



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: Interim final rule.

SUMMARY: The Department of Veterans Affairs (VA) amends its regulation regarding fertility counseling and treatment available to certain veterans and spouses. VA currently provides certain infertility services other than in vitro fertilization (IVF) to veterans as part of the medical benefits package. IVF is the process of fertilization by manually fertilizing an egg, and then transferring the embryo to the uterus. This interim final rulemaking adds a new section authorizing 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, we add 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. VA will provide ART treatment, including IVF, to these veterans and spouses as specified in the Continuing Appropriations and Military Construction, Veterans Affairs, and Related Agencies Appropriations Act, 2017, and Zika Response and Preparedness Act to the extent such services are consistent with the services available to enrolled veterans under the medical benefits package.

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

Comment date: Comments must be received on or before [insert date 60 days after date of publication in the FEDERAL REGISTER].

ADDRESSES: Written comments may be submitted by e-mail through <http://www.regulations.gov>; by mail or hand-delivery to Director, Regulation Policy and Management (00REG), Department of Veterans Affairs, 810 Vermont Avenue, NW, Room 1068, Washington, DC 20420; or by fax to (202) 273-9026. (This is not a toll-free number.) Comments should indicate that they are submitted in response to “RIN 2900AP94 - Fertility Counseling and Treatment for Certain Veterans and Spouses.” Copies of comments received will be available for public inspection in the Office of Regulation Policy and Management, Room 1068, between the hours of 8:00 a.m. and 4:30 p.m. Monday through Friday (except holidays). Please call (202) 461-4902 for an appointment. (This is not a toll-free number.) In addition, during the comment period, comments may be viewed online through the Federal Docket Management System (FDMS) at <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Patricia M. Hayes, Ph.D. Chief Consultant, Women’s Health Services, Patient Care Services, Veterans Health Administration, Department of Veterans Affairs, 810 Vermont Ave. NW, Washington, DC 20420. (202) 461-0373. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: 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) states that VA may use appropriated funds available to VA for the Medical Services account to provide fertility counseling and treatment using assisted reproductive technology (ART) to a covered veteran or the spouse of a covered veteran, or adoption reimbursement to a covered veteran. This rulemaking expands the types of ART treatment available to certain veterans and makes fertility counseling and treatment including ART treatment available to spouses of those veterans, consistent with this statutory authority. Reimbursement of adoption expenses will be the subject of a separate rulemaking.

According to this law, Veterans who will receive this benefit are those with a service-connected disability that results in the inability of the veteran to procreate without the use of fertility treatment. The ART treatments referred to in this law are those relating to reproductive assistance provided to a member of the Armed Forces who incurs a serious injury or illness on active duty pursuant to title 10 of the United States Code (U.S.C.) section 1074(c)(4)(A), as described in a policy memorandum issued by the Assistant Secretary of Defense for Health Affairs on April 3, 2012, titled “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 to implement such policy, including any limitations on the amount of such benefits available to such a member. See Pub. L. 114-223, section 260(b)(2) and (3). The implementing guidance is contained in a document attached to the policy memorandum. We will refer to the April 3, 2012, policy memorandum and guidance issued by the

Department of Defense (DoD) to implement that policy collectively as DoD policy guidance. DoD has established a system for categorizing injured servicemembers for purposes of coordinating care. Those in Category II have a serious injury or illness, are unlikely to return to duty within a time specified by their Military Department, and may be medically separated from the military. Servicemembers in Category III have a severe or catastrophic injury or illness, are highly unlikely to return to duty, and will most likely be medically separated from the military.

ART is defined at Pub. L. 114-223, section 260(b)(3) to mean the benefits relating to reproductive assistance in DoD policy guidance, including any limitations on the amount of such benefits in that policy. DoD policy guidance addresses assisted reproductive services available to servicemembers, providing specific guidance on the availability of IVF, as well as a wide range of services that VA considers as fertility treatment. Under this statute, VA is authorized to provide ART benefits, consistent with DoD policy guidance, to a veteran with a service-connected disability that results in the inability of the veteran to procreate without the use of fertility treatment, as well as the spouse of that veteran. The conference report accompanying this legislation makes clear that the implementing guidance developed by the Secretary shall not be materially different from, and in no way more expansive than, DoD's policy. Joint Explanatory Statement. 162 Congressional Record at S6011 (2016).

The Veterans' Health Care Eligibility Reform Act of 1996, Public Law 104-262, mandated that VA implement a national enrollment system to manage the delivery of healthcare services. A key component of managing delivery of healthcare services to eligible veterans is identifying the medical services provided by VA. The medical

benefits package, defining the medical services provided to all enrolled veterans by VA, is found at 38 CFR 17.38. VA may provide services under the medical benefits package that are determined by appropriate healthcare professionals to be needed to promote, preserve, or restore the health of the individual and to be in accord with generally accepted standards of medical practice.

As part of the medical benefits package, VA provides many different types of fertility treatments and procedures to veterans. 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. Most of the ART evaluation and treatment modalities offered by VA are consistent with DoD policy guidance. The exception is IVF. DoD offers IVF to servicemembers who have sustained serious or severe illness/injury while on active duty that led to the loss of their natural procreative ability, while IVF is excluded from VA's medical benefits package under § 17.38(c)(2). IVF is the process of fertilization by manually fertilizing an egg, and then transferring the embryo to the uterus. IVF is a common and medically accepted procedure for addressing infertility that cannot be overcome with other types of infertility treatment. Although we are not revising the medical benefits package itself, we are revising paragraph (c)(2) to add a note referencing the benefit available in § 17.380, as discussed below. We believe that this clarification will help veterans better understand the benefits available from VA.

Pursuant to Public Law 114-223 section 260, VA is adding new § 17.380 which states that IVF may be provided when clinically appropriate to a veteran who has a

service-connected disability that results in the inability of the veteran to procreate without the use of fertility treatment, as well as a spouse of such veteran. Per 38 U.S.C. 101(2), the term veteran means a person who served in the active military, naval, or air service, and who was discharged or released therefrom under conditions other than dishonorable. Under this provision, IVF services available to such veterans are the same as those provided by DoD to a member of the Armed Forces who incurs a serious injury or illness on active duty pursuant to 10 U.S.C. 1074(c)(4)(A), as described in DoD policy guidance, including any limitations on the amount of such benefits available to such a member. For the purposes of this section, “a service-connected disability that results in the inability of the veteran to procreate without the use of fertility treatment” means, for a male veteran, a service-connected injury or illness that prevents the successful delivery of sperm to an egg; and, for a female veteran with ovarian function and a patent uterine cavity, a service-connected injury or illness that prevents the egg from being successfully fertilized by a sperm. This definition parallels requirements in DoD policy guidance for an active duty service member who is seriously or severely ill/injured (Category II or III) to receive fertility counseling and treatment using ART.

Public Law 114-223 provides appropriations for FY 2017. The benefits authorized under section 260 are thereby limited to FY2017. Paragraph (b) of § 17.380 states that the authority to provide IVF to covered veterans under this section expires September 30, 2017. If the authority is extended, we will amend this section accordingly.

In addition, VA adds a new § 17.412. This new section states that VA may provide fertility counseling and treatment using ART 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 to the extent such services are available to enrolled veterans under the medical benefits package. It also states that VA may provide 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. Such health care services may be provided when clinically appropriate and consistent with the 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 DoD policy guidance. .

Paragraph (b) states that authority to provide fertility counseling and treatment including IVF to spouses of covered veterans under this section expires September 30, 2017. If the authority is extended we will amend this section accordingly.

DoD policy guidance addresses various issues including eligibility for ART, testing to predict fertility potential, infertility testing and treatment (including correction of the physical cause of infertility), provisions on the total number of IVF cycles that may be provided, and required processes and procedures. VA intends to issue policy and develop clinical guidelines consistent with DoD policy guidance.

Finally, we also revise the center heading immediately preceding § 17.410 to read “Hospital Care and Medical Services for Spouses and Families.” VA provides medical care to certain families of Camp LeJeune veterans under § 17.410, and the center heading referred to those services. The current rulemaking adds a new section immediately following § 17.410, and VA believes the center heading should be revised to avoid any confusion.

Administrative Procedure Act

In accordance with U.S.C. 553(b) (B) and (d)(3), the Secretary of Veterans Affairs has concluded that there is good cause to publish this rule as an interim final rule without prior opportunity for public comment and to publish this rule with an immediate effective date. As stated above, this rule makes IVF treatment available to certain veterans, and fertility counseling and treatment using ART to the spouses of those veterans. The Secretary finds that it is impracticable and contrary to the public interest to delay this rule for the purpose of soliciting advance public comment or to have a delayed effective date. This rulemaking will benefit those veterans and spouses most in need of ART services including IVF, and delay might cause a significant hardship for affected veterans and spouses. The Joint Theater Trauma Registry (JTTR) reflects the most common single cause of battle injuries is explosive devices (36.3%). Such trauma frequently results in genitourinary injury. For example, 1 in 5 warriors were evacuated from Operation Enduring Freedom (OEF) combat in October 2011 with a genitourinary injury. This increasingly common trauma can have catastrophic reproductive results. While the JTTR tracks combat trauma only for OEF and Operation Iraqi Freedom, genitourinary or spinal cord injury, or pelvic trauma related to combat injuries was also common in previous combat operations, and these injuries may make it impossible for affected veterans to procreate without the use of fertility treatment. In many cases ART, including IVF, is the only viable option for procreation. Further, since age is a factor in successful fertilization and completion of a pregnancy, rulemaking delay may result in some veterans or spouses losing fertility potential prior to a later effective date. In addition, this rulemaking will ensure that covered veterans leaving service at this time, and their spouses, will experience continuity of care when transferring from health care

provided by DoD to that provided by VA, with no difference in the level or types of available ART. For the above reason, the Secretary issues this rule as an interim final rule. VA will consider and address comments that are received within 60 days of the date this interim final rule is published in the Federal Register.

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 interim 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 this interim 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 interim final rule will directly affect 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 Order 12866 and 13563

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,” requiring review by the Office of Management and Budget (OMB), unless OMB waives such review, 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 this Executive Order.”

The economic, interagency, budgetary, legal, and policy implications of this regulatory action have been examined, and it has been determined not to be 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 Web site at <http://www.va.gov/orpm/>, by following the link for "VA Regulations Published From FY 2004 Through Fiscal Year to Date."

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 interim 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 64.007, Blind Rehabilitation Centers; 64.008, Veterans Domiciliary Care; 64.009, Veterans Medical Care Benefits; 64.010, Veterans Nursing Home Care; 64.011, Veterans Dental Care; 64.012, Veterans Prescription Service; 64.013, Veterans Prosthetic Appliances; 64.014, Veterans State Domiciliary Care;

64.015, Veterans State Nursing Home Care; 64.018, Sharing Specialized Medical Resources; 64.019, Veterans Rehabilitation Alcohol and Drug Dependence; 64.022, Veterans Home Based Primary Care; and 64.024, VA Homeless Providers Grant and Per Diem Program.

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.

Signing Authority

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. Gina S. Farrisee, Deputy Chief of Staff, Department of Veterans Affairs, approved this document on December 23, 2016, for publication.

Janet Coleman,

Chief,
Regulation Policy & Management,
Office of the Secretary,
Department of Veterans Affairs.

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

PART 17 – MEDICAL

1. The authority citation for part 17 is revised to read as follows:

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

Section 17.38 also issued under 38 U.S.C. 101, 501, 1701, 1705, 1710, 1710A, 1721, 1722, 1782, and 1786.

Sections 17.380 and 17.412 are also issued under sec. 260, Pub. L. 114-223, 130 Stat. 857.

Section 17.415 is also issued under 38 U.S.C. 7301, 7304, 7402, and 7403.

Sections 17.640 and 17.647 are also issued under sec. 4, Pub. L. 114-2, 129 Stat. 30.

Sections 17.641 through 17.646 are also issued under 38 U.S.C. 501(a) and sec. 4, Pub. L. 114-2, 129 Stat. 30.

2. Amend § 17.38 by:

- a. Revising paragraph (c)(2).
- b. Removing the sectional authority citation.

The revision reads as follows:

§ 17.38 Medical benefits package.

* * * * *

(c) * * *

(2) In vitro fertilization. Note: See § 17.380.

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3. Add an undesignated center heading and § 17.380 to read as follows:

In Vitro Fertilization Treatment

§ 17.380 In vitro fertilization treatment.

(a)(1) In vitro fertilization may be provided when clinically appropriate to -

(i) A veteran who has a service-connected disability that results in the inability of the veteran to procreate without the use of fertility treatment; and,

(ii) The spouse of such veteran, as provided in § 17.412.

(2) For the purposes of this section, "a service-connected disability that results in the inability of the veteran to procreate without the use of fertility treatment" means, for a male veteran, a service-connected injury or illness that prevents the successful delivery of sperm to an egg; and, for a female veteran with ovarian function and a patent uterine cavity, a service-connected injury or illness that prevents the egg from being successfully fertilized by sperm.

(3) In vitro fertilization treatment will be provided under this section when clinically appropriate and to the same extent such treatment is provided to a member of the Armed Forces who incurs a serious injury or illness on active duty pursuant to 10 U.S.C. 1074(c)(4)(A), as 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 to implement such policy, including any limitations on the amount of such benefits available to such a member.

(b) Authority to provide in vitro fertilization treatment to covered veterans under this section expires September 30, 2017.

4. Revise the undesignated center heading immediately preceding § 17.410 to read as follows:

Hospital Care and Medical Services for Spouses and Families

5. Add § 17.412 to read as follows:

§ 17.412 Fertility counseling and treatment for certain spouses.

(a)(1) VA may provide fertility counseling and treatment to a spouse of a veteran described in § 17.380 to the extent such services are available to a veteran under § 17.38, and consistent with the benefits relating to reproductive assistance provided to a member of the Armed Forces who incurs a serious injury or illness on active duty pursuant to 10 U.S.C. 1074(c)(4)(A), as 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 to implement such policy, including any limitations on the amount of such benefits available to such a member.

(2) VA may provide in vitro fertilization to a spouse of a veteran described in § 17.380 when clinically appropriate and consistent with the benefits relating to reproductive assistance provided to a member of the Armed Forces who incurs a serious injury or illness on active duty pursuant to 10 U.S.C. 1074(c)(4)(A), as 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 to implement such policy, including any limitations on the amount of such benefits available to such a member.

(b) Authority to provide fertility counseling and treatment, including in vitro fertilization under this section, expires September 30, 2017.

[FR Doc. 2017-00280 Filed: 1/18/2017 8:45 am; Publication Date: 1/19/2017]