumptions, the Departments estimate that there are 32,545 State and local government employer-sponsored plans, in addition to 490,266 private sector employer-sponsored plans, that could be affected by these proposed rules. In total, these proposed rules are

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[141] This includes private-sector and public-sector employer-sponsored health plans, except those offered by the Federal government.

[142] RESOLVE, *Insurance Coverage by State* (2026), https://resolve.org/learn/financial-resources/insurance-coverage/insurance-coverage-by-state/. The States listed as requiring IVF treatments are Arkansas, California, Colorado, Connecticut, Delaware, Hawaii, Illinois, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Rhode Island, and Utah as well as the District of Columbia.

[143] The Departments separately looks at a high-cost scenario which assumes that those mandates do not preclude plans from offering the excepted benefit/ in the Uncertainty Section.

expected to affect 522,811 plans and entities. These calculations are detailed in the table below. The Departments request comments on these assumptions.

TABLE 3. Affected Plan Counts

	Plans (A)	Not Currently Offering[1] (A) × 73% = (B)	Currently Offering (A) × 27% = (C)	Expected to Offer[2] ((B) × 65%) + ((C) × 18%)
Public Entities				
Self-insured (States with Requirements)	11,081	8,089	2,992	5,818
Self-insured (States without Requirements)	21,581	15,754	5,827	11,330
Fully insured (States without Requirements)	29,327	21,409	7,918	15,397
Total Public	**61,988**	**45,251**	**16,737**	**32,545**
Private Entities				
Self-insured (States with Requirements)	217,651	158,885	58,766	114,271
Self-insured (States without Requirements)	401,392	293,016	108,376	210,739
Fully insured (States without Requirements)	314,761	229,775	84,985	165,256
Total Private	**933,803**	**681,677**	**252,127**	**490,266**
All Plans	**995,792**	**726,928**	**268,864**	**522,811**

*Totals displayed in the table may not sum due to rounding.
1 Estimated from the KFF *2024 Employer Health Benefits Survey* where 27% indicated that they offered IVF benefits for fertility-related treatment.
2 Estimated from the Agency for Healthcare Research and Quality (AHRQ) 2023 Medical Expenditure Panel Survey – Insurance Component (MEPS), which indicated 17.9% of establishments with medical coverage of vision and dental benefits offered excepted benefit plans for vision and dental benefits, while 65.3% of establishments with no medical coverage of vision and dental benefits offered excepted benefit plans for vision and dental benefits.

3. Participants and Beneficiaries

These proposed rules would impact individuals who are currently eligible for an employer-sponsored health plan. However, because 15 States and the District of Columbia have required some level of IVF benefits for fully insured plans in their States, the Departments have limited this analysis to plans and participants in non-Federal group health plans in States without such requirements and only self-insured plans and their participants in non-Federal group health

plans in States with such requirements.[144] Additionally, the Departments have limited this analysis to participants in plans with 10 or more participants, as those would be the most likely to offer the excepted benefit. Finally, in order to capture the number of eligible employees that could be offered these plans, the Departments use the number of current employer sponsored health insurance participants and then divide this number by the take-up rate of eligible employees offered employer coverage. This provides an estimate of the number of employees eligible for coverage.

The estimates in this analysis use imperfect proxies to provide estimates of the number of excepted fertility benefit plans that might be offered and potential enrollment in those plans. The estimates are likely an overestimate due to reasons discussed in section III.K.

Plans and issuers that decide to offer these benefits would need to provide notices to plan participants and beneficiaries. Therefore, the Departments first estimate the number of participants in non-Federal group health plans, both by whether they are fully insured or self-insured and also whether they are in States with an IVF mandate. Utilizing data from the 2024 Auxiliary Database and the MEPS-IC, the Departments estimate that there are 78.9 million employees eligible for non-Federal, group insurance arrangements in States without fertility requirements and an additional 24.7 million employees eligible for non-Federal, self-insured group insurance arrangements in States with fertility requirements.[145, 146]

The Departments assume that participants already offered fertility benefits as part of their comprehensive health plans would be offered excepted fertility benefits on a more limited basis,

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[144] The Departments also include a sensitivity analysis that relaxes this restriction in the Uncertainty section.

[145] Employee Benefits Security Administration, Health Insurance Coverage Bulletin Abstract of Auxiliary Data for the March 2024 Annual Social and Economic Supplement to the Current Population Survey, U.S. Department of Labor (Aug. 30, 2024), https://www.dol.gov/sites/dolgov/files/EBSA/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2023.pdf (The Departments used this source for the number of policyholders at non-Federal group health plans by State and plan funding. The Departments then used Tables I.B.2.a (private-sector) and III.B.2.b (State and local government) on the percent of employees eligible for health insurance that are enrolled from the 2024 MEPS-IC to augment these counts to estimate employees eligible for coverage). The Departments utilize this data source for all subsequent participant counts.

[146] This estimate is calculated as: 24,738,866 participants enrolled in non-Federal, self-insured employer-sponsored insurance arrangements in States with fertility requirements + 78,870,061 participants enrolled in non-Federal, employer-sponsored insurance arrangements in States without fertility requirements = 103,608,927 participants in non-Federal group health plans.

similar to the rate at which dental and/or vision benefits are also offered in standalone plans. The Departments have been unable to find data on the share of participants in group health plans that have fertility benefits coverage in their comprehensive plan. However, the KFF 2024 Employer Health Benefits Survey reported that 27 percent of plans with 200 or more participants offer coverage for IVF. While this likely overstates coverage in smaller plans, the Departments use this assumption to estimate that there are 75.6 million individuals eligible for non-Federal, group insurance arrangements that are not currently offered fertility benefits coverage and an additional 28.0 million individuals eligible for non-Federal, group insurance arrangements that are currently offered fertility benefits coverage. [147, 148]

Data from the Agency for Healthcare Research and Quality (AHRQ) suggest approximately 66 percent of private sector employees without medical coverage for vision and dental benefits are offered excepted benefits for vision and dental coverage, while 17 percent of private sector employees with medical coverage for vision and dental benefits are offered additional excepted benefits for vision and dental coverage. Utilizing this statistic to estimate how many individuals may be offered excepted fertility benefits, the Departments estimate that approximately 54.4 million participants and beneficiaries would be offered excepted fertility benefits.[149, 150]

Additionally, the Departments estimate that of those 54.4 million plan participants and beneficiaries that would be offered excepted fertility benefits, approximately 26.2 million participants and beneficiaries are aged 25 to 45. This population is expected to be the most likely

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[147] KFF, 2024 Annual Survey of Employer Health Benefits (Oct. 2024), https://files.kff.org/attachment/Employer-Health-Benefits-Survey-2024-Annual-Survey.pdf.

[148] This estimate is calculated as: 103,608,927 participants in non-Federal group health plans × 73 percent not offering coverage = 75,634,517 participants enrolled in non-Federal group health plans that do not offer fertility benefits. Additionally, 103,608,927 participants in non-Federal group health plans × 27 percent offering coverage = 27,974,410 participants enrolled in non-Federal group health plans that do offer fertility benefits.

[149] Agency for Healthcare Research and Quality, *2023 Medical Expenditure Panel Survey – Insurance Component, https://meps.ahrq.gov/survey_comp/survey_ic.jsp*.

[150] This estimate is calculated as: (75,634,517 participants in non-Federal group health plans without offer of fertility coverage × 65.8 percent offer rate) + (27,974,410 participants in non-Federal group health plans with offer of fertility coverage × 16.6 percent offer rate) = 54,411,264 eligible participants in non-Federal group health plans offered coverage of excepted fertility benefit.

to take advantage of an offered excepted fertility benefit.[151]

Using data from the NSFG, the Departments estimate that approximately 3 percent of female respondents in private health plans aged 25 to 45 are currently seeking medical assistance for themselves or their partner to become pregnant.[152] As such, the Departments estimate that approximately 743,361 participants or beneficiaries in non-Federal employer-sponsored health plans aged 25 to 45 would seek medical assistance to become pregnant each year.[153] The Departments estimate an equal share would likely enroll in excepted fertility benefits coverage, resulting in an estimated 743,361 individuals enrolling annually.[154] The Departments acknowledge the uncertainty around this estimate of the number of individuals that would enroll and request comment on ways to improve it.

G. Requests for Comments

The Departments invite comments addressing their estimates of the benefits, costs, and transfers associated with this proposed rulemaking, as well as any quantifiable data that could inform any aspect of the analysis. Specifically, the Departments request comments on the following:

1. Does the offering of excepted benefits vary by plan sponsor size? For other excepted benefits, what share of plans elect to offer them? Are similar rates for fertility benefits anticipated given the higher costs?

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[151] The estimate is calculated as: (36,384,174 participants aged 25 to 45 enrolled in non-federal, employer-sponsored health insurance without offer of fertility coverage in group plan × 65.8 percent offer rate) + (13,457,160 participants aged 25 to 45 enrolled in non-federal, employer-sponsored health insurance with offer of fertility coverage in group plan × 16.6 percent offer rate) = 26,174,675 participants aged 25 to 45 enrolled in non-federal, employer-sponsored health insurance offered excepted fertility benefits coverage.

[152] National Center for Health Statistics, *National Survey of Family Growth, 2022-2023*, Public Use Data File (last accessed April 16, 2026), https://www.cdc.gov/nchs/nsfg/nsfg-2022-2023-puf.htm#nsfg (This estimate is calculated as: 15.73 percent of female respondents aged 25 to 45 indicating they or their partner having ever sought medical assistance to become pregnant × 18.08 percent of those respondents indicating that they or their partner sought medical assistance in the past year = 2.84 percent of respondents seeking medical assistance to become pregnant in the past year).

[153] This estimate is calculated as: 26,174,675 estimated participants offered excepted benefits aged 25 to 45 × 2.84 percent currently seeking medical assistance for fertility = 743,361 participants and beneficiaries in covered plans seeking fertility-related medical care annually.

[154] National Center for Health Statistics, *National Survey of Family Growth, 2022-2023*, Public Use Data File (last accessed April 16, 2026), https://www.cdc.gov/nchs/nsfg/nsfg-2022-2023-puf.htm#nsfg.

2. Would employers that already offer fertility benefits through their health plan choose instead to only offer this coverage through an excepted benefit? If so, what share of employers already offering this benefit would choose to do so? Would this vary by employer size?
3. How many plans that provide excepted fertility benefits might be created under these proposed rules? Would there be a significant number of employers offering excepted fertility benefits immediately upon the applicability acdate of a final rule? Would there be a more gradual increase in the number of employers offering an excepted fertility benefit?
4. How would State requirements impact employers' decision to offer the excepted benefit?
5. What share of total premiums for the excepted fertility benefit plans would plan sponsors contribute? How would this vary by plan size?
6. What is the expected take-up rate for the benefit if premiums were expected to approach the full cost of treatment without coverage?

H. Benefits

1. Increased Utilization of Fertility Services

The Departments expect that these proposed rules, if finalized, would reduce barriers to accessing diagnostic procedures, medications, and treatments for infertility and infertility-related reproductive health conditions and would allow individuals who are attempting to conceive an opportunity to more readily assess their treatment needs or address any medical impediments that might prevent them from having children. Having coverage increases the likelihood of healthcare utilization and improves health outcomes for participants and beneficiaries.[155] Having coverage for these services may allow participants and beneficiaries to more quickly establish a diagnosis

[155] Joseph Freeman, Srikanth Kadiyala, Janice Bell and Diane Martin, *The Causal Effect of Health Insurance on Utilization and Outcomes in Adults: A Systematic Review of US Studies,* Medical Care, Vol. 46, No. 10 (Oct., 2008), https://pubmed.ncbi.nlm.nih.gov/18815523/.

(and understanding of the cause) of their infertility, enabling them to access more advanced treatments sooner than if care was delayed due to a lack of coverage. Additionally, having coverage for infertility medications and treatments may result in more expeditious resolution of fertility-related health issues for many individuals, limiting potential delays or impediments to seeking care. As such, the Departments anticipate that these proposed rules would result in an increase in the utilization of diagnostic fertility testing as well as subsequent medications and treatments.

These proposed rules would not require that employers or issuers offer these benefits, specify the scope of these benefits, or require that employers contribute financially to any coverage that they offer. These proposed rules also provide for a wide scope of potential benefit designs that could significantly vary which items and services are covered in such plans. Participation in these plans would likely be influenced by how generous the excepted benefits are and whether employers contribute, thereby potentially offsetting some of the cost of coverage for participants and beneficiaries. As a result, the Departments lack the data necessary to estimate the potential increase in utilization of fertility-related medical services resulting from these proposed rules. However, it is assumed that the covered, affected population would have high rates of enrollment in standalone fertility coverage and utilization of those covered fertility-related medical services, provided the participant's or covered individual's premium cost is less than the full cost of treatment without this coverage. The Departments request comments or data that may provide insight into potential plan design and utilization.

2. Improved Health Outcomes Among Patients

Given how complex the underlying causes of infertility can be, as well as the relationship between age and infertility, more expansive health benefits coverage for the diagnosis, mitigation, and treatment of infertility has the potential to improve health outcomes among participants and beneficiaries. The Departments expect the utilization of fertility-related medical care to expand and treatment to occur earlier than if participants and beneficiaries did not have

coverage made available in accordance with these proposed rules, if finalized. This has the potential to improve health outcomes for participants and beneficiaries experiencing infertility by allowing them to more readily obtain a diagnosis of infertility and to seek treatment sooner. As increased patient age is associated with higher rates of infertility as well as poorer outcomes for infertility treatments such as IVF, an earlier diagnosis and potential access to medication or treatment could improve later pregnancy-related health outcomes.[156]

States that have required more comprehensive insurance coverage for fertility-related treatments have also experienced better healthcare outcomes for these interventions, such as lower rates of multiple births, fewer embryo transfers per IVF cycle, and higher rates of live birth, suggesting that more insurance coverage may lead to better fertility outcomes.[157] While the lack of data to estimate the increase in utilization of fertility-related medical care limits further extrapolation to health and birth outcomes, the significant improvement in pregnancy outcomes from those receiving fertility-related treatments suggests that a significant share of the participants and beneficiaries gaining access to coverage for such treatments could result in many achieving positive birth outcomes that would not occur in the absence of these proposed rules.[158] As such, this increased utilization of fertility-related medical care that the Departments anticipate arising from these proposed rules is expected to produce better health outcomes for participants and beneficiaries as well as more live births. This is consistent with a 2025 study utilizing claims data for both covered and uncovered IVF cycles which found that "[i]nsurance coverage for IVF was significantly associated with a higher cumulative live birth rate but not multiple birth rate. This finding was driven by higher live birth rates per cycle and more IVF

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[156] Laxmi Shingshetty, Natalie Cameron, David McLernon, and Siladitya Bhattacharya, *Predictors of Success After In Vitro Fertilization,* Journal of Fertility and Sterility, Vol. 121, No.5 (Mar. 16, 2024), https://www.fertstert.org/article/S0015-0282(24)00173-0/pdf.

[157] Benjamin Peipert, Esther Chung, Benjamin Harris, and Tarun Jain, *Impact of Comprehensive State Insurance Mandates on In Vitro Fertilization Utilization, Embryo Transfer Practices and Outcomes in the United States*, American Journal of Gynecology (2022), https://pubmed.ncbi.nlm.nih.gov/35283088/.

[158] James Smith, Michael Eisenberg, Susan Millstein, Robert Nachtigall, Natalia Sadetsky, Marcelle Cedars, and Patricia Katz, *Fertility Treatments and Outcomes among Couples Seeking Fertility Care: Data from a Prospective Fertility Cohort in the United States,* Journal of Fertility and Sterility Vol. 95, No.1 (Jul. 25, 2010), https://pmc.ncbi.nlm.nih.gov/articles/PMC2966858/.

cycles initiated among insured patients."[159]

Additionally, individuals who have better fertility-related health outcomes may also experience improvements to their mental health, as infertility is associated with increased risk of common psychiatric disorders such as anxiety or depression.[160, 161] Persistent infertility has also been associated with an increased use of mental health medication, both among women experiencing infertility as well as their partners, in addition to an increased incidence of divorce.[162] However, successful delivery can also be associated with increased risk of mental health disorders, such as postpartum anxiety and depression.[163] The Departments lack the necessary data to compare these effects and quantify the value of these changes to health outcomes and live births and request comment on any data that might allow for quantification of the benefits related to these proposed rules.

3. Increased Tenure and Productivity of Covered Employees

Employers could also benefit from these proposed rules as research suggests that returns on investments for fertility benefits are significant for employers. A 2023 Maven report found that "workers whose employer-provided health care plans covered IVF treatment were more likely to remain in their job long-term, and more likely recommend [*sic*] their employer to others."[164] Additionally, there are downstream benefits to offering fertility benefits, such as

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[159] Benjamin Peipert, Phyllis Yan, Rodney Dunn, David Suh, Brandon Swinney, Edward Norton, Vanessa Dalton, Erica Marsh, Marissa Steinberg Weiss, and James Dupree. *Insurance Coverage and IVF Outcomes in the United States: A National Claims-Based Study of Privately Insured Patients, Fertility and Sterility*, Volume 124, Issue 6, e87 (Oct. 29, 2025), https://www.fertstert.org/action/showPdf?pii=S0015-0282%2825%2900880-5.

[160] Myles Doyle and Angela Carballedo, *Infertility and Mental Health*, Advances in Psychiatric Treatment, Vol. 20 (2014), https://www.cambridge.org/core/services/aop-cambridge-core/content/view/12C29995CD4A52912CF84503C721EB62/S1355514600011822a.pdf/infertility_and_mental_health.pdf.

[161] Brent Hanson, Erica Johnstone, Jessie Dorais, Bob Silver, C. Matthew Peterson and James Hotaling, *Female Infertility, Infertility-Associated Diagnoses, and Comorbidities: A Review*, Journal of Assisted Reproduction Technologies (Nov. 5, 2017), https://pmc.ncbi.nlm.nih.gov/articles/PMC5306404/pdf/10815_2016_Article_836.pdf.

[162] Sarah Bogl, Jasmin Moshfegh, Petra Persson, and Maria Polyakova, *The Economics of Infertility: Evidence from Reproductive Medicine,* National Bureau of Economic Research, Working Paper 32445 (May. 2024), https://www.nber.org/papers/w32445.

[163] Om Suryawanshi, and Sandhya Pajai. *A comprehensive review on postpartum depression*, Cureus (Dec. 20, 2022), https://doi.org/10.7759/cureus.32745.

[164] Michelle Travis, *Why Reproductive Health Benefits Are a Good Investment for Employers*, Forbes (Mar. 26, 2025), https://www.forbes.com/sites/michelletravis/2025/03/26/why-employers-should-invest-in-reproductive-health-benefits/.

reducing potential stays in neonatal intensive care units and associated high-risk maternity-related expenses by prioritizing first-line interventions and medical policies that lead to more singleton births, fewer preterm births and ultimately lower health care costs.[165] Finally, because these proposed rules would offer flexibility in the manner and generosity of the excepted fertility benefits and would not require a set contribution by plan sponsors, employers and plan sponsors would be able to determine how and at what level they want to provide these benefits in order to maximize the net returns for plan sponsors. The Departments request comments on quantifying the value of these benefits.

4. Improved Birth Outcomes for Participants

The Departments believe that these proposed rules would likely result in additional births due to greater access to fertility-related care. A recent study of women in the United States using self-reported infertility and treatment status found that 10 percent of women who undergo fertility treatments achieve a live birth.[166] However, while the Departments are able to estimate the number of women that would receive fertility coverage under an excepted benefit plan and pursue treatment, it is unclear how many of these women would receive treatment absent these proposed rules. As a result, the Departments are unable to estimate the number of births that would arise from changes to improved treatment access due to these proposed rules, though the Departments acknowledge that an increase in births would provide substantial benefits to individuals and their families, as well as society.

I. Costs

1. Plan Administration Expenses

As excepted fertility benefits would constitute a new category of limited excepted

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[165] Benjamin Peipert, Esther Chung, Benjamin Harris, and Tarun Jain, *Impact of Comprehensive State Insurance Mandates on In Vitro Fertilization Utilization, Embryo Transfer Practices and Outcomes in the United States,* American Journal of Gynecology (Mar. 11, 2022), https://pubmed.ncbi.nlm.nih.gov/35283088/.
[166] Theresa Boyer, Linh Tran, Michael Fang, Elizabeth Selvin, and Anum S. Minhas, *The Fertility Cascade: Infertility Prevalence, Access to Treatment, and Successful Live Birth*, American Journal of Obstetrics and Gynecology (Jan. 2026), https://www.ajog.org/article/S0002-9378(25)00573-3/abstract.

benefits, employers that elect to offer such coverage would incur certain administrative costs to initiate and maintain a plan.

The Departments anticipate that the administrative costs of such a program would be considerably lower than those for traditional group health plans given that limited excepted benefits are exempt from ERISA Part 7 requirements. Additionally, the Departments are of the view that many of the issuers that elect to offer coverage for such plans would mostly likely be those that already provide fertility-related coverage in traditional group health plans, which the Departments believe would mitigate many of the startup expenses to issuers. For those issuers that do not currently offer coverage of fertility-related medical care in traditional group health plans, the Departments assume that these issuers could utilize existing providers that offer carve out coverage as a way to offer excepted fertility benefit. Some of these costs could also be offset through the use of third-party administrators that could more efficiently service the plan documentation and reporting requirements than could a plan sponsor. The Departments lack sufficient data on the exact value of such administrative costs and request comments on the average administrative expenditures for an excepted fertility benefit plan in addition to the other assumptions stated.

Additionally, the Departments estimate the 811 issuers acting as service providers to plans would incur a one-time cost of approximately $304,255 to familiarize themselves with these proposed rules as they help plan sponsors develop excepted fertility benefit plans in response to these proposed rules.[167]

2. Employer Contributions

Employers that elect to offer excepted fertility benefits coverage could also elect to make contributions towards plan premiums, though there would be no requirement that they contribute under these proposed rules. Employer contributions would be expected to vary widely based on

[167] This cost is estimated as: 2 hours × $187.58 hourly wage rate for attorney × 811 issuers = $304,255. The one-hour time estimate is derived from the amount of time it would take for the rule to be reviewed at an average reading rate of 250 words per minute.

factors such as employer size, plan type, and coverage level. For excepted benefits like vision and dental insurance, the employer costs are often lower than for traditional group health plans and, as such, employers may cover a higher share of the premium expense. The 2023 KFF Employer Health Benefits Survey indicates that about half of small firms and two-thirds of large firms that offer dental plans contribute toward the premiums.[168] For vision plans, this rate is approximately one-quarter and one-third, respectively. The potentially high costs of fertility-related items and services may limit the share of premiums that employers would be willing to cover if electing to offer such a plan. The Departments request comments on the share of employers that might elect to contribute towards the plan premiums for fertility-related items and services, and the share of total premiums they might elect to contribute.

3. Notice to Participants and Eligible Employees

These proposed rules aim to establish, as a limited excepted benefit, standalone coverage for diagnostic procedures, medications, and treatments related to infertility. This coverage would be available to eligible participants and beneficiaries of employer-sponsored health plans. Under these proposed rules, the Departments propose to require that a notice be sent to eligible participants and beneficiaries. This notice would include a description of the coverage, including a summary of benefits and limitations of the coverage, how to identify and utilize a network provider, if applicable, as well as procedures for claims reimbursement, including whether the benefit utilizes the same claim procedures as for the sponsor's other group health plans. The notice is expected to be approximately one page in length, would be sent to eligible employees, and any printed notices would be sent with minimal additional costs.[169]

The Departments expect this notice would be prepared by attorneys for the issuers of such benefits or service providers assisting a plan at a burden of approximately 2 hours. This is

[168] KFF, *2023 Employer Health Benefits Survey* (Oct.. 2023), https://files.kff.org/attachment/Employer-Health-Benefits-Survey-2023-Annual-Survey.pdf.

[169] The Departments assume that for private sector plans, approximately 58% of plan documents would be sent electronically, while 42% would be physical notices mailed to participants. For public sector plans, approximately 34% of plan documents would be sent electronically, while 66% would be physical notices mailed to participants.

estimated to result in a total cost for all issuers of approximately $0.3 million in the first year.[170] In each subsequent year, the Departments anticipate that attorneys for the issuer or service provider would review and provide any required updates to the notice at a burden of approximately 1 hour, incurring a total annual cost for all issuers of approximately $0.2 million.[171] The Departments estimate that approximately 25.5 million paper notices would be sent to eligible employees each year at an annual cost of approximately $1.3 million to produce the notices. [172, 173]

4. Increased Health Expenditures Due to Additional Births

The introduction of excepted fertility benefit coverage has the potential to increase the birth rate by making it easier for individuals to access treatments that support conception and pregnancy. Pregnancy and even uncomplicated births are costly medical events, often involving pre-natal care, hospital stays, specialized care, and follow-up services. This could lead to increased expenditures for employers, plan participants and government programs. Due to the uncertainty regarding the number of women that would become pregnant as a result of these proposed rules, carry to term and give birth, and any additional medical items or services that may be required during the process, the Departments are not able to quantify the costs that would arise from expanded access to fertility-related medical care under these proposed rules, if finalized.

5. Summary of Quantified Costs

The quantified costs associated with these proposed rules are summarized in Table 4.

TABLE 4. Summary of Quantified Costs

[170] This cost is estimated as: 2 hours × $187.58 hourly wage rate for attorney × 811 issuers = $304,255.
[171] This cost is estimated as: 1 hours × $187.58 hourly wage rate for attorney x 811 issuers = $152,127.
[172] This is estimated as: (42,849,310 potentially eligible private-sector individuals x 42 percent notice mailing rate) + (11,561,954 potentially eligible public-sector individuals x 66 percent notice mailing rate) = 25,499,052 notices mailed.
[173] This cost is estimated as: 25,499,052 notices mailed × $0.05 material cost per notice = $1,274,953.

	First Year	Subsequent Years
Prepare Notices	$304,255	$0
Review and Update Notices	$0	$152,127
Distribute Notices	$1,274,953	$1,274,953
Rule Familiarization	$304,255	$0
Total Costs	**$1,883,462**	**$1,427,080**

*Totals displayed in the table may not sum due to rounding.

J. Transfers

The following sections are primarily qualitative discussions of transfers that the Departments expect would occur due to these proposed rules. The Departments request comments or data that might help in quantifying these transfers.

1. Transfers of Contributions from Participants to Plans

The Departments anticipate that, upon enrollment in an excepted fertility benefit plan, most participants would begin to make premium contributions to maintain their coverage. These premium contributions would represent a transfer from participants and beneficiaries that utilize fertility-related medical care below the value of their premium contributions to those participants and beneficiaries who utilize their benefits beyond the value of their premium contributions. The Departments lack data on the potential expenditures related to these transfers and request comments on how best to estimate the value of these transfers.

2. Transfers of Risk from Participants and Beneficiaries to Issuers or Self-Insured Plans

As discussed in section III.C, large shares of insured individuals currently lack coverage for diagnostic procedures, medications, and treatments for infertility. When issuers or plan sponsors offer excepted fertility benefits to participants and beneficiaries, the issuers or self-insured plans assume some risk in covering the costs related to the utilization of these items and services. While these participants and beneficiaries previously paid such expenses out-of-pocket,

issuers and plans would bear some of the risk associated with the expenditures under these proposed rules, if finalized. As such, these proposed rules would result in a transfer of risk from participants and beneficiaries to issuers or plans offering excepted fertility benefits.

3. Transfers of Tax Revenue from Government to Individuals and Employers through Tax-Advantaged Employee Benefits

When employers and employees are permitted to pay plan premiums for excepted benefits with pre-tax dollars, these contributions are excluded from taxable income. As a result, both employer and employee tax liabilities are reduced. This is turn impacts the federal government as the expansion of pre-tax benefits decreases overall tax receipts, constituting a transfer from the government to individuals and employers. The magnitude of these impacts would depend on the number of employers that would offer excepted fertility benefits and the level of employee participation. It would also depend on the marginal tax rate of the individual, the premiums associated with these plans, and the amount of any employer contribution.

The favorable tax treatment is likely to encourage greater offering of excepted fertility benefit plans, thereby expanding access to valuable fertility items and services. It could also make enrollment in an excepted fertility benefit plan more attractive and affordable for employees as the ability to pay premiums with pre-tax dollars could reduce the cost of coverage. This could further encourage those with infertility to obtain care through excepted fertility benefit plans.

K. Uncertainty

As noted throughout this preamble, due to a lack of data and information, there are several areas of uncertainty regarding the potential impacts of the proposed rule. Much of this uncertainty arises from potential issues of adverse selection and how such concerns may impact risk pools and, subsequently, offers of coverage.

1. Coverage and Enrollment in Excepted Benefits

Participants and beneficiaries opting to enroll in the excepted fertility benefit may be

aware that they plan to attempt to conceive or have a health condition that may increase the likelihood that they experience infertility. Additionally, they may time their enrollment to coincide with plans to conceive or have other knowledge that could ultimately limit their financial risk by enrolling in coverage when their perceived need for such coverage is high. As such, risk pools for this type of insurance coverage may be complicated by adverse selection, where many participants and beneficiaries that elect to enroll in this type of coverage are aware of their need to utilize the benefits offered.

Additionally, the availability of such coverage may induce some participants and beneficiaries to delay attempting to conceive in the knowledge that such benefits could minimize the financial risks of fertility-related medical care when they ultimately decide to attempt to conceive if fertility-related medical care is required. This may produce a pool of participants and beneficiaries that utilize fertility-related medical care at very high rates and more frequently require advanced fertility treatments or medications which could subsequently generate high costs for the insurers that provide such plans. Given the sizeable expense for fertility-related treatment such as IVF, this could yield substantial expenditures for issuers and plans.

While there are some steps that plans and issuers might be able to take to mitigate these risks through enrollment and benefit design, these issues might ultimately impact not only the extent to which issuers and plans offer coverage but potentially increase the premiums of such coverage. As such, the Departments are uncertain how many plans and issuers would offer excepted fertility benefits, how enrollment would affect the risk pool, and how premiums for participants would be subsequently impacted. The Departments request comments on any information that may indicate the extent to which issuers and participants and beneficiaries would offer and enroll in such an arrangement, respectively.

2. Offer Rates of Employers

The Departments based their assumptions regarding offer rates by employers of limited excepted fertility benefits on existing data for vision and dental limited excepted benefits plans.

Fertility benefits, however, are significantly more expensive than vision or dental benefits, and appeal to a much smaller population. As a result, the actual offer rates for these limited excepted benefits may be substantially less than those for vision or dental excepted benefits. Additionally, employers may delay offering these benefits until they observe the advantages early adopters of these plans receive, or else choose not to offer them at all. Additionally, because of sensitivities regarding fertility care, it is possible that some employers may hold religious objections to offering these benefits, which would further reduce the share of entities that would offer this limited excepted benefit plan option. The Departments request comments on any information that may clarify the rate at which employers chose to offer limited excepted fertility benefit plans.

3. Costs to Plans of Providing Benefits

These proposed rules would not require a minimum level of coverage nor would they require that plan sponsors contribute to the costs of the plans. As a result, it is not clear how much plan sponsors would subsidize the total premium costs of participants covered by the excepted fertility benefits. The Departments request comments on any information that may clarify the level of contributions offered by plan sponsors to participants for these benefits.

4. Sponsors Already Covering IVF Benefits

According to KFF, 27 percent of employers with 200 or more employees already offer IVF coverage as part of their medical plan.[174] The decision by employers to offer an excepted fertility benefit plan may stem from a belief that such benefits may help them attract and retain talent and support overall employee well-being.[175] As such, the Departments have assumed that plans already offering these benefits would continue to offer, with some even supplementing

[174] KFF, *2024 Annual Survey of Employer Health Benefits* (Oct. 2024), https://files.kff.org/attachment/Employer-Health-Benefits-Survey-2024-Annual-Survey.pdf.
[175] Dawn Kawamoto, *Why More than 40% of U.S. Employers Now Offer Fertility Benefits*, HR Executive (Sept. 16, 2024). https://hrexecutive.com/why-more-than-40-of-u-s-employers-now-offer-fertility-benefits/#:~:text=According%20to%20a%20recent%20survey%20by%20the%20International,consider%20fertility%20and%20family-building%20benefits%20imperative%20business%20tools.

existing coverage by offering an excepted fertility benefit plan as an additional option to eligible employees.

However, it is possible that some plans currently offering IVF and other fertility benefits through their medical plans would, under these proposed rules, remove such coverage from their existing plan and offer fertility benefits through an excepted benefit plan instead. This could reduce costs for plan sponsors because plans under these proposed rules would not be subject to ACA market reforms or HIPAA portability requirements, while still allowing employers to offer some level of fertility services to their employees. Moreover, while plan sponsors may contribute to these plans, they are not required to, and in the case of dental and vision plans, a significant portion do not, further reducing costs to plan sponsors.

The Departments request comments on the likelihood and extent that employers who currently offer fertility benefits in their medical plans would instead choose to only offer fertility coverage through an excepted benefit plan.

5. Effects of State Insurance Requirements

As discussed in the regulatory baseline (section III.D), 15 States and the District of Columbia require various levels of IVF coverage, while 23 States and the District of Columbia require various levels of fertility-related care coverage. The Departments are unsure of the extent to which these fertility-related care requirements currently cover IVF, and other types of items and services detailed in these proposed rules. The RIA currently assumes that fully insured plans covered by IVF mandates would not be affected by these proposed rules, because they are already required to provide fertility items and services at or similar to what would be covered in an excepted fertility benefit plan, or at additional levels under their State requirements. However, it is possible that those fully insured plans could still be affected, depending on the State coverage requirements. This would produce a higher number of affected entities, and a higher estimated cost for these proposed rules.

To address this uncertainty, the Departments have re-calculated their analysis including

fully insured plans in the 15 States and the District of Columbia that require IVF as an alternative baseline, which would result in more fully insured plans potentially impacted by the proposed rulemaking. These alternative calculations are presented in Table 5.

TABLE 5. State Insurance Requirement Uncertainty Analysis

	RIA Estimate	Alternative Baseline
Jurisdiction Fertility Mandate Assumption	16	16
Total Affected Public Plans	32,545	48,033
Total Affected Private Plans	490,266	709,272
Sent Notices (All Offered Participants)	54,411,264	64,149,681
Enrolled Participants and Beneficiaries	743,361	877,731
First Year Total Costs	**$1,883,462**	**$1,946,030**
Subsequent Year Total Costs	**$1,427,080**	**$1,489,648**

L. Alternatives

In addition to the regulatory approach outlined in these proposed rules for the group market, as well as the approach under consideration by HHS to adopt standards for the individual market that would be similar to the proposed rules for the group market, as discussed in section II.A.6 of this preamble, the Departments considered several alternative approaches during the development of these proposed rules. These alternatives are discussed in greater detail below.

1. Limiting the Excepted Benefits to Include Only Diagnostic Procedures

The Departments considered reducing the scope of the proposed excepted fertility benefit by excluding coverage of IVF cycles, and instead limiting the proposed excepted fertility benefit to pre-IVF items and services. However, because IVF is one of the key fertility benefits that individuals seek when facing fertility-related pregnancy challenges, the Departments are of the view that these proposed rules would be more beneficial for participants and beneficiaries if employers and issuers had the flexibility to cover these costs. Additionally, such coverage is also consistent with President Trump's Executive Order 14216, which specifically calls for expanding access to IVF, as well as aggressively reducing out-of-pocket and health plan costs for IVF treatment.

2. Impose IVF Cycle Limitations on Benefits

The Departments also considered including a limit on the number of IVF cycles permitted by the proposed excepted fertility benefit. However, in an effort to provide plan sponsors and issuers with greater flexibility in terms of the types of infertility-related benefits that they cover, while still ensuring that the benefits are sufficiently "similar" and "limited" to constitute the type of ancillary benefit contemplated within the meaning of "similar, limited benefits" under Code section 9832(e)(2)(C), ERISA section 733(e)(2)(C), and PHS Act section 2791(c)(2)(C), the Departments are not proposing to impose specific limitations on infertility treatments or the number of IVF cycles; rather, the Departments are proposing to impose a $120,000 lifetime dollar limitation on benefits coverage, in addition to a limit on the scope of excepted fertility benefits, as discussed in sections II.A.1 and II.A.2 of this preamble. The complexity of fertility-related care and services like IVF is such that, given the need to apply a limiting principle for fertility benefits to qualify as limited excepted benefits, participants and beneficiaries would be better served by a limitation not on the quantity of the items and services that are provided but by a limitation on the lifetime dollar amount for those items and services as they choose the combination of services to utilize.

IV. Paperwork Reduction Act

A. Paperwork Reduction Act

1. Paperwork Reduction Act – Departments of Labor and Treasury

As part of their continuing effort to reduce paperwork and respondent burden, the Departments conduct a preclearance consultation program to allow the general public and Federal agencies to comment on proposed and continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA).[176] This helps to ensure that the public understands the Departments' collection instructions, respondents can provide the requested data in the desired format, reporting burden (time and financial resources) is

[176] 44 U.S.C. 3506(c)(2)(A) (1995).

minimized, collection instruments are clearly understood, and the Departments can properly assess the impact of collection requirements on respondents.

Currently, the Departments are soliciting comments concerning the proposed information collection request (ICR) included in this rulemaking. To obtain a copy of the ICR, contact the PRA addressee shown below or go to https://www.RegInfo.gov.

The Departments have submitted a copy of these proposed rules to OMB in accordance with 44 U.S.C. 3507(d) for review of its information collections. The Departments and OMB are particularly interested in comments that:

- Evaluate whether the collection of information is necessary for the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the Departments' estimate of the burden for the collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology (for example, permitting electronically delivered responses).

Commenters may send their views on the Departments' PRA analysis in the same way they send comments in response to these proposed rules (for example, through the https://www.regulations.gov website), including as part of a comment responding to the broader NPRM.

PRA Addressee: Address requests for copies of the ICR to PRA Clearance Officer, Office of Research and Analysis, U.S. Department of Labor, Employee Benefits Security Administration, 200 Constitution Avenue NW, Room N-5718, Washington, DC 20210;

ebsa.opr@dol.gov (https://www.reginfo.gov/public/do/PRAMain).

For a full discussion of all burden related to this information collection please see the supporting statement which is part of the ICR available at https://www.reginfo.gov/public/do/PRAMain.

These proposed rules are intended to provide participants and beneficiaries with greater access to and coverage options for items and services related to fertility. Under these proposed rules, the Departments propose to require that a notice be sent to eligible participants and beneficiaries, which would contain a summary of their coverage benefits and limitations, as well as any claims procedures, among other details that the Departments propose to include in the notice, as discussed in more detail in section II.A.4 of this preamble. A summary of the hour and cost burdens are presented below in Table 6. For a description of how the estimates are obtained please see section III.I (Costs) of the preamble.

TABLE 6. Summary of Annual Hour and Cost Burden – Departments of Labor and Treasury

	Hour Burden	**Cost Equivalent of Hour Burden**	**Cost Burden**
Notice Drafting (Year One)	811	$152,127	-
Review & Update Notice (Subsequent Years)	406	$76,064	-
Mail Disclosure (Annually)	-	-	$893,408
First Year Total	**811**	**$152,127**	**$893,408**
Subsequent Year Total	**406**	**$76,064**	**$893,408**
Three-Year Average Total	**541**	**$101,418**	**$893,408**

Below is a summary of the burden associated with the collection of information.

Type of Review: New.

Agency: Employee Benefits Security Administration, U.S. Department of Labor; Internal Revenue Service, U.S. Department of the Treasury.

Title: Fertility Limited Excepted Benefits

OMB Control Number: 1210-New, 1545-New

Affected Public: Businesses or other for-profits.

Estimated Number of Respondents: 490,266

Estimated Number of Annual Responses: 17,868,973

Frequency of Response: Annual

Estimated Total Annual Burden Hours: 541 (270 for Treasury and 270 for DOL)

Estimated Total Annual Burden Cost: $893,408 ($446,704 for Treasury and $446,704 for DOL)

2. Paperwork Reduction Act - Department of HHS

As part of its continuing effort to reduce paperwork and respondent burden, HHS conducts a preclearance consultation program to allow the general public and Federal agencies to comment on proposed and continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA).[177] This helps to ensure that the public understands HHS's collection instructions, respondents can provide the requested data in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and HHS can properly assess the impact of collection requirements on respondents.

Currently, HHS is soliciting comments concerning the proposed information collection request (ICR) included in this rulemaking. To obtain a copy of the ICR, contact the PRA addressee shown below or go to https://www.RegInfo.gov.

HHS has submitted a copy of these proposed rules to OMB in accordance with 44 U.S.C. 3507(d) for review of its information collections. HHS and OMB are particularly interested in comments that:

- Evaluate whether the collection of information is necessary for the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and

[177] 44 U.S.C. 3506(c)(2)(A) (1995).

- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology (e.g., permitting electronically delivered responses).

Commenters may send their views on HHS PRA analysis in the same way they send comments in response to the NPRM as a whole (e.g., through the https://www.regulations.gov website), including as part of a comment responding to the broader NPRM.

PRA Addressee: To obtain copies of the supporting statement and any related forms for the proposed collections, please visit CMS's website at https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.

TABLE 7. Summary of Annual Hour and Cost Burden – Department of Health and Human Services

	Hour Burden	**Cost Equivalent of Hour Burden**	**Cost Burden**
Notice Drafting (Year One)	811	$152,127	-
Review & Update Notice (Subsequent Years)	406	$76,064	-
Mail Disclosure (Annually)	-	-	$381,544
First Year Total	**811**	**$152,127**	**$381,544**
Subsequent Year Total	**406**	**$76,064**	**$381,544**
Three-Year Average Total	**541**	**$101,418**	**$381,544**

Overall Summary

The paperwork burden associated with the proposed rule is presented in Table 7 above.

Type of Review: New

Agency: U.S. Department of Health and Human Services.

Title: Fertility Limited Excepted Benefits

OMB Control Number: 0938-XXXX

Affected Public: Businesses or other for-profits, Not-for-profit institutions, State, Local, or Tribal Governments

Estimated Number of Respondents: 32,545

Estimated Number of Annual Responses: 7,631,701

Frequency of Response: Annual

Estimated Total Annual Burden Hours: 541

Estimated Total Annual Burden Cost: $381,544

V. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA)[178] imposes certain requirements with respect to Federal rules that are subject to the notice-and-comment requirements of section 553(b) of the Administrative Procedure Act and are likely to have a significant economic impact on a substantial number of small entities. Unless the head of an agency certifies that a rule will not, if promulgated, have a significant economic impact on a substantial number of small entities, section 603[179] of the RFA requires the agency to present an initial regulatory flexibility analysis (IRFA) of these proposed rules. The RFA generally defines a "small entity" as (1) a proprietary firm meeting the size standards of the Small Business Administration (SBA), (2) a not-for-profit organization that is not dominant in its field, or (3) a small government jurisdiction with a population of less than 50,000. States and individuals are not included in the definition of "small entity." The Departments do not anticipate that these regulations would have a significant impact on a substantial number of small entities. However, there is significant uncertainty about take-up of excepted benefit coverage and costs related to provision of the coverage. Therefore, the Departments are preparing an initial regulatory flexibility analysis and request data or other information that would assist in making a final determination.

A. Need for the Rule

There is a growing concern over declining fertility rates in the United States, which has been influenced by changing birth patterns. Fewer women under the age of 30 are giving birth

[178] 5 U.S.C. 601 *et seq.* (1980).
[179] 5 U.S.C. 603 (1980).

while an increasing number of women are delaying reproductive decision making past the age of 30.[180] Despite this, there has been little change to the "ideal" family size and many adults intend to have children.[181]

These shifting reproductive patterns, combined with age-related declines in fertility, heighten the growing demand for fertility care. As testing and treatment for infertility are not covered to the same extent as other health conditions, there is a widening gap in the demand for such items and services and their accessibility to patients. The financial burden of accessing fertility-related healthcare is significant, with many individuals facing high out-of-pocket costs, making regulation in this area essential to improving access and affordability.[182]

B. Objectives of the Rule

These proposed rules would expand access to diagnostic procedures, medications, and treatments for infertility, which could potentially reduce out-of-pocket costs to participants and beneficiaries and may encourage employers to expand fertility benefits coverage to assist in addressing the widening disparity in demand and access for fertility care and services.

C. Affected Small Entities

The following sections and Table 8 below summarize the number of small entities that would be affected by these proposed rules. The Departments anticipate that these proposed rules would primarily impact issuers acting as service providers to excepted fertility benefit health plans and employers that sponsor such plans.

1. Group Health Insurance Issuers

The provisions in these proposed rules would affect issuers of insurance providing

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[180]Anne Driscoll and Brady Hamilton, *Effects of Age-Specific Fertility Trends on Overall Fertility Trends: United States, 1990-2023*, Centers for Disease Control and Prevention, National Vital Statistics Reports, Vol. 74, No. 3 (Mar. 6, 2025), https://stacks.cdc.gov/view/cdc/174576.

[181] Gallup News Service, *Americans' Ideal Family Size Remains Above Two Children* (Sept. 4. 2025), https://news.gallup.com/poll/694640/americans-ideal-family-size-remains-above-two-children.aspx.

[182]Patricia Katz, Jonathan Showstack, James Smith, Robert Nachtigall, Susan Millstein, Holly Wing, Michael Eisenberg, Lauri Pasch, Mary Croughan, and Nancy Adler, *Costs of Infertility Treatment: Results from an 18-month Prospective Cohort Study,* Journal of Fertility & Sterility, Vol. 95 No. 3 (Mar. 1, 2011), https://pmc.ncbi.nlm.nih.gov/articles/PMC3043157/pdf/nihms253376.pdf.

standalone, limited excepted benefits of diagnostic procedures, medications, and treatments for infertility and infertility-related health conditions. Health insurance issuers are generally classified under the North American Industry Classification System (NAICS) code 524114 (Direct Health and Medical Insurance Carriers). According to SBA size standards,[183] entities with average annual receipts of $47.0 million or less are considered small entities for this NAICS code. The Departments expect that few, if any, insurance companies underwriting health insurance policies for non-federal group health plans fall below these size thresholds. These entities provide services such as plan management to level-funded and self-insured group health plans. They also provide insurance coverage to fully insured plans and are the issuers most likely to offer standalone limited excepted benefits. Based on data from the CMS Medical Loss Ratio (MLR) annual report submissions for the 2023 reporting year, approximately 65 out of 373 health insurance companies had total premium revenue of $47 million or less.[184] However, it should be noted that at least 76 percent of these small companies belong to larger holding groups that may not be small, and many, if not all, of these companies are likely to have non-health lines of business that would result in their revenues exceeding $47 million. The Departments expect this to be the case for issuers of insurance that would provide standalone excepted fertility benefits pursuant to these proposed rules, if finalized. However, due to a lack of data, the Departments are unable to quantify the number of small issuers of insurance for fertility-related limited excepted benefits would be affected by these proposed rules. The Departments seek comments on this analysis and seek information on the number of small issuers of insurance that would provide standalone, limited excepted benefits of diagnostic procedures, medications, and treatments for infertility.

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[183] Small Business Administration, *SBA Table of Size Standards* (Mar. 17, 2023), https://www.sba.gov/sites/default/files/2023-06/Table%20of%20Size%20Standards_Effective%20March%2017%2C%202023%20%282%29.pdf.
[184] Centers for Medicare and Medicaid Services, *2023 Medical Loss Ratio Data* (as of Dec. 16, 2024), https://www.cms.gov/marketplace/resources/data/medical-loss-ratio-data-systems-resources.

2. Health Plans and Plan Sponsors

For purposes of the IRFA, the Departments consider employee benefit plans with fewer than 100 participants to be small entities.[185] The basis of this definition is found in section 104(a)(2) of ERISA, which permits the Secretary of Labor to prescribe simplified annual reports for plans that cover fewer than 100 participants. Under section 104(a)(3) of ERISA, the Secretary may also provide for exemptions or simplified annual reporting and disclosure for welfare benefit plans. Pursuant to the authority of section 104(a)(3), the Department of Labor has previously issued (*see* 29 CFR 2520.104–20, 2520.104–21, 2520.104–41, 2520.104–46, and 2520.104b–10) simplified reporting provisions and limited exemptions from reporting and disclosure requirements for small plans, including unfunded or insured welfare plans that satisfy certain requirements.

While some large employers sponsor small plans, small plans are generally maintained by small employers. Thus, the Departments believe that assessing the impact of this proposed exemption on small plans is an appropriate way to evaluate its effect on small entities. The definition of small entity applied for this purpose differs, however, from a definition of small business based on size standards promulgated by the Small Business Administration[186] pursuant to the Small Business Act and Section 601 of the RFA.[187] Therefore, the Departments request comments on the appropriateness of the size standard used in evaluating the impact of these proposed rules on small entities.

The Departments have data on the share of private group health plans that have less than 100 employees, but not the share of public group health plans. However, 93.4 percent of all group health plans are small, so the Departments assume that the share of small public plans will

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[185] The Department of Labor consulted with the Small Business Administration in making this determination, as required by 5 U.S.C. 603(c) and 13 CFR 121.903(c). Memorandum received from the U.S. Small Business Administration, Office of Advocacy on July 10, 2020.
[186] 13 CFR 121.201 (2011).
[187] 15 U.S.C. 631 et seq. (2011).

match this figure.[188] These proposed rules would impact non-Federal group health plans that decide to sponsor excepted fertility benefits. However, issuers providing insured coverage to fully insured group health plans in States already requiring IVF coverage would likely not be able to meet State requirements by offering those benefits through excepted fertility benefit plans. As a result, the Departments limit their analysis to only self-insured group health plan sponsors in those States. The Departments also assume that plan sponsors that already offer comprehensive fertility benefits as part of their major medical coverage would offer excepted fertility benefits on a more limited basis, similar to plans that offer dental and/or vision benefits that also offer these benefits in standalone plans. The Departments relied on dental and vision excepted benefit offer rates as a proxy for excepted fertility benefits offer rates, though because those benefits are substantially less expensive and affect a larger population, this may overstate the actual offer rates for excepted fertility benefits. Finally, the Departments assume that the smallest of plans, those with fewer than 10 participants, would be unlikely to offer such an excepted benefit as the prevalence of infertility among such a small group would likely impact few, if any, participants and the potential costs may be prohibitive for these small groups. For more information on these assumptions, see the RIA above. The calculations of affected small entities are detailed below. The Departments request comments on these assumptions.

[188] *See* Agency for Healthcare Research and Quality, *2023 Medical Expenditure Panel Survey Insurance Component (MEPS–IC)*, https://datatools.ahrq.gov/meps-ic/ (last accessed Apr. 16, 2026); *see also* U.S. Census Bureau*, 2021 County Business Patterns*, https://www.census.gov/programs-surveys/cbp/data.html (last accessed Apr. 16, 2026).

TABLE 8. Affected Plan Counts

	Small Plans (A)	Not Currently Offering (A) × 73% = (B)	Currently Offering (A) × 27% = (C)	Expected to Offer ((B) × 65%) + ((C) × 18%)
Small Public Entities				
Small Self-insured (States with Requirements)	10,349	7,555	2,794	5,434
Small Self-insured (States without Requirements)	20,156	14,714	5,442	10,582
Small Fully insured (States without Requirements)	27,391	19,996	7,396	14,381
Total Small Public	**57,897**	**42,265**	**15,632**	**30,397**
Small Private Entities				
Small Self-insured (States with Requirements)	176,478	128,829	47,649	92,654
Small Self-insured (States without Requirements)	312,151	227,870	84,281	163,885
Small Fully insured (States without Requirements)	281,018	205,143	75,875	147,540
Total Small Private	**769,646**	**561,842**	**207,805**	**404,080**
All Small Plans	**827,543**	**604,107**	**223,437**	**434,477**

*Totals displayed in the table may not sum due to rounding.

3. Cost of Proposed Rules

a. Small Plan Sponsors and Plans

Small plan sponsors would be able to choose to offer excepted fertility benefits and would be able to design a plan that fits their needs including their share of the premiums. The Departments cannot rule out the possibility that these premium payments could be significant under the requirements of the RFA. However, due to the voluntary nature of these proposed rules, plan sponsors would be expected to make decisions that would not create an adverse impact on themselves.

Excepted fertility benefit plans that would be created in accordance with these proposed rules would be required to send a notice containing specific information, including a description of the coverage, including a summary of benefits and limitations of the coverage, how to identify and utilize a network provider, if applicable, as well as procedures for claims reimbursement, including whether the benefit utilizes the same claim procedures as for the sponsor's other group health plans.

Service providers, likely issuers, would help plans by reviewing these proposed rules requirements and preparing and distributing the notice. Plan expenses charged by issuers would include these costs. The Departments assume that costs borne by issuers to familiarize themselves with these proposed rules and prepare the appropriate notices would be passed along to the 434,477 small plans. These costs for small plans are summarized in Table 9. These costs would not have a significant impact on a substantial number of small entities.

TABLE 9. Costs for Small Entities

	First Year	Subsequent Years	Per Small Entity Cost*
Rule Familiarization (Year One)	$304,255	$0	$0.70
Notice Drafting (Year One)	$304,255	$0	$0.70
Review & Update Notice (Subsequent Years)	$0	$152,127	$0.35
Average Mail Disclosure (20 participants)	$316,513	$316,513	$0.73
Per Plan First Year Costs	**-**	**-**	**$2.13**
Per Plan Subsequent Year Costs	**-**	**-**	**$1.08**

*The cost per entity reflects the total costs of the regulation averaged to account for the 434,477 small, non-Federal group health plans.

D. Duplicate, Overlapping, or Relevant Federal Rules

There are no duplicate, overlapping, or relevant Federal rules.

E. Significant Alternatives Considered

The regulatory alternatives considered in developing these proposed rules are discussed in section III.L of this preamble. The Departments are of the view that none of these alternatives would both achieve the policy objectives and goals of these proposed rules as previously stated and be less burdensome to small entities. The Departments emphasize that because these proposed rules would provide a voluntary means of providing benefits, administrators would be free to begin offering excepted fertility benefits at any time on or after the applicability date of any finalized rules, if they choose to do so. For a more detailed discussion of the regulatory alternatives considered, please refer to section III.L of this preamble.

VI. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed

or final agency rule that may result in an expenditure of $100 million or more (adjusted annually for inflation with the base year 1995) in any one year by State, local, and Tribal governments, in the aggregate, or by the private sector.[189] For purposes of the UMRA, this rulemaking is not expected to have such an impact. For the purposes of this rulemaking, the RIA shall meet the UMRA obligations.

VII. Federalism Statement

Executive Order 13132 outlines fundamental principles of federalism, and requires the adherence to specific criteria by Federal agencies in the process of their formulation and implementation of policies that have "substantial direct effects" on the States, the relationship between the Federal Government and States, or on the distribution of power and responsibilities among the various levels of government.[190] Federal agencies promulgating regulations that have federalism implications must consult with State and local officials and describe the extent of their consultation and the nature of the concerns of State and local officials in the preamble to these proposed rules.

In the Departments' view, these proposed rules would not have federalism implications because they would have no substantial direct effect on the States, on the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government. Section 514 of ERISA provides, with certain exceptions specifically enumerated, that the provisions of Titles I and IV of ERISA supersede any and all laws of the States as they relate to any employee benefit plan covered under ERISA.

Section 2724 of the PHS Act (implemented in 45 CFR 146.143(a) and 148.210(b)) apply so that the requirements of title XXVII of the PHS Act are not to be construed to supersede any provision of State law which establishes, implements, or continues in effect any standard or requirement solely relating to health insurance issuers in connection with individual or group

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[189] 2 U.S.C. 1501 *et seq*. (1995).
[190] *Federalism*, 64 Fed. Reg. 153 (Aug. 4, 1999).

health insurance coverage except to the extent that such standard or requirement prevents the application of a federal requirement. The conference report accompanying HIPAA indicates that this is intended to be the "narrowest" preemption of State laws (See House Conf. Rep. No. 104–736, at 205, reprinted in 1996 U.S. Code Cong. & Admin. News 2018).

These proposed requirements, if implemented in a final rule, would not alter the fundamental requirements of any State with respect to employee benefit plans nor would it alter State benefit requirements, and, as such, would have no implications for the States or the relationship or distribution of power between the Federal Government and the States. The Departments welcome input from affected States regarding this assessment.

List of Subjects

26 CFR Part 54

Excise taxes, Health care, Pensions, Reporting and recordkeeping requirements

29 CFR Part 2590

Child support, Employee benefit plans, Health care, Health insurance, Infants and children, Maternal and child health, Penalties, Pensions, Privacy, Reporting and Recordkeeping requirements.

45 CFR Part 146

Health care, Health insurance, Reporting and recordkeeping requirements.

Frank J. Bisignano,
Chief Executive Officer,
Internal Revenue Service.

Daniel Aronowitz,
Assistant Secretary, Employee Benefits Security Administration,
Department of Labor.

Robert F. Kennedy, Jr.,
Secretary,
Department of Health and Human Services.

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Accordingly, the Treasury Department and the IRS propose to amend 26 CFR part 54 as follows:

PART 54—PENSION EXCISE TAXES

1. The authority citation for part 54 continues to read as follows:

Authority: 26 U.S.C. 7805, unless otherwise noted.

2. Section 54.9831-1 is amended by—

a. Revising paragraph (c)(3)(i); and

b. Adding new paragraph (c)(3)(ix).

The revisions and additions read as follows:

§ 54.9831-1 Special rules relating to group health plans.

* * * * *

(c) * * *

(3) * * *

(i) *In general.* Limited-scope dental benefits, limited-scope vision benefits, or long-term care benefits are excepted if they are provided under a separate policy, certificate, or contract of insurance, or are otherwise not an integral part of a group health plan as described in paragraph (c)(3)(ii) of this section. In addition, benefits provided under a health flexible spending arrangement (health FSA) are excepted benefits if they satisfy the requirements of paragraph (c)(3)(v) of this section; benefits provided under an employee assistance program are excepted benefits if they satisfy the requirements of paragraph (c)(3)(vi) of this section; benefits provided under limited wraparound coverage are excepted benefits if they satisfy the requirements of paragraph (c)(3)(vii) of this section; benefits provided under a health reimbursement arrangement or other account-based group health plan, other than a health FSA, are excepted benefits if they satisfy the requirements of paragraph (c)(3)(viii) of this section; and fertility

benefits are excepted benefits if they satisfy the requirements of paragraph (c)(3)(ix) of this section.

* * * * *

(ix) *Excepted fertility benefits.* For plan years beginning on or after January 1, 2027, fertility benefits are excepted fertility benefits if they are provided under a separate policy, certificate, or contract of insurance or are otherwise not an integral part of the plan as described in paragraph (c)(3)(ix)(C) of this section , and satisfy the requirements of paragraphs (c)(3)(ix)(A), (B), and (D) of this section.

(A) *Benefits covered.* 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, which may include medically appropriate items or services targeted to address such conditions.

(B) *Lifetime dollar amount.* The total lifetime benefit per participant, together with their beneficiaries (if such beneficiaries are eligible for the fertility benefit), does not exceed $120,000. In the case of any plan year beginning after December 31, 2027, the maximum lifetime dollar amount in the preceding sentence shall be increased by medical inflation. For these purposes, medical inflation is calculated as $120,000 multiplied by the difference between the overall medical care component of the Consumer Price Index for All Urban Consumers (CPI–U) (unadjusted) published by the Department of Labor for December of the previous plan year and 587.144 (the overall medical care component of the CPI-U (unadjusted) for December 2025), divided by 587.144.

(C) *Not an integral part of the plan.* For purposes of this paragraph (c)(3)(ix), fertility benefits are not an integral part of a group health plan if other group health plan coverage that is not limited to excepted benefits and that is not an HRA or other account-based group health plan

is made available by the same plan sponsor for the plan year to participants that are offered the fertility benefit (and beneficiaries, if eligible for the fertility benefit), and participants (and beneficiaries, if eligible for the fertility benefit) enrolling in the fertility benefit may decline coverage for the other group health plan coverage. For example, a participant may decline the other group health plan coverage if the participant can opt out of that coverage, whether or not there is a contribution required for the coverage.

(D) *Notice requirement.* The plan or issuer provides written notice to participants and beneficiaries of the fertility benefit coverage in accordance with the requirements of this paragraph (c)(3)(ix)(D).

(*1*) *Content.* Such notice must be written in a manner calculated to be understood by the average plan participant and must also include a description of the coverage, including a summary of benefits and limitations of the coverage (including the lifetime dollar amount limit established by the plan or issuer that complies with the lifetime dollar amount limit described in paragraph (c)(3)(ix)(B) of this section), how to identify and utilize a network provider, if applicable, and how to submit a claim for reimbursement, including whether the benefit utilizes the same claims procedure as for the sponsor's other group health plans.

(*2*) *Timing.* The plan or issuer must provide the notice no later than the first date on which the participant or beneficiary is eligible to enroll in coverage, and annually thereafter, as well as upon request of the participant or beneficiary.

(*3*) *Special rule.* If a single notice is provided to a participant and any beneficiaries at the participant's last known address, the requirement to provide the notice to the participant and any beneficiaries is generally satisfied. However, if a beneficiary's last known address is different than the participant's last known address, a separate notice is required to be provided to the beneficiary at the beneficiary's last known address.

(E) *Examples.* The rules of this paragraph (c)(3)(ix) are illustrated by the following examples:

(*1*) *Example 1.*

(*i*) *Facts.* An employer offers benefits for fertility counseling through a separate insurance policy that satisfy the requirements of paragraph (c)(3)(ix)(A) of this section. The fertility counseling coverage issuer also provides notice to plan participants and beneficiaries at or before the time individuals are given the opportunity to enroll in the coverage and annually thereafter. The notice is written in a manner calculated to be understood by the average plan participant and includes a description of the coverage, including a summary of benefits and limitations of the coverage, how to identify and utilize a network provider, how to submit a claim for reimbursement and that the benefit utilizes the same claims procedure as for the sponsor's other group health plans. The fertility counseling coverage also has a lifetime dollar limit that complies with the requirements of paragraph (c)(3)(ix)(B) of this section.

(*ii*) *Conclusion.* In this Example, the fertility counseling coverage satisfies the conditions in this paragraph (c)(3)(ix), because the employer offers such fertility benefit through a separate fully insured policy that satisfies the requirements of paragraph (c)(3)(ix)(A) of this section, provides written notice as required by paragraph (c)(3)(ix)(D) of this section, and includes a lifetime dollar limit on fertility benefits that complies with paragraph (c)(3)(ix)(B) of this section.

(*2*) *Example 2.*

(*i*) *Facts.* An employer sponsors a group health plan that is not limited to excepted benefits and that is not an HRA or other account-based group health plan and also offers fertility benefits for the mitigation or treatment of infertility that satisfy the requirements of paragraph (c)(3)(ix)(A) of this section. The fertility benefits are self-funded by the employer. The employer offers both the group health plan and the fertility benefits to participants and permits participants to enroll in either or both benefit options, or decline to participate in either or both options for the plan year. The employer also includes a lifetime dollar limit on fertility benefits that satisfies the

requirements of paragraph (c)(3)(ix)(B) of this section and provides written notice to participants in accordance with the requirements of paragraph (c)(3)(ix)(D) of this section.

(*ii*) *Conclusion.* In this Example, the fertility benefit plan satisfies the conditions in this paragraph (c)(3)(ix). Because the fertility benefits are not provided under a separate policy, certificate, or contract of insurance, the requirements under paragraph (c)(3)(ix)(C) of this section apply. In this Example, the fertility benefits are not an integral part of the group health plan because the employer offers, to participants that are offered the fertility benefit, coverage under another group health plan that is not limited to excepted benefits for the plan year and that is not an HRA or other account-based group health plan, and participants may decline coverage for such other group health plan coverage. In addition, the fertility benefit plan satisfies the requirements of paragraph (c)(3)(ix)(A) of this section, includes a lifetime dollar limit on fertility benefits that complies with paragraph (c)(3)(ix)(B) of this section, and provides written notice as required by paragraph (c)(3)(ix)(D) of this section.

(*3*) *Example 3.*

(*i*) *Facts.* An employer sponsors a fertility benefit plan for the mitigation or treatment of infertility that satisfies the requirements of paragraphs (c)(3)(ix)(A), (C) and (D) of this section in a plan year. The fertility benefits are self-funded by the employer. The fertility benefit plan imposes a lifetime, per participant limitation on benefits of $120,000. During the plan year, the fertility benefit plan covers a given participant's claims for treatment of infertility by medical professionals authorized to practice under applicable law totaling $65,000. In December of the plan year, the overall medical care component of the CPI–U (unadjusted) published by the Department of Labor is 625.522. During the following plan year, the plan again covers $65,000 in claims for the same participant for treatment of infertility by medical professionals authorized to practice under applicable law pursuant to such plan's terms.

(*ii*) *Conclusion.* In this Example, the plan fails to satisfy the conditions in paragraph (c)(3)(ix)(B) of this section because lifetime benefits to the participant in the following plan year exceed $127,843.66 ($120,000 increased by an amount equal to $120,000 multiplied by the difference between the overall medical care component of the CPI–U (unadjusted) published by the Department of Labor for December of the previous plan year (625.522) and 587.144, divided by 587.144, i.e., 120,000+120,000((625.522-587.144)/587.144)). The employer may still cover fertility benefits that are in excess of the lifetime dollar limit through its group health plan that is not limited to excepted benefits and that is not an HRA or other account-based group health plan, provided it otherwise complies with the requirements of Chapter 100 of the Code.

(F) *Severability.* If any provision of this paragraph (c)(3)(ix) is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, the provision shall be construed so as to continue to give the maximum effect to the provision permitted by law, unless such holding shall be one of invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

* * * * *

DEPARTMENT OF LABOR

Employee Benefits Security Administration

For the reasons stated in the preamble, the Department of Labor proposes to amend 29 CFR part 2590 as set forth below:

PART 2590—RULES AND REGULATIONS FOR GROUP HEALTH PLANS

3. The authority citation for part 2590 continues to read as follows:

Authority: 29 U.S.C. 1027, 1059, 1135, 1161-1168, 1169, 1181-1183, 1181 note, 1185, 1185a-n, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Pub. L. 104-191, 110 Stat. 1936; sec. 401(b), Pub. L. 105-200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Pub. L. 110-343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Pub. L. 111-148, 124 Stat. 119, as amended by Pub. L. 111-152, 124 Stat. 1029; Division M, Pub. L. 113-235, 128 Stat. 2130; Pub. L. 116-260, 134 Stat. 1182; Secretary of Labor's Order 1-2011, 77 F. R. 1088 (Jan. 9, 2012).

4. Section 2590.732 is amended by—

a. Revising paragraph (c)(3)(i); and

b. Adding new paragraph (c)(3)(ix).

The revisions and additions read as follows:

§ 2590.732 Special rules relating to group health plans.

* * * * *

(c) * * *

(3) * * *

(i) *In general.* Limited-scope dental benefits, limited-scope vision benefits, or long-term care benefits are excepted if they are provided under a separate policy, certificate, or contract of insurance, or are otherwise not an integral part of a group health plan as described in paragraph (c)(3)(ii) of this section. In addition, benefits provided under a health flexible spending arrangement (health FSA) are excepted benefits if they satisfy the requirements of paragraph (c)(3)(v) of this section; benefits provided under an employee assistance program are excepted benefits if they satisfy the requirements of paragraph (c)(3)(vi) of this section; benefits provided

under limited wraparound coverage are excepted benefits if they satisfy the requirements of paragraph (c)(3)(vii) of this section; benefits provided under a health reimbursement arrangement or other account-based group health plan, other than a health FSA, are excepted benefits if they satisfy the requirements of paragraph (c)(3)(viii) of this section; and fertility benefits are excepted benefits if they satisfy the requirements of paragraph (c)(3)(ix) of this section.

* * * * *

(ix) *Excepted fertility benefits.* For plan years beginning on or after January 1, 2027, fertility benefits are excepted fertility benefits if they are provided under a separate policy, certificate, or contract of insurance or are otherwise not an integral part of the plan as described in paragraph (c)(3)(ix)(C) of this section, and satisfy the requirements of paragraphs (c)(3)(ix)(A), (B), and (D) of this section.

(A) *Benefits covered.* 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, which may include medically appropriate items or services targeted to address such conditions.

(B) *Lifetime dollar amount.* The total lifetime benefit per participant, together with their beneficiaries (if such beneficiaries are eligible for the fertility benefit), does not exceed $120,000. In the case of any plan year beginning after December 31, 2027, the maximum lifetime dollar amount in the preceding sentence shall be increased by medical inflation. For these purposes, medical inflation is calculated as $120,000 multiplied by the difference between the overall medical care component of the Consumer Price Index for All Urban Consumers (CPI–U) (unadjusted) published by the Department of Labor for December of the previous plan

year and 587.144 (the overall medical care component of the CPI-U (unadjusted) for December 2025), divided by 587.144.

(C) *Not an integral part of the plan.* For purposes of this paragraph (c)(3)(ix), fertility benefits are not an integral part of a group health plan if other group health plan coverage that is not limited to excepted benefits and that is not an HRA or other account-based group health plan is made available by the same plan sponsor for the plan year to participants that are offered the fertility benefit (and beneficiaries, if eligible for the fertility benefit), and participants (and beneficiaries, if eligible for the fertility benefit) enrolling in the fertility benefit may decline coverage for the other group health plan coverage. For example, a participant may decline the other group health plan coverage if the participant can opt out of that coverage, whether or not there is a contribution required for the coverage.

(D) *Notice requirement.* The plan or issuer provides written notice to participants and beneficiaries of the fertility benefit coverage in accordance with the requirements of this paragraph (c)(3)(ix)(D).

(*1*) *Content.* Such notice must be written in a manner calculated to be understood by the average plan participant and must also include a description of the coverage, including a summary of benefits and limitations of the coverage (including the lifetime dollar limit established by the plan or issuer that complies with the lifetime dollar limit described in paragraph (c)(3)(ix)(B) of this section), how to identify and utilize a network provider, if applicable, and how to submit a claim for reimbursement, including whether the benefit utilizes the same claims procedure as for the sponsor's other group health plans.

(*2*) *Timing.* The plan or issuer must provide the notice no later than the first date on which the participant or beneficiary is eligible to enroll in coverage, and annually thereafter, as well as upon request of the participant or beneficiary.

(*3*) *Special rule.* If a single notice is provided to a participant and any beneficiaries at the participant's last known address, the requirement to provide the notice to the participant and any

beneficiaries is generally satisfied. However, if a beneficiary's last known address is different than the participant's last known address, a separate notice is required to be provided to the beneficiary at the beneficiary's last known address.

(E) *Examples.* The rules of this paragraph (c)(3)(ix) are illustrated by the following examples:

(*1*) *Example 1.*

(*i*) *Facts.* An employer offers benefits for fertility counseling through a separate insurance policy that satisfy the requirements of paragraph (c)(3)(ix)(A) of this section. The fertility counseling coverage issuer also provides notice to plan participants and beneficiaries at or before the time individuals are given the opportunity to enroll in the coverage and annually thereafter. The notice is written in a manner calculated to be understood by the average plan participant and includes a description of the coverage, including a summary of benefits and limitations of the coverage, how to identify and utilize a network provider, how to submit a claim for reimbursement and that the benefit utilizes the same claims procedure as for the sponsor's other group health plans. The fertility counseling coverage also has a lifetime dollar limit that complies with the requirements of paragraph (c)(3)(ix)(B) of this section.

(*ii*) *Conclusion.* In this Example, the fertility counseling coverage satisfies the conditions in this paragraph (c)(3)(ix), because the employer offers such fertility benefit through a separate fully insured policy that satisfies the requirements of paragraph (c)(3)(ix)(A) of this section, provides written notice as required by paragraph (c)(3)(ix)(D) of this section, and includes a lifetime dollar limit on fertility benefits that complies with paragraph (c)(3)(ix)(B) of this section.

(*2*) *Example 2.*

(*i*) *Facts.* An employer sponsors a group health plan that is not limited to excepted benefits and that is not an HRA or other account-based group health plan and also offers fertility benefits for the mitigation or treatment of infertility that satisfy the requirements of paragraph

(c)(3)(ix)(A) of this section. The fertility benefits are self-funded by the employer. The employer offers both the group health plan and the fertility benefits to participants and permits participants to enroll in either or both benefit options, or decline to participate in either or both options for the plan year. The employer also includes a lifetime dollar limit on fertility benefits that satisfies the requirements of paragraph (c)(3)(ix)(B) of this section and provides written notice to participants in accordance with the requirements of paragraph (c)(3)(ix)(D) of this section.

(*ii*) *Conclusion.* In this Example, the fertility benefit plan satisfies the conditions in this paragraph (c)(3)(ix). Because the fertility benefits are not provided under a separate policy, certificate, or contract of insurance, the requirements under paragraph (c)(3)(ix)(C) of this section apply. In this Example, the fertility benefits are not an integral part of the group health plan because the employer offers, to participants that are offered the fertility benefit, coverage under another group health plan that is not limited to excepted benefits for the plan year and that is not an HRA or other account-based group health plan, and participants may decline coverage for such other group health plan coverage. In addition, the fertility benefit plan satisfies the requirements of paragraph (c)(3)(ix)(A) of this section, includes a lifetime dollar limit on fertility benefits that complies with paragraph (c)(3)(ix)(B) of this section, and provides written notice as required by paragraph (c)(3)(ix)(D) of this section.

(*3*) *Example 3.*

(*i*) *Facts.* An employer sponsors a fertility benefit plan for the mitigation or treatment of infertility that satisfies the requirements of paragraphs (c)(3)(ix)(A), (C) and (D) of this section in a plan year. The fertility benefits are self-funded by the employer. The fertility benefit plan imposes a lifetime, per-participant limitation on benefits of $120,000. During the plan year, the fertility benefit plan covers a given participant's claims for treatment of infertility by medical professionals authorized to practice under applicable law totaling $65,000. In December of the plan year, the overall medical care component of the CPI–U (unadjusted) published by the Department of Labor is 625.522. During the following plan year, the plan again covers $65,000

in claims for the same participant for treatment of infertility by medical professionals authorized to practice under applicable law pursuant to such plan's terms.

(*ii*) *Conclusion.* In this Example, the plan fails to satisfy the conditions in paragraph (c)(3)(ix)(B) of this section because lifetime benefits to the participant in the following plan year exceed $127,843.66 ($120,000 increased by an amount equal to $120,000 multiplied by the difference between the overall medical care component of the CPI–U (unadjusted) published by the Department of Labor for December of the previous plan year (625.522) and 587.144, divided by 587.144, i.e., 120,000+120,000((625.522-587.144)/587.144)). The employer may still cover fertility benefits that are in excess of the lifetime dollar limit through its group health plan that is not limited to excepted benefits and that is not an HRA or other account-based group health plan, provided it otherwise complies with the requirements of Part 7 of ERISA.

(F) *Severability.* If any provision of this paragraph (c)(3)(ix) is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, the provision shall be construed so as to continue to give the maximum effect to the provision permitted by law, unless such holding shall be one of invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

* * * * *

DEPARTMENT OF HEALTH AND HUMAN SERVICES

For the reasons stated in the preamble, the Department of Health and Human Services proposes to amend 45 CFR part 146 as set forth below:

PART 146—REQUIREMENTS FOR THE GROUP HEALTH INSURANCE MARKET

5. The authority citation for part 146 continues to read as follows:

Authority: 42 U.S.C. 300gg-1 through 300gg-5, 300gg-11 through 300gg-23, 300gg-91, and 300gg-92.

6. Section 146.125 is amended by revising the first sentence to read as follows:

§ 146.125 Applicability dates.

Unless otherwise specified, section 144.103 of this subchapter and §§ 146.111 through 146.119, 146.143, and 146.145 are applicable for plan years beginning on or after July 1, 2005.

* * *

7. Section 146.145 is amended by—

a. Revising paragraph (b)(3)(i); and

b. Adding new paragraph (b)(3)(ix).

The revisions and additions read as follows:

§ 146.145 Special rules relating to group health plans.

* * * * *

(b) * * *

(3) * * *

(i) *In general.* Limited-scope dental benefits, limited-scope vision benefits, or long-term care benefits are excepted if they are provided under a separate policy, certificate, or contract of insurance, or are otherwise not an integral part of a group health plan as described in paragraph (b)(3)(ii) of this section. In addition, benefits provided under a health flexible spending arrangement (health FSA) are excepted benefits if they satisfy the requirements of paragraph (b)(3)(v) of this section; benefits provided under an employee assistance program are excepted benefits if they satisfy the requirements of paragraph (b)(3)(vi) of this section; benefits provided under limited wraparound coverage are excepted benefits if they satisfy the requirements of

paragraph (b)(3)(vii) of this section; benefits provided under a health reimbursement arrangement or other account-based group health plan, other than a health FSA, are excepted benefits if they satisfy the requirements of paragraph (b)(3)(viii) of this section; and fertility benefits are excepted benefits if they satisfy the requirements of paragraph (b)(3)(ix) of this section.

* * * * *

(ix) *Excepted fertility benefits.* For plan years beginning on or after January 1, 2027, fertility benefits are excepted fertility benefits if they are provided under a separate policy, certificate, or contract of insurance or are otherwise not an integral part of the plan as described in paragraph (b)(3)(ix)(C) of this section, and satisfy the requirements of paragraphs (b)(3)(ix)(A), (B), and (D) of this section.

(A) *Benefits covered.* 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, which may include medically appropriate items or services targeted to address such conditions.

(B) *Lifetime dollar amount.* The total lifetime benefit per participant, together with their beneficiaries (if such beneficiaries are eligible for the fertility benefit), does not exceed $120,000. In the case of any plan year beginning after December 31, 2027, the maximum lifetime dollar amount in the preceding sentence shall be increased by medical inflation. For these purposes, medical inflation is calculated as $120,000 multiplied by the difference between the overall medical care component of the Consumer Price Index for All Urban Consumers (CPI–U) (unadjusted) published by the Department of Labor for December of the previous plan year and 587.144 (the overall medical care component of the CPI-U (unadjusted) for December 2025), divided by 587.144

(C) *Not an integral part of the plan.* For purposes of this paragraph (b)(3)(ix), fertility benefits are not an integral part of a group health plan if other group health plan coverage that is not limited to excepted benefits and that is not an HRA or other account-based group health plan is made available by the same plan sponsor for the plan year to participants that are offered the fertility benefit (and beneficiaries, if eligible for the fertility benefit), and participants (and beneficiaries, if eligible for the fertility benefit) enrolling in the fertility benefit may decline coverage for the other group health plan coverage. For example, a participant may decline the other group health plan coverage if the participant can opt out of that coverage, whether or not there is a contribution required for the coverage.

(D) *Notice requirement.* The plan or issuer provides written notice to participants and beneficiaries of the fertility benefit coverage in accordance with the requirements of this paragraph (b)(3)(ix)(D).

(*1*) *Content.* Such notice must be written in a manner calculated to be understood by the average plan participant and must also include a description of the coverage, including a summary of benefits and limitations of the coverage (including the lifetime dollar amount limit established by the plan or issuer that complies with the lifetime dollar amount limit described in paragraph (b)(3)(ix)(B) of this section), how to identify and utilize a network provider, if applicable, and how to submit a claim for reimbursement, including whether the benefit utilizes the same claims procedure as for the sponsor's other group health plans.

(*2*) *Timing.* The plan or issuer must provide the notice no later than the first date on which the participant or beneficiary is eligible to enroll in coverage, and annually thereafter, as well as upon request of the participant or beneficiary.

(*3*) *Special rule.* If a single notice is provided to a participant and any beneficiaries at the participant's last known address, the requirement to provide the notice to the participant and any beneficiaries is generally satisfied. However, if a beneficiary's last known address is different

than the participant's last known address, a separate notice is required to be provided to the beneficiary at the beneficiary's last known address.

(E) *Examples.* The rules of this paragraph (b)(3)(ix) are illustrated by the following examples:

(*1*) *Example 1.*

(*i*) *Facts.* An employer offers benefits for fertility counseling through a separate insurance policy that satisfy the requirements of paragraph (b)(3)(ix)(A) of this section. The fertility counseling coverage issuer also provides notice to plan participants and beneficiaries at or before the time individuals are given the opportunity to enroll in the coverage and annually thereafter. The notice is written in a manner calculated to be understood by the average plan participant and includes a description of the coverage, including a summary of benefits and limitations of the coverage, how to identify and utilize a network provider, how to submit a claim for reimbursement and that the benefit utilizes the same claims procedure as for the sponsor's other group health plans. The fertility counseling coverage also has a lifetime dollar limit that complies with the requirements of paragraph (b)(3)(ix)(B) of this section.

(*ii*) *Conclusion.* In this Example, the fertility counseling coverage satisfies the conditions in this paragraph (b)(3)(ix), because the employer offers such fertility benefit through a separate fully insured policy that satisfies the requirements of paragraph (b)(3)(ix)(A) of this section, provides written notice as required by paragraph (b)(3)(ix)(D) of this section, and includes a lifetime dollar limit on fertility benefits that complies with paragraph (b)(3)(ix)(B) of this section.

*(*2) *Example 2.*

(*i*) *Facts.* An employer sponsors a group health plan that is not limited to excepted benefits and that is not an HRA or other account-based group health plan and also offers fertility

benefits for the mitigation or treatment of infertility that satisfy the requirements of paragraph (b)(3)(ix)(A) of this section. The fertility benefits are self-funded by the employer. The employer offers both the group health plan and the fertility benefits to participants and permits participants to enroll in either or both benefit options, or decline to participate in either or both options for the plan year. The employer also includes a lifetime dollar limit on fertility benefits that satisfies the requirements of paragraph (b)(3)(ix)(B) of this section and provides written notice to participants in accordance with the requirements of paragraph (b)(3)(ix)(D) of this section.

(*ii*) *Conclusion.* In this Example, the fertility benefit plan satisfies the conditions in this paragraph (b)(3)(ix). Because the fertility benefits are not provided under a separate policy, certificate, or contract of insurance, the requirements under paragraph (b)(3)(ix)(C) of this section apply. In this Example, the fertility benefits are not an integral part of the group health plan because the employer offers, to participants that are offered the fertility benefit, coverage under another group health plan that is not limited to excepted benefits for the plan year and that is not an HRA or other account-based group health plan, and participants may decline coverage for such other group health plan coverage. In addition, the fertility benefit plan satisfies the requirements of paragraph (b)(3)(ix)(A) of this section, includes a lifetime dollar limit on fertility benefits that complies with paragraph (b)(3)(ix)(B) of this section, and provides written notice as required by paragraph (b)(3)(ix)(D) of this section.

(*3*) *Example 3.*

(*i*) *Facts.* An employer sponsors a fertility benefit plan for the mitigation or treatment of infertility that satisfies the requirements of paragraphs (b)(3)(ix)(A), (C) and (D) of this section in a plan year. The fertility benefits are self-funded by the employer. The fertility benefit plan imposes a lifetime, per-participant limitation on benefits of $120,000. During the plan year, the fertility benefit plan covers a given participant's claims for treatment of infertility by medical professionals authorized to practice under applicable law totaling $65,000. In December of the

plan year, the overall medical care component of the CPI–U (unadjusted) published by the Department of Labor is 625.522. During the following plan year, the plan again covers $65,000 in claims for the same participant for treatment of infertility by medical professionals authorized to practice under applicable law pursuant to such plan's terms.

(*ii*) *Conclusion.* In this Example, the plan fails to satisfy the conditions in paragraph (b)(3)(ix)(B) of this section because lifetime benefits to the participant in the following plan year exceed $127,843.66 ($120,000 increased by an amount equal to $120,000 multiplied by the difference between the overall medical care component of the CPI–U (unadjusted) published by the Department of Labor for December of the previous plan year (625.522) and 587.144, divided by 587.144, i.e., 120,000+120,000((625.522-587.144)/587.144)). The employer may still cover fertility benefits that are in excess of the lifetime dollar limit through its group health plan that is not limited to excepted benefits and that is not an HRA or other account-based group health plan, provided it otherwise complies with the requirements of Title XXVII of the PHS Act.

(F) *Severability.* If any provision of this paragraph (b)(3)(ix) is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, the provision shall be construed so as to continue to give the maximum effect to the provision permitted by law, unless such holding shall be one of invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

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