

EXHIBIT C

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Department of Veterans Affairs
Veterans Health Administration
Washington, DC 20420

VHA DIRECTIVE 1334
Transmittal Sheet
March 12, 2021

**IN VITRO FERTILIZATION COUNSELING AND SERVICES AVAILABLE TO
CERTAIN ELIGIBLE VETERANS AND THEIR SPOUSES**

1. REASON FOR ISSUE: This Veterans Health Administration (VHA) directive defines policy for ensuring access to in vitro fertilization (IVF) services for Veterans who are unable to procreate as a result of their service-connected condition.

2. SUMMARY OF CONTENT: This is a new directive addressing the delivery of IVF services to Veterans with specific service-connected conditions that result in infertility and their legal spouses who are eligible for the benefit.

3. RELATED ISSUES: VHA Directive 1332(2), Fertility Evaluation and Treatment, dated June 20, 2017, amended August 12, 2019.

4. RESPONSIBLE OFFICE: VHA Office of Women's Health (WHS, 10W) and the National Surgery Office (NSO, 11SURG) are responsible for the contents of this VHA directive. Questions may be referred to the Director of Reproductive Health, WHS at 202-461-0373.

5. RESCISSION: None.

6. RECERTIFICATION: This VHA directive is scheduled for recertification on or before the last working day of March 2026. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

**BY DIRECTION OF THE OFFICE OF THE
UNDER SECRETARY FOR HEALTH:**

/s/ Richard Stone, MD, MS
Acting Under Secretary for Health

NOTE: All references herein to Department of Veterans Affairs (VA) and VHA documents incorporate by reference subsequent VA and VHA documents on the same or similar subject matter.

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1. PURPOSE

a. This Veterans Health Administration (VHA) directive defines policy for the Department of Veterans Affairs (VA)'s special treatment authority that authorizes the use of Medical Services funds to provide In Vitro fertilization (IVF) counseling and services to eligible Veterans and their spouses. Section 234 of the Military Construction, Veterans Affairs, and Related Agencies Appropriations Act, 2021, (Division J of Public Law (P.L.) 116-260) provides that amounts appropriated or otherwise made available to VA for the "Medical Services" account may be used for fertility counseling and treatment using assisted reproductive technology to a covered Veteran or the spouse of a covered Veteran. Because this Act included an advance appropriation for the "Medical Services" account for Fiscal Year (FY) 2022, VA can use funds appropriated in P.L. 116-260 for that account for FY 2022 to make this treatment available through September 30, 2022.

b. The terms of section 234 are identical and unchanged from the preceding appropriations law that authorized this program, i.e., P.L. 116-94, Division F, Section 235 (2019). Specifically, section 234(b)(3) defines "assisted reproductive technology" as: assistance provided to a member of the Armed Forces who incurs a serious injury or illness on active duty pursuant to section 1074(c)(4)(A) of title 10, United States Code, as described in the memorandum on the subject of "Policy for Assisted Reproductive Services for the Benefit of Seriously or Severely Ill/Injured (Category II or III) Active Duty Service Members" issued by the Assistant Secretary of Defense for Health Affairs on April 3, 2012 and the guidance issued to implement such policy, including any limitations on the amount of such benefits available to such a member except that—

(1) the time periods regarding embryo cryopreservation and storage set forth in part III(G) and in part IV(H) of such memorandum shall not apply; and

(2) such term includes embryo cryopreservation and storage without limitation on the duration of such cryopreservation and storage.

c. As discussed in more detail below, the above-referenced Department of Defense (DoD) Policy will continue to govern VA's provision of IVF counseling and services. Any substantive changes made to VA's statutory authority by future laws or changes to the DoD policy will supersede any conflicting terms of this policy. **AUTHORITY:** Section 234 of the Military Construction, Veterans Affairs, and Related Agencies Appropriations Act, 2021, (Division J of P.L. 116-260); Title 38 Code of Federal Regulations (C.F.R.) 17.380 and 17.412.

2. BACKGROUND

a. The VA is committed to promoting, preserving and restoring to the greatest extent possible the health and well-being of all Veterans to the extent authorized by law. For many individuals, having children is an important aspect of life. Those who desire but are unable to conceive children themselves may experience reduced quality of life.

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Under VA's medical benefits package (codified at 38 C.F.R. 17.38), treatment of infertility is offered to contribute to the promotion, preservation, or restoration of the health and well-being of enrolled Veterans. Under VHA Directive 1332(2), Fertility Evaluation and Treatment, dated June 20, 2017, amended May 13, 2020, all enrolled Veterans, but not their spouses, are provided fertility evaluations and treatments with the exception of IVF. IVF is, however, expressly excluded from the medical benefits package at 38 C.F.R. 17.38(c)(2).

b. VA has regulated its statutory IVF authority. Specifically, VA regulation 38 C.F.R. 17.380 governs VA's delivery of IVF counseling and services to eligible Veterans and 38 C.F.R. 17.412 governs the delivery of these services to their lawful spouses. The law and regulations, in defining who is an eligible Veteran, incorporate, with two stated exceptions, the requirements of the Department of Defense Implementing Guidance Memorandum dated April 3, 2012, (the "Memorandum") and the guidance issued to implement such policy, including any limitations on the amount of such benefits except for the two stated statutory exceptions.

c. The purpose for providing IVF counseling and services is set forth in Clause III.B. of the Memorandum, which states that: "The policy provides for the provision of assisted reproductive technologies to assist in the reduction of the disabling effects of the member's qualifying condition."

d. In VA, IVF is available only to certain seriously injured Veterans no longer able to procreate without the use of IVF. For male Veterans, their service-connected injury or illness must prevent the successful delivery of their sperm to their spouse's egg. (Autologous sperm must be produced or previously cryopreserved; alternative sperm collection technologies are allowable.) For female Veterans, their service-connected injury or illness must prevent their egg from being successfully fertilized by their spouse's sperm, but they must maintain ovarian function and have a patent uterine cavity. (That is, they must retain ovarian function or previously cryopreserved autologous eggs and have a patent uterine cavity that would allow them to successfully carry a fetus even if unable to conceive naturally (e.g., through damage to their fallopian tubes).)

e. VA may furnish IVF fertility counseling and treatment to Veterans as described herein and their lawful spouses. More specifically, consistent with the Memorandum, VA allows for assisted reproductive services, including evaluations, intrauterine insemination, sperm retrieval, oocyte retrieval, in-vitro fertilization, blastocyst transfer and embryo transfer, to be available to eligible Veterans. VA considers that the cryopreservation of gametes (for both the Veteran and the spouse), not only embryos, is within the scope of available benefits described in the Memorandum. Gamete and embryo cryopreservation and storage are each without limitation on duration until, as explained below, the death of an eligible Veteran or an eligible Veteran's lawful divorce. In determining clinical eligibility for IVF services, VA treating providers are to use the same evidence-based clinical eligibility standards outlined in VHA Directive 1332(2), Fertility Evaluation and Treatment.

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f. Clause IIIA of the Memorandum states: It is the intent of this policy to provide Invitro (sic) Fertilization (IYF) services only to consenting male members whose injury or illness prevents the successful delivery of their sperm to their spouse's egg and to consenting female members whose injury or illness prevents their egg from being successfully fertilized by their spouse's sperm but who maintain ovarian function and have a patent uterine cavity.

g. Furthermore, clause III E of the Memorandum states: Third party donations and surrogacy are not covered benefits- the benefit is designed to allow the member and spouse to become biological parents through reproductive technologies where the Active Duty injury or illness has made it impossible to conceive naturally.

h. Therefore, under this treatment authority, VA bars the use of donated sperm, oocytes, or embryos, or gestational surrogacy. Thus, IVF services are only available to a cisgender opposite-sex legally married couple or other legally married couple with opposite-sex gametes/reproductive organs.

i. VA is responsible only for providing IVF counseling and services and, consistent with Clause III.H. of the Memorandum, issues regarding ownership, future embryo use, donation or destruction etc., will be governed by the applicable state law and will be the responsibility of the Veteran and his/her lawful spouse and the facility storing the cryopreserved embryos. VA's role is limited to paying for this benefit when requested by the consenting eligible Veteran. VA will not have ownership or custody of cryopreserved embryos and will not be involved in the ultimate disposition of excess embryos.

j. Although the benefits of cryopreservation and storage of gametes and embryos are not time-limited, these benefits are, practically-speaking, checked or limited by two life events: the death of an eligible Veteran or an eligible Veteran's lawful divorce. This is also the practical implication of Clause III.F. of the Memorandum, which requires that VA obtain the separate consent of both the Veteran and the spouse for IVF, with third-party consent being prohibited. In other words, IVF counseling and services require the individual consent of both members of the eligible lawfully married couple and this cannot occur if the Veteran is either deceased or divorced. In addition, Clause III.H. of the Memorandum, cited above, implicitly recognizes that the disposition of cryopreserved or stored gametes and embryos is a private domestic concern and hence state law matter, which estate or divorce proceedings, as applicable, will properly address and settle.

k. Eligible Veterans are not required to be enrolled in VA's health care system (or exempt from enrollment) to receive IVF services under this policy. We note, however, that some Veterans may be eligible for IVF under this policy as well as be enrolled in VA's health care system. Overlap may therefore occur between general fertility services available to enrollees, e.g., evaluation, sperm retrieval, intrauterine insemination and those same services available under this policy. If a Veteran is eligible for IVF services and is also enrolled in VA's health care system, then VA should seek to deliver any general fertility services not constituting IVF that is available under both authorities to

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the Veteran in a way that is most cost-effective with no duplication of services. For instance, if Veteran John Doe is enrolled in VA's health care system and also eligible for IVF services, then, for example, sperm retrieval services needed for IVF may be provided under either authority. In these cases, VA should deliver this general fertility service (not constituting IVF) in the manner that is the most cost-effective. (In general, it is typically more economical to provide general fertility services that are common to both programs in-house as part of the medical benefits package, because IVF services are provided only through authorized IVF specialists in the community at negotiated cost.) Using this same example, VHA should ensure the provision of a general fertility service, again here sperm retrieval, is not duplicated, as a Veteran may seek to obtain these services from both the Veteran's treating VA fertility provider as well as from the IVF specialist contractor to maximize the number of retrievals for use in IVF. Close coordination is required to ensure which provider is providing the covered fertility service for purposes of services delivered under this policy.

l. Without exception, a Veteran's spouse may receive IVF and fertility services only as authorized under 38 C.F.R. 17.412. As explained below, the spouse's IVF benefit derives from and is dependent on the Veteran-spouse's eligibility.

m. To be eligible for IVF, a Veteran must meet the definition of "Veteran" in 38 U.S.C. 101(2) and have a service-connected condition, as defined in 38 U.S.C. 101(16) (regardless of the disability rating awarded), that results in the inability of the Veteran to procreate without the use of fertility treatment.

n. Service-connected conditions covered under this policy include, but are not limited to, poly-trauma, genitourinary injury and spinal cord injury and other anatomical, neurological, infectious and physiological injury and/or illness that are adjudicated by the Veterans Benefits Administration to be service-connected after which VHA IVF program staff will clinically determine if the service-connected condition meets the IVF clinical eligibility criteria i.e., whether the service-connected condition results in loss of procreative ability that cannot be corrected without the use of fertility treatment. The terms of III.C. state that this benefit "is limited to permitting a qualified member to procreate with his or her lawful spouse, as defined in federal statute [sic] and regulation." As discussed above, this benefit is limited to a cisgender opposite-sex legally married couple or other legally married couple with opposite-sex gametes/reproductive organs. This means lawfully married same-sex couples are ineligible for this benefit. The Veteran and spouse's respective eligibility determinations will be made by VHA's Health Eligibility Center, with assistance from the VHA Program Office, if needed.

3. DEFINITIONS

a. **Andrologist.** An andrologist is a urologist who focuses on the treatment of conditions affecting male fertility and sexuality.

b. **Assisted Reproductive Technology.** Assisted Reproductive Technology is any treatment or procedure that includes the in vitro handling of human oocytes and sperm, or embryos, for the purpose of establishing a pregnancy. This includes, but is not limited

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to, IVF, embryo transfer, gamete intrafallopian transfer, zygote intrafallopian transfer, tubal embryo transfer, gamete and embryo cryopreservation.

c. **Consent to In Vitro Fertilization.** Consistent with the Memorandum, consent to IVF requires the informed consent of both the eligible Veteran and the Veteran's legal spouse. Each must have decision-making capacity to consent to the treatment. Consent by a third party, including a surrogate decision-maker, is not permitted. **NOTE:** *This is referred to as "third party consent" by DoD and barred in the Memorandum.*

d. **Cryopreservation.** Cryopreservation is the freezing of gametes (oocytes or sperm), zygotes (1-cell fertilized oocytes), embryos (typically cryopreserved on day 2, 3, 5, or 6 of development), or gonadal (ovarian or testicular) tissue to allow storage for future use. Cryopreserved sperm can be used for intrauterine insemination (IUI) or IVF after thawing or rewarming. Cryopreserved oocytes require IVF after thawing or rewarming. Cryopreserved tissue may be re-implanted into the body or cultured in vitro after thawing or rewarming. Duration of embryo cryopreservation and storage are without limitation under 38 C.F.R. 17.380 and 17.412 until the death of an eligible Veteran or an eligible Veteran's lawful divorce, provided VA continues to have authority to provide these non-limited services.

e. **Diminished Ovarian Reserve.** Diminished Ovarian Reserve (DOR) occurs when one's ovaries lose their reproductive potential. Aging is the primary cause of diminished ovarian reserve, but DOR can also be caused by genetic abnormalities, some medical treatments and injury.

f. **Endocrinologist.** An endocrinologist is a physician qualified to diagnose and treat disorders of the endocrine glands and hormones.

g. **Fecundability.** Fecundability is the probability of conception per menstrual cycle.

h. **Gamete.** A gamete is a mature male (sperm) or female (oocyte or egg) germ cell.

i. **Gestational Surrogacy.** Gestational surrogacy is a method of family building in which a person with an intact uterus (the gestational carrier) bears a genetically unrelated child with the help of ART for an individual or couple who intends to be the legal and rearing (also known as psychosocial) parent(s). Gestational surrogacy is an excluded service under this special treatment program.

j. **Infertility.** Infertility is the inability to achieve a pregnancy after one year of regular unprotected sexual intercourse with their lawful spouse. Veterans who have a diagnosis of repetitive miscarriage would also be eligible. For eligible Veterans who have an obvious service-connected cause of infertility, such as spinal cord injury, the 1-year requirement may not apply.

k. **Intracytoplasmic Sperm Injection.** Intracytoplasmic sperm injection (ICSI) is a technique for in vitro fertilization in which an individual sperm cell is introduced into an egg cell.

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l. **Intrauterine Insemination.** Intrauterine insemination (IUI), also known as artificial insemination, is a procedure in which a fine catheter (tube) is inserted through the cervix (the natural opening of the uterus) into the uterus (the womb) to deposit a washed and concentrated sperm sample directly into the uterus.

m. **In Vitro Fertilization.** IVF is a procedure in which an oocyte is removed from a mature ovarian follicle and fertilized by a sperm cell outside the human body. The fertilized oocyte can divide in a protected environment for several days prior to transfer of an embryo(s) into the uterus.

n. **In Vitro Fertilization Cycle.** An IVF cycle is the retrieval of gametes (both egg and sperm), which are mixed in a petri dish, given time to grow into an embryo over 3–5 days and transferred into the endometrial cavity.

o. **In Vitro Fertilization Cycle Attempt.** For purposes of IVF under 38 C.F.R. 17.380 and 17.412, an IVF cycle attempt includes instances in which no eggs are retrieved, an egg is retrieved from an ovary, but no embryo is frozen or transferred, or if no embryos are viable. ***NOTE: Over the lifetime of the Veteran, the IVF benefit is completed after 3 embryo transfer episodes of care. The Veteran is eligible for 6 attempts to create embryos to achieve the 3 embryo transfer episodes of care. If after 6 attempts no embryos are created for transfer, no additional IVF services will be authorized. VA's IVF benefit for that Veteran has ended.***

p. **In Vitro Fertilization Cycle Completed.** For purposes of IVF under 38 C.F.R. 17.380 and 17.412, a cycle of IVF is considered complete upon successful embryo transfer to the endometrial cavity, regardless if the embryo implanted. Both fresh and frozen embryos transferred count as a cycle. A cycle can sometimes include intracytoplasmic sperm injection (ICSI) and/or preimplantation genetic diagnosis (PGD) as needed. ***NOTE: Over the lifetime of the Veteran, the IVF benefit is completed after 3 embryo transfer episodes of care. The Veteran is eligible for 6 attempts to create embryos to achieve the 3 embryo transfer episodes of care. If embryos are created during up to 6 attempts, the Veteran is eligible for a maximum of 3 embryo transfer episodes of care. After 3 embryo transfer episodes are completed, VA's IVF benefit for that Veteran has ended.***

q. **Oocyte.** An oocyte is the human female gamete or egg.

r. **Ovarian Reserve.** Ovarian reserve refers to the quality and quantity of one's eggs and diminished ovarian reserve means those factors are decreasing.

s. **Preimplantation Genetic Diagnosis.** Preimplantation genetic diagnosis (PGD) is the testing of pre-implantation stage embryos or oocytes for genetic defects.

t. **Reproductive Endocrinology & Infertility Specialist.** Reproductive Endocrinology & Infertility (REI) specialists are physicians who specialize in infertility, including factors affecting male infertility. After completing a 4-year residency in obstetrics and gynecology, they then complete a 3-year fellowship in this subspecialty.

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u. **Service-Connected Condition.** A service-connected (SC) condition is a disability or injury for which there is a formal adjudicated determination by Veterans Benefits Administration (VBA) that the disability or injury was incurred or aggravated in line of duty in the active military, naval, or air service. **NOTE:** *VBA's separate disability rating awards for SC conditions are irrelevant to determinations of eligibility under the special treatment authority; these ratings are primarily used in VBA's administration of disability compensation benefits. All that is required for this program is existence of an adjudicated SC condition that results in the inability to procreate. NOTE: A SC condition may be confirmed by the Veteran by providing VHA his/her the formal rating letter from VBA (i.e., SC rating from 0–100 percent) or VHA can contact the VHA Health Eligibility Center (HEC) to obtain documentation of the Veteran's SC conditions.*

v. **Service-Connected Condition Resulting in the Inability to Procreate.** SC condition resulting in the inability to procreate is a clinical determination by the VA treating provider, that, in the provider's clinical judgment, the SC condition renders the Veteran unable to procreate without fertility treatment. To make this clinical eligibility determination, providers are to use the clinical criteria set forth in VHA Directive 1332(2), Fertility Evaluation and Treatment. **NOTE:** *The provision of IVF services to otherwise eligible Veterans and spouses may still be clinically contraindicated due to other factors (e.g., decreased ovarian follicular reserve).*

w. **Semen.** Semen is the sperm (human male gamete) along with prostatic and seminal secretions that constitute male ejaculatory fluid.

x. **Sperm.** Sperm, also known as spermatozoon, is the human male reproductive cell, or gamete, produced by cells in the testicle and found in ejaculated seminal fluid, or semen. Sperm has measurable characteristics such as motility, morphology and viability; and fertility is influenced by these characteristics as well as by characteristics of the seminal fluid.

y. **Sperm Retrieval.** Sperm retrieval techniques are methods used to retrieve sperm when one is unable to ejaculate sperm. Techniques include electroejaculation, vibratory stimulation, or surgical sperm retrieval (e.g., microsurgical epididymal sperm aspiration, percutaneous epididymal sperm aspiration, testicular sperm extraction and percutaneous testicular sperm aspiration).

z. **Urologist.** A urologist is a physician who specializes in diseases of the urinary tract and the male reproductive system.

4. POLICY

It is VHA policy that VA will provide, consistent with law, IVF counseling and services to eligible consenting Veterans and their lawful consenting spouses. Approved IVF services will be provided only through authorized community providers. The benefit over the lifetime of the Veteran is completed after 3 embryo transfer episodes of care. The Veteran is eligible for 6 attempts to create embryos to achieve the 3 embryo transfer episodes of care. If after 6 attempts no embryos are created for transfer, then no

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additional IVF services will be authorized. The IVF benefit for the Veteran has ended. If embryos are created during up to 6 attempts, then the Veteran will be eligible for a maximum of 3 embryo transfer episodes of care after which this benefit will have ended. VA authorization is required for every cycle.

5. RESPONSIBILITIES

a. **Under Secretary for Health.** The Under Secretary for Health is responsible for ensuring overall compliance with this directive.

b. **Assistant Under Secretary for Health for Clinical Services.** The Assistant Under Secretary for Health for Clinical Services is responsible for supporting the implementation and oversight of this directive.

c. **Assistant Under Secretary of Health for Operations.** The Assistant Secretary of Health for Operations is responsible for:

(1) Communicating the contents of this directive to each of the Veterans Integrated Services Networks (VISNs).

(2) Assisting VISN Directors to resolve implementation and compliance challenges in all VA medical facilities within that VISN.

(3) Providing oversight of VISNs to ensure compliance with this directive and its effectiveness.

d. **Chief Consultant, Pharmacy Benefits Management.** The Pharmacy Benefits Management Chief Consultant is responsible for identifying medications in VA's formulary and non-formulary medications (included in VA's outpatient pharmacy program) that are available for use under this program.

e. **Chief Consultant, Women's Health Services.** The Chief Consultant, Women's Health Services, is responsible for establishing a process for assisting with VISN-level consultations when questions arise about Veterans' or their legal spouses' eligibility under this program or medical evidence-based standards applicable to this program. ***NOTE: Additional programs may need to be consulted including Spinal Cord Injury and Disorders (SCI/D) Services, VHA National Center for Ethics in Health Care, VHA National Surgery Office, Specialty Care (e.g., endocrinology) and the VHA Office of Community Care.***

f. **Director, National Surgery Office.** The Director of the National Surgery Office is responsible for identifying experts on the Urology Surgical Advisory Board to collaborate with the Office of Women's Health Services on clarifying processes and guidance for relevant VISN-level consultations.

g. **Veterans Integrated Service Network Director.** The VISN Director is responsible for confirming that each VISN has and utilizes, on an ongoing basis, a

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means for ensuring the terms of this directive are fulfilled in all the VA medical facilities of their VISN.

h. **VA Medical Facility Director.** The VA medical facility Director is responsible for:

(1) Ensuring that VA medical facilities have a process in place to provide prescription fulfillment services for eligible Veterans under the special treatment authority and for their spouses, consistent with VHA Handbook 1108.05(1), Outpatient Pharmacy Services, June 16, 2016, amended August 20, 2019 and applicable community care program rules and procedures.

(2) Ensuring that VA medical facilities have processes in place to avoid undue interruption of the delivery of authorized pharmacological medications and the clinical management of their authorized ovulation induction cycles and treatment cycles for fertility management provided under the program.

(3) Ensuring a local process is established for addressing at the local level all unresolved clinical questions or clinical disagreements needed to determine a Veteran's or the Veteran's spouse's eligibility for IVF. See responsibilities set forth in VHA Directive 1041, Appeal of Veterans Health Administration Clinical Decisions, dated September 28, 2020.

i. **VA Medical Facility Chief of Staff.** The VA medical facility Chief of Staff is responsible for ensuring that unresolved clinical eligibility-related questions are addressed appropriately and efficiently. For issues related to clinical treatment or clinical eligibility-related determinations, the VA medical facility Chief of Staff is responsible for ensuring that the Veteran and spouse are notified of such decision and that the Veteran and spouse receive information on how to pursue a clinical appeal if they wish. **NOTE:** *For additional information on the appeals process, see VHA Directive 1041.* Denials of a Veteran's or a spouse's eligibility for IVF counseling or services under law and this policy should follow normal appeals procedures.

j. **Director, VA Medical Facility Office of Community Care.** The Director of the VA medical facility Office of Community Care is responsible for:

(1) Ensuring completion and submission of documentation to the VHA Office of Community Care.

(2) Ensuring that authorizations to obtain care in the community from an infertility specialist, including any limitations to coverage of services, are documented clearly and provided to the specialist.

(3) Ensuring processes are in place to facilitate the authorized exchange of medical information between VA and the authorized infertility specialists.

(4) Ensuring that a clinical utilization review system is available to prevent either under- or over-treatment by an authorized community infertility specialist.

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(5) Ensuring that processes are in place for the coordination of general fertility services (not constituting IVF) available to the Veteran under both this policy and the medical benefits package, as described in paragraph 2.i.

6. ELIGIBILITY REQUIREMENTS

To be eligible for IVF under this directive, the following criteria apply:

- a. The consenting Veteran must have a SC condition that results in the inability to procreate without the use of fertility treatment, as defined above.
- b. The Veteran and spouse are a cisgender opposite-sex legally married couple or other legally married couple with opposite-sex gametes/reproductive organs.
- c. The female Veteran must have an intact uterus and either be able to make eggs or have had their own eggs (i.e., autologous gametes) cryopreserved; a male Veteran must either be able to make sperm or have had his own sperm (i.e., autologous gametes) cryopreserved. **NOTE:** *For additional eligibility information, see Appendix A.*

7. PRACTICES AND PROCEDURES

a. Clinical Eligibility Assessment and Treatment.

(1) The first step is clinical determination of infertility in the Veteran, regardless of the spouse's reproductive health status. The facility will determine whether to provide this clinical assessment in-house or in the community. Second, the responsible clinician must determine if the cause of the Veteran's infertility, if established, is due to a SC condition that results in the inability of the Veteran to procreate without the use of fertility treatment, including IVF. This may require consults with other specialists and subspecialists. If the clinician makes a negative determination, then the Veteran and the Veteran's spouse are not eligible for IVF services because they do not meet the clinical eligibility criteria.

(2) The legal spouse of the eligible Veteran is eligible for fertility services using assisted reproductive technology, including IVF. VA can provide these fertility services - other than actual IVF- either in-house or through the authorized IVF provider. The spouse's eligibility for these health care benefits derives from the Veteran's eligibility under the noted IVF authority, not from any independent known or suspected infertility condition of the spouse. Once the Veteran's eligibility has been confirmed, the legal spouse will be provided with IVF counseling and treatment unless doing so is clinically contraindicated. As stated above, spouses are only eligible for the scope of IVF services authorized by this policy. They are not eligible to receive fertility services as part of the medical benefits package. **NOTE:** *Consistent with the requirements of the Memorandum, eligible Veterans and their spouses are limited to a maximum of 6 attempts to achieve 3 completed IVF cycles, as these terms are defined herein. VA authorization is required for every cycle. This means that over the lifetime of the Veteran, the IVF benefit is completed after 3 embryo transfer episodes of care. More specifically, the Veteran is eligible for 6 attempts to create embryos to achieve the 3*

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embryo transfer episodes of care. If after 6 attempts no embryos are created for transfer, then no additional IVF services will be authorized. The IVF benefit has ended for the Veteran. If embryos are created during up to 6 attempts, then the Veteran will be eligible for a maximum of 3 embryo transfer episodes of care after which this benefit will have ended. See also Appendix A.

(3) IVF counseling and treatment as defined herein (consistent with the Memorandum).

(4) Additional medical or surgical treatment directly related to the optimization of fertility treatment outcomes (e.g., salpingectomy of severely damaged fallopian tubes prior to IVF, normalization of the uterine cavity prior to embryo transfer sperm retrieval, varicocele repair).

(5) Treatment for mental health complications when directly related to the receipt of, or participation in, IVF and needed to optimize the IVF outcome. VA interprets fertility counseling broadly to include all stages of the IVF process, provided there is a nexus between the IVF procedure/process and the mental health condition requiring counseling. More specifically, the Veteran and/or spouse may receive behavioral health services when VA determines they are necessary as part of the IVF treatment episode and needed to optimize the outcome of the IVF. Because the treating infertility specialist cannot provide these services (which would be outside the specialist's scope of practice), the specialist must refer the Veteran to VA for such services as part of the covered IVF treatment episode. A non-Veteran spouse in need of infertility-related behavioral health care should likewise be referred to VA by the treating infertility specialist for such services as part of the covered IVF treatment episode. If VA is unable to provide the needed services in-house, VA may authorize a community provider to provide them under applicable contract authority. **NOTE: A contract infertility specialist cannot authorize, or obligate VA funds to obtain, such services. If the contract infertility specialist makes a direct referral to a community behavioral health care provider who provides such services, VA has no authority to pay or reimburse such costs. Because the behavioral health care provider would not be a party to the sharing agreement or contract entered between VA and the specialist infertility provider, a behavioral health care provider who provides services based on a specialist's direct referral without prior VA authorization would end up billing the patient to recoup costs. Questions related to the need for these services should be directed to VHA's Office of Community Care and/or VHA's Sharing Office.**

(6) Treatment of physical complications (e.g., bleeding, infection following IVF) resulting from covered IVF and fertility services.

(7) Evaluation and procedures required for follow-up and management of complications will be provided for the duration established by the applicable standard of care, which is currently for up to 10 weeks post egg retrieval (up to 10 weeks gestation).

(8) Treatment of complications provided by an infertility specialist in some practice settings (e.g., sperm retrieval).

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a. **Cycles.** For purposes this policy, IVF consists of a maximum of 6 attempts to achieve 3 completed IVF cycles, as these terms are defined herein. VA authorization is required for every cycle. This means that over the lifetime of the Veteran, the IVF benefit is completed after 3 embryo transfer episodes of care. More specifically, the Veteran is eligible for 6 attempts to create embryos to achieve the 3 embryo transfer episodes of care. If after 6 attempts no embryos are created for transfer, then no additional IVF services will be authorized. If embryos are created during up to 6 attempts, then the Veteran will be eligible for a maximum of 3 embryo transfer episodes of care after which this benefit will have ended. See also Appendix A.

b. **Disputes.** Should a health care ethics conflict arise, a request for a VHA Ethics Consult at either the local or national level must be placed. For instance, VA providers may dispute ethical considerations related to clinical determinations or actions taken in the evaluation, management, or treatment of infertility. These professional conflicts may be general in nature or specific to a particular case. **NOTE:** For additional information, please see the VHA National Center for Ethics in Health Care, National Ethics Consultation Service website at: <https://vawww.ethics.va.gov/activities/consult.asp>. This is an internal VA website that is not available to the public.

c. **Cryopreservation and Storage.**

(1) VA will cover costs of cryopreservation and storage at an independent community laboratory indefinitely up through the life or lawful marriage of eligible Veterans. Storage of cryopreserved gametes and embryos will take place at an independent facility in the community, per guidelines outlined in Appendix A.

(2) As noted above, issues regarding ownership, future embryo use, donation or disposition, etc., will be governed by the applicable state law and will be the responsibility of the Veterans and their lawful spouses and the facilities storing the cryopreserved embryos. VA does not have ownership or custody of cryopreserved gametes or embryos and VA will not be involved in the ultimate disposition of excess gametes or embryos. This provision likewise applies to cryopreserved and stored gametes.

(3) VA will pay the costs of cryopreservation and storage of cryopreserved oocytes, sperm and embryos indefinitely until the end of the life or lawful marriage of the eligible Veteran, or until the cryopreserved oocytes, sperm, or embryos are transferred to a third party (for any purpose outside this treatment program).

(4) The Veteran is responsible for arranging physical transportation of cryopreserved gametes or embryos, but not storage fees, should the Veteran decide to use them in the future.

d. **Pharmacy Prescriptions.**

(1) VA pharmacies will provide prescription fulfillment services for eligible Veterans and their legal spouses that are written by VA-authorized infertility providers, in accordance with VHA Handbook 1108.05(1), Outpatient Pharmacy Services, dated

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June 16, 2016, amended August 20, 2019, paragraph 8.a.(15). Copayments do not apply to the receipt of prescribed medications that are part of the fertility services authorized under C.F.R. 17.380 and 17.412. See 38 C.F.R. 17.110(c)(2). Medications prescribed by non-VA infertility providers under these authorities may therefore be dispensed by VA and delivered through a VA pharmacy or through other authorized VA delivery mechanisms.

(2) Specifically, consistent with VHA Handbook 1108.05(1), Outpatient Pharmacy Services, paragraph 8.a.(15), medications prescribed by an authorized non-VA Care provider may be dispensed by a VA pharmacy. Under the non-VA Care Program, every effort must be made to utilize VA pharmacies for prescription services and VA pharmacies must be used to fill authorized non-VA Care prescriptions in accordance with applicable law, VA regulations and current VA policy in such a way that it is consistent with the needs and in the best interests of the patient. VHA Handbook 1108.05(1), paragraph 11.b., citing VHA Directive 1601, Non-VA Medical Care Program, dated January 23, 2013. When supplementary VA prescription fulfillment services are not available at the time they are needed, arrangements will be made to provide them utilizing a non-VA pharmacy in the community or through the Non-VA Care Program. VHA Handbook 1108.05(1), paragraph 11.a. Any pharmacy licensed by a State, commonwealth, or territory of the United States is eligible to accept and fill prescriptions for VA patients. Prescribers are to collaborate with Community Care program staff to ensure arrangements to obtain needed medications are made on an individual basis, after careful determination of the type and recurring nature of the prescription. Consistent with VHA Handbook 1108.05(1), paragraph 11.a, reimbursement to the patient requires prior approval in accordance with current local medical facility policy.

(3) Prescriptions issued by authorized non-VA providers who are providing authorized IVF services do not have to be re-written. However, if the clinical pharmacist and the prescribing provider authorized by VA to provide non-VA care disagree as to the status of the prescription for non-VA Care, a reviewing VA medical facility provider must be consulted to validate that the medication was appropriate for the condition authorized, as stated in VHA Handbook 1108.05(1), paragraph 11.b.(1).

(4) Paragraph 11.b.(2) of VHA Handbook 1108.05(1) provides that national and VISN formulary policy must be applied to non-VA Care medication orders. In most cases only formulary medications are to be provided; however, if the clinical justification is consistent with VA non-formulary policy, see VHA Directive 1108.08(1), VHA Formulary Management Process, dated November 2, 2016, amended August 29, 2019, non-formulary medication may be dispensed.

e. Services not included in the Memorandum and Consequently Outside the Scope of VA IVF Services are as follows:

(1) Use of donated gametes or embryos, including donor sperm, donor oocytes, or donor embryos.

(2) Gestational surrogacy.

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f. Other Medical Care for which a Participating Female Spouse is Not Eligible under this Policy.

In the event of a successful pregnancy under this program, VA IVF services do not include the provision of obstetrical care beyond the period established by the applicable standard of care, which is currently 10 weeks gestation, see paragraph 7.a.(3)(e), above. Because inclusion of obstetrical care up to 10 weeks gestation is the current IVF standard of care, it is part of the covered IVF episode of care. Maternity/obstetrical care that goes beyond this point is beyond the applicable standard of care and so not covered by this policy. If the spouse is female and enrolled in VA's health care system, then she has independent eligibility to receive VA maternity care benefits under the medical benefits package.

8. TRAINING

There are no formal training requirements associated with this directive.

9. RECORDS MANAGEMENT

All records regardless of format (paper, electronic, electronic systems) created in the requirements of this directive shall be managed per the National Archives and Records Administration (NARA) approved records schedules found in VHA Records Control Schedule 10-1. Questions regarding any aspect of records management should be addressed to the appropriate Records Officer.

10. REFERENCES

a. P.L. 116-260. Section 234 of the Military Construction, Veterans Affairs, and Related Agencies Appropriations Act, 2021.

b. 38 U.S.C. § 101(2), (16).

c. 38 C.F.R. 17.380 and 17.412.

d. VHA Directive 1041, Appeal of Veterans Health Administration Clinical Decisions, dated September 28, 2020.

e. VHA Directive 1108.08(1), VHA Formulary Management Process, dated November 2, 2016.

f. VHA Directive 1330.01(2), Health Care Services for Women Veterans, dated February 15, 2017.

g. VHA Directive 1332(2), Fertility Evaluation and Treatment, dated June 20, 2017.

h. VHA Directive 1601, Non-VA Medical Care Program, dated January 23, 2013.

i. VHA Handbook 1108.05(1), Outpatient Pharmacy Services, dated June 16, 2016.

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j. US Department of Veterans Affairs, Veterans Health Administration, National Center for Ethics in Health Care, National Ethics Consultation Service, available at: <https://www.ethics.va.gov/activities/consult.asp>.

k. US Department of Veterans Affairs, Veterans Health Administration, Office of Pharmacy Benefits Management Services, available at: <http://www.pbm.va.gov/>.

l. Hoffman BL, Schorge JO, Bradshaw KD, Halvorson LM, Schaffer JI, Corton MM. *Williams Gynecology*, 3rd Edition, Treatment of the Infertile Couple; 2016. Available at: <https://accessmedicine.mhmedical.com/content.aspx?bookid=1758§ionid=118170583&jumpsectionID=118170751>. **NOTE:** *This linked document is outside of VA control and may not be conformant with Section 508 of the Rehabilitation Act of 1973. Additionally, to access this report in full, a subscription may be required. Please check with your organization's administrator as to whether an existing subscription is available.*

m. Department of Defense (DoD), Policy for Assisted Reproductive Services for the Benefit of Seriously or Severely Ill/Injured (Category II or III) Active Duty Service Members, dated April 3, 2012 (the "Memorandum").

n. Practice Guidelines of the American Society of Reproductive Medicine (ASRM), available at: <https://www.asrm.org/Guidelines/>. **NOTE:** *This website is outside of VA control and may not be conformant with Section 508 of the Rehabilitation Act of 1973.*

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**VHA DIRECTIVE 1334
APPENDIX A**

ELIGIBILITY CRITERIA

1. To be eligible for In Vitro Fertilization (IVF) under 38 Code of Federal Regulations (C.F.R.) 17.380, a Veteran must meet the following set of criteria:

a. Have a service-connected (SC) condition that results in the Veteran's inability to procreate naturally.

b. Be a legally married cisgender opposite-sex legally married couple or other legally married couple with opposite-sex gametes/reproductive organs.

c. Have, if a female, an intact uterus and either able to make eggs or have their own eggs (i.e., autologous gametes) which have been cryopreserved; be able, if a male, to make sperm or have their own sperm (i.e., autologous gametes) which have been cryopreserved.

2. Lawful spouses of eligible Veterans are eligible for fertility counseling and treatment under the program pursuant to 38 C.F.R. 17.41.

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**VHA DIRECTIVE 1334
APPENDIX B**

IN VITRO FERTILIZATION SERVICES

- 1.** From a clinical perspective, some general fertility services used in the In Vitro Fertilization (IVF) treatment episode for Veterans are the same general fertility services that Department of Veterans Affairs (VA) already provides to enrolled Veterans, with the exception of those that constitute actual IVF services or procedures.
- 2.** With these key exceptions, VA's general fertility services in Veterans Health Administration(VHA) Directive 1332(2), Fertility Evaluation and Treatment, dated June 20, 2017, amended August 12, 2019, overlap with general fertility services used in the IVF treatment episode. As VA is to provide IVF services in the most economical and efficient manner with no duplication, a Veteran who is enrolled in VA's health care system and who is also eligible for IVF services should receive the general fertility services that do not constitute IVF under the medical benefits package.
- 3.** For more information and a handy comparison of the VA's fertility services program for enrollees and VA's IVF services, please see the tables below.

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a. VHA Directive 1332(2) Fertility Evaluation and Treatment:

Veterans listed as female at birth (available to all enrolled Veterans or those exempt from enrollment and eligible for care in the medical benefits package)	Veterans listed as male at birth (available to all enrolled Veterans or those exempt from enrollment and eligible for care in the medical benefits package)
<ol style="list-style-type: none"> 1. Laboratory blood testing (e.g., follicle-stimulating hormone (FSH), thyroid stimulating hormone). 2. Genetic counseling and testing. 3. Pelvic and/or transvaginal ultrasound. 4. Hysterosalpingogram. 5. Saline-infused sonohysterogram. 6. Surgical correction of structural pathology consistent with standard of care including operative laparoscopy and operative hysteroscopy. 7. Reversal of tubal ligation (tubal reanastomosis). 8. Hormonal therapies (e.g., controlled ovarian hyperstimulation). 9. Oral medication for ovulation induction (e.g., clomiphene). 10. Injectable gonadotropin medications for ovulation induction (e.g., human menopausal gonadotropins). 11. Additional hormonal therapies as approved by VA Pharmacy Benefits Management. 12. Intrauterine insemination. 13. Oocyte cryopreservation for medically indicated conditions up to 5 years. 	<ol style="list-style-type: none"> 1. Laboratory blood testing (e.g., serum testosterone, FSH, luteinizing hormone, estradiol). 2. Genetic counseling and testing. 3. Transrectal and/or scrotal ultrasonography. 4. Semen analysis. 5. Evaluation and treatment of erectile dysfunction. 6. Surgical correction of structural pathology (e.g., varicocele, Peyronie's repair). 7. Vasectomy reversal (vasovasostomy). 8. Hormonal therapies (e.g., clomiphene citrate, human chorionic gonadotropin, phosphodiesterase type 5 medications, testosterone). 9. Sperm retrieval techniques. 10. Post-ejaculatory urinalysis. 11. Sperm cryopreservation for medically indicated conditions as described therein. 12. Ejaculation techniques (e.g., electroejaculation, vibratory stimulation).

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b. VHA Directive 1334, VA IVF Services: What is meant and covered as IVF attempts and completed cycles:

IVF Attempt	IVF Completed Cycle
Embryo transfer does not occur.	Embryo is transferred into the uterus.
It counts as an attempt if: 1. An egg retrieval occurs and a. No eggs are retrieved or b. Eggs are retrieved but embryos are not transferred due to (1) No embryos are available for transfer. (2) Embryos are cryopreserved but not yet transferred. 2. A cryopreserved embryo is thawed/rewarmed and is not viable for transfer and thus is not transferred.	It counts as a completed cycle if: 1. There is a fresh embryo transfer (regardless of number of embryos transferred). 2. There is a cryopreserved and thawed/rewarmed embryo transfer (regardless of number of embryos transferred). 3. Each transfer counts as a completed cycle, regardless of whether or not a pregnancy and/or live birth results.
No more than six (6) cycle attempts. If no transfer occurs after 6 attempts, the IVF benefit ends. VA must authorize each cycle attempt.	The IVF benefit is completed after three (3) completed cycles. VA must authorize each transfer cycle.

c. As discussed in this policy, some enrolled Veterans will be eligible for general fertility services under both this policy and VHA Directive 1332(2). Their receipt of fertility services that do not constitute IVF is to be coordinated. For easy reference, see the comparison table, below.

Comparison of Fertility Services Included in Directive 1332(2) and this policy	Directive 1332(2)	Directive 1334
Authority	38 U.S.C. 1710, as implemented by 38 C.F.R. 17.38, Medical Benefits Package (MBP) and, as applicable, 38 C.F.R. 17.37	Section 234 of Division J of Public Law 116-260 (and any other successor authorizations), as implemented by 38 C.F.R. 17.380 and 17.412

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Comparison of Fertility Services Included in Directive 1332(2) and this policy	Directive 1332(2)	Directive 1334
Eligibility	Enrolled Veterans, or as otherwise authorized by 38 C.F.R. 17.37	Certain Veterans + lawful eligible spouses
Services	All appropriate and necessary fertility services except IVF	IVF + everything included in the MBP for both the Veteran and lawful spouse
Service Connection	No	Requires that a service-connected (SC) condition prevent the Veteran from procreating naturally; determined at local facility level
Marital status	No	Only legally married couples with opposite-sex gametes
Couples	Not limited to couples with opposite-sex gametes	Only couples with opposite-sex gametes
IUI	Yes (procedure for female Veteran, sperm washing for male Veteran)	Yes, Veteran + lawful spouse with opposite-sex gametes
IVF (with blastocyst transfer and embryo transfer).	No	Yes
Cryopreservation for gametes	Yes for medical indication	Yes
Time limits for cryopreservation of gametes	Yes, see directive	Unlimited until the death of an eligible Veteran or an eligible Veteran's lawful divorce, provided VA continues to have authority to provide this service or until they are transferred to a third party for use or purposes outside the IVF program
Cryopreservation for embryos	No, IVF not authorized	Yes, unlimited until the death of an eligible Veteran or an eligible Veteran's lawful divorce, provided VA continues to have authority to provide this service or until they are transferred to a third party for use or purposes outside the IVF program

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Comparison of Fertility Services Included in Directive 1332(2) and this policy	Directive 1332(2)	Directive 1334
Transportation of gametes/embryos paid by VA	No	No
Genetic counseling	Yes	Yes
Surrogacy	No	No
Fertility counseling	Yes	Yes
IUI	6 cycles per pregnancy	6 cycles per pregnancy
IVF	No	6 attempts to achieve 3 completed cycles as described in this policy
Donated sperm	Allowable but not paid for by VA (Veteran pays for non-Veteran sperm preparation or procedure to non-Veteran)	No
Embryo storage paid by VA	No	Yes, with no time limits until the death of an eligible Veteran or an eligible Veteran's lawful divorce, provided VA continues to have authority to provide this service or until the cryopreserved embryos are transferred to a third party for use or purposes outside the IVF program