

Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This proposed rule involves waterway use restrictions that would be otherwise published as a Temporary Final Rule within the Savannah Captain of the Port Zone. This rule is categorically excluded from further review under paragraph 34(g) of Figure 2–1 of the Commandant Instruction. A preliminary environmental analysis checklist supporting this determination and a Categorical Exclusion Determination are available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

#### List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 165 as follows:

#### PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

- 1. The authority citation for part 165 continues to read as follows:

**Authority:** 33 U.S.C. 1231; 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

- 2. Add § 165.732 to read as follows:

##### § 165.732 Safety Zone; Marine Safety Unit Savannah Safety Zone for Heavy Weather and other Natural Disasters, Savannah Captain of the Port Zone, Savannah, GA.

(a) *Regulated Areas*. The following areas are established as safety zones during the specified conditions:

(1) *Savannah, GA*. All waters within the Port of Savannah, GA, encompassed within following locations: starting at the demarcation line drawn across the seaward extremity of the Savannah River entrance, and encompassing all of the waters of the Savannah River, Savannah GA.

(2) *Brunswick, GA*. All waters starting at the demarcation line drawn across the seaward extremity of the Savannah River entrance, and encompassing all of the waters of the Brunswick River, Brunswick GA.

(3) All coordinates are North American Datum 1983.

##### (b) *Definition*.

(1) The term “designated representative” means Coast Guard Patrol Commanders, including Coast Guard coxswains, petty officers, and other officers operating Coast Guard vessels, and Federal, state, and local officers designated by or assisting the Captain of the Port Savannah in the enforcement of the regulated area.

(2) *Hurricane Port Condition YANKEE*. Set when weather advisories indicate that sustained Gale Force winds from a tropical or hurricane force storm are predicted to make landfall at the port within 24 hours.

(3) *Hurricane Port Condition ZULU*. Set when weather advisories indicate that sustained Gale Force winds from a tropical or hurricane force storm are predicted to make landfall at the port within 12 hours.

##### (c) *Regulations*.

(1) *Hurricane Port Condition YANKEE*. All commercial, oceangoing vessels and barges over 500 gross tons are prohibited from entering the regulated areas designated as being in Port Condition YANKEE; within 24 hours of anticipated landfall of gale force winds (39mph) from tropical or hurricane force storm; or upon the Coast Guard setting Port Condition YANKEE for inbound ocean going commercial vessel traffic over 500 GT. Oceangoing commercial vessel traffic outbound will be authorized to transit through the regulated areas until Port Condition ZULU.

(2) *Hurricane Port Condition ZULU*. All commercial, oceangoing vessels and barges over 500 gross tons are prohibited from entering the regulated areas designated as being in Port Condition ZULU; within 12 hours of anticipated landfall of a tropical storm or hurricane; or upon the Coast Guard setting Port Condition ZULU, unless written permission is obtained from the Captain of the Port. All ship-to-shore cargo operations must cease six hours prior to setting Port Condition Zulu.

(3) *Emergency Waterway Restriction for Other Disasters*. Any natural or other disasters that are anticipated to affect the Captain of the Port Savannah area of responsibility will result in the prohibition of commercial vessel traffic transiting or remaining in any of the two regulated areas predicted to be affected as designated by the Captain of the Port Savannah.

(4) Persons and vessels desiring to enter, transit through, anchor in, or remain in the regulated area may contact the Captain of the Port Savannah via telephone at (912) 247–0073, or a designated representative via VHF radio on channel 16, to request

authorization. If authorization to enter, transit through, anchor in, or remain in the regulated area is granted by the Captain of the Port Savannah or a designated representative, all persons and vessels receiving such authorization must comply with the instructions of the Captain of the Port Savannah or a designated representative.

(5) Coast Guard Marine Safety Unit Savannah will attempt to notify the maritime community of periods during which these safety zones will be in effect via Broadcast Notice to Mariners or by on-scene designated representatives.

(6) The Coast Guard will provide notice of the regulated area via Broadcast Notice to Mariners or by on-scene designated representatives.

(7) This regulation does not apply to authorized law enforcement agencies operating within the regulated area.

Dated: February 2, 2015.

**A.M. Beach,**

*Commander, U.S. Coast Guard, Captain of the Port Savannah.*

[FR Doc. 2015–04163 Filed 2–26–15; 8:45 am]

**BILLING CODE 9110–04–P**

#### DEPARTMENT OF VETERANS AFFAIRS

##### 38 CFR Part 4

RIN 2900–AP13

##### Schedule for Rating Disabilities; Gynecological Conditions and Disorders of the Breast

**AGENCY:** Department of Veterans Affairs.  
**ACTION:** Proposed rule.

**SUMMARY:** The Department of Veterans Affairs (VA) proposes to amend the portion of the VA Schedule for Rating Disabilities (VASRD or rating schedule) that addresses gynecological conditions and disorders of the breast. The purpose of these changes is to incorporate medical advances that have occurred since the last review, update current medical terminology, and provide clear evaluation criteria. The proposed rule reflects advances in medical knowledge, recommendations from the Gynecological Conditions and Disorders of the Breast Work Group (Work Group), which is comprised of subject matter experts from both the Veterans Benefits Administration (VBA) and the Veterans Health Administration (VHA), and comments from experts and the public gathered as part of a public forum. The public forum, focusing on revisions to the gynecological conditions and disorders of the breast section of the VASRD, was held on January 24, 2012.

**DATES:** Comments must be received on or before April 28, 2015.

**ADDRESSES:** Written comments may be submitted through [www.Regulations.gov](http://www.Regulations.gov); by mail or hand-delivery to Director, Regulation Policy and Management (02REG), Department of Veterans Affairs, 810 Vermont Avenue NW., Room 1068, Washington, DC 20420; or by fax to (202) 273-9026. Comments should indicate that they are submitted in response to “RIN 2900-AP13—Schedule for Rating Disabilities; Gynecological Conditions and Disorders of the Breast.” 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 [www.Regulations.gov](http://www.Regulations.gov).

**FOR FURTHER INFORMATION CONTACT:** Ioulia Vvedenskaya, Medical Officer, Part 4 VASRD Regulations Staff (211C), Compensation Service, Veterans Benefits Administration, Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420, (202) 461-9700. (This is not a toll-free telephone number.)

**SUPPLEMENTARY INFORMATION:** As part of VA’s ongoing revision of the VA Schedule for Rating Disabilities (VASRD or rating schedule), VA proposes changes to 38 CFR 4.116, which pertains to gynecological conditions and disorders of the breast. The proposed changes will: (1) Update the medical terminology of certain gynecological conditions and disorders of the breast, (2) add medical conditions not currently in the rating schedule, and (3) refine evaluation criteria based on medical advances that have occurred since the last revision and current understanding of functional changes associated with or resulting from disease or injury (pathophysiology).

#### **Schedule of Ratings—Gynecological Conditions and Disorders of the Breast**

Section 4.116 currently lists 19 diagnostic codes encompassing conditions involving injury or disease of female reproductive organs and of the breast. VA proposes to revise these codes, through addition, removal, or other revisions, to reflect current medical science and terminology, and functional impairment.

#### **Diagnostic Code 7610 “Vulva, disease or injury of (including vulvovaginitis)”**

Current diagnostic code 7610 addresses impairments associated with disease or injury of the vulva. The vulva refers to the exterior anatomical portion of the female genitalia and includes the clitoris. “Vulva,” Mayo Clinic, <http://www.mayoclinic.org/vulva/img-20005974> (last visited June 20, 2014). To provide clarity as to the applicability of this diagnostic code and to promote consistent and adequate evaluations, VA proposes to update the title of this diagnostic code to specifically include injury or disease of the clitoris, in addition to the vulva.

#### **Diagnostic Code 7615 “Ovary, disease, injury, or adhesions of”**

Current diagnostic code 7615 addresses impairments associated with disease, injury or adhesions of the ovaries. VA proposes to place a note under diagnostic code 7615 to identify two common diseases associated with ovarian dysfunction resulting in abnormal menstrual cycles: Dysmenorrhea and secondary amenorrhea. Dysmenorrhea is pain associated with menstruation and is the most commonly reported menstrual disorder. “Dysmenorrhea,” American College of Obstetricians and Gynecologists (July 2012), <http://www.acog.org/~media/For%20Patients/faq046.pdf?dmc=1&ts=20130904T1049007771> (last visited Jan. 21, 2014). Secondary amenorrhea occurs when a woman who has been having normal menstrual cycles stops menstruating for 6 or more months. Tarannum Master-Hunter & Diana L. Heiman, “Amenorrhea: Evaluation and Treatment,” 73 American Family Physician 1374, 1374-82 (2006). The proposed note will state that for the purpose of disability evaluation, a disease, injury, or adhesions of the ovaries resulting in ovarian dysfunction affecting the menstrual cycle, such as dysmenorrhea and secondary amenorrhea, shall be rated under diagnostic code 7615.

#### **Diagnostic Code 7619 “Ovary, removal of”**

Diagnostic code 7619, “Ovary, removal of,” addresses impairment associated with complete and partial removal of the ovaries. Service-connected complete removal of both ovaries is currently evaluated at 100 percent for the three months following removal and then 30 percent thereafter. With the continued expansion of women’s roles in military service, better understanding of the health effects on

women during and after service is essential. Women who suffer premature loss of function in both ovaries are at increased risk for cardiovascular disease, stroke, lung cancer, cognitive impairment or dementia, Parkinsonism, osteoporosis, depressive or anxiety symptoms, and sexual dysfunction. The risks appear to be greater for women who are younger at the time of premature loss of ovarian function. Studies have shown that even women who have both ovaries removed “after the onset of natural menopause had an increased risk of deleterious outcomes.” Lynne T. Shuster et al., “Prophylactic bilateral oophorectomy jeopardizes long-term health,” 18(4), American Society for Reproductive Medicine, Menopausal Medicine S1, S1-S5 (2010).

Currently, a male Veteran is entitled to a 30 percent evaluation for service-connected removal of one testicle when the second testicle, for reasons unrelated to service, is absent or ceases to function. 38 CFR 4.115b, Diagnostic Code 7524, Note. However, the current VASRD does not provide a similar evaluation for a female Veteran whose second ovary is absent or ceases to function for reasons unrelated to service. With consideration of the studies discussed above demonstrating the significant health risks from removal or loss of function of both ovaries, VA proposes to add a note to diagnostic code 7619 in order to equalize VA compensation for female Veterans.

#### **Diagnostic Codes 7621 “Uterus, prolapse,” 7622 “Uterus, displacement of,” and 7623 “Pregnancy, surgical complications of”**

Current diagnostic codes 7621 through 7623 address impairment associated with various degrees of female pelvic organ prolapse. Uterine prolapse is evaluated under current diagnostic code 7621, as either (1) complete uterine prolapse through the vagina and introitus at 50 percent, or (2) incomplete uterine prolapse at 30 percent. Uterine displacement is evaluated under current diagnostic code 7622, as either (1) marked uterine displacement and frequent or continuous menstrual disturbances at 30 percent, or (2) uterine displacement with adhesions and irregular menstruation at 10 percent. Finally, surgical complications of pregnancy are evaluated under current diagnostic code 7623, as either (1) with rectocele or cystocele at 50 percent, or (2) with relaxation of perineum at 10 percent.

To update VASRD, VA proposes to consolidate these three diagnostic codes into one diagnostic code. Specifically, VA proposes to amend diagnostic code

7621 to be titled, “Pelvic organ prolapse due to injury, disease, or surgical complications of pregnancy.” VA proposes this consolidation because all of these diagnostic codes represent different types of pelvic organ prolapse (displacement) and describe various degrees of their displacement to or beyond the vaginal walls. Furthermore, as discussed in more detail below, current medicine has a reliable classification system that provides for uniform evaluation of functional impairment due to pelvic organ prolapse (displacement), regardless of which pelvic organ is involved. Therefore, combining the evaluations currently found in diagnostic codes 7621 through 7623 would better reflect the current understanding of anatomy, physiology, and functional impairment due to disease or injury of pelvic organs. VA also proposes to place a note under diagnostic code 7621 that will describe pelvic organ prolapse and identify common types of prolapse, including uterine or vaginal vault prolapse, cystocele, urethrocele, rectocele, enterocele, or any combination. This note would assist field personnel in selecting the appropriate diagnostic code for these diagnosed conditions.

Currently, diagnostic codes 7621 and 7622 address uterine prolapse and uterine displacement, respectively; however, uterine displacement is just an outdated reference to uterine prolapse. Therefore, separate diagnostic codes are redundant and unnecessary. As for diagnostic code 7623, it provides for evaluation of pelvic organ displacement such as rectocele, cystocele, and relaxation of perineum when due to surgical complications of pregnancy. However, all of these pelvic organ displacements can occur independently from surgical complications of pregnancy. Therefore, an update to VASRD is needed to account for these situations.

This proposed revision is also necessary to eliminate disparate treatment of pelvic organ displacement found in the current VASRD. In this regard, rectocele or cystocele are rated under current diagnostic code 7623 without regard to the severity of the displacement (and, in turn, the symptoms associated with the displacement), whereas uterine prolapse and displacement (rated under diagnostic codes 7621 and 7622) are evaluated based on the degree of displacement.

Pelvic organs, such as the uterus, bladder or bowel, may protrude into the vagina due to weakness in the tissues that normally support them. In the most severe cases, part or all of the uterus or

vagina can protrude beyond the vaginal opening (introitus). Pelvic organ prolapse includes anterior vaginal wall prolapse (cystocele, urethrocele), posterior vaginal wall prolapse (enterocele, rectocele, perineal deficiency) and uterine or vaginal vault prolapse. A woman can present with prolapse of one or more of these sites. Christopher Maher et al., “Surgical management of pelvic organ prolapse in women,” *Cochrane Database of Systematic Reviews* (2010), <http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD004014.pub4/abstract> (last accessed Jan. 21, 2014). A woman’s symptoms are largely based on the severity of her prolapse. Women with mild cases of uterine prolapse may have no obvious symptoms or require no active intervention. However, as the uterus slips further out of normal position, it can place pressure on other pelvic organs (such as the bladder or bowel) causing a variety of symptoms such as a feeling of heaviness or pressure in the pelvis, pelvic pain, abdomen or lower back pain, pain during intercourse, a protrusion of tissue from the opening of the vagina, recurrent bladder infections, constipation, difficulty with urination or urinary frequency or urgency. G. Willy Davila et al., “Vaginal Vault Suspension” (updated Sept. 6, 2013), *Medscape*, <http://emedicine.medscape.com/article/1848619-overview#aw2aab6b9> (last accessed Jan. 21, 2014). Therefore, it is essential to identify the severity of any pelvic organ prolapse in order to determine the level of functional impairment.

To ensure consistent evaluation of pelvic organ prolapse, VA proposes to base its rating criteria on the pelvic organ prolapse (POP) classification system. POP presents the herniation of the pelvic organs to or beyond the vaginal opening (at the level of the hymen) and is described using the findings during pelvic examination. “Pelvic Organ Prolapse,” *American College of Obstetricians and Gynecologists Practice Bulletin*, Vol. 110, No. 3 (Sept. 2007). The severity of prolapse is graded using the standard Pelvic Organ Prolapse Quantification (POP-Q) classification system. The POP-Q examination is an objective, site-specific system that is used to quantify, describe, and stage pelvic support. The POP-Q system has proven interobserver and intraobserver reliability. A.F. Hall et al., “Interobserver and intraobserver reliability of the proposed International Continence Society, Society of Gynecologic Surgeons, and American

Urogynecologic Society pelvic organ prolapse classification system,” *175 Am J Obstet Gynecol* 1467, 1467–70 (1996).

As for the functional impairment associated with each stage of severity, VA proposes to assign a 50 percent evaluation in cases of severe pelvic organ prolapse, where on examination complete or almost complete eversion of the total length of the vagina is present, and the length of the protrusion beyond the hymen is within 2 centimeters of the total vaginal length. VA proposes to assign a 30 percent evaluation in cases of moderate prolapse, where on examination, the most severe portion of the prolapse is more than 1 centimeter below the hymen, but no further than 2 cm less than the total vaginal length. Finally, VA proposes to assign a 10 percent evaluation in cases of mild prolapse, where on examination, the most severe portion of the prolapse is between 1 cm or less above and 1 cm or more below the hymen.

VA also proposes to eliminate references to frequent or continuous menstrual disturbances, adhesions, and irregular menstruation as a measure of the degree of uterine displacement, because the symptoms noted are either outdated or adequately contemplated by the POP-Q system. For example, uterine displacement, also known as uterine prolapse, occurs when pelvic floor muscles and ligaments stretch and weaken and the uterus slips down into or protrudes out of the vagina. Minimal uterine prolapse generally does not require therapy or cause any impairment because the patient usually does not have any symptoms. However, uterine descent of the cervix at or through the vaginal opening (introitus) can become symptomatic. Symptoms of moderate and severe uterine prolapse include a sensation of vaginal fullness or pressure, back pain, vaginal spotting from ulceration of the protruding cervix or vagina, difficulty with sexual intercourse, lower abdominal discomfort, and voiding and difficulties with defecation. Typically, the patient feels a bulge in the lower vagina or the cervix protruding through the vaginal opening. Cystoceles, rectoceles, or enteroceles may cause symptoms commonly associated with pelvic organ prolapse and lead to patient complaints of difficulty with voiding or bowel movements, recurrent urinary infections, and/or “splinting” (manually supporting the perineum) to defecate. Cespedes RD, Cross CA, McGuire EJ., “Pelvic Prolapse: Diagnosing and Treating Uterine and Vaginal Vault Prolapse,” *1(3) MedGenMed* (1999). Menstrual abnormalities may occur in women with or without pelvic organ

prolapse, but there is usually no causal relationship or association. Therefore, the references to menstrual disturbances, irregular menstruation and adhesions as symptoms of uterine prolapse (displacement) should be removed, because they do not reflect current medical science and practice.

Finally, and as a consequence of this proposed consolidation, VA also proposes to delete current diagnostic codes 7622 “Uterus, displacement of” and 7623 “Pregnancy, surgical complications of” as the evaluation criteria are now contained in the proposed diagnostic code 7621.

**Diagnostic Codes 7627 “Malignant neoplasms of gynecological system or breast” and 7628 “Benign neoplasms of the gynecological system or breast”**

Current diagnostic codes 7627 and 7628 address impairment associated with malignant and benign neoplasms of the gynecological system and the breast. VA proposes to restructure the current rating criteria by separating the evaluations for impairments due to gynecological neoplasms from the evaluations for impairments due to breast neoplasms. This proposed separation keeps disability compensation data related to male breast cancer and non-cancerous tumors separate from disability compensation data related to gynecological neoplasms and also provides ease of use for disability rating specialists. Men possess a small amount of nonfunctioning breast tissue (breast tissue that cannot produce milk) that is concentrated in the area directly behind the nipple on the chest wall. Like breast cancer in women, cancer of the male breast is the uncontrolled growth of the abnormal cells of this breast tissue. Male breast cancer constitutes about 1 percent of all cases of breast cancers. “Male Breast Cancer,” National Cancer Institute—National Institutes of Health (Updated Sept. 19, 2013), <http://www.cancer.gov/cancertopics/pdq/treatment/malebreast/Patient/page1> (last accessed Jan. 21, 2014).

Therefore, VA proposes to retitle diagnostic code 7627 as, “Malignant neoplasms of gynecological system” and diagnostic code 7628 as, “Benign neoplasms of gynecological system.” Additionally, under diagnostic codes 7627 and 7628, VA proposes to clarify the existing note which instructs rating specialists to rate chronic residuals (following surgery or other treatments). Specifically, VA proposes to identify those chronic residuals commonly associated with treatment for neoplasms of the gynecological system, to include impairment of function due to scars,

lymphedema, or disfigurement, as well as to direct rating specialists to evaluate any other residual impairment of function, including gynecological, under appropriate diagnostic code(s) within the appropriate body system. The surgical management of gynecologic malignancies and benign diseases has evolved over the last decades. However, these sometimes complex procedures encompass radical pelvic and upper abdominal surgery, including associated urologic and intestinal procedures that may be required to remove the neoplasm. Oliver Zivanovic & Dennis Chi, “Surgical Resection and Reconstruction for Advanced and Recurrent Gynecologic Malignancies,” 3 Expert Rev. of Obstetrics & Gynecology 677, 677–690 (2008). Additionally, VA proposes a minor editorial revision of replacing the word “X-ray” with the word “radiation” as it pertains to therapeutic procedure to reflect a change in medical terminology.

Within this reorganization, VA also proposes to add two new diagnostic codes, 7630 “Malignant neoplasms of the breast” and 7631 “Benign neoplasms of the breast and other injuries of the breast” in order to account for impairment due to benign and malignant breast tumors (neoplasms) as well as other injuries to the breast not included elsewhere in the VASRD. This addition would allow VA to adequately evaluate and track disabilities due to benign breast neoplasms as well as other injuries, such as blast trauma. VA proposes to place two notes under diagnostic codes 7630 and 7631 to identify common chronic residuals associated with injuries of the breast and benign and malignant breast tumors and to instruct rating specialists to rate accordingly. Breast surgery is the most common choice of treatment for benign and malignant tumors of the breast and is an established risk factor for development of scars, lymphedema, or disfigurement. These chronic post-treatment residuals result in functional impairment such as limitation of arm, shoulder, and wrist motion, or loss of grip strength, or loss of sensation, or residuals from harvesting of muscles for reconstructive purposes. Angelique F. Vitug & Lisa A. Newman, “Complications in Breast Surgery,” 87 Surgical Clinics of North America 431, 431–451 (2007).

The proposed notes will therefore instruct rating specialists to rate chronic residuals according to impairment of function due to scars, lymphedema, or disfigurement (e.g., limitation of arm, shoulder, and wrist motion, or loss of grip strength, or loss of sensation, or residuals from harvesting of muscles for

reconstructive purposes), and/or under diagnostic code 7626, if appropriate. Again, no change to the existing evaluation criteria (found in current diagnostic codes 7627 and 7628) is proposed.

**New Diagnostic Code 7632 “Female sexual arousal disorder (FSAD)”**

VA proposes to add a new diagnostic code 7632, titled “Female sexual arousal disorder (FSAD),” in order to account for impairment due to this condition in the female Veteran population. FSAD refers to the continual or recurrent inability of a woman to accomplish or maintain an ample lubrication-swelling reaction during sexual intercourse. This lack of physical response may be either lifelong or acquired, and either generalized or situation-specific. FSAD is the second most common sexual health concern for women, affecting 26 percent of adult women. Emma Hitt, “Alprostadiol Shows Efficacy in Female Sexual Arousal Disorder” (May 25, 2012), Medscape, <http://www.medscape.com/viewarticle/764590> (last accessed Jan. 21, 2014). Current statistics show that FSAD affects an estimated 30 to 45 million women in the United States alone. Medscape Medical News, “Potential Drug Therapy for Female Sexual Dysfunction Presented” (June 28, 2000), Medscape, <http://www.medscape.com/viewarticle/411930> (last accessed Jan. 21, 2014). Clinical research shows that some aspects of FSAD are likely caused in part by decreased blood flow to the genital area. Therefore, poor genital blood flow is believed to contribute to FSAD similar to the role of vascular disease in male erectile dysfunction. Medscape Medical News, “New Approaches to Female Sexual Arousal Disorder” (May 31, 2001), Medscape, <http://www.medscape.com/viewarticle/434478> (last accessed Jan. 21, 2014). Although treatment of sexual dysfunction in men has been improved by currently marketed pharmaceuticals there are no US Food and Drug Administration (FDA) approved treatments for FSAD. FDA recently issued draft guidance for industry regarding clinical development of drug products for FSAD.

Currently, male Veterans with service connected penile deformity and loss of erectile power receive a 20 percent disability evaluation under diagnostic code 7522 and are eligible for special monthly compensation. In cases where there is no penile deformity present, but there is service connected loss of erectile power, VA’s policy is to evaluate male Veterans analogous to diagnostic code 7522, assigning a 0 percent rating; Eligibility for special

monthly compensation due to loss of use of a creative organ (SMC-K) is also considered. See 38 CFR 4.20 and 4.115b, Diagnostic Code 7522.

In order to ensure gender parity, VA proposes the creation of a new diagnostic code 7632 “Female sexual arousal disorder (FSAD).” There is no diagnostic code in current § 4.116 which allows for analogous rating of female sexual arousal disorder, to include consideration of special monthly compensation. Under proposed diagnostic code 7632, female Veterans with service connected FSAD but without physical damage to female genitalia would be evaluated at 0 percent with a note directing rating personnel to consider eligibility for special monthly compensation (SMC-K).

#### *Technical Amendments*

VA also proposes several technical amendments. We would add a citation reference to 38 U.S.C. 1155 at the end of § 4.116, and we would update Appendix A, B, and C of part 4 to reflect the above noted proposed amendments.

#### *Executive Orders 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 proposed rule 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 this 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.”

#### *Regulatory Flexibility Act*

The Secretary hereby certifies that this proposed rule would 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 proposed rule would not affect any small entities. Only certain VA beneficiaries could be directly affected. Therefore, pursuant to 5 U.S.C. 605(b), this rulemaking is exempt from the initial and final regulatory flexibility analysis requirements of sections 603 and 604.

#### *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 proposed rule would have no such effect on State, local, and tribal governments, or on the private sector.

#### *Paperwork Reduction Act*

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

#### *Catalog of Federal Domestic Assistance*

The Catalog of Federal Domestic Assistance program numbers and titles for this rule are 64.009, Veterans

Medical Care Benefits; 64.104, Pension for Non-Service-Connected Disability for Veterans; 64.109, Veterans Compensation for Service-Connected Disability; and 64.110, Veterans Dependency and Indemnity Compensation for Service Connected Death.

#### *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. Jose D. Riojas, Chief of Staff, Department of Veterans Affairs, approved this document on December 1, 2014, for publication.

#### **List of Subjects in 38 CFR Part 4**

Disability benefits, Pensions, Veterans.

Dated: February 20, 2015.

**William F. Russo,**

*Acting Director, Office of Regulation Policy & Management, Office of the General Counsel, U.S. Department of Veterans Affairs.*

For the reasons set out in the preamble, VA proposes to amend 38 CFR part 4 as follows:

#### **PART 4—SCHEDULE FOR RATING DISABILITIES**

■ 1. The authority citation for part 4 continues to read as follows:

**Authority:** 38 U.S.C. 1155, unless otherwise noted.

#### **Subpart B—Disability Ratings**

■ 2. Amend § 4.116 as follows:

- a. Revise the entry for diagnostic code 7610;
- b. Add a note at the end of the entries for diagnostic codes 7615 and 7619;
- c. Revise the entry for diagnostic code 7621;
- d. Remove the entries for diagnostic codes 7622 and 7623;
- e. Revise the entries for diagnostic codes 7627 and 7628;
- f. Add entries for diagnostic codes 7630 through 7632 in numerical order; and
- g. Add an authority citation at the end of the section.

The revisions and additions to read as follows:

**§ 4.116 Schedule of ratings—gynecological conditions and disorders of the breast.**

						Rating
	*	*	*	*	*	*
7610	Vulva or clitoris, disease or injury of (including vulvovaginitis).					
	*	*	*	*	*	*
7615	***					
	<b>Note:</b> For the purpose of VA disability evaluation, a disease, injury, or adhesions of the ovaries resulting in ovarian dysfunction affecting the menstrual cycle, such as dysmenorrhea and secondary amenorrhea, shall be rated under diagnostic code 7615.					
	*	*	*	*	*	*
7619	***					
	<b>Note:</b> In cases of the removal of one ovary as the result of a service-connected injury or disease, with the absence or non-functioning of a second ovary unrelated to service, an evaluation of 30 percent will be assigned for the service-connected ovarian loss.					
	*	*	*	*	*	*
7621	Pelvic organ prolapse due to injury, disease, or surgical complications of pregnancy.					
	Severe prolapse: Complete or almost complete eversion of the total length of the vagina shown on examination, with the length of the protrusion (or prolapse) extending beyond the hymen within 2 cm of total vaginal length .....					50
	Moderate prolapse: On examination the most severe portion of the prolapse is more than 1 cm below the hymen, but protrudes no further than 2 cm less than the total vaginal length .....					30
	Mild prolapse: On examination the most severe portion of the prolapse is between 1 cm or less above the hymen and 1 cm or more below the hymen .....					10
	<b>Note:</b> Pelvic organ prolapse occurs when a pelvic organ such as bladder, urethra, uterus, vagina, small bowel, or rectum drops (prolapse) from its normal place in the abdomen. Conditions associated with pelvic organ prolapse include: Uterine or vaginal vault prolapse, cystocele, urethrocele, rectocele, enterocele, or any combination thereof.					
	*	*	*	*	*	*
7627	Malignant neoplasms of gynecological system .....					100
	<b>Note:</b> A rating of 100 percent shall continue beyond the cessation of any surgical, radiation, antineoplastic chemotherapy or other therapeutic procedures. Six months after discontinuance of such treatment, the appropriate disability rating shall be determined by mandatory VA examination. Any change in evaluation based upon that or any subsequent examination shall be subject to the provisions of §3.105(e) of this chapter. Rate chronic residuals to include scars, lymphedema, disfigurement, and/or other impairment of function under the appropriate diagnostic code(s) within the appropriate body system.					
7628	Benign neoplasms of gynecological system. Rate chronic residuals to include scars, lymphedema, disfigurement, and/or other impairment of function under the appropriate diagnostic code(s) within the appropriate body system.					
	*	*	*	*	*	*
7630	Malignant neoplasms of the breast .....					100
	<b>Note:</b> A rating of 100 percent shall continue beyond the cessation of any surgical, radiation, antineoplastic chemotherapy or other therapeutic procedure. Six months after discontinuance of such treatment, the appropriate disability rating shall be determined by mandatory VA examination. Any change in evaluation based upon that or any subsequent examination shall be subject to the provisions of §3.105(e) of this chapter. Rate chronic residuals according to impairment of function due to scars, lymphedema, or disfigurement (e.g., limitation of arm, shoulder, and wrist motion, or loss of grip strength, or loss of sensation, or residuals from harvesting of muscles for reconstructive purposes), and/or under diagnostic code 7626.					
7631	Benign neoplasms of the breast and other injuries of the breast. Rate chronic residuals according to impairment of function due to scars, lymphedema, or disfigurement (e.g., limitation of arm, shoulder, and wrist motion, or loss of grip strength, or loss of sensation, or residuals from harvesting of muscles for reconstructive purposes), and/or under diagnostic code 7626.					
7632	Female sexual arousal disorder (FSAD) .....					10

<sup>1</sup> Review for entitlement to special monthly compensation under § 3.350 of this chapter.

(Authority: 38 U.S.C. 1155)

■ 3. Amend Appendix A to Part 4 as follows:

- a. At Sec. 4.116, revise the entries for diagnostic codes 7610, 7615, 7619, 7621, 7622, 7623, 7627, and 7628; and
- b. At Sec. 4.116, add entries for diagnostic codes 7630 through 7632 in numerical order.

The revisions and additions to read as follows:

**Appendix A to Part 4—Table of Amendments and Effective Dates Since 1946**

Sec.	Diagnostic code No.					
		*	*	*	*	*
4.116.		*	*	*	*	*
		*	*	*	*	*

7610 Criterion May 22, 1995; title [effective date of final rule].

Sec.	Diagnostic code No.						
*	7615	Criterion May 22, 1995; note [effective date of final rule].	*	*	*	*	*
*	7619	Criterion May 22, 1995; note [effective date of final rule].	*	*	*	*	*
*	7621	Criterion May 22, 1995; evaluation [effective date of final rule].	*	*	*	*	*
	7622	Removed [effective date of final rule].					
	7623	Removed [effective date of final rule].					
*	7627	Criterion March 10, 1976; criterion May 22, 1995; title, note [effective date of final rule].	*	*	*	*	*
	7628	Added May 22, 1995; title, criterion [effective date of final rule].					
*	7630	Added [effective date of final rule].	*	*	*	*	*
	7631	Added [effective date of final rule].					
	7632	Added [effective date of final rule].					

■ 4. Amend Appendix B to Part 4 as follows:  
 ■ a. Revise the entries for diagnostic codes 7610, 7621, 7627, and 7628; and

■ b. Add entries for diagnostic codes 7630 through 7632 in numerical order. The revisions and additions to read as follows:

**Appendix B to Part 4—Numerical Index of Disabilities**

Diagnostic code No.							
<b>Gynecological Conditions and Disorders of the Breast</b>							
7610	.....	Vulva or clitoris, disease or injury of (including vulvovaginitis).	*	*	*	*	*
7621	.....	Pelvic organ prolapse due to injury or disease or surgical complications of pregnancy.	*	*	*	*	*
7627	.....	Malignant neoplasms of gynecological system.	*	*	*	*	*
7628	.....	Benign neoplasms of gynecological system.	*	*	*	*	*
7630	.....	Malignant neoplasms of the breast.	*	*	*	*	*
7631	.....	Benign neoplasms of the breast and other injuries of the breast.	*	*	*	*	*
7632	.....	Female sexual arousal disorder (FSAD).	*	*	*	*	*

■ 5. Amend Appendix C to Part 4 as follows:  
 ■ a. Add in alphabetical order the heading “Female sexual arousal disorder (FSAD)” and its diagnostic code “7632”.  
 ■ b. Under the heading “Injury” add in alphabetical order new entry “Breast” and its diagnostic code “7631”.  
 ■ c. Under the heading “Neoplasms: Benign:” add in alphabetical order an entry “Breast” and its diagnostic code “7631”.

■ d. Under the heading “Neoplasms: Benign:” remove “Gynecological or breast” and in its place add the entry “Gynecological”.  
 ■ e. Under the heading “Neoplasms: Malignant:” add in alphabetical order new entry “Breast” and its diagnostic code “7630”.  
 ■ f. Under the heading “Neoplasms: Malignant:” remove “Gynecological or breast” and in its place add the entry “Gynecological”.

■ g. Add in alphabetical order the heading “Pelvic organ prolapse due to injury or disease or surgical complications of pregnancy, including uterine or vaginal vault prolapse, cystocele, urethrocele, rectocele, enterocele, or combination” and its diagnostic code “7621”.  
 ■ h. Remove the heading “Pregnancy, surgical complications” and its diagnostic code “7623”.

■ i. Under the heading “Uterus” remove the entry “Displacement” and its diagnostic code “7622”.

■ j. Remove the heading “Vulva disease or injury of” and add in its place “Vulva or clitoris, disease or injury of”.

The additions and revisions to read as follows:

**Appendix C to Part 4—Alphabetical Index of Disabilities**

	Diagnostic code No.
Female sexual arousal disorder (FSAD) .....	7632
Injury:	
Breast .....	7631
Neoplasms:	
Benign:	
Breast .....	7631
Gynecological .....	7628
Malignant:	
Breast .....	7630
Gynecological .....	7627
Pelvic organ prolapse due to injury or disease or surgical complications of pregnancy, including uterine or vaginal vault prolapse, cystocele, urethrocele, rectocele, enterocele, or combination .....	7621
Vulva or clitoris, disease or injury of .....	7610

[FR Doc. 2015-03851 Filed 2-26-15; 8:45 am]

BILLING CODE 8320-01-P

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 52**

[EPA-R05-OAR-2012-0991; EPA-R05-OAR-2013-0435; FRL-9923-43-Region 5]

**Approval and Promulgation of Air Quality Implementation Plans; Indiana; Infrastructure SIP Requirements for the 2010 NO<sub>2</sub> and SO<sub>2</sub> NAAQS**

**AGENCY:** Environmental Protection Agency.

**ACTION:** Proposed rule.

**SUMMARY:** The Environmental Protection Agency (EPA) is proposing to approve elements of state implementation plan (SIP) submissions from Indiana regarding the infrastructure requirements of section 110 of the Clean Air Act (CAA) for the 2010 nitrogen dioxide (NO<sub>2</sub>) and sulfur dioxide (SO<sub>2</sub>) National Ambient Air Quality Standards

(NAAQS). The infrastructure requirements are designed to ensure that the structural components of each state’s air quality management program are adequate to meet the state’s responsibilities under the CAA.

**DATES:** Comments must be received on or before March 30, 2015.

**ADDRESSES:** Submit your comments, identified by Docket ID No. EPA-R05-OAR-2012-0991 (2010 NO<sub>2</sub> infrastructure SIP elements) and Docket ID No. EPA-R05-OAR-2013-0435 (2010 SO<sub>2</sub> infrastructure SIP elements) by one of the following methods:

1. *www.regulations.gov*: Follow the on-line instructions for submitting comments.
2. *Email*: [aburano.douglas@epa.gov](mailto:aburano.douglas@epa.gov).
3. *Fax*: (312) 408-2279.
4. *Mail*: Douglas Aburano, Chief, Attainment Planning and Maintenance Section, Air Programs Branch (AR-18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604.
5. *Hand Delivery*: Douglas Aburano, Chief, Attainment Planning and

Maintenance Section, Air Programs Branch (AR-18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604. Such deliveries are only accepted during the Regional Office normal hours of operation, and special arrangements should be made for deliveries of boxed information. The Regional Office official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

*Instructions:* Direct your comments to Docket ID. EPA-R05-OAR-2012-0991 and EPA-R05-OAR-2013-0435. EPA’s policy is that all comments received will be included in the public docket without change and may be made available online at [www.regulations.gov](http://www.regulations.gov), including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through [www.regulations.gov](http://www.regulations.gov) or email. The