Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 17

RIN 2900–AP46

Prosthetic and Rehabilitative Items and Services

AGENCY: Department of Veterans Affairs.

ACTION: Supplemental notice of proposed rulemaking.

SUMMARY: On October 16, 2017, the Department of Veterans Affairs published a proposed rulemaking to amend its regulations on the provision of prosthetic and rehabilitative items and services. This supplemental notice of proposed rulemaking (SNPRM) provides clarification about provisions of that proposed rulemaking and seeks additional public comments on them. This SNPRM also provides notice regarding certain communications between VA and external parties regarding the proposed rule, and a summary of these communications has been added to the public docket of this rulemaking.

DATES: Comments must be received by VA on or before December 28, 2018.

ADDRESSES: Written comments may be submitted by through *http://www.Regulations.gov*; by mail or hand-delivery to Director, Regulations Management (00REG), Department of Veterans Affairs, 810 Vermont Avenue NW, Room 1063B, Washington, DC 20420; or by fax to (202) 273–9026. Comments should indicate that they are submitted in response to ''RIN 2900–AP46, Prosthetic and rehabilitative items and services; Supplemental notice of proposed rulemaking''. Copies of comments received will be available for public inspection in the Office of Regulation Policy and Management, Room 1063B, between the hours of 8:00 a.m. and 4:30 p.m. Monday through Friday (except holidays). Please call (202) 461–4902 for an appointment. (This is not a toll-free number.) In addition, during the comment period, comments may be viewed online through the Federal Docket Management System (FDMS) at *http://www.Regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Penny Nechanicky, National Program Director for Prosthetic and Sensory Aids Service (10P4RK), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420; (202) 461–0337. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: On October 16, 2017, VA published a proposal to amend VA regulations governing the provision of prosthetic and rehabilitative items and services to eligible veterans. **Federal Register** (82 FR 48018). That rulemaking proposed to reorganize and update the regulations on prosthetic and rehabilitative items and define the types of items and services available to eligible veterans. That rulemaking also proposed to eliminate the existing prosthetics regulations at section 17.150 of title 38, Code of Federal Regulations (CFR) and establish entirely new sections at §§ 17.3200, *et seq.*

VA asked for comments on the proposed rule on or before December 15, 2017, and we received 305 comments. A number of those commenters raised concerns about proposed § 17.3240, ''Furnishing Authorized Items and Services,'' and whether the proposal would alter VA's current practices regarding veterans' choice, particularly with regard to the provision of artificial limbs, as reflected, in part, in two Veterans Health Administration (VHA) Handbooks. Commenters also raised concerns about whether the proposal conflicts with the Veterans Access, Choice, and Accountability Act of 2014 (''Choice Act''), which established VA's Veterans Choice Program.

With this SNPRM, we seek to clarify the intended effect of proposed § 17.3240, explain our current practices and processes relating to that provision, and request additional comments on it. We also propose edits to proposed § 17.3240 as explained in more detail below. We will address all of the comments that VA received on the proposed rule and any comments VA receives on this SNPRM in our final rulemaking.

We clarify that the proposed rule and this SNPRM would not result in a different experience for most veterans receiving prosthetics and related care from VA. In proposed § 17.3240, we are codifying our current practice of providing all prosthetic and rehabilitative items and services under § 17.3230. With regard to the provision of artificial limbs under the proposed rule, we propose to revise VHA's existing policies that allow veterans to choose the provider of artificial limbs in limited circumstances. We also propose to align policies and practices to be consistent with the provision of all other prosthetic and rehabilitative items and services, with the community care authorities (*e.g.,* Choice Act), and with our current national preferred process for the provision of artificial limbs (which we intend to continue as the national standard pursuant to this rulemaking). This current national preferred process would be implemented pursuant to this rulemaking as it will provide consistency in how artificial limbs are provided throughout VA. In the provision of artificial limbs across VHA, medical facilities have not consistently applied certain provisions of its current handbooks, specifically paragraph 6.c.(1)(b) of VHA Handbook 1173.2 and paragraphs 4.c. and 7.a. of VHA Handbook 1173.3, as written, and these policies have led to ambiguity and misinterpretation within VA and by the public. Pursuant to this rulemaking, VA proposes to revise these policies, as following them as written in these two handbooks could limit consideration of important factors, such as the veteran's clinical needs. It was not our intent that VA clinical providers would not be involved in this very important decision on how the veteran's needs can be best met. As prosthetists have varying levels of expertise and familiarity with artificial limbs, if VA followed these policies as written, VA would not be able to confirm or validate that the prosthetist chosen by the veteran would be the most appropriate prosthetist to provide the artificial limb and associated services.

Following these policies would also not be consistent with our contracting authorities, such as the Federal Acquisition Regulations (FAR) and VA Acquisition Regulations (VAAR). These policies have been left to each medical facility to interpret and apply, which has resulted in inconsistent application across the country. In a 2012 audit of the management and acquisition of

prosthetic limbs within VHA, VA's Office of the Inspector General (OIG) found varying procurement practices among different test regions in VHA ''[d]ue to the inconsistencies in the available guidance.'' See, *Veterans Health Administration, Audit of the Management and Acquisition of Prosthetic Limbs,* Report No. 11–02254–102, VA OIG, Office of Audits and Evaluations, March 8, 2012, page 9. The OIG concluded that such variability led to ''overlap and gaps in services'' and that ''contracting staff may be performing unnecessary workload.'' *Id.* The OIG further concluded that ''[i]t is important that VHA monitors contract workload and ensures the contracts it awards and administers are necessary to support veterans' requirements.'' *Id.* Through this rulemaking, we seek to create a uniform standard and process for the provision of artificial limbs to ensure all VA medical facilities are in alignment with the current process for the provision of all other prosthetic and rehabilitative items and services, and with our current national preferred process for the provision of artificial limbs, which we intend to continue pursuant to this rulemaking. In the following paragraphs, we will explain our processes for the provision of all prosthetic and rehabilitative items and services, as well as artificial limbs, and address certain public comments regarding proposed § 17.3240.

General Current Process for the Provision of Prosthetic and Rehabilitative Items and Services Other Than Artificial Limbs

The current decision making process for providing prosthetic and rehabilitative items and services starts with a clinical evaluation of a veteran's needs by a VA health care provider or authorized community (*i.e.,* non-Department) provider. The decision on the prosthetic or rehabilitative item or service to be provided to the veteran is a clinical decision made by the veteran's health care provider, in consultation with the veteran, and results in a prescription for a prosthetic or rehabilitative item or service. This ensures that the veteran's clinical needs will be met by the item or service prescribed, that the item or service prescribed is safe, that the veteran is involved in this process because he or she is a necessary member of the health care delivery team, and that the item or service will serve as a direct and active component of the eligible veteran's medical treatment and rehabilitation. A VA prosthetics representative at a VA medical facility then determines how best to provide the item or service to the veteran. While sections 1701 and 1710 of title 38, United States Code (U.S.C.), require VA to furnish medical services, including medically necessary prosthetic and rehabilitative items and services to certain eligible veterans and authorize VA to provide them to other eligible veterans, the decision as to how VA provides such items and services is discretionary. As explained at 82 FR 48025, if VA has the capacity or inventory to directly provide such item or service, VA will do so. VA may use authorized community vendors on a case-by-case basis to provide greater access, lower cost, and a wider range of items and services. Pursuant to the FAR, VA utilizes national and regional agreements to provide prosthetic and rehabilitative items and services and also, on a case by case basis, enters into agreements with vendors in the community who are not part of these national or regional agreements in the instance that VA is unable to provide these items and services directly or pursuant to an existing agreement. While VA has general authority to provide necessary health care services to eligible veterans, VA's authority to provide such services through community sources is constrained by statute and regulation. For example, except where authorized, VA complies with the FAR and the VAAR, which ensure that the prescribed items and services meet the veteran's clinical needs and that VA obtains such items and services in a fiscally responsible and legally sufficient manner.

We note that the decision of *what* prosthetic or rehabilitative item or service is to be provided is a clinical decision and results in a prescription. The decision of *how* that prescribed item or service is provided is a separate decision, and VA retains the authority to make this determination. As long as the prescribed item or service (whether prescribed by a VA or an authorized community provider) serves as a direct and active component of the veteran's medical treatment and rehabilitation, VA prosthetics representatives will honor the prescription and procure the prescribed item or service for the veteran. While the veteran's clinical needs are always considered in the determination of how the item or service is procured, administrative factors are also considered on a case by case basis, as explained in more detail throughout this SNPRM. Under the proposed rulemaking and this SNPRM, we would continue to ensure that the veteran's clinical needs drive how the agency determines whether VA can directly provide the prescribed item or service, or whether VA will use an authorized vendor in the community to provide the item or service. VA's procurement practices with respect to prosthetic and rehabilitative items and services are aimed at ensuring that veterans' needs are met with the most appropriate and highest quality items and services in a consistent manner throughout VA and that VA complies with Federal and VA acquisition regulations as applicable.

Current National Preferred Process for the Provision of Artificial Limbs

As previously discussed, there is some variation in the provision of artificial limbs throughout VHA, specifically with regard to the role of the veteran and the clinician in the determination of how prescribed items and services are provided. The following is a discussion on the current national preferred process for the provision of such items and encompasses the process VA intends to continue pursuant to proposed § 17.3240. Similar to the provision of other prosthetic and rehabilitative items and services under proposed 38 CFR 17.3230 as explained above, in the instance of the provision of an artificial limb, VA first requires an evaluation of a veteran's clinical need for such item. This evaluation is typically done by the amputee clinic team. If a veteran has been evaluated by an authorized community provider, any prescription for an artificial limb and related components written by that authorized community provider is referred to the amputee clinic team, particularly because the authorized community provider may not specialize in artificial limb evaluation. Oftentimes, the prescription does not contain sufficient information for VA to provide directly or through a VA-authorized prosthetist all the components, accessories, supplies, and related services necessary to fabricate an artificial limb. Furthermore, agreements with VA-authorized prosthetists for the artificial limb and related services must include Healthcare Common Procedure Coding System (HCPCS) codes, which VA determines based on an evaluation of the patient by the amputee clinic team. The amputee clinic team conducts an assessment to determine the veteran's clinical needs, and along with the veteran, identifies the appropriate artificial limb and related components needed and makes a determination on how the item(s) will be provided. As discussed in the previous section, this decision is in consultation with the veteran and prioritizes veterans' clinical needs. Generally, if a VA medical

facility accessible to the veteran offers the orthotic and prosthetic services that meet the veteran's clinical needs, then VA provides the limb and all associated services (*e.g.,* fitting, minor repairs, routine servicing) directly to the veteran. If VA's decision is that the veteran should receive the item and services from a community (*i.e.,* non-Department) prosthetist, VA utilizes its established orthotic and prosthetic agreements in the region to authorize a community prosthetist to provide the artificial limb and associated services to the veteran. The veteran is able to select, in consultation with his or her VA clinician or amputee clinic team, from a list of vendors in the geographic area that have an existing agreement with VA and are able to meet the veteran's clinical needs. While most facilities have a number of established agreements already in place for use, in the instance that there is no prosthetist under an established agreement that is able to meet the veteran's clinical needs, VA and the veteran will work together to identify the appropriate community prosthetist, and VA would seek to establish an agreement with that prosthetist for the needed artificial limb and related services. In purchasing such items and services, VA complies with the FAR and VAAR as applicable. We note that some of the above process may vary if the veteran is eligible for the Veterans Choice Program, operated pursuant to § 17.1500 *et seq.* Under proposed § 17.3240, we would standardize this process of determining whether to directly provide the artificial limb and associated services or whether to use a VA-authorized vendor (*i.e.,* a community/non-Department prosthetist). This would result in several benefits. First, it would ensure VA provides such items and services in a consistent and standardized manner throughout VA, which would also be consistent with the provision of all other prosthetic and rehabilitative items and services. Second, it would be consistent with the current national preferred practice, while also ensuring compliance with Federal acquisition requirements. Finally, and most importantly, this would ensure veterans receive the most appropriate and highest quality item or service that meets their clinical needs. We note that VA retains authority over this determination to ensure that there is consistency across VHA in the provision of these prescribed items and services, and for quality control purposes.

Public Comments About Proposed § 17.3240

Many commenters raised concerns about VA's statement in the proposed rule at 82 FR 48025 that the decision as to whether VA or a VA-authorized vendor (*i.e.,* community/non-Department vendor) will furnish the prescribed item or service to the veteran is an administrative business decision; the commenters stated that this is instead a clinical issue that should also be based on the veterans' preferences. Some commenters were concerned that making this an administrative business decision would restrict veterans' choice of providers and delay care. We agree and now clarify that our description of the proposed rule failed to state that clinical decisions are necessary to issue the clinically-appropriate prosthetic or rehabilitative item or service to a veteran. Furthermore, as mentioned in the discussions above, the decision about what item or service VA will provide to the veteran is a clinical decision made by the veteran's health care provider, in consultation with the veteran, which results in a medical prescription. Additionally, there is a related decision about *how* VA will provide the prescribed items and services (whether by VA or by a VA-authorized vendor). The veteran's clinical needs will drive this determination. However, while the clinical needs are always part of this determination, VA may consider administrative factors when making this determination. Such administrative factors considered may include, but would not be limited to, VA capacity and availability, geographic availability, and cost. We note that VA capacity and availability can refer to whether a VA medical facility has the resources and equipment to fabricate an authorized item or service, and whether VA providers are available and have the skills, abilities, and experience to provide an authorized item or service. For example, a VA prosthetist may have the ability to fabricate an artificial limb, but may not be able to fabricate the limb because of his or her workload. In that instance, VA may determine that an authorized VA vendor will provide the authorized item or service. If the authorized item or service requires certain expertise or experience that a VA provider does not have, VA may determine that an authorized VA vendor will provide that item or service instead. Relatedly, some VA medical facilities have laboratories in which artificial limbs can be fabricated while others do not, and this would be a consideration in determining whether VA or an authorized VA vendor provides the artificial limb. We also note that how geographic availability is considered in this determination of whether VA or an authorized VA vendor provides the authorized item or service will vary. There would be no set distance or mileage that we would define when considering geographic availability in this determination, as this can be dependent on the health and mobility of the veteran and his or her clinical needs. For example, in considering geographic availability, a veteran amputee who has no other medical conditions that would limit his or her mobility and may have regular access to a vehicle will likely have substantially different clinical needs in this regard than a veteran amputee with medical conditions that impede his or her mobility and who may lack dependable access to a vehicle. For veterans who have mobility issues, geographic availability can vary significantly. In such situations, it would be appropriate for the provider to consider whether a specific limb under consideration can be fabricated, serviced, and repaired by a VA or non-VA prosthetist. We further note that although cost is not a factor providers consider when determining which item or service to prescribe, it may be relevant in determining whether VA or an authorized VA vendor provides the prescribed item or service. For example, if an authorized vendor sells the authorized item at a lower cost than what it would cost VA to provide the item itself, then VA may decide to procure the item from the authorized VA vendor based on cost.

While the factors VA considers in making the determination of how to provide the authorized item or service will vary, we would continue to ensure that the veteran's clinical needs drive how the agency determines whether VA can directly provide the prescribed item or service, or whether VA will use an authorized vendor in the community to provide the item or service, while also ensuring that VA is administering these benefits in a fiscally responsible and consistent manner.

Other commenters expressed concern that administrative business decisions would not be consistent with other authorities, particularly the Choice Act. First, we note that since the publication of the proposed rule in October 2017, the President signed into law the VA MISSION Act of 2018 (Pub. L. 115–182). Section 143 of this Act provides that VA may not use the Choice Act authority to furnish care and services after June 6, 2019. While we address, in this SNPRM, the concerns regarding the Choice Act that were raised by commenters, we

realize that these concerns and our responses will become moot once VA's authority to furnish care and services pursuant to the Choice Act ends. As a result of the VA MISSION Act of 2018, VA is developing new regulations for the new Veterans Community Care Program required by section 101 of that Act and will also be revising or eliminating the regulations implementing the Choice Act; should any further revisions to VA's prosthetic regulations be needed as a result of these efforts, VA will address those changes through a subsequent rulemaking and further explain or modify these regulations as necessary.

We note that eligibility for the Veterans Choice Program implemented pursuant to the Choice Act is dependent on meeting certain criteria defined in § 17.1510. In comparison, eligibility for prosthetics and rehabilitative items and services is set forth in proposed § 17.3220, which would only require that the veteran be enrolled in VA health care pursuant to § 17.36 or exempt from enrollment under § 17.37, or that the veteran be otherwise receiving care or services under chapter 17 of title 38 U.S.C. If the veteran meets any of these criteria, he or she would be eligible to receive a prosthetic or rehabilitative item or service so long as such item or service serves as a direct and active component of the veteran's treatment or rehabilitation. Similar to the Choice Program, factors such as geographic availability are considered in making the determination. However, VA always considers clinical factors in making the determination of who will provide the prescribed item or service. While the eligibility criteria for when a veteran is able to seek care from a community provider under the Veterans Choice Program are generally administrative, the determination of who provides the prosthetic and rehabilitative item or service under § 17.3240 is both administrative and clinical. We note that this latter determination is broader and less stringent than the determination under the Veterans Choice Program and provides the veteran with input into whether VA or an authorized VA vendor provides him or her with the prescribed item or service.

Relatedly, general concerns were raised that proposed § 17.3240 is inconsistent with the Choice Act. While VA may not use the Choice Act to furnish care and services after June 6, 2019, as described above, we believe these authorities are consistent with one another, or where they are potentially inconsistent, they are so in a way to the benefit of the veteran in that this proposed rule is broader and less stringent than the eligibility requirements under the Veterans Choice Program. We note that the Choice Act requires VA approval prior to obtaining care from a community provider, and there are specific criteria that veterans and community providers must meet for care to be authorized and approved. See §§ 17.1500 *et seq.* If a veteran is eligible and approved by VA to seek care outside VA under § 17.1510, that veteran may obtain care from eligible entities and providers under § 17.1530. An agreement must be in place prior to the authorized care being furnished, and the agreement or authorization for care must be specific as to the care to be provided to the veteran. If the authorized entity or provider prescribes a prosthetic or rehabilitative item or service, VA would then proceed to procure that item or service as long as it is part of the original authorized care and serves as a direct and active component of the veteran's treatment or rehabilitation. In this context, the proposed rule as modified by this SNPRM is consistent with the Choice Act, as the Choice Act requires VA to authorize prosthetic and rehabilitative items and services from a VA-authorized vendor in the community prior to those items or services being provided. See, *e.g.,* Public Law 113–146, sec. 101(a)(1)(A), (c)(1)(B)(i), (d)(4)(B)(iii), and (h). See also 38 CFR 17.1505 (the definition of appointment, in particular), 17.1510(d) (''prior to obtaining authorization for care''), 17.1515(a), and 17.1535(c). Thus, proposed § 17.3240 is consistent with, and less restrictive than, the Choice Act.

In addition to the Choice Act, commenters raised concerns about whether the proposed rule would implicate other community care authorities, such as 38 U.S.C. 8153 and 1703. Sections 8153 and 1703 are used by VA to obtain medical care in the community; however, we note that section 1703 will be revised significantly by 101 of the VA MISSION Act of 2018. These changes will become effective when VA publishes regulations implementing section 101 of the VA MISSION Act of 2018. The proposed rule, as amended by this SNPRM, would not limit, impact, or be inconsistent with VA's existing or future authorities under sections 8153 and 1703. These are not authorities that we have used to purchase prescribed prosthetic and rehabilitative items or services. Similar to the Choice Program, if the entity or provider authorized under sections 1703 and 8153 to provide care to a veteran prescribes a prosthetic or rehabilitative item or service, VA would then proceed to procure that item or service as long as it is part of the original authorized care and serves as a direct and active component of the veteran's treatment or rehabilitation. VA would then use its prosthetic procurement authorities (*i.e.,* 38 U.S.C. 8123, FAR, and VAAR) to obtain the prescribed prosthetic and rehabilitative items and services. In this context, the proposed rule as modified by this SNPRM is consistent with sections 1703 and 8153. Similar to the Choice Act, these authorities have separate eligibility criteria than what is in proposed § 17.3220. See 38 U.S.C. 1703, 8153, and 38 CFR 17.52. We note that proposed § 17.3220 would be less restrictive than the eligibility criteria for these community care programs, as these community care authorities require facilities to consider only certain factors when determining whether a veteran may obtain care outside VA. For example, pursuant to 38 CFR 17.52, in instances when VA facilities are incapable of furnishing care due to geographic inaccessibility or are not capable of furnishing care or services required, VA may contract with non-VA facilities for the care. As the regulations implementing these community care authorities are undergoing revision due to the enactment of the VA MISSION Act of 2018, should any further revisions to VA's prosthetic regulations be needed as a result, VA will address those changes through a subsequent rulemaking and further explain or modify these regulations as necessary.

Additionally, we note that 38 U.S.C. 1703 distinguishes between veterans with service connected and nonservice connected disabilities when determining their eligibility to obtain care outside VA under that authority. Section 101 of the VA MISSION Act of 2018 will revise section 1703 to remove this distinction, and to the extent necessary, such elimination would be reflected under these prosthetics regulations. We note that the proposed prosthetics regulations, as amended by this SNPRM, do not distinguish between veterans with service connected conditions and nonservice connected conditions.

Commenters also raised concerns about the authority for proposed § 17.3240, as VA did not cite to or reference the statutory authority for that section. As mentioned previously in this discussion, 38 U.S.C. 1710, the authorizing statute, requires VA to furnish medical services to certain eligible veterans and authorizes VA to provide them to other eligible veterans. See also, 38 U.S.C. 1701(6), which defines the term ''medical services'' in

a manner that covers prosthetic and rehabilitative items and services. Sections 1701 and 1710 do not, however, mandate how VA provides these items and services. In other words, how VA provides them is discretionary, and VA proposes § 17.3240 pursuant to this authority.

VA also received many comments stating that the proposed rule contradicted existing VHA policies and practices relating to the provision of artificial limbs and the veteran's choice of provider. We note that VHA Handbooks 1173.2 ''Furnishing Prosthetic Appliances and Services'' and 1173.3 ''Amputee Clinic Teams and Artificial Limbs'' indicate that a veteran is able to choose his or her prosthetist, including community (*i.e.,* non-Department) prosthetists, if the veteran has a preexisting relationship with that prosthetist. VHA Handbook 1173.2 paragraph 6.c.(1)(b) states that, ''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.'' Paragraph 4.c. of VHA Handbook 1173.3 states, ''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.'' Paragraph 7.a. of that same Handbook further states, ''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.''

As mentioned previously in this document, these provisions in these two handbooks have not been consistently applied as written throughout VA's medical facilities in the provision of artificial limbs. We propose to revise these policies, because following them as written has resulted in inconsistent application, and ambiguity and misinterpretation within VA and by the public. Additionally, as prosthetists have varying levels of expertise and familiarity with artificial limbs, if VA followed these policies as written, VA would not be able to confirm or validate that the prosthetist chosen by the veteran would be the most appropriate prosthetist to provide the artificial limb and associated services. It was not our intent that VA clinical providers would not be involved in this very important decision on how the veteran's needs can be best met. As previously mentioned, the veteran and the VA provider would work together to determine what item or service is needed to meet the veteran's clinical needs, and who may be able to provide such item or service. The veteran's preferences will be part of that decision with the VA provider. Through this rulemaking, we seek to ensure a standardized and consistent process across VA for the provision of artificial limbs that is consistent with the current national preferred process and with the process for the provision of all other prosthetic and rehabilitative items and services.

After this rulemaking is final, VA will rescind VHA Handbooks 1173.2 and 1173.3 and develop new policies to update and clarify its procedures, consistent with this regulation.

Corrections to Proposed § 17.3240

Based on these comments received and the discussion above, VA now proposes to revise the language of § 17.3240, as proposed in 82 FR 48018. In revised proposed § 17.3240(a)(1), we would state that VA providers will prescribe items and services based on the veteran's clinical needs and will do so in consultation with the veteran. Once the prescribed item or service is determined to be authorized under § 17.3230, 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 § 17.3220. We would add paragraph (a)(2) to § 17.3240 to state that this determination on whether VA or a VA-authorized vendor will furnish the authorized item or service under § 17.3230 will be based on, but not limited to, such factors as the veteran's clinical needs, VA capacity and availability, geographic availability, and cost.

Revising the language of § 17.3240, as proposed in 82 FR 48018, would codify our current practices and the current national preferred process for the provision of artificial limbs; it also would clarify that the item or service that is authorized is prescribed based on the veteran's clinical needs and is done in consultation with the veteran. In response to many comments regarding this clinical decision and the veteran's involvement in that decision, we explicitly note that the prescription is clinical and based on the veteran's clinical needs. For similar reasons, we would also clarify that the prescription is generated in consultation with the veteran. This would be explained in proposed 17.3240(a)(1).

Additionally, as mentioned, we received comments that the decision on how to provide an authorized item or service should not be administrative, but rather clinical. Relatedly, at least one commenter raised the concern that we did not identify or explain the factors we would use in making this determination. In response to the comments received, we would revise proposed § 17.3240 to clarify that the determination on how the item or service is provided is based on clinical and administrative factors. In proposed § 17.3240(a)(2), we would list factors that would be considered when procuring and providing the authorized item or service. This list of factors is non-exhaustive. Not all factors would be considered in every instance, as the provision of each authorized item or service will vary, and additional factors could be considered as needed. For example, a specific wheelchair may be prescribed as that may be the only wheelchair that would meet the veteran's clinical needs, and there may be only one manufacturer of that wheelchair. In that instance, if the wheelchair meets the direct and active component standard, it will be authorized and VA would proceed to procure that wheelchair directly from the manufacturer without consideration of the other factors. Additionally, a provider may prescribe diabetic shoes to meet a veteran's clinical needs, and if VA has those in its inventory, it will provide those to the veteran. If there are none in inventory and VA needs to procure the prescribed shoes, then we will look at our existing contracts to purchase such items. Additional factors such as cost may be considered in that instance to ensure that we are being fiscally responsible. As explained previously, VA capacity and availability can refer to whether a VA medical facility has the resources and equipment to fabricate an authorized item or service, or whether VA providers are available or have the skills, abilities, and experience to provide an authorized item or service. With regard to geographic availability, we note that how this factor may be considered would vary. There would be no set distance or mileage that we would define when considering geographic

availability in this determination, as this can be dependent on the health and mobility of the veteran and his or her clinical needs. Although cost is not a factor providers consider when determining which item or service to prescribe, it may be relevant in determining whether VA or an authorized VA vendor provides the prescribed item or service, as an authorized vendor may sell the authorized item at a lower cost than what it would cost VA to provide the item itself.

How the authorized item or service is obtained and provided to the veteran will vary based on each individual case. However, we note that the veteran's clinical needs are always prioritized when VA determines how to provide the authorized item or service. Proposed § 17.3240 would ensure that VA is fiscally responsible. VA retains authority over this determination of how the authorized item or service is provided to ensure that there is consistency across VHA in the provision of authorized prosthetic and rehabilitative items and services, and to ensure quality control.

One commenter also noted that we incorrectly referenced proposed § 17.3210 in proposed § 17.3240. Proposed § 17.3210 is the section on definitions whereas proposed § 17.3220 is the section on eligibility. In order to correctly reference the eligibility section, we would update proposed § 17.3240 to refer to § 17.3220 instead of § 17.3210.

As previously mentioned, since the publication of VA's proposed rule in October 2017, the President signed into law the VA MISSION Act of 2018 (Pub. L. 115–182). VA is working to implement this new authority, and should any further revisions to VA's prosthetic regulations be needed as a result of this recently enacted legislation, VA will address those changes through subsequent rulemaking related specifically to the VA MISSION Act of 2018.

Certain Communications Between VA and External Parties

The Office of the VA Secretary also received two inquiry letters during the public comment period for the proposed rule. One from former Senator Bob Dole and the other from Peter Thomas, General Counsel for the National Association for the Advancement of Orthotics and Prosthetics. Both of these letters were treated as public comments and added to docket ID VA–2017–VHA–0023 in *regulations.gov*. Both of these letters raised concerns regarding proposed § 17.3240 and were similar to the public comments we received that led to the proposed clarification of that section in this SNPRM. The VA Secretary at the time and VHA's Executive in Charge, respectively, responded to these two inquiries in letters sent to Senator Dole and Mr. Thomas.

The letters stated the intent and purpose of the proposed rule to organize and update the current prosthetic and rehabilitative items and services regulations and define the items and services available. These letters also explained that these rules were proposed in order to ensure standardization and consistency in the provision of such items and services throughout VA, while also ensuring that veterans receive the most appropriate and highest quality items. The then-Secretary's letter to Senator Dole further explained that VA was codifying its practice of determining whether VA has the capacity or capability to provide items and services directly to veterans, or whether a VA-authorized vendor may be utilized, which is based on several factors including the veteran's clinical needs, costs of items and services, or wider selection of items and services. In both letters, VA stated that these letters would be treated as public comments and that VA will consider and respond to their issues in the final rulemaking. Additionally, the Department's letters containing our responses to the two letters have been made publicly available in the supplemental notice of proposed rulemaking docket.

On June 14, 2018, VHA met with individuals from McGuire Woods Consulting, who represent American Orthotic and Prosthetic Association (AOPA), at their request, to discuss several prosthetic issues, including the proposed rulemaking at 82 FR 48018 (RIN 2900–AP46). During this discussion, VHA was asked the status of RIN 2900–AP46 and where VHA thought the policy on veterans being able to see outside providers was going. VHA explained that we will continue to provide the necessary care inside and outside VA and that reducing the amount of care in the community is not our intent. With regard to RIN 2900–AP46, VHA conveyed that it received comments, including those of AOPA; is considering these comments; and is drafting the final rule, which will have to be approved by the Administration, and VHA cannot say when it anticipates the final rule to be published. VHA was also asked about the impact of the VA MISSION Act of 2018 on RIN 2900–AP46. VHA stated that this Act will provide more flexibility to provide care in the community and that VHA did not believe the Act would affect the provision of prosthetic and rehabilitative items and services. A summary of this meeting has been made publicly available in the supplemental notice of proposed rulemaking.

Lastly, the House Veterans' Affairs Committee, Health Subcommittee, held a roundtable regarding prosthetics issues on July 25, 2018. VA was a participant at this roundtable. During this roundtable, concerns were raised about the proposed rule, RIN 2900–AP46, that were similar to those concerns raised during the public comment period. Within this SNPRM, we have addressed these concerns, which were similar to those raised during the public comment period.

Based on all of the comments received regarding proposed § 17.3240, we propose to revise the text of proposed § 17.3240 as explained previously in this SNPRM.

Effect of Rulemaking

The Code of Federal Regulations, as proposed to be revised by the proposed rulemaking at 82 FR 48018 and this SNPRM, would represent the exclusive legal authority on this subject. No contrary guidance or procedures would be authorized. All VA guidance would be read to conform with the proposed rulemaking at 82 FR 48018 and this SNPRM if possible or, if not possible, such guidance would be superseded by this SNPRM and the proposed rulemaking at 82 FR 48018.

Paperwork Reduction Act

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

Regulatory Flexibility Act

The Secretary hereby certifies that this SNPRM 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. Therefore, pursuant to 5 U.S.C. 605(b), these amendments would be exempt from the initial and final regulatory flexibility analysis requirements of 5 U.S.C. 603 and 604.

Executive Orders 12866, 13563, and 13771

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety

effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Executive Order 12866 (Regulatory Planning and Review) defines a ''significant regulatory action,'' requiring review by the Office of Management and Budget (OMB) as ''any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.'' The economic, interagency, budgetary, legal, and policy implications of this regulatory action have been examined, and it has been determined not to be a significant regulatory action under Executive Order 12866.

This rule is not an Executive Order 13771 regulatory action because this rule is not significant 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.''

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 SNPRM would have no such effect on State, local, and tribal governments, or on the private sector.

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance numbers and titles for the programs affected by this document are 64.009, Veterans Medical Care Benefits; 64.013, Veterans Prosthetic Appliances.

List of Subjects in 38 CFR Part 17

Administrative practice and procedure, Government contracts, Health care, Health facilities, Health professions, Medical devices, Veterans.

Signing Authority

The Secretary of Veterans Affairs approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. Robert L. Wilkie, Secretary, Department of Veterans Affairs, approved this document on October 23, 2018, for publication.

Dated: November 5, 2018.

Consuela Benjamin,

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

For the reasons set forth in the preamble, we propose to amend 38 CFR part 17 as follows:

PART 17—MEDICAL

■ 1. The authority citation for part 17 continues to read as follows:

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

■ 2. Add § 17.3240, to read as follows:

§ 17.3240 Furnishing authorized items and services.

(a)(1) VA providers will prescribe items and services based on the veteran's clinical needs and will do so in consultation with the veteran. Once the prescribed item or service is determined to be authorized under § 17.3230, 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 § 17.3220.

(2) This determination on whether VA or a VA-authorized vendor will furnish the authorized item or service under § 17.3230 will be based on, but not limited to, such factors as the veteran's clinical needs, VA capacity and availability, geographic availability, and cost.

(b) Except for emergency care reimbursable under 38 CFR 17.120 through 17.132 or 38 CFR 17.1000 through 17.1008, prior authorization of items and services under § 17.3230 is required for VA to reimburse VA-authorized vendors for furnishing such items or services to veterans. Prior authorization must be obtained from VA by contacting any VA medical facility.

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