EXHIBIT B

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Department of Veterans Affairs
Veterans Health Administration
Washington, DC 20420

AMENDED
May 13, 2020

VHA DIRECTIVE 1332(2)
Transmittal Sheet
June 20, 2017

FERTILITY EVALUATION AND TREATMENT

1. REASON FOR ISSUE: This Veterans Health Administration (VHA) directive establishes policies and procedures for providing fertility evaluation and treatment to Veterans enrolled in the Department of Veterans Affairs (VA) healthcare system.

2. SUMMARY OF CONTENT:

This is a new directive that defines the parameters of infertility evaluation and treatment services within VA available to all enrolled Veterans. ***NOTE:*** *VA can provide Assisted Reproductive Technology (ART) services, including in-vitro fertilization (IVF), to certain Veterans that are unable to procreate as a result of service-connected conditions and to their spouses. Those services are delineated in a separate policy, VHA Directive 1334, Assisted Reproductive Technology (ART) Services for the Benefit of Veterans with Service-Connected Illness or Injury Resulting in Infertility, pending publication.*

3. SUMMARY OF MAJOR CHANGES:

a. Amendment, dated August 1, 2019, removes IUI language and adds controlled ovarian stimulation in Appendix A, paragraph 2, Diagnostic and Treatment of Female Veterans and paragraph 4, Summary of Diagnostic and Treatment of Female Veterans.

b. Amendment, dated May 13, 2020, adds elective sterilization (e.g. salpingectomy, tubal occlusion procedures, and vasectomy) and surgery to reverse elective sterilization to this policy as part of fertility services. The amendment also includes clarifying language in the policy statement (Paragraph 4) and technical edits.

4. RELATED ISSUES: VHA Directive 1334, Assisted Reproductive Technology (ART) Services for the Benefit of Veterans with Service-Connected Illness or Injury Resulting in Infertility, pending publication.

5. RESPONSIBLE OFFICE: The Office of Women's Health Services (10P4W) is responsible for the contents of this VHA directive. Questions may be referred to the Director of Reproductive Health at 202-461-0373.

6. RESCISSION: VHA Directive 1331, Elective Sterilization and Reversal (Tubal Ligation / Occlusion / Salpingectomy and Vasectomy, dated April 27, 2016.

7. RECERTIFICATION: This VHA directive is scheduled for recertification on or before the last working day of June 2022. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

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NOTE: *All references herein to VA and VHA documents incorporate by reference subsequent VA and VHA documents on the same or similar subject matter.*

DISTRIBUTION: Emailed to the VHA Publications Distribution List on June 22, 2017.

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INFERTILITY EVALUATION AND TREATMENT

INFERTILITY EVALUATION AND TREATMENT

1. PURPOSE

This Veterans Health Administration (VHA) directive establishes policy and procedures for Department of Veterans Affairs (VA) health care systems for the evaluation and treatment of fertility as authorized under the VA medical benefits package for eligible Veterans enrolled in the VA health care system. ***NOTE:*** *Except for certain Veterans who have a service-connected disability that results in their inability to procreate without the use of assisted reproductive technology (ART), and their spouses, VA cannot perform or pay for in vitro fertilization (IVF) because it is specifically excluded from the VA medical benefits package (Title 38 Code of Federal Regulations (CFR) 17.38). VA may also provide ART and fertility counseling and treatment that is available under the medical benefits package to spouses of Veterans authorized to receive IVF.* **AUTHORITY:** Title 38 United States Code (U.S.C.) 7301(b), Public Law 114-223 section 260, 38 CFR §§ 17.38, 17.380, and 17.412.

2. BACKGROUND

a. VA is committed to promote, preserve, or restore to the greatest extent possible the health and well-being of all Veterans. For many individuals, having children is an important and essential aspect of life. Those who desire but are unable to conceive children themselves may experience feelings of depression, grief, and inadequacy; poor adjustment; and reduced quality of life. Thus, treatment of infertility may contribute to the promotion, preservation, or restoration of the health and well-being of Veterans.

b. Over the past several years, the number of requests from Veterans for reproductive health services has increased dramatically. There are several underlying reasons for this growing demand. Women Veterans from Operation Enduring Freedom, Operation Iraqi Freedom, and Operation New Dawn are enrolling in VA health care in record numbers. Many incoming women Veterans are of reproductive age. In the US, about 10 percent of women have difficulty becoming pregnant or carrying a pregnancy to term. The most common causes of female infertility include ovulatory dysfunction (lack of egg production) and tubal disease or blockage. Factors that lead to these as well as other causes of infertility include but are not limited to anatomical, neurologic, infectious, and/or physiologic injury and/or illness. There is also an increased incidence of infertility and erectile dysfunction in male Veterans, especially those with spinal cord injuries and disorders. Moreover, genital injuries in combat are not uncommon and with the advent of improvised explosive devices there is an increase in the risk of genital damage in military personnel. Infertility may also affect Veterans with genitourinary injuries or poly-trauma injuries as a result of their service. Males with a spinal cord injury/disorder can experience a loss of fertility due to nervous system dysfunction resulting in ejaculatory dysfunction, erectile dysfunction, and/or poor sperm quality. Other identifiable factors for male infertility include testicular cancer, genetic abnormalities, surgical infertility, and side effects of chronic medical conditions and medications. Enrolled Veterans should be offered infertility evaluation and treatment in accordance with generally accepted standards of medical practice, regardless of service

connection, sexual orientation, gender identity, gender expression, or relationship or marital status.

c. Unintended pregnancies are a significant problem in the United States. Therefore, it is essential that effective contraception be available to those who seek it. Some Veterans choose permanent elective sterilization (i.e., salpingectomy, tubal occlusion procedures, and vasectomy) as their contraceptive method of choice. This is a covered benefit under the medical benefits package.

3. DEFINITIONS

a. **Assisted Reproductive Technologies.** Assisted reproductive technologies (ART) are all treatments or procedures that include the in vitro handling of both human oocytes and sperm, or of embryos, for the purpose of establishing a pregnancy. This includes, but is not limited to, in vitro fertilization; embryo transfer; gamete intrafallopian transfer; zygote intrafallopian transfer; tubal embryo transfer; gamete and embryo cryopreservation; oocyte and embryo donation; and, gestational surrogacy. ***NOTE:*** *VA cannot provide ART/IVF to most Veterans because it is specifically excluded from the VA medical benefits package (38 CFR 17.38(c)(2)). However, VA may provide ART to certain Veterans who have a service-connected disability that results in their inability to procreate without ART under 38 CFR 17.380. VA may also provide ART to spouses of Veterans authorized to receive ART, as well as fertility counseling and treatment that is available under the medical benefits package, under 38 CFR 17.412. These benefits are further delineated in VHA Directive 1334, Assisted Reproductive Technology (ART) Services for the Benefit of Veterans with Service-Connected Illness or Injury Resulting in Infertility, pending publication.*

b. **Cryopreservation.** Cryopreservation is the freezing or vitrification of gametes (oocytes or sperm), zygotes (1-cell fertilized oocytes), embryos (stage after zygote cleavage, typically cryopreserved on day 2, 3, 5 or 6 of development), or gonadal tissue to allow storage for future use. Further development and aging remain arrested during the storage of these cryopreserved tissues. Cryopreserved sperm can be used for intrauterine insemination or in vitro fertilization after thawing or rewarming. Cryopreserved oocytes require in vitro fertilization after thawing or rewarming. Cryopreserved tissue may be re-implanted into the body or cultured in vitro after thawing or rewarming.

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

d. **Gamete.** A mature male (sperm) or female (oocyte or egg) germ cell that is able to unite with another of the opposite sex in the process of sexual reproduction.

e. **Gestational Surrogacy.** Gestational surrogacy is a method of family building in which a woman (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).

f. **Hysterosalpingogram.** Hysterosalpingogram (HSG) is an x-ray study in which a contrast dye is injected through the cervix (the natural opening of the uterus) into the uterus (the womb) to show the delineation of the cavity of the uterus and the patency of the fallopian tubes.

g. **Infertility.** Infertility for male and female Veterans is the inability to achieve a pregnancy after 1 year of regular unprotected sexual intercourse with their partner(s) of choice. Women who have had repeated miscarriages may also benefit from an infertility evaluation for recurrent pregnancy loss. Age is significantly related to fertility and thus women who are older than 35 should receive expedited evaluation if they fail to conceive after 6 months. If there is a clear cause of decreased fecundability (e.g., spinal cord injury/disorder and inability to ejaculate, those with same-sex partners, a single person or a man born without vas deferens), evaluation and fertility treatment may be offered immediately or after a shortened period of attempting unassisted conception.

h. **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.

i. **In Vitro Fertilization.** In vitro fertilization (IVF) is an assisted reproductive technology 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 is allowed to divide in a protected environment for several days prior to transfer of an embryo(s) into the uterus. ***NOTE:*** *IVF is specifically excluded from the VA medical benefits package for most Veterans and generally, Veterans cannot be provided with IVF by VA. However, under 38 CFR 17.380 certain Veterans who have a service-connected disability that results in the inability of the Veteran to procreate without the use of ART may receive IVF treatment. The spouse of such a Veteran authorized to receive IVF may be provided with fertility counseling and treatment that is available under the medical benefits package, as well as IVF (38 CFR 17.412). These benefits are further delineated in VHA Directive 1334, Assisted Reproductive Technology (ART) Services for the Benefit of Veterans with Service-Connected Illness or Injury Resulting in Infertility, pending publication.*

j. **Laparoscopy.** Laparoscopy involves the visualization of the abdominal and pelvic cavity and potential surgical treatment of abdominal and pelvic organs using a fiber-optic viewing scope and instruments that are inserted through small incisions in the abdominal wall.

k. **Oncofertility.** Oncofertility is an interdisciplinary field at the intersection of oncology and reproductive medicine that expands fertility options for patients who have been, or are being, treated for cancer.

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

m. **Preconception Care.** Preconception care refers to the health of women and men during their reproductive years, which are the years they can have a child. It focuses on taking steps to protect the health of a baby they might have sometime in the future.

n. **Semen Analysis.** Semen analysis is the study of fresh ejaculated semen under the microscope to count the number of million sperm per milliliter (concentration), to check the shape and size of the sperm (morphology), and to note their ability to move (motility), among other indices.

o. **Sperm Retrieval Techniques.** Sperm retrieval techniques are methods used to retrieve sperm when a male is unable to ejaculate sperm, which can be a frequent result of a spinal cord injury/disorder. 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).

4. POLICY

It is VHA policy to provide needed fertility evaluation, management, and select treatment for fertility-related conditions to Veterans who are enrolled and are eligible for health care in the VA health care system, regardless of service connection, sexual orientation, gender identity, gender expression, or relationship or marital status. For purposes of this policy, fertility evaluation, management, and select treatment includes provision of elective sterilization (e.g., salpingectomy, tubal occlusion procedures and vasectomy) and surgery to reverse elective sterilization. ***NOTE:*** *For currently authorized fertility assessment, counseling and treatment services for all enrolled Veterans, see Appendix A.* ***NOTE:*** *IVF is specifically excluded from the VA medical benefits package for most Veterans and generally, Veterans cannot be provided with ART by VA. However, the limited use of ART, including IVF, is authorized under 38 CFR 17.380 for certain Veterans who have a service-connected disability that results in the inability of the Veteran to procreate without the use of ART including IVF. The spouse of such a Veteran authorized to receive IVF may be provided with fertility counseling and treatment that is available under the medical benefits package, as well as IVF (38 CFR 17.412). These benefits are further delineated in VHA Directive 1334, Assisted Reproductive Technology (ART) Services for the Benefit of Veterans with Service-Connected Illness or Injury Resulting in Infertility, pending publication.*

5. RESPONSIBILITIES

a. **Office of Women's Health Services (Reproductive Health).** The Office of Women's Health Services (Reproductive Health), in collaboration with experts designated by the National Surgery Office (NSO), will be available to assist with Veterans Integrated Service Network (VISN) level consultations when the medical standards for providing fertility services and treatment related to gamete (sperm or oocyte) cryopreservation or other fertility services are unavailable or unclear. Women's Health Services (WHS) may need to involve Spinal Cord Injury/Disorders (SCI/D) National Program Office, National Center for Ethics in Health Care and the NSO).

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

(1) Ensuring that Veterans have access to fertility care throughout the VA health care system. Such care may be provided locally by VA or through programs including but not limited to academic affiliations, sharing agreements, or authorized Community Care.

(2) Ensuring processes are in place for determining eligibility for fertility services as described in paragraph 6.a. of this policy and communicating that to the Veteran when applicable.

(3) Ensuring processes are in place to facilitate appropriate and timely communication between community care authorized fertility care providers and applicable VA-based program offices and appropriate staff.

(4) Ensuring that local processes are developed for utilization review of fertility care to enable avoidance of under- or over-treatment in regard to ovulation induction and/or treatment limitations described in Appendix A.

c. **VA Medical Facility Chief of Staff.** The VA medical facility Chief of Staff is responsible for:

(1) Ensuring that when questions arise involving treatment because standards of care for fertility services are unavailable or unclear, resolution of the issue is achieved in an appropriate and timely manner consistent with paragraph 6.b.(1) of this policy.

(2) Ensuring that when irresolvable conflicts arise over values between the clinician, the patient, or the family regarding ethically justifiable decisions or actions about evaluation, management, and treatment of fertility, such conflicts are resolved in an appropriate and timely manner consistent with paragraph 6.b.(2) of this policy.

(3) Ensuring that adequate staffing is provided for all care coordination and utilization review needs involving fertility patients, including the identification of support staff to perform these duties and not assigning them as a collateral duty of the Women Veterans Program Manager (WVPM) or Providers.

d. **VA Medical Facility Community Care Office.** The VA medical facility Community Care Office is responsible for:

(1) Ensuring that coverage authorization and limitations as described herein are communicated to the VA-authorized contracted or Community Care provider.

(2) Ensuring that a utilization review system is employed to enable avoidance of under- or over-treatment in regard to ovulation induction and/or treatment limitations as described in Appendix A.

e. **VA Medical Facility Chief of Pharmacy.** Consistent with VHA Directive 1601, Non-VA Medical Program, and VHA Handbook 1108.05, Outpatient Pharmacy Services,

the VA medical facility Chief of Pharmacy is responsible for ensuring processes are in place to enable timely provision of formulary, and approval and provision of non-formulary medications that may be prescribed by authorized non-VA infertility providers so that interruption of care or cycle management is avoided.

f. **VA Medical Facility Providers.** VA medical facility Providers are responsible for providing infertility care within their respective scope of practice and in accordance with generally accepted clinical standards. ***NOTE:*** *If the Veteran requires resources or more specialized fertility care than can be provided by VA, appropriate request for community care fertility authorizations should be placed. All providers of contraceptive counseling, fertility, and pregnancy planning services for patients and all surgeons performing sterilization procedures must ensure that the patient is aware of the risks and benefits of the sterilization procedure, including the potential for regret, the chances of failure, the permanence of the sterilization procedure as described in this paragraph, and the availability of reversible, highly effective contraceptives (e.g., intrauterine device and subcutaneous contraceptive implants) that are equally effective at preventing pregnancy. Providers must ensure patients are aware that sterilization reversal is not always possible or successful; e.g., tubal reversal procedures may result in an increased risk of ectopic pregnancy. Providers must ensure patients are aware that there are clinical criteria that may determine effectiveness and eligibility for reversal. For example, in females, tubal reversal success is affected significantly by the age of the patient, presence of other coexisting infertility diagnosis and type of original tubal procedure which will affect the amount of remaining tube available for reanastomosis. Currently, data is scant on reversal of sterilization for tubal occlusion procedures and surgical reversal of sterilization is not possible for complete salpingectomy. In males, vasovasostomy success is correlated to the length of time from vasectomy, presence or absence of sperm granuloma, and intrinsic testicular function. The surgeon must evaluate for medical contraindications to surgery and is responsible for obtaining informed consent prior to surgery from the patient, or other authorized surrogate, as specified in VHA Handbook 1004.01, Informed Consent for Clinical Treatments and Procedures*.

6. PRACTICES AND PROCEDURES

a. **Eligibility.** Veterans eligible to receive health care under the medical benefits package may receive VA-covered fertility evaluation, management, and treatment. IVF is specifically excluded from the medical benefits package. However, ART including IVF, is authorized under 38 CFR 17.380 for certain Veterans who have a service-connected disability that results in the inability of the Veteran to procreate without the use of assisted reproductive technology (ART). The spouse of a Veteran authorized to receive IVF may be provided with fertility counseling and treatment that is available under the medical benefits package, as well as ART, including IVF (38 CFR 17.412). The aforementioned ART/IVF benefit for certain Veterans and their spouse is further delineated in VHA Directive 1334, Assisted Reproductive Technology (ART) Services

for the Benefit of Veterans with Service-Connected Illness or Injury Resulting in Infertility, pending publication. Otherwise, non-Veteran partners (spouses or significant others), if applicable, are not eligible to receive infertility treatment services from VA unless they are eligible for the Civilian Health and Medical Program of the Department of Veterans Affairs (CHAMPVA), which allows VA to provide infertility services and treatment to certain family members of Veterans under 38 CFR 17.270-278. In cases where a non-Veteran partner is not eligible for VA-covered infertility services, the Veteran and non-Veteran partner must be informed that payment for such service to the community provider is the responsibility of the Veteran and non-Veteran partner. These requirements must be discussed with the Veteran before any treatment course is undertaken.

b. **Assessment and Treatment.** VHA will provide evaluation, management, and treatment of infertility in accord with generally accepted standards of medical practice, including but not limited to those described in Appendix A.

(1) If medical standards are unavailable or unclear, providers should consult with the following VA national program offices for guidance: WHS, SCI/D National Program Office, National Center for Ethics in Health Care, and/or the NSO (and its Urology Surgical Advisory Board) as clinically indicated. When the medical standards are unavailable or unclear, an expert panel may be required. Such panel could include local VA medical facility staff members in the ethics office, health care providers, and other infertility evaluation and treatment experts.

(2) Should an irresolvable conflict arise over values between the clinician, the patient, or the family regarding ethically justifiable decisions or actions about evaluation, management, and treatment of infertility, a consult should be placed to the facility IntegratedEthics® consultation service.

c. **Cryopreservation.** Gamete cryopreservation (sperm or oocytes) is allowable when it is determined by appropriate health care professionals that the care is needed to promote, preserve, or restore the health of the individual and is in accord with generally accepted standards of medical practice (e.g., for oncofertility with cryopreservation of gametes to preserve fertility prior to cancer treatment which would ordinarily render the patient permanently sterile). ***NOTE:*** *Providers should consult with the following VA national program offices when the medical standards for gamete cryopreservation are unavailable or unclear – WHS and, as needed, with SCI/D National Program Office, National Center for Ethics in Health Care, and the NSO). When the medical standards are unavailable or unclear, an expert panel may be required. Such panel could include local VA medical facility staff members in the ethics office, health care providers, and other infertility evaluation and treatment experts.*

(1) In considering whether the patient's medical condition and/or planned treatment will affect fertility, evaluation and counseling is appropriate. This may include laboratory and ultrasound testing as well as counseling to consider whether the time needed for sperm collection or retrieval, or oocyte stimulation and retrieval, poses additional risks to the patient (e.g., delaying cancer chemotherapy in order to stimulate and/or collect gametes).

(2) Storage of cryopreserved gametes will take place at an independent non-VA facility and storage costs will be covered for up to 5 years. Guidance for proper handling, labeling, and storage of cryopreserved specimens can be provided through Care in the Community network referrals for those Veterans in whom it is medically indicated. The storage agreement and permissions will be between the Veteran and the independent non-VA storage facility. VA will not have ownership or custody of cryopreserved gametes and will not be involved in the ultimate disposition of excess sperm or oocytes. The Veteran will be informed of their respective financial responsibility for the storage of the gametes after the 5 years are complete. Maximum time limits for storage and other limitations on gamete use will be dictated by the storage facility (vendor) and the non-VA medical facility that may be engaged to perform treatment using these gametes in the future. The Veteran will be responsible for arranging transportation of these cryopreserved gametes should the Veteran decide to use them in the future. Contingencies for length of storage and disposition of oocyte or sperm in the case of an unexpected life event (such as divorce or death of the Veteran) must be delineated in an authorization form between the Veteran and the vendor.

(3) VA will stop payment for cryopreservation in the following circumstances:

(a) Ownership of the cryopreserved oocytes or sperm is transferred to a third party;

(b) The time limit for payment of storage is exceeded;

(c) Cryopreservation is not in accord with generally accepted standards of medical practice;

(d) VA determines that preservation is not needed to preserve, promote, or restore health of the Veteran; or

(e) Upon death of the Veteran.

d. **Benefit Exclusions.** The following procedures or services are not covered VA medical benefits:

(1) Gestational surrogacy treatment;

(2) Costs of obtaining, transporting, and storing donor sperm and oocytes;

(3) IVF procedures, except for certain Veterans who have a service-connected disability that results in the inability of the Veteran to procreate without the use of assisted reproductive technology (ART) (38 CFR 17.380). The spouse of a Veteran authorized to receive IVF may be provided with fertility counseling and treatment that is available under the medical benefits package, as well as IVF (38 CFR 17.412).

(4) Costs of cryopreservation, storage, and transport of embryo(s), except for certain Veterans who have a service-connected disability that results in the inability of the Veteran to procreate without the use of ART and their non-Veteran spouses. (38 CFR 17.380 and 17.412); and

(5) Infertility, evaluation, and management of non-Veteran partners except for the spouse of certain Veterans who have a service-connected disability that results in the inability of the Veteran to procreate without the use of assisted reproductive technology (ART), including IVF.

7. REFERENCES

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ASSESSMENT, COUNSELING AND TREATMENT

The first step in assessing fertility needs is to include a complete history and physical examination A complete patient history includes but is not limited to: age, past medical and surgical events, medications, diet, tobacco, alcohol and other substance use, occupational risks, exercise, previous methods of contraception, past methods of infertility management, past pregnancies, sexually transmitted infections (including human immunodeficiency virus and Hepatitis B), current sexual practices, and family history.

When consistent with medical standards, VHA will provide infertility evaluation, management and treatment as described, but not limited to, the descriptions below. Specific exclusions will apply for procedures and treatments described in the section on Benefit Exclusion of this directive. Some diagnoses or co morbidities may make the Veteran ineligible for the service based on best medical practices and medical eligibility.

1. PRECONCEPTION COUNSELING

a. Evidence demonstrates that preconception counseling, for both women and men, is an intervention that reduces maternal and neonatal complications. This is especially important for infertile couples who may be at increased risk for some adverse pregnancy outcomes if they do conceive. Many patients are unaware that their medical conditions, medications, occupational exposures, or social practices may have consequences on fertility as well as in the earliest weeks of pregnancy.

b. Consistent with evidence-based clinical standards, clinicians may refer patients undergoing infertility assessments to specialists for preconception counseling and evaluation of high-risk clinical conditions (e.g., high-risk pregnancy, inheritable genetic disorders, transmissible infectious diseases, usage of teratogenic medications). There are several genetic factors that can contribute to female and/or male infertility. Therefore, it is important to address potential inheritable genetic abnormalities. Providers are encouraged to counsel Veterans with infertility problems and refer for genetic counseling, screening, and testing prior to pursuing infertility evaluation and treatment services when indicated and when in accord with generally accepted standards of medical practice.

c. Preconception counseling may require a multidisciplinary approach. This is particularly true for Veterans with coexisting mental and medical health conditions that may complicate infertility treatment or may increase the emotional and physical challenges of infertility assessment, treatment and pregnancy.

d. When a Veteran has a medical or mental health condition that involves ongoing treatment with medication, the prescribing provider should engage in shared decision making about the reproductive and other risks and benefits of various treatment options, including no treatment. This includes informing the patient of the reproductive risks of current medication (e.g., teratogenicity, pregnancy complications) the availability and risks of alternative treatments with less reproductive risk, and the risks and reproductive

benefits of stopping medication. For example, some medications are potentially harmful, yet the risks of maternal use of and fetal exposure to the medication may still be outweighed by the other benefits (e.g., reduction in depression relapse) in some situations and for some patients.

e. Preconception counseling should also include evaluation and optimization of Veteran preventive or well care and services (e.g., immunizations, nutrition, cessation of tobacco and substance use and other high risk behavior). Additional recommendations for women include but are not limited to initiation of folic acid supplementation for prevention of nonsyndromic neural tube defects

2. DIAGNOSTIC AND TREATMENT FOR FEMALE VETERANS

a. Laboratory blood testing (e.g., follicle-stimulating hormone (FSH), thyroid stimulating hormone (TSH);

b. Genetic counseling, screening, and diagnostic testing;

c. Pelvic and/or transvaginal ultrasound (with or without saline infusion);

d. Hysterosalpingogram;

e. Surgical correction of structural pathology consistent with standard of care including operative laparoscopy and operative hysteroscopy;

f. Reversal of tubal ligation (tubal reanastomosis);

g. Intrauterine insemination, (maximum of 6 ovulatory cycles per pregnancy).

NOTE: *Injectable or oral hormonal therapies may be needed for ovulation induction in the female partner. Certain causes of infertility may be appropriate for more than 6 ovulatory cycles and can be reviewed locally on a case by case basis.*

h. Hormonal therapies (i.e., for controlled ovarian stimulation or ovulation induction). The following maximum cycle numbers are based on cost and efficacy. The maximum limits are per pregnancy, regardless of pregnancy outcome;

(1) Oral medications (e.g., clomiphene citrate): Maximum of 6 ovulatory cycles.

(2) Injectable gonadotropin medications (e.g., FSH, luteinizing hormone (LH), combination human menopausal gonadotropins). Maximum of 6 ovulatory cycles.

(3) Additional hormonal therapies that are indicated to support ovulation induction treatment cycles (e.g., progesterone for luteal phase support, human chorionic gonadotropin (hCG) to trigger ovulation).

i. Hormonal therapies for ovarian stimulation prior to oocyte retrieval and in vitro insemination for IVF treatment. These include medications to stimulate oocyte

maturation, and/or support the luteal phase and/or early pregnancy in IVF treatment. VA will cover medications for up to 6 attempts to achieve 3 completed cycles of IVF.

NOTE: *Since ovulation induction or controlled ovarian stimulation medications are highly specialized, when providing a medication through VA for ovulation induction or controlled ovarian stimulation for infertility treatment performed at a non-VA facility, there will be a need for coordination of use and communication between the VA and non-VA provider consistent with VHA Directive 2009-038, VHA National Dual Care Policy, or subsequent policy issue. Arrangements must be determined early in the process to avoid fragmented care and potential interruption of care or cycle management.*

3. DIAGNOSTIC AND TREATMENT FOR MALE VETERANS

a. Laboratory blood testing (e.g., serum testosterone, FSH, LH, estradiol);

b. Semen analysis;

c. Evaluation and treatment of erectile dysfunction (e.g., in spinal cord injury/disorder);

d. Surgical correction of structural pathology (e.g., varicocelectomy);

e. Vasectomy reversal (e.g., vasovasostomy);

f. Hormonal and other pharmacologic therapies (e.g., hCG, testosterone, clomiphene citrate, phosphodiesterase (PDE) type 5 (PDE5) inhibitors). **NOTE:** Greater quantities of PDE5 inhibitors outside of usual limits imposed on these drugs may be approved when requested and justified on a case-by-case basis (e.g., couples trying to conceive, Veterans with an inconsistent response to PDE5 inhibitors);

g. Genetic counseling, screening, and diagnostic testing;

h. Sperm retrieval techniques;

i. Post-ejaculatory urinalysis; and,

j. Transrectal and/or scrotal ultrasonography

4. SUMMARY DIAGNOSTIC AND TREATMENT FOR VETERANS

Diagnostic and Treatment for Female Veterans	Diagnostic and Treatment for Male Veterans
– Laboratory blood testing (i.e., follicle-stimulating hormone (FSH), thyroid stimulating hormone)	– Laboratory blood testing (i.e., serum testosterone, FSH, luteinizing hormone, estradiol, etc.)

EXHIBIT B

Diagnostic and Treatment for Female Veterans	Diagnostic and Treatment for Male Veterans
– Genetic counseling and testing – Pelvic and/or transvaginal ultrasound – Hysterosalpingogram – Saline infused sonohysterogram – Surgical correction of structural pathology consistent with standard of care including operative laparoscopy and operative hysteroscopy – Reversal of tubal ligation (tubal reanastomosis) – Hormonal therapies (e.g., controlled ovarian hyperstimulation) – Oral medication for ovulation induction (e.g., clomiphene) – Injectable gonadotropin medications for ovulation induction or controlled ovarian stimulation (e.g., human menopausal gonadotropins) – Additional hormonal therapies as approved by VA Pharmacy Benefits Management – Intrauterine insemination – Oocyte cryopreservation for medically indicated conditions	– Genetic counseling and testing – Transrectal and/or scrotal ultrasonography – Semen analysis – Evaluation and treatment of erectile dysfunction – Surgical correction of structural pathology (e.g., varicocelectomy, Peyronie's repair) – Vasectomy reversal (vasovasostomy) – Hormonal therapies (e.g., clomiphene citrate, human chorionic gonadotropin, phosphodiesterase type 5 medications, testosterone) – Sperm retrieval techniques – Post-ejaculatory urinalysis – Sperm cryopreservation for medically indicated conditions – Ejaculation techniques (e.g. electroejaculation, vibratory stimulation)

NOTE: *Providers should consult with the following VA national program offices when the medical standards for gamete cryopreservation are unavailable or unclear: Women's Health Services and as needed with Spinal Cord Injury/Disorders National Program Office, National Center for Ethics in Health Care, and the National Surgical Office (and its Urology Surgical Advisory Board). When the medical standards are unavailable or unclear, an expert panel may be required. Such panel could include local VA medical facility staff members in the ethics office, health care providers, and other infertility evaluation and treatment experts.*

EXHIBIT B

5. ELECTIVE STERILIZATION PROCEDURES

a. Salpingectomy.

b .Tubal occlusion procedures.

c. Vasectomy.

EXHIBIT B

PATIENT RESOURCES ON INFERTILITY SERVICES

a. American Society for Reproductive Medicine Patient (ASRM), www.reproductivefacts.org.

b. ASRM Evaluation of the Uterus, http://www.reproductivefacts.org/FACTSHEET_Evaluation_of_the_Uterus/.

c. ASRM Hysterosalpingogram, http://www.reproductivefacts.org/FACTSHEET_Hysterosalpingogram/.

d. ASRM Intrauterine Insemination, http://www.reproductivefacts.org/FACTSHEET_Intrauterine_Insemination_IUI/.

e. ASRM Medications for Inducing Ovulation, http://www.reproductivefacts.org/BOOKLET_Medications_for_Inducing_Ovulation/.

f. ASRM Oral Medicines for Inducing Ovulation, http://www.reproductivefacts.org/FACTSHEET_Oral_Medicines_For_Inducing_Ovulation/.

g. ASRM Stress and Infertility, http://www.reproductivefacts.org/FACTSHEET_Stress_and_Infertility/.

h. ASRM Surgical Sperm Retrieval in Men with Spinal Cord Injury, http://www.reproductivefacts.org/uploadedFiles/ASRM_Content/Resources/Patient_Resources/Fact_Sheets_and_Info_Booklets/SpinalCordInjury-Fact.pdf.