DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 17

RIN 2900–AQ65

Transplant Procedures With Live Donors and Related Care and Services

AGENCY: Department of Veterans Affairs.

ACTION: Proposed rule.

SUMMARY: The Department of Veterans Affairs (VA) proposes to amend its medical regulations to implement legislation providing it stand-alone authority to provide surgical procedures to remove a solid organ or bone marrow from a live donor for transplantation into a veteran and to furnish the live donor any care or services before and after the surgical procedure required in connection with the veteran's transplantation procedure. This rulemaking would implement the mandates of section 153 of the VA MISSION Act of 2018.

DATES: Comments must be received on or before May 24, 2021.

ADDRESSES: Comments may be submitted through *www.Regulations.gov.* Comments received will be available at *regulations.gov* for public viewing, inspection or copies.

FOR FURTHER INFORMATION CONTACT: Mani Murugavel, DNP, NE–BC, CSSGB, RN, National Director, Clinical Services, National Surgery Office (10NC2), Veterans Health Administration, 810 Vermont Avenue NW, Washington, DC 20420, (202) 461–7130. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: VA provides eligible veterans complete medical and hospital services as authorized in chapters 17 and 73 of title 38, United States Code (U.S.C.). Consistent with that authority, VA has administered the VA transplant program to provide eligible veterans timely, high-quality care and treatment.

Moreover, VA transplant programs are members of the Organ Procurement and Transplantation Network (OPTN) established by section 372 of Public Law (Pub. L.) 98–507 (1984), as amended, and codified at 42 U.S.C. 274. The regulatory scheme in part 121 of title 42, Code of Federal Regulations (CFR) governs OPTN operations, and the provisions of section 373 of Public Law 98–507 (codified at 42 U.S.C. 274a) require the operation of a Scientific Registry (''Registry'') to allow for an ongoing evaluation of the scientific and clinical status of solid organ transplantation. Approved transplant programs must thus report specified data to the Registry. Admission to and membership in the OPTN is governed by 42 CFR 121.3; the provisions of 42 CFR 121.9 establish the requirements for OPTN-designated transplant programs and expressly include VA transplant programs. *Id.* at § 121.9(a)(3). The OPTN Board of Directors is charged with developing policies that are enforceable once approved by the Secretary of Health and Human Services. *Id. at* § 121.4. Compliance with OPTN rules and policies by designated transplant programs is required by 42 CFR 121.10. VA designated transplant programs comply with approved and applicable OPTN by-laws and policies. In addition, clinical standards of care and patient safety standards apply to VA's delivery of care, including transplant care.

Section 153 of Public Law 115–182, the John S. McCain III, Daniel K. Akaka, and Samuel R. Johnson VA Maintaining Internal Systems and Strengthening Integrated Outside Networks Act of 2018, or the VA MISSION Act of 2018 (June 6, 2018), as amended, Public Law 115–251 (Sep. 29, 2018) added section 1788 to title 38, United States Code. It codified and clarified VA's authority to provide a person a surgical procedure to remove a solid organ, part of a solid organ, or bone marrow (including peripheral blood stem cells) to donate to, and transplant into, an intended veteran-recipient (hereinafter referred to as ''intended recipient''). It clarifies that a person is eligible for the surgical procedure even if not otherwise eligible for VA health care. This law also requires VA to furnish the person with any care and services required in connection with the intended recipient's transplantation procedure. This can include non-medical care and services. It also authorizes VA to provide these benefits through agreements with community providers.

Prior to enactment of 38 U.S.C. 1788, VA had long deemed live donor care and services to be integral and medically necessary to the treatment of veterans who are eligible for a transplantation procedure under our general treatment authority. 38 U.S.C. 1710 (authorizing the provision of medically needed treatment). VA, through its OPTN-designated transplant programs, therefore provided surgical procedures for a person otherwise ineligible for VA health care to obtain a solid organ, part of a solid organ, or bone marrow, as well as providing pre- and post-surgical care and services. This included limited follow-up as specified and required by OPTN policy. VA also invoked available purchased care authorities when necessary to obtain community care for live donors. New section 1788 provides stand-alone authority to treat live donors, directly or through community providers. (VA previously relied on its general treatment authority to provide live donor care, which was clinically deemed to be integral to the transplant treatment of the Veteran.)

This proposed rule would establish new 38 CFR 17.395 to implement the mandates of section 1788, as added by the VA MISSION Act of 2018, as amended. We interpret section 1788 to remove perceived obstacles to donating a solid organ, part of a solid organ, or bone marrow. For instance, some prospective live donors fear being held financially responsible for the cost of their live donor care, including pre- or post-evaluations and care, or not being followed-up after they participate in the transplant procedure. This regulation addresses these concerns, helping us to address our ultimate objective: To help veteran-transplant candidates receive a solid organ, part of a solid organ, or bone marrow from a live donor. H.R. Rep. No. 115–671, pt. 1, at 15 (2018).

Initially, we note that section 1788 states, in subsection (a), that VA may ''provide for'' an operation of a live donor as specified therein, but in subsection (b), it states that, with respect to a live donor receiving an operation under subsection (a), VA shall ''furnish'' any care or services before and after conducting the transplant procedure that may be required in connection with the veteran's transplant procedure. We find the difference in wording (''provide for'' vs. ''furnish'') to be a distinction without a difference. The proposed regulation would therefore use ''provide'' throughout regardless if the operation or the care and services are provided within VA or in the community.

Proposed paragraph (a) would be titled ''Scope.'' It would inform the reader that the section provides for medical and non-medical care and services of persons who volunteer to donate a solid organ, part of a solid organ, or bone marrow for transplantation into an eligible veteran transplant candidate, irrespective of a donor's eligibility to receive VA health care for any reason other than to donate a solid organ, part of a solid organ, or bone marrow. It further explains that this section prescribes the type, timing, and duration of hospital care and medical services VA provides, including medical care or services purchased by agreement from a non-VA facility. It also provides for non-medical care and services essential to the prospective live donor's or the live donor's participation

and for VA reimbursement for that care and services. It clarifies that the section does not provide VA medical benefits for eligible veteran transplant candidates.

Proposed paragraph (b) would be titled ''Definitions'' and would define terms for this section. In general, it includes the terms that describe the individuals who may volunteer to donate or are donating a solid organ, part of a solid organ, or bone marrow, and the veterans who receive them throughout the course of the donation process (up through the period of a live donor's follow-up after the organ donation procedure). Two of the terms, ''kidney paired donation'' and ''live donor follow-up'', describe processes within the broader process of organ donation and transplantation. Although we propose to list the terms alphabetically in the regulation, we will describe the terms by like topics for clarity here.

The term ''prospective live donor'' would be defined as a person who has volunteered to donate a solid organ, part of a solid organ, or bone marrow, to an intended recipient, and who has agreed to participate in any activity VA deems necessary to carry out the intended recipient's transplant procedure. For example, a person who completes and submits a medical history or takes any other first step in the sequence of events potentially leading to their donation of a solid organ, part of a solid organ, or bone marrow would be a prospective live donor. A person would be considered a prospective live donor from the time the person volunteers to donate a solid organ, part of a solid organ, or bone marrow, through the screening process to determine whether the person is a match to the intended recipient.

The term ''live donor'' would be defined to comport with OPTN policy(ies) as an individual who is: (1) Medically suitable for donation; (2) is a compatible match to an identified transplant candidate; and (3) has provided informed consent to undergo elective removal of one solid organ, part of a solid organ, or of bone marrow. Therefore, the individual would be considered a live donor after it has been determined that the individual is medically suitable for donation, is a match to the intended recipient, and the individual has provided informed consent to donate. OPTN policy requires that a medical evaluation of the live donor be performed by the recovery hospital (*i.e.,* the hospital at which the recovery of the organ from the live donor will take place) and by a physician or surgeon experienced in living donation. Organ Procurement and Transplantation Network, Policy 14: Living Donation. U.S. Department of Health and Human Services, Health Resources and Services Administration. Retrieved from: *https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf* (Accessed: 12 March 2020). This evaluation includes general donor history, general family history, social history, physical exam, general laboratory and imaging tests, and additional screenings. *Id.* This leads to a determination as to whether the live donor is a compatible match to the identified transplant candidate. OPTN policy also requires informed consent be obtained from the live donor prior to organ recovery. *Id.* Pursuant to OPTN policy, the recovery hospital and evaluating physician or surgeon are responsible for compliance with OPTN policies for live donor selection. *Id.* The determination of whether an individual meets the definition of ''live donor'' involves clinical determinations that VA will not challenge when made by a provider in the community.

These clinical determinations can be made by either VA or the community provider, and will depend on the particular circumstances of the donation process. Thus, we would not define in the regulation who makes these determinations that an individual meets this proposed definition of ''live donor.''

We would define the term ''live donor follow-up'' to comport with OPTN policy(ies) and applicable standards of care and patient safety standards for the follow-up of live donors of solid organs as: For live donors of a solid organ or part of a solid organ, the collection of clinically relevant post-donation live donor data and the provision of recommended clinical laboratory tests and evaluations consistent with OPTN policy; and the provision of direct medical care required to address reasonably foreseeable donor health complications resulting directly from the donation procedure. Examples of clinically relevant post-donation living donor data would include physical capacity, current weight, and kidney function. Examples of provision of recommended clinical laboratory tests and evaluations would include serum creatinine and urine protein. Examples of direct medical care required would include treatment of an incisional hernia or infection related to the donation procedure.

To clarify, OPTN policy requires reporting of these data and related outcomes to help ensure donor safety and well-being. These data also help transplant centers provide information to future donors on risks and health consequences of donation. (Organ Procurement and Transplantation Network: Procedures to collect post-donation follow-up data from living donors. U.S. Department of Health and Human Services, Health Resources and Services Administration. Retrieved from *https://optn.transplant.hrsa.gov/resources/guidance/procedures-to-collect-post-donation-follow-up-data-from-living-donors/* (Accessed: 22 January 2020)). The goal of follow-up is, thus, to promote positive donor outcomes and thereby encourage further voluntary donations in an ''atmosphere of safety.'' *Ibid.*

We would define ''live donor follow-up'' for live donors of bone marrow as: For live donors of bone marrow, the provision of direct medical care required to address reasonably foreseeable donor health complications resulting directly from the donation procedure. We define this follow-up differently from follow-up for solid organ and part of a solid organ donors because bone marrow donors typically need far less follow-up than donors of solid organs. The OPTN does not regulate bone marrow transplantation and therefore does not require live donors of bone marrow to be followed for data and medical monitoring after donation as it does for solid organ donors. VA would nonetheless afford bone marrow donors follow-up care directly related to the bone marrow donation for a period not greater than two years, as explained in proposed paragraph (c)(4). We note that during this period of follow-up care, VA would collect data on the outcome of the bone marrow transplant. This is necessary because of data reporting requirements, such as reporting of adverse outcomes, with which VA must comply.

The term ''initial prospective live donor'' would be defined as the intended recipient's prospective live donor who volunteers to donate a kidney to a recipient other than the intended recipient through kidney paired donation. To clarify, the initial prospective live donor would be an individual who agrees to participate in a kidney paired donation exchange so the transplant candidate to whom a prospective live donor sought to donate a kidney will be eligible to receive a kidney from another person through a kidney paired donation exchange.

The initial prospective live donor might know upon volunteering that he or she will not match the intended recipient, or evaluation might reveal the initial prospective live donor and the intended recipient do not match. The intended recipient's initial prospective live donor would nonetheless provide a

kidney for kidney paired donation. Kidney paired donation is often not a direct swap. A series of persons might each provide a kidney for kidney paired donation. In due course, the initial prospective live donor's intended recipient would receive a matching kidney.

The term ''kidney paired donation'' would be defined as one prospective live donor's voluntary donation of a kidney for transplantation into a recipient other than an intended recipient, paired with the transplantation into the intended recipient of a compatible kidney from a different live donor.

The term ''transplant candidate'' would be defined as an enrolled veteran or a veteran otherwise eligible for VA's medical benefits package who VA determines has a medical need for a solid organ, part of a solid organ, or bone marrow transplant.

The term ''intended recipient'' would be defined as the transplant candidate who VA identifies to receive a live donor's solid organ, part of a solid organ, or bone marrow.

The term ''transplant recipient'' would be defined as a transplant candidate who has undergone transplantation and received a solid organ, part of a solid organ, or bone marrow from a live donor.

Proposed paragraph (c) would be titled ''Hospital care and medical services'' and would establish the types of hospital care and medical services VA would provide a prospective live donor or a live donor.

Paragraph (c)(1) would describe the types and purposes of hospital care and medical services VA would provide to a prospective live donor prior to the surgical removal of the solid organ, part of a solid organ, or bone marrow. In particular, VA would provide examinations, tests, and studies necessary to qualify a prospective live donor to donate a solid organ, part of a solid organ, or bone marrow. This typically includes initial screening, blood tests, physical examination, psychological evaluation, informed consent, and final evaluation.

Paragraph (c)(2) would describe the type and purpose of hospital care and medical services VA would provide the live donor during the period of the removal of the solid organ, part of a solid organ, or bone marrow. In particular, VA would provide the surgical procedure to remove a solid organ, part of a solid organ, or bone marrow from the living donor whose solid organ, part of a solid organ, or bone marrow will be transplanted into an intended recipient. This includes the care and services required to meet the immediate preoperative and postoperative standards of care and patient safety standards appropriate to the specific procedure. This surgical procedure would be limited to that required for the donor transplant procedure. For example, it would exclude any surgical procedure to treat a disease inadvertently discovered during the surgical procedure to remove the organ or bone marrow.

Paragraph (c)(3) would describe the type and purpose of follow-up that VA would provide a live donor of a solid organ or part of a solid organ after the surgical procedure. It would qualify the type of follow-up as all hospital care, medical services, and other services which are ''necessary and appropriate.'' The care and service provided would be as described in the definition of ''Live donor follow-up'' In paragraph (b). In addition, it would define the period of follow-up to be a period not less than that which the Organ Procurement and Transplantation Network prescribes or recommends or for a period of 2 years, whichever is greater. The OPTN-established period for live donor follow-up is expected to capture any complications associated with a live donor's participation in a solid organ transplant procedure. VA therefore believes that this is sufficient time to ensure proper follow-up.

Paragraph (c)(4) would describe the follow-up of bone marrow donors, which is less extensive than for live donors of a solid organ or part of a solid organ. VA has no protocol, requirement, or recommendation from OPTN for the follow-up of bone marrow donors. Donation of bone marrow is different from donation of a solid organ or part of a solid organ because the donor's bone marrow regenerates and replaces itself. In this sense, bone marrow donation is like blood donation, for which there is also no follow-up, because of the body's ability to regenerate and replace the lost blood volume. Effects of donation such as pain at the site of the bone marrow extraction or fatigue are minimal and resolve within a short time. This approach is aligned with community standards, as neither OPTN nor applicable standards of care or patient safety standards provide for the follow-up of bone marrow donors. Nonetheless, under proposed paragraph (c)(4), VA would provide direct medical care required to address reasonably foreseeable live donor health complications resulting directly from the bone marrow donation procedure for a period not greater than 2 years.

Proposed paragraph (c)(5) would clarify the legal authority that applies to care and services provided under paragraphs (c)(1) through (4) for a prospective live donor or a live donor who is also a veteran enrolled in VA's health care system. We note that a prospective live donor who also happens to be a veteran enrolled in VA's health care system would receive care and services authorized in paragraphs (c)(1) and (c)(2) only under this section, not as part of VA's medical benefits package available to enrollees pursuant to 38 CFR 17.38. These health care benefits are outside the scope of VA's treatment authority in section 1710, as implemented by the medical benefits package codified at 38 CFR 17.38, because they are not medically necessary. Serving as a prospective live donor is voluntary and not based on the medical needs of the prospective live donor; rather, it furthers only the necessary medical needs of the intended recipient. For live donors who are also veterans enrolled in VA's health care system, the care and services authorized under paragraphs (c)(1) and (c)(2) are not medically necessary for the live donor, as stated above; however, after they undergo the transplant operation or procedure, we believe they will have their own medical needs apart from those of the transplant recipient. We therefore think it necessary to provide a live donor who is enrolled in VA's health care system the option to receive care and services authorized under paragraphs (c)(3) and (c)(4) as an enrolled veteran, if desired. Proposed paragraph (c)(5) would therefore provide that a live donor who is also an enrollee may opt to receive his or her care and services authorized under paragraph (c)(3) under either the medical benefits package in § 17.38 of this chapter or under this section, but not both at the same time. Similarly, proposed paragraph (c)(5) would also state that a live donor who is also an enrollee may opt to receive his or her care and services authorized under paragraph (c)(4) under either the medical benefits package in § 17.38 or under this section, but not both at the same time. To clarify, the live donor may opt to receive the benefits authorized in paragraphs (c)(3) and (c)(4) only under one authority, as combining them would not be feasible. We note that, upon request, VA would explain the benefit implications for the veteran under each program, such as the difference in travel and lodging benefits. In either case, however, the follow-up of a live donor would terminate per the terms of this program.

Proposed paragraph (d) of this section would be titled ''Non-hospital care and non-medical services'' and would describe the costs of non-hospital care and non-medical services for which VA may reimburse the prospective live donor or live donor. (This benefit is wholly separate from veteran beneficiary travel benefits under 38 U.S.C. 111.) Section 1788(b) provides for VA to ''furnish'' a live donor any care or services before and after the veteran's transplantation procedure required in connection with that procedure.

We note that 38 U.S.C. 1788(b) provides broad authority for VA to furnish to a live donor any care or services before and after conducting the transplant procedure that may be required in connection with such procedure. As explained in the subsequent paragraph, VA believes that reimbursing live donors for travel costs, including temporary lodging as VA determines to be needed, is appropriate. However, VA takes this opportunity to invite public comment on whether VA should consider paying for other non-hospital care and non-medical services.

VA believes reimbursement for travel costs, including temporary lodging as appropriate, may be required for a prospective live donor or live donor and a needed attendant or support person. VA has authority to reimburse these travel costs under 38 U.S.C. 1788(b). Section 1788(b) does not, however, specify reimbursement rates or limitations. Because VA has an established travel reimbursement program for veterans, see 38 CFR part 70, we would identify the modes of travel and payment principles and derive the rates of travel reimbursement for travel and temporary lodging from 38 CFR 70.30 as set forth in paragraph (d) of the proposed regulation. The deductibles set forth in § 70.31 would not apply regardless of whether the donor or other traveler is a veteran or a non-veteran. Imposing the deductible would be contrary to the purposes of section 1788; that is, it would impose a barrier to participation, and so VA would not reduce the travel reimbursement of a prospective live donor or live donor who happens to be a veteran and who is not traveling as a veteran. Taxes associated with temporary lodging would be reimbursed to the extent and consistent with the manner in which VA covers such expenses under 38 CFR 70.30. Prospective live donors and live donors would also not be subject to eligibility or any other criteria of 38 CFR part 70.

Proposed paragraph (d)(1) would provide that, if VA determines the prospective live donor's or live donor's presence or proximity is necessary, VA would reimburse the travel costs of the prospective live donor or live donor and, if applicable, one needed attendant or support person, for travel between the prospective live donor's or live donor's residence and the site of the hospital care or medical services authorized in proposed paragraph (c). While there may be instances when VA contracts with providers in the community for the transplant procedure, VA would retain the authority to make the determination as to whether the prospective live donor's or live donor's presence or proximity is necessary. This would ensure consistency across the country in administering these benefits and this program and would ensure that there are no unauthorized commitments made by non-VA providers, as this determination can lead to reimbursement for travel costs related to the transplant procedure. It would thus be fiscally responsible for VA to retain this authority. In determining whether the prospective live donor's or live donor's presence or proximity is necessary, VA would obtain and consider input from the transplant care team, including the provider responsible for the intended recipient's transplant procedure, the provider responsible for the prospective live donor's or live donor's donation procedure, and a VA transplant specialist not participating in the care of the recipient, as indicated. This would be consistent with OPTN policies that focus on donor advocacy and on having decisions related to the donor not be solely directed by the transplant recipient's care team.

Proposed paragraph (d)(2) would provide for VA reimbursement of the prospective live donor or live donor for temporary lodging, including for a needed attendant or support person, while the prospective live donor or live donor is hospitalized for the organ removal procedure or while participating in the live donor program which requires the prospective live donor's or live donor's presence away from home at least overnight as determined necessary by VA. VA considers a prospective live donor's or live donor's need for temporary lodging or the assistance of a needed attendant before or after the donation procedure to be determinations to be made by VA. Consistent with the intent to remove barriers to live donors donating a solid organ, part of a solid organ, or bone marrow, VA considers these costs to be essential, and therefore medically necessary, to the treatment of intended recipients. As explained in the preceding discussion regarding proposed paragraph (d)(1), while there may be instances when VA contracts with providers in the community for the transplant procedure, VA would similarly retain the authority to make the determination as to whether the prospective live donor's or live donor's presence or proximity is necessary. This would ensure consistency across the country in administering these benefits and this program. It would ensure that there are no unauthorized commitments made by non-VA providers, as this determination can lead to reimbursement for travel costs related to the transplant procedure, and it would thus be fiscally responsible for VA to retain this authority. In determining whether the prospective live donor's or live donor's presence or proximity is necessary, VA would obtain and consider input from the transplant care team, including the provider responsible for the intended recipient's transplant procedure, the provider responsible for the prospective live donor's or live donor's donation procedure, and a VA transplant specialist not participating in the care of the recipient, as indicated. This would also be consistent with OPTN policies that focus on donor advocacy and on having decisions related to the donor not be solely directed by the transplant recipient's care team, as to avoid any potential conflicts.

Proposed paragraph (e) of this section, titled ''Use of non-VA facilities and non-VA service providers,'' construes 38 U.S.C. 1788(c) as it applies to 38 U.S.C. 1788(a) and (b). It would provide for VA to purchase community care and to purchase travel services to facilitate a prospective live donor's or a live donor's donation. The agreements under this paragraph must be governed by 38 U.S.C. 8153, or by any other applicable authority in title 38, United States Code, permitting VA to purchase such care and services in the community. Paragraph (e)(1)(i) would provide for VA to enter into agreements with non-VA facilities for them to provide a surgical procedure and care and services described in paragraph (c) of this section. Paragraph (e)(1)(ii) would provide for VA to enter agreements with service facilities and providers for non-hospital care or non-medical services (*i.e.,* travel services and lodging) that are described and otherwise reimbursable under paragraph (d) of this section. Proposed paragraph (e)(2), as 38 U.S.C. 1788(c) requires, would limit hospital care and medical services under these

agreements to those described in paragraph (c) of this section and would limit travel services to those described in paragraph (d) of this section. To avoid repetition, paragraph (e) would identify the hospital care and medical services to which it applies as those described in paragraph (c) of this section. It would identify the travel services to which it applies as those described in paragraph (d) of this section.

Proposed paragraph (f) of this section, titled ''Participation terminated without completion of the intended recipient's transplantation procedure,'' would ensure that a prospective live donor or live donor is not financially penalized because of termination of the transplantation process. Proposed paragraph (f)(1) would state that VA would provide the prospective live donor or live donor the care and services described in this section for any VA-authorized participation in the intended recipient's organ or bone marrow transplantation process even if the transplantation procedure for which the prospective live donor or live donor volunteered to donate a solid organ, part of a solid organ, or bone marrow is not completed. There are any number of reasons an intended recipient might not receive a prospective live donor's solid organ, part of a solid organ, or bone marrow. Any of these could occur at any time during the transplantation process. Rather than identify discrete steps or procedures for which VA will pay, this paragraph prescribes that VA authorization for a prospective live donor to participate in the transplantation process is the event that triggers VA's commitment to pay all of that donor's transplant costs authorized under this section up through the point when that individual's participation in the transplantation process ends. For example, if VA authorizes the prospective live donor to undergo assessments and diagnostic testing to assess suitability for donation, VA would pay for these costs even if the screening results subsequently disqualify the prospective donor. In addition, VA's obligations to the live donor under this section would be honored throughout the live donor's participation in the transplantation process even if the live donor's removal surgery reveals a previously unidentified disqualifying medical condition or the intended recipient dies before transplantation occurs.

A prospective live donor or a live donor may withdraw their informed consent at any time and for any reason. In these cases, VA will recognize and honor the donor's right to autonomy. Therefore, paragraph (f)(2) makes that clear and also provides that, in the case of revocation of consent, VA would still pay all the costs authorized under this section for the prospective live donor or live donor up until when the donor revokes consent and ends participation. To condition payment of these donors' costs on their completion of the live donor transplantation process would be coercive. Whatever a prospective live donor's or a live donor's reasons to revoke their informed consent, they could feel pressured to proceed against their wishes if revocation meant VA would not be financially liable for costs they had already incurred. Donor participation under these circumstances would be coercive. Even the appearance of coercion could impugn the integrity of the program. This paragraph seeks to avoid even that appearance. Apart from this concern, including this provision furthers the purpose of section 1788 by removing obstacles to donor participation in the program.

Proposed paragraph (g) of this section, titled ''Limitation on VA obligation in kidney paired donations,'' would limit VA's obligation to provide the care or services paragraph (c) of this section describes in the context of kidney paired donations. Kidney paired donation increases an intended recipient's pool of potential live kidney donors and often involves a series of matched donor exchanges. If a prospective live donor and the intended recipient do not match, that individual can become an initial prospective live donor. An initial prospective live donor agrees to donate his or her kidney to a different individual who is a match, and the intended recipient is ultimately paired with a different prospective live donor who is a match.

In a paired kidney donation, VA would provide the initial prospective live donor the examinations, tests, and studies described in proposed paragraph (c)(1) of this section. These are the same care and services that VA would provide a prospective live donor before kidney removal. Another party (such as a health insurance company or the intended recipient) would be responsible, however, for the costs of the initial prospective live donor's surgical, post-operative, live donor follow-up, and other care and services. The proposed regulation would identify as the live donor in kidney paired donation the person who is determined independently to match the intended recipient and whose kidney the intended recipient receives. VA would provide this live donor's surgical procedure and all care and services, including live donor follow-up, provided to live organ donors under this regulation.

More specifically, proposed paragraph (g)(1) would establish that VA will provide any procedure, care, or services under this section to the initial prospective live donor who elects to participate in a kidney paired donation matching program, but only for the examinations, tests, and studies described in paragraph (c)(1) for a prospective live donor before kidney removal. Proposed paragraph (g)(2) would establish that VA would provide any procedure, care, or services under this section to the live donor whose kidney the intended recipient will receive or has received but only for the services described in paragraphs (c)(2) and (c)(3). VA may use a non-VA facility as authorized in paragraph (e) to provide any care or services required in a kidney paired donation, limited, however, as described in paragraph (g) of this section.

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. The Office of Information and Regulatory Affairs has determined that this rule is 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 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). VA has determined that this rule would not have a significant impact on a substantial number of small entities

because the proposed rule does not directly regulate or impose costs on small entities and any effects would be indirect. Therefore, pursuant to 5 U.S.C. 605(b), the initial and final regulatory flexibility analysis requirements of 5 U.S.C. 603 and 604 do not apply.

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 will 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 numbers and titles for the programs affected by this document are 64.009, Veterans Medical Care Benefits; 64.029, Purchased Care Program; 64.047, VHA Primary Care; 64.042, 64.045, VHA Ancillary Outpatient Services; 64.042, VHA Inpatient Surgery; 64.040, VHA Inpatient Medicine; 64.041,VHA Outpatient Specialty Care; 64.035 Veterans Transportation Program.

List of Subjects in 38 CFR Part 17

Administrative practice and procedure, Alcohol abuse, Alcoholism, Claims, Day care, Dental health, Drug abuse, Foreign relations, 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, Philippines, Reporting and recordkeeping requirements, Scholarships and fellowships, Travel and transportation expenses, Veterans.

Signing Authority

The Secretary of Veterans Affairs approved this document on March 12, 2021 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.

Consuela Benjamin,

Regulations Development Coordinator, Office of Regulation Policy & Management, Office of the Secretary, Department of Veterans Affairs.

For the reasons stated in the preamble, the Department of Veterans Affairs proposes to amend 38 CFR part 17 as set forth below:

PART 17—MEDICAL

■ 1. The general authority citation for part 17 continues and an authority citation for § 17.395 is added in numerical order to read as follows:

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

* * * * *

Section 17.395 is also issued under 38 U.S.C. 1788.

■ 2. Add an undesignated center heading following 38 CFR 17.390 to read as follows:

Hospital Care, Medical Services, and Other Services for Live Donors

■ 3. Add § 17.395 to read as follows:

§ 17.395 Transplant procedures with live donors, and related services.

(a) *Scope.* This section provides for medical and non-medical care and services of persons who volunteer to donate a solid organ, part of a solid organ, or bone marrow for transplantation into an eligible veteran transplant candidate, irrespective of a donor's eligibility to receive VA health care for any reason other than to donate a solid organ, part of a solid organ, or bone marrow. It prescribes the type, timing, and duration of hospital care and medical services VA provides, including medical care or services purchased by agreement from a non-VA facility. It also provides for non-medical care and services essential to the prospective live donor's or live donor's participation and for VA reimbursement for that care and services. The section does not provide for eligible veteran transplant candidates' VA medical benefits.

(b) *Definitions.* For purposes of this section:

Initial prospective live donor means an intended recipient's prospective live donor who volunteers to donate a kidney to a recipient other than the intended recipient through kidney paired donation.

Intended recipient means the transplant candidate who VA identifies to receive a live donor's solid organ, part of a solid organ, or bone marrow.

Kidney paired donation means one prospective live donor's voluntary donation of a kidney for transplantation into a recipient other than an intended recipient, paired with the transplantation into the intended recipient of a compatible kidney from a different live donor.

Live donor means an individual who is:

(1) Medically suitable for donation;

(2) Is a compatible match to an identified veteran transplant candidate; and

(3) Has provided informed consent to undergo elective removal of one solid organ, part of a solid organ, or of bone marrow.

Live Donor Follow-Up Means

(1) For live donors of a solid organ or part of a solid organ, the collection of clinically relevant post-donation live donor data and the provision of recommended clinical laboratory tests and evaluations consistent with Organ Procurement and Transplantation Network policy, and the provision of direct medical care required to address reasonably foreseeable donor health complications resulting directly from the donation procedure.

(2) For live donors of bone marrow, the provision of direct medical care required to address reasonably foreseeable donor health complications resulting directly from the donation procedure.

Prospective live donor means a person who has volunteered to donate a solid organ, part of a solid organ, or bone marrow to an intended recipient, and who has agreed to participate in any activity VA deems necessary to carry out the intended recipient's transplant procedure.

Transplant candidate means an enrolled veteran or a veteran otherwise eligible for VA's medical benefits package who VA determines has a medical need for a solid organ, part of a solid organ, or bone marrow transplant.

Transplant recipient means a transplant candidate who has undergone transplantation and received a solid organ, part of a solid organ, or bone marrow from a live donor.

(c) *Hospital care and medical services.* To obtain a solid organ, part of a solid organ, or bone marrow for a VA transplant candidate, VA may provide the following hospital care and medical services to a prospective live donor or live donor:

(1) Before removal of a solid organ, part of a solid organ, or bone marrow, VA will provide examinations, tests, and studies necessary to qualify a

prospective live donor to donate a solid organ, part of a solid organ, or bone marrow.

(2) During removal of a solid organ, part of a solid organ, or bone marrow, VA will provide the surgical procedure to remove a solid organ, part of a solid organ, or bone marrow from the living donor whose solid organ, part of a solid organ, or bone marrow will be transplanted into an intended recipient.

(3) After removal of a solid organ or part of a solid organ, VA will provide all hospital care, medical services, and other services which are necessary and appropriate to live donor follow-up as defined in paragraph (b) of this section for a period not less than that which the Organ Procurement and Transplantation Network prescribes or recommends or for a period of 2 years, whichever is greater.

(4) After bone marrow removal, VA will provide direct medical care required to address reasonably foreseeable live donor health complications resulting directly from the bone marrow donation procedure for a period not greater than 2 years.

(5) A prospective live donor who is also a veteran enrolled in VA's health care system may receive care and services authorized in paragraphs (c)(1) and (c)(2) only under this section. A live donor who is also a veteran enrolled in VA's health care system may opt to receive the care and services authorized under paragraph (c)(3) or (c)(4) under either the medical benefits package codified at § 17.38 of this part or under this section, but not both at the same time.

(d) *Non-hospital care and non-medical services.* If VA determines the prospective live donor's or the live donor's presence or proximity is necessary, VA will reimburse the travel costs of the prospective live donor or live donor, including one needed attendant or support person, at the rates provided in § 70.30 of this chapter, without the deductibles required by § 70.31 of this chapter, for:

(1) Travel between the prospective live donor's or live donor's residence and the site of hospital care or medical services authorized in paragraph (c) of this section; and

(2) Temporary lodging:

(i) While the live donor is hospitalized for the organ removal procedure; or

(ii) While the prospective live donor's or live donor's participation in the live donor program requires the prospective live donor's or live donor's presence away from home at least overnight and the prospective live donor's or live donor's presence or proximity is determined necessary by VA.

(e) *Use of non-VA facilities and non-VA service providers.* (1) If and only if VA and a non-VA facility or non-VA service provider have an agreement governed by 38 U.S.C. 8153 or any other applicable authority in title 38, United States Code, a non-VA facility may provide—

(i) A surgical procedure and care and services described in paragraph (c) of this section; or

(ii) Non-hospital care or non-medical services described and otherwise reimbursable under paragraph (d) of this section.

(2) The prospective live donor or live donor is eligible for hospital care and medical services, or travel services, at a non-VA facility solely for the procedure, care, and services described in paragraphs (c) and (d) of this section as governed by an agreement described in paragraph (e)(1) of this section.

(f) *Participation terminated without completion of the intended recipient's transplantation procedure.*

(1) VA will provide the prospective live donor or live donor the care and services described in this section for any VA-authorized participation in the intended recipient's organ or bone marrow transplantation process even if the transplantation procedure for which the prospective live donor or live donor volunteered to donate a solid organ, part of a solid organ, or bone marrow is not completed.

(2) A prospective live donor or a live donor may withdraw his or her informed consent at any time and for any reason. In the case of revocation of consent, VA will pay all the costs authorized under this section for the prospective live donor or live donor up until when the donor revokes consent and ends his or her participation.

(g) *Limitation on VA obligation in kidney paired donations.* In kidney paired donations, VA's obligation to provide any procedure, care, or services under this section extends:

(1) To the initial prospective live donor who elects to participate in a kidney paired donation matching program, but only for the examinations, tests, and studies described in paragraph (c)(1) of this section for a prospective live donor before kidney removal.

(2) To the live donor whose kidney the intended recipient will receive or has received but only for the services described in paragraphs (c)(2) and (c)(3).

[FR Doc. 2021–05682 Filed 3–23–21; 8:45 am]

BILLING CODE 8320–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2021–0069; FRL–10021–35–Region 3]

Air Plan Approval; Delaware; Nonattainment New Source Review Requirements for 2015 8-Hour Ozone National Ambient Air Quality Standard

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a state implementation plan (SIP) revision submitted by the Delaware Department of Natural Resources and Environmental Control (DNREC). This SIP revision will fulfill Delaware's nonattainment new source review (NNSR) SIP element requirement for the 2015 8-hour ozone National Ambient Air Quality Standard (NAAQS). This action is being taken under the Clean Air Act (CAA).

DATES: Written comments must be received on or before April 23, 2021.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R03–OAR–2021–0069 at *https://www.regulations.gov,* or via email to *Opila.MaryCate@epa.gov.* For comments submitted at *Regulations.gov*, follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* For either manner of submission, EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be confidential business information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Amy Johansen, Permits Branch (3AD10),