



DEPARTMENT OF VETERANS AFFAIRS

8320-01

38 CFR Part 17

RIN 2900-AP94

Fertility Counseling and Treatment for Certain Veterans and Spouses

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: The Department of Veterans Affairs (VA) adopts as final, with changes based on subsequent changes to our statutory authority, an interim final rule adding a new section to the medical regulations authorizing in vitro fertilization (IVF) for a veteran with a service-connected disability that results in the inability of the veteran to procreate without the use of fertility treatment. In addition, the rule added a new section stating that VA may provide fertility counseling and treatment using assisted reproductive technologies (ART), including IVF, to a spouse of a veteran with a service-connected disability that results in the inability of the veteran to procreate without the use of fertility treatment. As a result of this rulemaking, VA may provide both a covered veteran and spouse of a covered veteran all ART treatments available to enrolled veterans under the medical benefits package, as well as IVF. The interim final rule was effective on the date of publication. We provided a 60-day comment period, and received 13 comments from the public, all of which were supportive of this rulemaking. However, the commenters raised several issues that we address here. Following publication of the interim final rule, a statute was enacted that made several substantive changes to VA's authority to provide ART and IVF to covered veterans and spouses. This final rule reflects those changes.

DATES: Effective Date: This rule is effective on **[insert date of publication in the FEDERAL REGISTER]**.

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SUPPLEMENTARY INFORMATION: On January 19, 2017, VA published an interim final rule regarding fertility counseling and treatment available to certain veterans and spouses. 82 FR 6275. This interim final rulemaking added a new § 17.380 to VA's medical regulations authorizing in vitro fertilization (IVF) for a veteran with a service-connected disability that results in the inability of the veteran to procreate without the use of fertility treatment. As explained in the preamble to the interim final rulemaking, IVF is expressly excluded from the medical benefits package at 38 CFR 17.38(c)(2), but to help clarify the full scope of fertility treatment benefits available to veterans through VA, the rulemaking added a Note to § 17.38(c)(2) to reference § 17.380 of the same title. 82 FR at 6275. Section 17.380 is regulatory authority independent of the medical benefits package that permits VA to use the "Medical Services" appropriation account to provide IVF to certain veterans, as originally authorized by section 260 of the Continuing Appropriations and Military Construction, Veterans Affairs, and Related Agencies Appropriations Act, 2017, and Zika Response and Preparedness Act (Public Law 114-

223) (the “2017 Act”). In addition, consistent with the 2017 Act, we added a new § 17.412 stating that VA may provide fertility counseling and treatment using assisted reproductive technologies (ART) to a spouse of a covered veteran to the extent such services are consistent with the services available to enrolled veterans under the medical benefits package, as well as IVF to the spouse of a covered veteran, subject to certain limitations.

On February 21, 2017, VA published a correction to the interim final rulemaking regarding the new regulations’ expiration date. 82 FR 11152. In particular, we corrected both sections to reflect that authority to provide health care services under these sections would expire on September 30, 2018.

While the above-referenced 2017 Act was the original authority for VA’s IVF program, it lapsed once the relevant funding period ended. VA’s authority to use Medical Services Funds to provide IVF services to the same cohort described in the 2017 Act was subsequently renewed and extended in similar form in section 236 of Division J, Military Construction, Veterans Affairs, and Related Agencies Appropriations Act, 2018, Public Law 115-141 (March 23, 2018) (the “2018 Act”). Under this recent provision, VA’s IVF authority is subject to the funding period covered by the 2018 Act, and the availability of appropriations, but notably the 2018 Act includes two changes to the IVF authority as established under the 2017 Act.

As with the 2017 Act, the 2018 Act continues to require VA to deliver benefits in a manner consistent with the benefits described in the April 3, 2012, memorandum issued by the Assistant Secretary of Defense for Health Affairs 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," and the guidance issued by the Department of Defense (DoD) to implement such policy, including any limitations on the amount of such benefits available to the members. As mentioned, however, the 2018 Act included two changes to the original IVF authority established under the 2017 Act. First, under the 2018 Act, VA's IVF authority is no longer subject to the time periods regarding embryo cryopreservation and storage set forth in part III(G) and in part IV(H) of the April 2012 DoD memorandum. Second, the term "assisted reproductive technology" includes embryo cryopreservation and storage without limitation on the duration of such cryopreservation and storage. See section 236(b)(3)(A)-(B), Div. J, of the 2018 Act. Thus, the DoD time-limits applicable to the duration of embryo cryopreservation and storage no longer apply to VA's IVF authority. Consequently, we are amending §§ 17.380(b) and 17.412(b) to reflect these changes. VA's IVF authority is still subject to the other terms of the DoD program as reflected in the DoD 2012 memorandum, including those relating to ownership and future embryo use.

This final rulemaking thus implements VA's IVF authority as described in the interim final rule and as extended and modified by the 2018 Act. The 2018 Act is essentially an extension of the original authority, albeit with limited modifications aimed at increasing the benefit to eligible veterans and their spouses. Consequently, the interim final rule has been revised to accord with changes in the statutory authority.

Reimbursement of adoption expenses, an infertility benefit first authorized in the 2017 Act and subsequently renewed in the 2018 Act, is the subject of a separate rulemaking.

We provided a 60-day period for public comment of the interim final rule based on the original authority, i.e., the 2017 Act. The comment period expired on March 20, 2017. We received 13 public comments, all of which were generally supportive of the rule. Some commenters raised specific issues. Several commenters asked whether the rule would be applied retroactively to a course of IVF treatment completed prior to the effective date of the rule. Another commenter asked whether Post-traumatic stress disorder (PTSD) is considered a service-connected disability that results in the inability of the veteran to procreate without the use of fertility treatment. Several commenters stated that IVF should be available to all veterans with a service-connected disability. A commenter stated that VA should share the cost of IVF with a veteran with a preexisting condition that results in the inability of the veteran to procreate without the use of fertility treatment. One commenter was concerned about the expiration of VA's statutory authority at the end of FY 2018. Another commenter raised the issues of cryopreservation and creating a nationwide network of providers. We address these issues below.

Retroactivity

Three commenters asked whether the rule would be applied retroactively to provide VA with the authority to reimburse veterans for the private cost of IVF treatment completed prior to the publication of the interim final rule. The commenters reference a specific case involving two of these three commenters. One stated that he is a veteran with a service-connected disability that resulted in the inability to procreate without the use of fertility treatment. His spouse, who was treated outside of the VA health care

system, was prescribed a course of IVF treatment that concluded prior to publication of the interim final rule. The covered veteran incurred out-of-pocket expenses related to this course of treatment and inquired about reimbursement of those expenses.

The interim final rule was effective on January 19, 2017. It therefore does not cover IVF services previously furnished to eligible beneficiaries before that date. The Administrative Procedure Act generally contemplates rulemaking to apply prospectively, and the term “rule” is defined at 5 U.S.C. 551(4) to mean, in pertinent part, “an agency statement of general or particular applicability and future effect.” The Supreme Court has stated that retroactivity is not favored in the law and that retroactive rulemaking is only appropriate when Congress has explicitly authorized it. Bowen v. Georgetown Univ. Hosp., 488 U.S. 204 (1988); see also Landgraf v. USI Film Products, 511 U.S. 244 (2014). The statute is silent on the issue of retroactive application of the statute or of the implementing regulation VA published to exercise that authority. Given that the statute does not expressly authorize VA to engage in rulemaking that would apply retroactively to infertility treatment or counseling and IVF provided to a covered veteran or spouse prior to the effective date of the rule, we reiterate that VA has determined that such services provided prior to the effective date of the interim final rule are not covered by the rule.

We make no changes based on these comments.

Post-traumatic stress disorder (PTSD)

One commenter inquired as to whether a diagnosis of PTSD would qualify as a service-connected disability that results in the inability of the veteran to procreate

without the use of fertility treatment. That is a medical determination that must be made on a case-by-case basis. VA will provide benefits to a veteran with any service-connected disability resulting in an inability to procreate without the use of fertility treatment, regardless of the specific disability. We make no changes based on this comment.

Expanded coverage

Several commenters supported the rule but stated that IVF should be available to all veterans with a service-connected disability. One commenter stated that VA should share the cost of IVF with a veteran with a preexisting condition that results in the inability of the veteran to procreate without the use of fertility treatment.

The medical benefits package at 38 CFR 17.38 defines the medical services provided to all enrolled veterans by VA. VA may provide care under the medical benefits package that is determined by appropriate healthcare professionals to be both necessary to promote, preserve, or restore the health of the veteran and in accord with generally accepted standards of medical practice. As part of the medical benefits package, VA provides many different types of medically necessary fertility treatments and procedures to enrolled veterans, irrespective of whether their condition is service-connected. These include infertility counseling, laboratory blood testing, surgical correction of structural pathology, reversal of a vasectomy or tubal ligation, medication, and various other diagnostic studies or treatments and procedures. This list is not all-inclusive; however, IVF is expressly excluded from VA's medical benefits package under § 17.38(c)(2).

VA will continue to consider whether to remove the exclusion of IVF from the medical benefits package. We note this type of decision is multifactorial and complex, particularly because the benefit, if made available, would have to be offered to all veteran-enrollees in need of such care.

The comment related to cost-sharing for IVF (provided as part of the medical benefits package) is thus premature. As a general matter, we note that copayments do, by law, apply to some veterans receiving care under the medical benefits package based on their enrollment priority group status. To address the issue of copayments, we note that the IVF program authorized under the 2017 Act, as renewed and extended under the 2018 Act, does not establish copayment obligations. Moreover, under the interim final rule, again as amended here to accord technically with the 2018 Act, VA shares the cost of cryopreservation and storage. Under the 2018 Act, the prior DoD time-limits on the period of cryopreservation and storage no longer apply to VA's IVF authority. We make no changes based on this comment, excluding the needed execution of conforming amendments.

Expiration of authority

One commenter was concerned that the Act is temporary, expiring on September 30, 2018. Although the original authority lapsed, VA's IVF authority was renewed and extended up through the funding period covered by the 2018 Act. Although this treatment authority is still temporary in nature (because it is again tied to a specific timeframe), there has been no lapse in program operations. The commenter's specific concern relating to the authority expiring after September 30, 2018, has thus been

rendered moot by the 2018 Act, although we note that, in principle, this concern remains because the authority is still subject to a delimiting date. However, Congress could again renew and extend this authority. For this reason and to avoid the need to continually update these regulations when a subsequent appropriations law (or other law) renews this authority, we have revised §§ 17.380(b) and 17.412(b) to eliminate the sentence therein that specifies the expiration date. We make no other changes based on this comment.

Cryopreservation

One commenter stated that the fertility counseling and treatment program would be most cost-efficient if servicemembers were allowed to provide a sperm or egg for cryopreservation prior to entering active combat. The commenter noted that delayed sample collection would inevitably result in cases where the servicemember suffers a pelvic injury so severe that sample collection is no longer medically possible. The commenter asserted that cryopreservation of sperm or ovum prior to entry into active combat would save money and allow servicemembers who have prioritized childbearing to preserve the ability to procreate. The commenter further noted that approximately 9% of servicemembers wounded in action in Operation Iraqi Freedom and Operation Enduring Freedom received genitourinary injuries. The commenter also provided cost estimates related to cryopreservation and related fertility treatment.

Semen cryopreservation (commonly called sperm banking) is a procedure to preserve sperm cells. Oocyte cryopreservation (egg freezing) is a process in which a woman's egg (oocytes) is extracted, frozen and stored. The semen or egg can later be

thawed and used to create an embryo that can then be implanted in a uterus. VA does provide cryopreservation services in those cases where an appropriate health care professional determines that the care is needed to promote, preserve, or restore the health of the veteran and is in accord with generally accepted standards of medical practice. However, the decision on whether to offer cryopreservation of sperm or ovum to servicemembers prior to participating in combat operations lies with DoD, not VA. We make no changes based on this comment.

Provider network

One commenter recommended that VA establish a nationwide standardized network of reproductive medicine providers. The commenter stated this is most important for servicemembers and military families who must frequently move to new duty stations. Further, veterans and active duty servicemembers may provide a sample in one location and then later receive treatment in a different location.

The creation of provider networks (for purposes of VA's ART program or any other VHA clinical program) is beyond the scope of this rulemaking. However, we note that VA is working with reproductive medicine and infertility specialists both in VA and in the community to provide necessary fertility counseling and treatment to veterans and spouses covered by 38 CFR 17.380 and 17.412. We make no changes based on this comment.

Based on the rationale set forth in the interim final rule and in this document, VA adopts the interim final rule as a final rule, as modified to accommodate the changes made by the 2018 Act, as noted above.

Administrative Procedure Act

In accordance with 5 U.S.C. 553(b)(B), the Secretary of Veterans Affairs concluded that there was good cause to publish amendments to this rule without prior opportunity for public comment, and to publish this rule with an immediate effective date. The 2018 Act revised our authority to provide ART and IVF to covered veterans and spouses by removing time limitations on cryopreservation and storage of embryos reflected in the April 3, 2012 DoD memorandum titled “Policy for Assisted Reproductive Services for the Benefit of Seriously or Severely Ill/Injured (Category II or III) Active Duty Service Members.” Prior to this revision VA was required to provide ART and IVF benefits to covered veterans and spouses consistent with benefits relating to reproductive assistance provided to a member of the Armed Forces who incurs a serious injury or illness on active duty as described in that memorandum. This final rule incorporates a specific requirement mandated by Congress. Accordingly, this final rule is exempt from the prior notice-and-comment and delayed-effective-date requirements of 5 U.S.C. 553(b) and (d).

Effect of rulemaking

Title 38 of the Code of Federal Regulations, as revised by this final rulemaking, represents VA’s implementation of its legal authority on this subject. Other than future

amendments to this regulation or governing statutes, no contrary guidance or procedures are authorized. All existing or subsequent VA guidance must be read to conform with this rulemaking if possible or, if not possible, such guidance is superseded by this rulemaking.

Paperwork Reduction Act

This final rule contains no provisions constituting a collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3521).

Regulatory Flexibility Act

The Secretary hereby certifies that final rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601-612. This final rule directly affects only individuals and will not directly affect small entities. Therefore, pursuant to 5 U.S.C. 605(b), this rulemaking is exempt from the initial and final regulatory flexibility analysis requirements of 5 U.S.C. 603 and 604.

Executive Orders 12866, 13563, and 13771

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory

Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Executive Order 12866 (Regulatory Planning and Review) defines a “significant regulatory action,” which requires review by the Office of Management and Budget (OMB), as any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) Raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order.

VA has examined the economic, interagency, budgetary, legal, and policy implications of this regulatory action and determined that the action is not a significant regulatory action under Executive Order 12866. VA’s impact analysis can be found as a supporting document at <http://www.regulations.gov>, usually within 48 hours after the rulemaking document is published. Additionally, a copy of the rulemaking and its impact analysis are available on VA’s website at <http://www.va.gov/orpm> by following the link for VA Regulations Published from FY 2004 through FYTD. This rule is not an EO 13771 regulatory action because this rule is not significant under EO 12866.

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more (adjusted annually for inflation) in any one year. This final rule will have no such effect on State, local, and tribal governments, or on the private sector.

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance numbers and titles for the programs affected by this document are 64.012 - Veterans Prescription Service; 64.029 - Purchase Care Program; 64.040 - VHA Inpatient Medicine; 64.041 - VHA Outpatient Specialty Care; 64.042 - VHA Inpatient Surgery; 64.045 - VHA Outpatient Ancillary Services; 64.047 - VHA Primary Care; 64.050 - VHA Diagnostic Care.

List of Subjects in 38 CFR Part 17

Administrative practice and procedure, Alcohol abuse, Alcoholism, Claims, Day care, Dental health, Drug abuse, Government contracts, Grant programs-health, Grant programs-veterans, Health care, Health facilities, Health professions, Health records, Homeless, Medical and Dental schools, Medical devices, Medical research, Mental health programs, Nursing homes, Reporting and recordkeeping requirements, Travel and transportation expenses, Veterans.

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. Robert L. Wilkie, Secretary, Department of Veterans Affairs, approved this document on January 11, 2019, for publication.

Dated: March 3, 2019.

Michael P. Shores,

Director,

Office of Regulation Policy & Management

Office of the Secretary

Department of Veterans Affairs

For the reasons set forth in the preamble, the VA amends 38 CFR part 17 as follows:

PART 17 – MEDICAL

1. The authority citation for part 17 is amended in the entry for §§ 17.380, 17.390 and 17.412 by adding “, and sec. 236, div. J, Pub. L 115-141, 132 Stat. 348” immediately after “857” to read in part as follows:

Authority: 38 U.S.C. 501, and as noted in specific sections.

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2. Amend § 17.380 by revising paragraph (b) to read as follows:

§17.380 In vitro fertilization treatment.

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(b) The time periods regarding embryo cryopreservation and storage set forth in part III(G) and in part IV(H) of the memorandum referenced in paragraph (a)(3) of this section do not apply. Embryo cryopreservation and storage may be provided to an individual described in paragraph (a)(1) of this section without limitation on the duration of such cryopreservation and storage.

3. Amend § 17.412 by revising paragraph (b) to read as follows:

§17.412 Fertility counseling and treatment for certain spouses.

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(b) The time periods regarding embryo cryopreservation and storage set forth in part III(G) and in part IV(H) of the memorandum referenced in paragraph (a) of this section do not apply. Embryo cryopreservation and storage may be provided to a spouse of a covered veteran without limitation on the duration of such cryopreservation and storage.

[FR Doc. 2019-04096 Filed: 3/6/2019 8:45 am; Publication Date: 3/7/2019]