



December 15, 2017

Director, Regulations Management
Department of Veteran's Affairs
810 Vermont Avenue, N.W.
Room 1063-B
Washington, DC 20420

Re: RIN 2900-AP46, Prosthetic and Rehabilitative Items and Services

Submitted Electronically Via Regulations.gov

To Whom It May Concern:

The American Orthotic & Prosthetic Association (AOPA), founded in 1917, is the largest national orthotic and prosthetic trade association with a national membership that draws from all segments of the profession of artificial limbs and customized bracing for the benefit of patients who have experienced limb loss, or limb impairment resulting from a chronic disease or health condition. These include patient care facilities, manufacturers and distributors of prostheses, orthoses and related products, and educational and research institutions.

AOPA is pleased to offer the following comments on the proposed rule entitled, "Prosthetic and Rehabilitative Items and Services" that was published in the *Federal Register* on October 16, 2017. The stated purpose of the proposed rule is to, "revise its medical regulations related to providing prosthetic and rehabilitative items, primarily to clarify eligibility for prosthetic and other rehabilitative items and services, and to define the types of items and services available to eligible veterans."

While the need of the Veteran's Administration (VA) to establish formal regulations in order to ensure continued coverage for medically necessary prosthetic services is certainly understood, AOPA is deeply concerned regarding the provisions of the proposed rule contained in proposed section 17.3240 entitled, "Furnishing authorized items and services." This section, in part, if adopted, would state that solely the VA will determine whether VA or a VA-authorized vendor will furnish authorized items and services to veterans. The proposed section goes on to state that the VA would clarify in regulation that, "this administrative business decision is made solely by the VA to eliminate any possible confusion as to whether a veteran has a right to request items or

services generally, or to request specific items or services from a provider other than the VA, and to clarify for the benefit of VA-authorized vendors that VA retains this discretion as part of our duty to administer this program in a legally sufficient, fiscally responsible manner.”

The VA’s proposed rule inaccurately characterizes this as “clarifying.” In fact, this would abolish the long-standing policy where veterans have enjoyed a measure of choice, including whether they secure their prosthesis from a private sector provider, replacing it with a new policy, which places sole responsibility for the selection of the prosthetic care provider with the VA, and with no real prerogative for the veteran in choice of provider. AOPA’s research on this topic, which includes securing the Legal Memorandum which is attached to these comments, and which we incorporate in its entirety into these AOPA comments, has established four things relating to past policy and the changes to it embodied in this proposed rule:

1. There has been a solid basis to conclude the existing VA policy has afforded veterans a choice to receive their prosthetic care in the private sector.
2. VA has stated publicly, before Congress, that veterans enjoy that choice of provider/private sector care at the veteran’s option.
3. The VA OIG has confirmed that veterans enjoy choice to receive their prosthetic care in the private sector.
4. The strongest assurances/protections for veterans enjoying the choice to secure their prosthetic care in the private sector arise under the Choice Act, and there is substantial support for the view that the Choice Act protections do apply to veterans securing prosthetic care.

The proposed regulations at § 17.3240 appear to directly contradict the longstanding policy of the VA regarding a veteran’s right to receive prosthetic services through the VA directly or through a VA contracted provider as well as the provisions of the Veterans Access, Choice and Accountability Act of 2014 (Choice Act). Since the creation of the Veterans Administration in 1930, providers of artificial limbs and braces have worked closely with the Veterans Administration to ensure that veterans have complete access to high quality, clinically appropriate, prosthetic and orthotic care. Whether services were provided directly by the VA within their own facilities or by private companies through a contractual arrangement, the needs of the individual veteran have always been paramount in how care is delivered. The proposed rule completely disregards the long history of cooperation between the VA and its contracted prosthetic and orthotic providers, as well as the clinical needs of the individual veteran, by proposing regulations that would authorize the VA to exercise sole discretion as to how and by whom prosthetic and orthotic care is delivered to veterans. The proposed rule goes so far as to state that the decision regarding how care is delivered is an administrative decision. AOPA could not disagree more. The delivery of appropriate prosthetic and orthotic care is not an administrative issue, it is a clinical issue; one that should be made

based on the clinical needs of the individual veteran, and with the veteran's concurrence, not the administrative needs of a government agency.

AOPA's legal counsel has advised that the provisions proposed in § 17.3240 may be invalid because they are in direct conflict with existing regulation created by the Choice Act. Regulations at 38 U.S.C. § 8153 and 38 U.S.C. § 1703 which address sharing of health care resources and contracts for hospital care and medical services in non-department facilities respectively. The Choice Act provides veterans the most latitude in the receipt of non-VA care and therefore cannot be superseded by restrictions in the proposed rule. While certain conditions must be met in order for veterans to access outside medical services under the authority of the Choice Act, the proposed rule does not mention these conditions, it simply states that the decision regarding where care is delivered is determined solely by VA. As a result of the direct conflict between the proposed rule and the existing regulations that govern the Choice Act, AOPA respectfully requests the withdrawal of the proposed provisions at § 17.3240.

AOPA's legal counsel has also advised, that, in addition to being in direct conflict with existing VA policy and the provisions of the Choice Act, ambiguities in the language of the proposed rule raise the question as to whether the VA has met its obligation under the Administrative Procedures Act (APA) to adequately explain its rulemaking. For example, the proposed language in § 17.3240 initially states that "it would establish that VA will determine whether VA or a VA-authorized vendor will furnish authorized items and services." Later in the section however, the proposed change is discussed as a clarification intended to "eliminate any possible confusion as to whether a veteran has a right to request services from a provider other than VA." The proposed rule does not cite or otherwise explain the discretionary authority that the VA claims to be the basis for the proposed changes in § 17.3240. In addition, the proposed rule does not indicate how the VA would exercise the discretionary authority it proposes in § 17.3240. This proposed rule does not clearly and accurately state either the existing law or policy, nor how that policy would be changed. Any proposed rulemaking that does not follow the specific requirements of the APA cannot be considered valid and must be withdrawn.

Perhaps the most troubling implication of the proposed rule is the fact that the provisions at § 17.3240 make no distinction between treatment of service connected veterans and non-service connected veterans. Traditionally, veterans who require prosthetic and orthotic treatment as a direct result of injury or disease that is related to their military service (service connected) have been afforded significant flexibility regarding choice of provider, even as far as allowing service connected veterans to continue to receive treatment from a non-contracted VA provider when an existing patient care relationship exists. The proposed rule completely eliminates any consideration for the service connected veteran and their specific medical needs and is a true disservice to those who have sacrificed their health and well-being during their service in the United States military.

The citations above largely represent excerpts from the complete opinion that has been provided to APOA by its legal counsel. The complete opinion is appended to these comments for your review and consideration.

Legal concerns aside, AOPA believes that the proposed regulations at § 17.3240 are simply not in the best interest of veterans. The relationship between a veteran and their orthotic and prosthetic provider is often a long standing, personal relationship that extends beyond the simple distribution of a medical device. Orthotics and Prosthetics are not just another piece of medical equipment such as a cane or crutch that can simply be dispensed to a veteran from a large inventory of devices. O&P services are most often highly customized to meet the unique medical needs of the individual patient and the relationship between the veteran and the orthotist or prosthetist is as valuable as the device itself. These are not relationships that can be easily discarded as part of an “administrative” decision by the VA to dictate who provides O&P care to each veteran/patient. The concept of patient choice has been reflected in the longstanding VA policy that has always allowed flexibility to the veteran regarding the ability to be seen by a VA contracted provider. In addition, the proposed rule appears to be in direct conflict with statements made by high ranking VA officials, including the Secretary himself, as recently as October 24, 2017.

- In a hearing before the House Veteran’s Affairs Committee on this date, Secretary Shulkin stated the following:

“Veterans should get more choice in the say of their care. Nobody should feel trapped in the VA system.” He also stated, when referencing the proposed permanent replacement to the Choice Act, that, “The Department’s proposed Care Act would base eligibility for all community based care on clinical factors and the veteran-provider relationship.”

- The concept of veteran focused care is not new to VA policymakers. On July, 16, 2008, Frederick Downs Jr., at the time the VA Chief Prosthetics and Clinical Logistics Officer, provided testimony before the House Small Business Subcommittee on Contracting and Technology. Excerpts from Mr. Downs’ testimony included the following statements”

“In outsourcing to small prosthetic businesses, the VA allows veterans to seek more personalized care. We must ensure that amputees continue to have this option.”

“You can’t make an individual go to a prosthetist that is not doing a good job for them. And the strange thing about that is, is that I may think this prosthetist is good, but another amputee thinks that the prosthetist is terrible. So that chemistry stuff comes in there too.”

- The VA position regarding veterans’ ability to choose their provider was again supported by Dr. Lucille Beck in testimony before the House Veterans’ Affairs

Health Subcommittee. Excerpts from Dr. Beck's testimony on May 16, 2012 include:

"VA's Prosthetics and Sensory Aids Service has a robust clinical staff of orthotists and prosthetists at more than 75 locations and also partners with the private sector to provide custom fabrication and fitting of state-of-the-art orthotic and prosthetic devices. VA maintains local contracts with more than 600 accredited O&P providers to help deliver care closer to home. Commercial partners help fabricate and fit prosthetic limbs for veterans across the country."

"We do offer choice to our veterans. And in our amputee clinics, when we initiate the process for multi-disciplinary care that we provide, we have our physicians and our clinicians and our prosthetists there. We also have vendors, our contracted community partners, our contracted prosthetic vendors from the community are there as well. The veterans do have that choice. That is part of our policy."

- The VA position on veteran choice was reiterated once again in testimony dated July 31, 2012 before the same subcommittee by VA Under Secretary for Health Robert Petzel, M.D. Dr. Petzel testified that:

"Our policy is that this is a veteran's choice. Most of the prosthetics actually are fabricated and fitted by private vendors. Our policy very clearly states that there must be available in every one of the medical centers a list of contractors, and this must be explained to the veteran, that they have a choice in doing that.....if there is a connection between a patient and a prosthetist, that individual is invited in and is welcome to come to clinic and welcome to be a part of whatever activities are involved in our prosthetic clinic."

The excerpts from testimony above are just a few examples of the repeated statements of high ranking VA officials regarding the longstanding policy that has valued the ability of the veteran to work with contracted providers in order to have access to the most appropriate clinical care to meet their orthotic and prosthetic needs.

The apparent complete reversal of VA policy that is outlined in § 17.3240 begs the question of why. Why make such a drastic change when the potential negative impact on the quality of care available to veterans is immeasurable? Why would the VA suddenly propose a rule that is in direct conflict with current regulations and longstanding VA policy regarding veteran choice? Why would the VA want to limit the veteran population to only receive services within VA facilities that may not be readily accessible to veterans, either due to long distance or long wait times?

AOPA urges the VA to reconsider the language contained in section 17.3240 of the proposed rule, and to revise it consist with the Veteran's choice/option to secure his/her prosthetic care in the private sector, thereby maintaining consistency with both the long history of promises to both Congress and veterans by VA officials, and with the letter and spirit of commitments of the Choice Act. The elimination of the veteran's right to

choose to receive prosthetic and orthotic services directly through the VA or through a relationship with a contracted provider is in nobody's best interest and it is certainly not an "administrative" decision. It is a deeply personal decision that must involve input from all involved parties but especially from the veteran. Publication of a final rule without affirming the rights of the veteran would be a true disservice to those who have dedicated their lives to serving their country.

Sincerely,



Thomas F. Fise, JD
Executive Director

Cc: Thomas Bowman
Carolyn Clancy, MD
Penny Nechanicky
B.J. Randolph

**TORKILDSON, KATZ, MOORE,
HETHERINGTON & HARRIS**

ATTORNEYS AT LAW, A LAW CORPORATION
700 BISHOP STREET, 15TH FLOOR
HONOLULU, HAWAII 96813-4187
TELEPHONE (808) 523-6000 • FACSIMILE (808) 523-6001

RACHAEL T. BRANT
DIRECT DIAL: (808) 523-5391
E-MAIL: RTB@TORKILDSON.COM

MEMORANDUM

TO: Thomas F. Fise, Executive Director, American Orthotic & Prosthetic Association
FROM: Rachael T. Brant
DATE: October 30, 2017
RE: U.S. Department of Veterans Affairs Proposed Rule, “Prosthetic and Rehabilitative Items and Services,” 82 Fed. Reg. 48018 (Oct.16, 2017)

This memorandum addresses your questions regarding the U.S. Department of Veterans Affairs (“VA”) Proposed Rule, “Prosthetic and Rehabilitative Items and Services,” 82 Fed. Reg. 48018 (Oct. 16, 2017) (“Proposed Rule”).

I. Questions Presented

1. Does the current law allow Veterans to choose care in the private sector and does eligibility vary depending on service-connected disability status?
2. Does VA have authority to change current practice as done in the Proposed Rule?

II. Short Answers

1. Veterans meeting certain eligibility criteria may elect to receive care, including prosthetics-related care, from non-VA providers through VA’s Choice Program. According to VA guidance, prescriptions for prosthetics written by non-VA providers participating in the Choice Program are submitted to VA facilities for fulfillment. Basic eligibility for the Choice Program does not vary based on service connection, but VA is a secondary payor when care is for a nonservice-connected condition. Under VA’s other authorities for delivering non-VA care, VA applies certain criteria and determines whether to provide non-VA care. The decision is generally not at the election of the veteran. Service-connected disability status can be a factor, but generally only in terms of which non-VA care authority is used.

2. VA would generally be allowed to change its existing policy and practice. However, to the extent the Proposed Rule would operate in conflict with the Veterans Access, Choice, and Accountability Act of 2014, Pub. L. No. 113-146 (“Choice Act”), it would be invalid. In addition, ambiguities in the Proposed Rule raise a question as to VA’s compliance with the Administrative Procedure Act, 5 U.S.C. § 551 et seq. (“APA”).

III. Discussion

A. Proposed § 17.3240 represents a change from current VA policy

In the Proposed Rule, VA proposes to add new §§ 17.3200-.3250 to govern provision of prosthetics and other rehabilitative items and services to eligible veterans. This memorandum specifically addresses the validity of proposed § 17.3240, which would provide as follows:

§ 17.3240 Furnishing authorized items and services.

(a) VA will determine whether VA or a VA-authorized vendor will furnish authorized items and services under § 17.3230 to veterans eligible for such items and services under § 17.32[2]0.¹

(b) Except for emergency care reimbursable under 38 CFR 17.120 et seq. or 38 CFR 17.1000 et seq., prior authorization is required for VA to reimburse VA-authorized vendors for furnishing items or services under § 17.3230 to veterans. Prior authorization must be obtained from VA by contacting any VA medical facility.

82 Fed. Reg. 48029 (emphasis added). VA characterizes the new regulations as “primarily to clarify eligibility for prosthetic and other rehabilitative items and services, and to define the types of items and services available to eligible veterans.” 82 Fed. Reg. 48018. However, proposed § 17.3240 would significantly depart from VA’s longstanding policy regarding the provision of prosthetic items and services.

As discussed in the Proposed Rule preamble, the basic regulation governing provision of prosthetics² is 38 C.F.R. § 17.38, which describes the medical benefits package available to veterans eligible for VA healthcare. In addition, under 38 C.F.R. § 17.150, prosthetic items “may be purchased, made or repaired for any veteran upon a determination of feasibility and medical need.” Under 38 C.F.R. § 17.153, veterans supplied prosthetics are “entitled to fitting and training in the use of such appliances” and “[s]uch training will usually be given in [VA] facilities by [VA] employees, but may be obtained under contract if deemed necessary.” As noted in the preamble with respect to § 17.150, 82 Fed. Reg. 48019, both § 17.150 and § 17.153 long predate more modern VA healthcare authorities. The Proposed Rule states it would eliminate § 17.150 as “defunct” and remove § 17.153 because the substance would be incorporated in proposed § 17.3230(a)(15), which would authorize “[t]raining with and filling of prescribed items as considered necessary.” 82 Fed. Reg. 48109, 48025.

¹ Proposed § 17.3240(a) appears to incorrectly reference § 17.3210, Definitions, rather than § 17.3220, Eligibility.

² The Proposed Rule relates to all of the items under VA’s authority at 38 U.S.C. § 1701(6)(F) including but not limited to “wheelchairs, artificial limbs, trusses, and similar appliances.” This memorandum focuses on prosthetics.

Since at least 2000, VA's provision of prosthetic items and services has been governed primarily by sub-regulatory issuances in the form of VHA Handbooks 1173.1, 1173.2, and 1173.3.³ As described below, these policies are not entirely free of ambiguity. However, at the very least, these policies grant certain veterans their choice of prosthetics items and services from among VA-contracted providers. Moreover, VA appears to have interpreted these policies broadly to give veterans a choice of where to procure prosthetic items and services.

VHA Handbook 1173.1, *Eligibility* (November 2, 2000), governs eligibility for prosthetic items and services and provides: "Generally, all veterans enrolled in the VA health care system are eligible for needed prosthetics, medical equipment, and supplies," and that "[c]ertain veterans are eligible for needed prosthetics, medical equipment, and supplies even though not enrolled." VHA Handbook 1173.1, section 2.a. Thus, a veteran has basic eligibility for prosthetics so long as he or she is eligible to receive care from VA and has the medical need.

VHA Handbook 1173.2, *Furnishing Prosthetic Appliances and Services* (November 3, 2000), "establishes uniform and consistent national policy and procedures in furnishing prosthetic appliances to all eligible beneficiaries based on the medical recommendations of Prosthetic Clinic Teams, staff physicians, or authorized fee-basis physicians [i.e., non-VA community providers]." VHA Handbook 1173.2, section 1. Therefore, by its terms, VHA Handbook 1172.2 applies to the procurement of prosthetic items and services in connection with treatment provided by VA providers and contracted non-VA providers. The basic procurement policy described in VHA Handbook 1173.2 is that custom-fabricated prosthetics "may be procured from commercial vendors where adequate facilities are conveniently available," but "existing VA Prosthetic and Orthotic Laboratories will be used as a primary source and will be utilized to the fullest extent possible." VHA Handbook 1173.2, section 6.a.(3). More specifically, VHA Handbook 1173.2 establishes limitations for "non-service connected veterans who are new amputees," but otherwise grants veterans authority to choose from VA and VA-contracted providers, while giving "service-connected veterans" who most recently used a non-contract provider the additional choice of non-contract providers, as follows:

(a) Non-service connected veterans who are new amputees will be provided a preparatory limb using conventional endoskeletal componentry. Once the veteran has achieved appropriate shrinkage and is ready for a permanent prosthesis, the socket may be replaced and the limb cosmetically finished. These veterans will not be referred to a commercial contractor unless such action is necessary to expedite the treatment process.

³ Under the APA, "substantive" agency rules must go through notice-and-comment rulemaking, while "interpretive" rules do not require such procedures. In the Proposed Rule, VA states that the proposed changes are "appropriate for a rulemaking because they would affect VA's provision of prosthetic and similar items and services." 82 Fed. Reg. 48019. This statement appears to be inconsistent with VA's past practice of implementing prosthetic benefit policies outside of the notice-and-comment rulemaking process. However, any APA issues in this regard would be most relevant if seeking to challenge the existing policy, which is generally favorable to veterans and non-VA providers.

(b) Eligible veterans will select their provider for artificial limbs from the listing of contract vendors, including capable VA Prosthetic and Orthotic Laboratories. Service connected veterans who have obtained their most recent limb from a non-contract provider will be allowed to have their subsequent limb manufactured by the VA non-contract provider as long as the prosthetist is willing to accept the geographic VA preferred provider payment rate for the State in which the prosthetist performs this service. The VA Prosthetic and Orthotic Laboratory will be on the same listing, and may be selected to fabricate definitive limbs.

VHA Handbook 1173.2, section 6.c.(1)(a)-(b) (emphasis added).

VHA Handbook 1173.3, *Amputee Clinic Teams and Artificial Limbs* (Jun. 4, 2004) is generally consistent with VHA Handbook 1173.2. VHA Handbook 1173.3 provides that either contract vendors or VA Prosthetic and Orthotic Laboratories can be used for the procurement of prosthetics, as follows:

b. These artificial limbs (appliances) can be procured from contract vendors where adequate appliance facilities are available, the time required to receive delivery of the appliance is not excessive for patients, and the prices charged for such appliances are reasonable. NOTE: VA Orthotic Laboratories with a certified prosthetist may also be used as a source in the fabrication of preparatory, temporary, and permanent artificial limbs.

VHA Handbook 1173.3, section 4.b. (emphasis added).⁴ VHA Handbook 1173.3 also allows the additional choice of a non-contract prosthetist for veterans who received their last prosthetic from a non-contract provider. However, unlike VHA Handbook 1173.2, VHA Handbook 1173.3 does not differentiate between service-connected and non-service connected veterans. In addition, VHA Handbook 1173.3 appears to establish limitations for new amputees. In these regards, VHA Handbook 1173.3 provides:

c. Eligible veterans, as identified in VHA Handbook 1173.1, who have previously received artificial limbs from commercial sources, will continue to have their choice of vendors on contract with VA or their non-contract prosthetist, providing the prosthetist accepts the VA preferred provider rate for the geographic area. VA facilities with Orthotic Laboratories that have certified prosthetists, or facilities with access to a VA Laboratory, will provide eligible veteran amputees with the preparatory or temporary prosthesis and permanent limbs. NOTE: When the patient has achieved appropriate shrinkage and is ready for a permanent prosthesis, the preparatory or temporary prosthesis is replaced.

⁴ A prior version of this handbook included substantially similar language, but stated “These appliances should be from commercial vendors. . . .” VHA Handbook 1173.3, *Amputee Clinic Teams and Artificial Limbs* (November 2, 2000) (emphasis added).

VHA Handbook 1173.3, section 4.c. (emphasis added). Finally, VHA Handbook 1173.3 appears to be internally inconsistent. In particular, section 7, “Commercial Sources,” could be read as granting a choice of almost any prosthetic provider to eligible veterans:

a. Eligible veterans will be permitted to obtain authorized artificial limbs and/or terminal devices from any commercial artificial limb dealer who is under a current local contract to the VA or the veteran’s preferred prosthetist who agrees to accept the preferred provider rate.

* * *

b. To assist all eligible veterans authorized permanent artificial limbs using a commercial contractor, a current list of approved contractors in the immediate geographical area must be provided to each. Included in this list will be the VA Prosthetic-Orthotic Laboratories, when applicable. Except in those rare instances where a physician determines it to be necessary for the proper medical treatment of the veteran, VA personnel are not allowed to direct, guide, or prompt a veteran to go to a specific contractor. NOTE: A rotating contractor schedule will not be used as a method of selecting a contractor for the fabrication of a limb.

VHA Handbook 1173.3, section 7, 7.a., 7.b. (emphasis added).

Significantly, VA appears to have broadly interpreted and applied these policies. In 2012, in testimony before the House Committee on Veterans’ Affairs Subcommittee on Health, then VA Undersecretary for Health Dr. Robert A. Petzel stated:

[O]ur policy that is this is a veteran’s choice. That we have, as I mentioned earlier, 600 contracts. Most of the prosthetics actually are fabricated and fitted by private vendors. Our policy very clearly states that there must be available in every one of the medical centers a list of the contractors, and this must be explained to the veteran, that they have a choice in doing that.

U.S. Congress. Committee on Veterans’ Affairs Subcommittee on Health. “Optimizing Care for Veterans with Prosthetics: An Update.” (Date: 7/31/12) (emphasis added). Similarly, VA OIG has described VA policy as follows: “Existing VA Prosthetic and Orthotic Laboratories are expected to be used as a primary source and to the fullest extent possible,” however, “[a]s well, VHA allows eligible veterans to obtain authorized artificial limbs from any commercial artificial limb dealer who is under a current local contract with the VA or the veterans’ preferred prosthetist who agrees to accept the preferred provider rate.” VA OIG Report No. 11-02138-116, “Healthcare Inspection Prosthetic Limb Care in VA Facilities,” at 5 (March 8, 2012) (citing VHA Handbook 1173.3, *Amputee Clinic Teams and Artificial Limbs* (June 4, 2004)). In addition, VA OIG has stated that in interviews, veterans mentioned “appreciation for the choice and location of their prosthetic vendors.” *Id.* at 62. VA OIG has also noted, “At three of the four VISNs we visited, local prosthetic management did not identify an appropriate number of

contract vendors needed to provide prosthetic limb services to veterans who have the option to choose where they receive these services.” VA OIG Report No. 11-02138-116, “Audit of the Management and Acquisition of Prosthetic Limbs” (March 8, 2012).

Thus, proposed § 17.3240 would eliminate the choice granted to veterans under VA’s longstanding policy as contained in VHA Handbooks 1173.1, 1173.2, and 1173.3. As discussed below, although VA would generally be permitted to alter its policy, the Proposed Rule may insufficiently describe the change and underlying reasoning in violation of the requirements of the APA. In addition, the changes in the Proposed Rule could conflict with the Choice Act.

B. The Proposed Rule contains ambiguities which raise potential APA issues

The APA prohibits agencies from taking actions that are arbitrary and capricious. 5 U.S.C. § 706(2)(A). An agency may change policy so long as that change is permitted under existing authority. *See Nat’l Ass’n of Home Builders v. EPA*, 682 F.3d 1032 (2012) (citing *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 514-515 (2009)). However, “an agency is obligated ‘not to depart without reasoned explanation from its prior conclusions.’” *Troy Corp. v. Browner*, 120 F.3d 277, 286 (1997) (quoting *Nat’l Ass’n for Better Broadcasting v. FCC*, 849 F.2d 665, 669 (D.C. Cir. 1988)). If an agency were to “abandon a long-held . . . policy and take a new direction,” such a change would “require a thorough explanation of its reasons for doing so.” *Id.* at 287; *see also Public Citizen, Inc. v. FAA*, 988 F.2d 186, 197 (D.C. Cir. 1993) (“The requirement that agency action not be arbitrary or capricious includes a requirement that the agency adequately explain its result[.]”). In addition, “[g]enerally speaking, the requirement that an agency provide reasoned explanation for its action . . . demand[s] that it display awareness that it is changing position. An agency may not, for example, depart from a prior policy sub silentio or simply disregard rules that are still on the books.” *ABM Onsite Servs.-West, Inc. v. NLRB*, 849 F.3d 1137, 1146 (D.C. Cir. 2017) (citing *Fox Television Stations*, 556 U.S. at 515).

Ambiguities in the Proposed Rule raise the question of whether VA has satisfied its duty under the APA to adequately explain its rulemaking. First, the Proposed Rule does not clearly state whether proposed § 17.3240 represents a change from existing policy. For example, the preamble discussion of proposed § 17.3240 suggests that the provision is a departure from past practice, stating it “would establish that VA will determine whether VA or a VA-authorized vendor will furnish authorized items and services.” However, VA also suggests that the proposed change is merely a clarification by stating, “[w]e would clarify in regulation that this administrative business decisions is made solely by VA to eliminate any possible confusion as to whether a veteran has a right to request items or services generally, or to request specific items or services from a provider other than VA, and to clarify for the benefit of VA-authorized vendors that VA retains this discretion” 82 Fed. Reg. 48025. The Proposed Rule preamble says VA would eliminate use of the “Prosthetic Service Card” and rescind related VA policy including VHA Handbooks 1173.1-1173.3, 82 Fed. Reg. 48026, but does not explain how proposed § 17.3240 relates to the provisions in those policies granting veterans the choice of commercial provider.

In addition, VA does not cite or otherwise explain the authority underlying the discretionary authority contained in proposed § 17.3240. VA provides a parenthetical statutory authority for all sections of the Proposed Rule except proposed § 17.3240. The Proposed Rule does not address VA's prosthetic procurement authority at 38 U.S.C. § 8123, nor mention VA's relevant non-VA care authorities except those for emergency care at 38 U.S.C. §§ 1725 and 1728. The Proposed Rule defines the term "VA-authorized vendor" to mean "a vendor that has been authorized by VA to provide items and services under § 17.3230" and states that this definition "is self-explanatory." 82 Fed. Reg. 48023. However, the Proposed Rule contains no explanation of the relationship between the Proposed Rule and VA's non-VA care authorities.

Relatedly, VA does not explain how it would exercise the discretionary authority in proposed § 17.3240. VA gives the rationale that the determination is a "business decision" and that "VA retains this discretion as part of our duty to administer this program in a legally sufficient, fiscally responsible manner." 82 Fed. Reg. 48025. VA's explanation fails to address other factors such as whether or how clinical considerations would be taken into account.⁵ Likewise, the regulatory text contains no criteria for the exercise of discretion. In the absence of additional explanation in these regards, the Proposed Rule and any final rulemaking issuance may not provide sufficient explanation as required by the APA.

C. To the extent proposed § 17.3240 would conflict with the Choice Act it is invalid

VA primarily purchases private sector, non-VA care under one of three authorities: The Choice Act; 38 U.S.C. § 8153, Sharing of Health Care Resources; and 38 U.S.C. § 1703, Contracts for Hospital Care and Medical Services in Non-Department facilities. As discussed below, the Choice Act provides veterans the most latitude in the receipt of non-VA care and is thus the most likely authority to be implicated by the Proposed Rule.

An initial matter, prosthetics-related medical care may involve various aspects such as medical examination and treatment, prosthetic prescriptions, prosthetic repairs, and related fitting and training services. As described in more detail below, VA addresses the provision of medical care differently from the provision of prescribed prosthetic items.

Under the Choice Act, veterans meeting certain eligibility criteria based on wait-time, distance, or unusual or excessive travel burden, may elect to receive hospital care or medical services from non-VA providers who have agreed to provide care and services to such veterans. Pub. L. No. 113-146, § 101. Eligibility for the Choice Program does not depend on service connection but VA is a secondary payer for care and services related to a nonservice-connected disability. *See* Interim Final Rule, "Expanded Access to Non-VA Care Through the Veterans

⁵ VHA policy requires prosthetics procurements to follow all applicable provisions of the FAR and VA Acquisition Regulation or provide an adequate explanation for using sole source authority under 38 U.S.C. § 8123. *See* VHA Directive 1081, *Procurement Process for Individual Prosthetic Appliances and Sensory Aids Devices Above the Micro-Purchase Threshold* (March 25, 2014). Under this policy, the determination of which device is prescribed is solely clinical. *Id.* at 1 ("The authority to select what device is medically necessary to best meet the need(s) of the patient remains, however, with the prescribing clinician in consultation with the patient.").

Choice Program,” 79 Fed. Reg. 65578 (Nov. 5, 2014). VA implemented the Choice Act by establishing the Veterans Choice Program (“Choice Program”) and implementing regulations at 38 C.F.R. §§ 17.1500-17.1540.⁶

The Choice Program covers the provision of prosthetic items and services. Specifically, the Choice Act requires VA to furnish “[h]ospital care and medical services under chapter 17 of title 38, United States Code...to an eligible veteran.” Pub. L. No. 113-146, Sect. 101. In the Proposed Rule, VA makes clear that prosthetic and rehabilitative items and services are “medical services” as defined in 38 U.S.C. 1701(6)(F), and as authorized to be provided to veterans under VA’s general medical authority at 38 U.S.C. § 1710. 82 Fed. Reg. at 48018. The preamble to the Choice Program interim final rule states, “Any care that is covered by the medical benefits package, including prescriptions such as prescription medications or prosthetic devices, may be furnished through the Program.” 79 Fed. Reg. 65571, 65578 (Nov. 5, 2014). The interim final rule also states, “If prosthetics are prescribed as part of the care that is provided under the Program, VA will pay for these items as well.” *Id.* at 65578. To the extent proposed § 17.3240 would operate to limit an eligible veteran from receiving medical treatment outside of VA under the Choice Program, it would conflict with the Choice Act and be invalid. For example, VA would not be permitted to restrict a veteran to seeing a VA provider for prosthetics care if the veteran were otherwise eligible to see a non-VA Choice Program provider.

In terms of obtaining prosthetic items under the Choice Program, VA treats prescriptions for prosthetics like prescriptions for medication, which are generally filled through VA pharmacies even if prescribed by a non-VA provider. When a veteran receives care through the Choice Program, any prescriptions for durable medical equipment (“DME”), to include prosthetics, are fulfilled through the local VA facility.⁷ We were unable to identify specific VA guidance on exactly how such a prescription generated by a Choice provider would be filled by VA. We note that treating a DME prescription the same as a prescription for medication is not entirely consistent with the language of the Choice Act. The Choice Act provides that it is not to be construed “to alter the process of the Department for filling and paying for prescription medications,” Pub. L. No. 113-146, § 101(r), but contains no specific carve out for DME. Given

⁶ The Choice Program is a temporary program which will operate until all of the money in the Veterans Choice fund is expended. Pub. L. No. 115-26, § 1 (2017). In August 2017, Congress authorized \$2.1 billion in additional funding for the Choice Program. VA Choice and Quality Employment Act of 2017, Pub. L. No. 115-46.

⁷ For example, HealthNet, one of two third party administrators contracted to administer the Choice Program, instructs Choice Program providers to “[c]oordinate route durable medical equipment, prosthetics and orthotics (DMEPOS) requests through the referring VA facility.” See HealthNet Veterans Choice Program Participating Provider Handbook June 2017 (available at https://www.hnfs.com/content/dam/hnfs/va/provider/pdf/VCP_Participating_Prov_Handbook.pdf). The Choice Program as implemented allows for certain exceptions for emergent circumstances. VA has issued guidance allowing for a 14-day prescription fill anywhere in the community for urgently needed prescriptions. See <https://www.va.gov/health/newsfeatures/2015/july/10-things-to-know-about-choice-program.asp>. Similarly, effective April 7, 2017, urgent or emergent DME/prosthetics must be provided by the treating physician/facility and or a DME supplier at the time of treatment and prior to the veteran leaving the provider’s facility for an authorized episode of care. See <https://www.hnfs.com/content/hnfs/home/va/provider/resources/pccc-provider-news/supplying-urgent-and-emergent-dme.html>.

government pricing and volume purchasing considerations, the exclusion of DME makes sense. However, we also note that VA implemented the Choice Program by amending existing Patient-Centered Community Care contracts (as authorized under 38 U.S.C. § 8153), which already specifically excluded certain items including DME. See Fact Sheet 20-09: Veterans Choice Program (VCP) Overview (February 2017).

Under VA's other contracting authorities, the decision to provide non-VA care is based on a VA facility determination using certain criteria. Specifically, the VA facility may provide non-VA care if the facility determines that the service cannot be provided within an acceptable wait-time or acceptable distance, the service cannot be provided internally because the facility does not have the service or has chosen to purchase the particular service in the community, or the facility has determined there is a compelling reason the veteran needs care in the community. See 38 U.S.C. § 1703; 38 C.F.R. § 17.52; 38 U.S.C. § 8153. Service-connected disability status may be a factor in terms of which authority is used. Unlike the Choice Program, the decision to provide non-VA care is generally not at the election of the eligible veteran. In addition, VA has historically reserved the responsibility to provide prescribed prosthetic items and services under these traditional non-VA care authorities. See VHA Handbook 1173.2, section 1. For these reasons, proposed § 17.3240 is less likely to operate in conflict with these authorities.

Finally, we note that VA has sought legislation to consolidate its non-VA care contracting authorities into a single program. See "Plan to Consolidated Programs of Department of Veterans Affairs to Improve Access to Care," October 30, 2015. It could be beneficial for any such legislation to specifically address the provision of prosthetic items and services.

IV. Conclusion

VA has the authority to alter its policy regarding prosthetic items and services, but under the APA may have failed to adequately describe such changes and the reasoning for them in the Proposed Rule. In addition, proposed § 17.3240 would be invalid to the extent it would interfere with a veteran's choice of provider under the Choice Program. However, ambiguities in the Proposed Rule make it unclear whether and to what extent proposed § 17.3240 would interfere with the Choice Act. We recommend submitting comments to the agency raising these issues along with substantive policy objections to the Proposed Rule.