



DEPARTMENT OF VETERANS AFFAIRS

8320-01

38 CFR Part 17

RIN 2900- AP46

Prosthetic and Rehabilitative Items and Services

AGENCY: Department of Veterans Affairs.

ACTION: Proposed rule.

SUMMARY: The Department of Veterans Affairs (VA) proposes to revise its medical regulations related to providing prosthetic and rehabilitative items as medical services to veterans. These revisions would reorganize and update the current regulations related to 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.

DATES: Comments must be received by VA on or before [Insert date 60 days after date of publication in the FEDERAL REGISTER].

ADDRESSES: Written comments may be submitted by email through <http://www.regulations.gov>; by mail or hand delivery to Director, Regulations Management (00REG), Department of Veterans Affairs, 810 Vermont Avenue, N.W., 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.” 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, N.W., Washington, DC 20420; (202) 461-0337. (This is not a toll-free number.) Penny.Nechanicky@va.gov.

SUPPLEMENTARY INFORMATION: Section 1710 of title 38, United States Code (U.S.C.), authorizes VA to provide veterans with, among other things, “medical services” when VA determines that they are “needed.” “Medical services” is further defined in 38 U.S.C. 1701(6)(F) to include the following items and services, for veterans who are otherwise receiving care or services under chapter 17 of title 38 U.S.C.: wheelchairs, artificial limbs, trusses, and similar appliances; special clothing made necessary by the wearing of prosthetic appliances; and such other supplies or services as the Secretary determines to be reasonable and necessary. 38 U.S.C. 1701(6)(F)(i) - (iii). The language in clauses (i) through (iii) of section 1701(6)(F) is the source of VA’s authority to provide prosthetic and rehabilitative items and related services to veterans as necessary items and services (i.e., “medical services”). Historically, we have interpreted section 1701(6)(F)(iii) to authorize VA to provide other supplies and services only to the extent that they are similar or related to the expressly listed items in sections 1701(6)(F)(i) and (ii), i.e., wheelchairs, artificial limbs, trusses or similar appliances, and special clothing made necessary by the wearing of prosthetic appliances. We base this interpretation on tenets of statutory construction and opinions of VA’s Office of General Counsel. See 2A Norman J. Singer, Statutes and Statutory Construction § 47.17 (6th

ed. 2000) (explaining that as a matter of statutory interpretation, where general words follow specific words, "the general words are construed to embrace only objects similar in nature to those objects enumerated by the preceding specific words"). See also VAOPGCADV 7-2009, VAOPGCADV 9-2005, VAOPGCCONCL-8-98.

VA has considered those items expressly listed in section 1701(6)(F)(i) and (ii) as medically necessary because such items assist a veteran in compensating for the loss of mobility or loss of other functional abilities. Thus for a supply (i.e., hereafter referred to as an item) or service to be similar in nature to what is enumerated in section 1701(6)(F)(i) and (ii), it must assist a veteran to compensate for loss of mobility or loss of other functional abilities. For such items and services to be provided pursuant to section 1701(6)(F)(iii), the Secretary must first determine that the item or service could assist veterans to compensate for loss of mobility or loss of other functional abilities. Next, under that provision, the Secretary must determine that they are "reasonable and necessary." Once the Secretary makes these two determinations regarding an item or service under 1701(6)(F)(iii), VA may include them in the medical benefits package and provide them to individual eligible veterans as medical services if they are determined to be "needed" as required by section 1710(a) as implemented by 38 CFR 17.38(b).

VA's authority as described above to provide medically needed prosthetic and similar items to all veterans who are otherwise receiving care or services under chapter 17 of title 38 U.S.C. was established by section 103(a) of Public Law 104-262, The Veterans' Health Care Eligibility Reform Act of 1996, which amended the definition of medical services in 38 USC 1701(6). Prior to the enactment of Public Law 104-262, VA was effectively prohibited from providing prosthetic and similar items to most

nonservice-connected veterans except in preparation for a hospital admission or to obviate the need for hospital admission. Section 103(b) of Public Law 104-262 further directed VA to prescribe guidelines for the expanded prosthetics eligibility in section 103(a). These guidelines were issued through national Veterans Health Administration (VHA) policies beginning with VHA Directive 96-069 (as published November 7, 1996), culminating in VHA Handbook 1173.1 (as last published November 2, 2000). VA has further expressly listed “durable medical equipment and prosthetic and orthotic devices” as medical services available to eligible veterans as part of VA’s medical benefits package in 38 CFR 17.38(a)(1)(viii). Although VA administers its prosthetics program with the support of § 17.38(a)(1)(viii) as well as multiple VHA policies, neither § 17.38 (except for § 17.38(c)) nor these policies are appropriately descriptive of VA’s current practices in providing prosthetic and similar items. For instance, 17.38(a)(1)(viii) provides that eligible veterans may receive prosthetic and similar items as medical services, and § 17.38(b) further provides that such items may be considered medically necessary if they are “determined by appropriate healthcare professionals that the care is needed to promote, preserve, or restore the health” of eligible veterans; however, the “promote, preserve, or restore” criteria in §17.38(b) are not specific enough to properly articulate the concept of medical necessity in the context of prosthetic and similar items and services, versus for medical services more generally. VA finds it necessary now to clarify its current practices and to propose certain changes with regard to the provision of prosthetic and similar items and services, and such clarification and proposed changes are appropriate for a rulemaking because they would affect VA’s provision of prosthetic and similar items and services. We would not seek to substantively revise §

17.38 in this manner, however, as it would be cumbersome and potentially confusing to establish additional eligibility and other administrative criteria for prosthetic and similar items and services as a specific type of medical service. We would seek instead to establish new regulations in proposed §§ 17.3200-.3250, and would remove a current but defunct regulation specifically related to the provision of prosthetic and similar items, 38 CFR 17.150. Section 17.150 was first promulgated in 1967 and was never substantively revised to reflect eligibility for prosthetic and similar items as provided in section 103(a) of Public Law 104-262 and § 17.38(a)(1)(viii). Although § 17.150 does establish that there must be a VA determination of “feasibility and medical need” prior to the provision of prosthetic and rehabilitative items and services to veterans, the phrase “feasibility and medical need” does not properly articulate the concept of medical necessity in a manner that is consistent with current VA practices. Further, § 17.150 only provides a limited list of examples of prosthetic items and services that are provided to eligible veterans, which could be misinterpreted to be an exhaustive list. Removing § 17.150 and establishing proposed §§ 17.3200-.3250 would, among other things as described throughout this rulemaking, articulate the concept of medical necessity for these items and services in a manner consistent with current VA authority and practice, would provide a broader and expressly non-exhaustive list as well as definitions for items and services that may be provided, and would update veteran eligibility for these items and services in a manner consistent with section 103(a) of Public Law 104-262 and with § 17.38(a)(1)(viii).

The changes proposed in this rulemaking would also clarify the provision of prosthetic and rehabilitative items and services that VA provides as “medical services”

under sections 1701 and 1710, versus other similar items and services that VA provides under other authorities. Congress has enacted specific statutory provisions other than sections 1701 and 1710 to authorize VA to furnish veterans with particular items and services in connection with a disability or to assist veterans in overcoming a disability. For example, sections 1714(b) and 1717(c) authorize VA to furnish devices to blind and deaf veterans, respectively, for the broad purpose of “overcoming the disability” of blindness or deafness, without the criterion that such devices be considered medically necessary. This is not to say that such items and services could not be interpreted as being medically necessary. Rather, the enactment of statutes other than sections 1701(6)(F) and 1710(a) demonstrates Congressional intent that the items and services provided under these other statutes are to be provided in accordance with the criteria in those statutes and their implementing regulations. VA has established different regulatory criteria implementing these other statutes to control the provision of these other items (see, for instance, 38 CFR 17.3100 et seq., which controls the provision of home improvements and structural alterations permitted by 38 U.S.C. 1717(a)(2)). We propose to establish this distinction between sections 1701(6)(F) and 1710(a), and other statutes that control the provision of certain items and services, more clearly in proposed section 17.3200; specifically, we would provide a table of the statutory and regulatory authorities for items and services provided outside of sections 1701(6)(F) and 1710(a). This table would include authorities for items and services provided to veterans, but would not include authorities for items and services provided to non-veteran beneficiaries (such as the authorities to provide items necessary for care of a newborn as permitted by 38 U.S.C. 1786, or items necessary for care of certain

dependents as permitted by 38 U.S.C. 1781). We do not believe it is necessary to include authorities related to non-veterans in the proposed table, as proposed sections 17.3200 through 17.3250 only address the provision of these items and services to veterans.

17.3200. Purpose and scope.

Proposed § 17.3200 would establish a clearer purpose and scope for the provision of prosthetic and rehabilitative items and services as “medical services” than what is articulated in current § 17.150, to distinguish VA’s provision of prosthetic and rehabilitative items and services as medical services under sections 1701(6)(F) and 1710 from VA’s provision of other items and services under other authorities. Proposed § 17.3200(a) would state that the purpose of proposed §§ 17.3200 through 17.3250 would be to establish eligibility and other criteria for the provision of prosthetic and rehabilitative items and services to veterans as medical services under sections 1701(6)(F) and 1710(a). These items and services would be listed in proposed § 17.3230, and we would reference that section for ease of use.

Proposed § 17.3200(b) would establish that the scope of proposed §§ 17.3200 through 17.3250 would be limited to those prosthetic or rehabilitative items and services provided by VA as medical services under sections 1701(6)(F) and 1710(a), and would identify in a table other items or services controlled by other statutes and regulations. We propose to include this table because these items and services have different criteria (related to eligibility, restrictions, etc.) in accordance with distinct legal authorities other than sections 1701(6)(F) and 1710(a). The proposed rule would help reduce

confusion by telling users where to find the other statutes and regulations relevant to these other items and services.

17.3210. Definitions.

Proposed § 17.3210 would establish definitions relevant to the prosthetic and rehabilitative items and services to be provided by VA as medical services under sections 1701(6)(F) and 1710(a). The items and services that would be defined in this section are either expressly listed as medical services under section 1701(6)(F)(i) and (ii), or are similar or related to such expressly listed items and services because they are similarly deemed “needed” (as required by section 1710(a)), because they may be medically necessary to assist a veteran to compensate for loss of mobility or loss of other functional abilities as explained previously in this rulemaking. We note that some of the definitions below would propose additional qualifying criteria related to the items or services themselves. These additional qualifying criteria would be related to accomplishing specific tasks associated with the veteran’s rehabilitation plan in addition to the general requirement that the item be deemed medically necessary for the veteran.

“Activities of daily living (ADL)” would be defined as specific personal care activities that are required for basic daily maintenance and sustenance, to include eating, toileting, bathing, grooming, dressing and undressing, and mobility. This definition of ADLs is consistent with other VA regulatory definitions or uses of the term. See §§ 17.36, 51.120, 52.2, and 61.1.

“Adaptive household item” would be defined as a durable household item that has been adapted to compensate for, or that by design compensates for, loss of physical, sensory, or cognitive function and is necessary to complete one or more ADLs in the home or other residential setting. We believe this definition captures the common meaning and understanding of the word “adaptive” as something that compensates for loss of function, and we believe the further restrictions in this definition as explained below better explain the scope of items that would be considered covered. For instance, we would require that the adaptive household item must be “necessary” to complete one or more ADLs, because we believe this is a reasonable restriction for equipment that would be used in an individual’s home or other residential setting, and would ensure that common household items are not provided except in narrow circumstances when a veteran cannot complete an ADL without such an item due to the veteran’s loss of function. The definition of “adaptive household item” would further provide examples of such items, to include adaptive eating utensils, shower stools or chairs, hooks to assist in buttoning clothing, or shoe horns. The definition of “adaptive household item” would exclude household furniture or furnishing (which, as discussed later in this proposed rule, we would define as an item commonly used to make a home habitable or otherwise used to ornament a home, including but not limited to tables, chairs, desks, lamps, cabinets, non-hospital beds, curtains, carpet(s), etc.) because we do not find that common household furniture or furnishings are generally necessary to complete an ADL. For instance, a dining table is associated with the ADL of eating, but is distinguishable from an adaptive utensil that may be required to complete the ADL of eating. We further clarify that certain specialized items that may be medically

necessary and that could be interpreted as furniture (such as hospital beds) would be expressly included under the proposed definition of “home medical equipment” as explained later in this proposed rule. The definition of “adaptive household item” would also expressly exclude an “improvement or structural alteration” which we would define in this section the same as it is defined in 38 CFR 17.3101 (i.e., a modification to a home or to an existing feature or fixture of a home, including repairs to or replacement of previously improved or altered features or fixtures) because such improvements or alterations are authorized by section 1717(a)(2) and 38 CFR 17.3100 et seq., and are not within the scope of these proposed regulations, as stated in the table in proposed § 17.3200(b). The definition of “adaptive household item” would further exclude household appliances (which, as discussed later in this proposed rule, we would define as equipment for use in the home for performance of domestic chores or other domestic tasks, including but not limited to a refrigerator, stove, washing machine, and vacuum cleaner), except as necessary to complete an ADL, because generally most household appliances cannot be adapted to compensate, or by design do not compensate for, functional loss in such a manner as to be considered necessary to complete ADLs as defined above. An exception to this general exclusion would be permitted when the appliance would be necessary to complete an ADL, such as the provision of a blender or other food processing device to a veteran with a diagnosed swallowing disorder who must have all food pureed in order to complete the ADL of eating. In contrast, appliances that are commonly related to eating but not necessary to complete the ADL of eating, such as stoves or microwaves, would not be provided. We further would clarify that the definition of “adaptive household item” would exclude any requirement

that VA furnish such items in such a manner as to relieve any other person or entity of a contractual obligation to furnish these items to the veteran. This is because such items would not be needed as they have otherwise been provided for. For example, a veteran may have contracted with a residence or residential setting to furnish adaptive household items to the veteran.

“Adaptive recreation equipment” would be defined as an item that is designed to compensate for, or that by design compensates for, loss of physical, sensory, or cognitive function and is necessary for the veteran to actively and regularly participate in a sport, recreation, or leisure activity to achieve the veteran’s rehabilitation goals. The additional requirement that these items be deemed necessary for active and regular participation in an activity to achieve the veteran’s rehabilitation goals, which would be documented in the veteran’s medical record, ensures that items are only provided when their regular use is specifically tied to a medical goal, and not provided merely to support a veteran’s participation in an activity only for personal enjoyment. Examples of such equipment VA could provide to veterans include mono-skis and specially designed wheelchairs to play sports such as basketball.

“Cognitive device” would be defined as an item that compensates for a cognitive impairment and that is used to maintain or improve a veteran’s functional capabilities. Examples of such equipment VA could provide to veterans include tablets and smart phones, as well as associated technological equipment, applications, and/or software, that can assist a veteran in maintaining daily scheduling of important tasks or navigating their surroundings (e.g., global positioning system or GPS).

“Communication device” would be defined as an item that compensates for a communication deficiency and allows participation in daily communication activities. Examples of such equipment VA could provide to veterans include augmentation and alternative communication devices such as picture or symbol communication boards, or an electro larynx.

“Durable” would be defined to mean capable of, and intended for, repeat use. We believe this definition captures the common meaning and understanding of the term “durable.”

“Home exercise equipment” would be defined as an item used in a home or residential setting that compensates for a loss of physical, sensory, or cognitive function and is necessary for the veteran to actively and regularly participate in aerobic, fitness, strength, or flexibility activities to achieve the veteran’s rehabilitation goals. As with the definition of “adaptive recreation equipment,” the additional criteria in the definition that items are necessary for active and regular participation in an activity to achieve the veteran’s rehabilitation goals, which would be documented in the veteran’s medical record, ensures that items are only provided when their regular use is specifically tied to a medical goal, and not provided merely to support a veteran’s participation in an activity only for personal enjoyment. This criterion would also ensure that this equipment is only provided when there is no other means for the veteran to exercise to achieve the rehabilitation goal. Such “home exercise equipment” would only be provided for one location, the veteran’s primary residence, which is defined in this rulemaking (as discussed below) under proposed § 17.3210 as “the personal domicile or residential setting in which the veteran resides the majority of the year,” and this

additional criterion would be stated in proposed § 17.3230 as discussed later in this rulemaking. In identifying the veteran's primary residence, we would typically rely upon the veteran's record with VA, as well as the veteran's declared residence. The additional criterion that such equipment would only be provided for one location, the primary residence, is current VA practice, and VA has authority to determine that it is reasonable pursuant to 38 USC 1701(6)(F)(iii). In this case, VA has determined this criterion to be reasonable because it may not be cost effective to provide multiple sets of the same equipment for multiple locations. Because we will provide one set of equipment, we believe it is adequate to provide this equipment where it is used the most routinely and regularly, i.e., the veteran's primary residence. While we generally would provide home exercise equipment to the veteran's primary residence, there may be instances when it may be provided to a veteran's non-primary residence. For example, if a veteran's medical treatment or rehabilitation plan requires access to home exercise equipment and the veteran has access to a gym near his or her primary residence, but has another residence in a rural area in which the veteran does not have access to a gym, the equipment may be provided to the veteran at his or her non-primary residence based on a clinical determination that providing such equipment at the veteran's non-primary residence would be necessary as a direct and active component of the veteran's medical treatment and rehabilitation. We further would state that prior to any installation of "home exercise equipment", the owner of the residence would agree to the installation. We also note that to the extent the equipment is portable, an individual would be free to move it to another location where the veteran may temporarily reside, such as another residence during an extended seasonal stay. Examples of such

equipment VA could provide to veterans include an upper body ergometer and a functional electrical stimulation cycle.

“Home medical equipment” would be defined as movable and durable medical devices used in a home or residential setting to treat or support treatment of specific medical conditions and would include hospital beds, portable patient lifts (such as porch lifts or stair glides), portable ramps, ventilators, home dialysis equipment, and infusion, feeding, or wound therapy pumps. This definition is intended to encompass those medical devices typically found in a medical facility setting (e.g., hospital beds and infusion pumps), but that must be used in a home or residential setting for specific medical treatment (most typically, for continuation of treatment initially received in a medical facility setting). The definition of “home medical equipment” would specifically exclude household furniture or furnishings, improvements or structural alterations, or any household appliances for the same reasons as stated in the definition of “adaptive household item,” because such items could not reasonably be considered to be medical devices. For instance, a hospital bed could be provided as “home medical equipment,” whereas a common bed frame and mattress could not. As proposed in § 17.3230 (later in this rulemaking) “home medical equipment” would only be provided for one residential setting, the veteran’s primary residence, for the same reasons as stated for “home exercise equipment” above. In the instance that at-home installation or delivery is required and the veteran has more than one residence, the Department will deliver the equipment to the veteran’s primary residence. We note that to the extent the equipment is portable, an individual would be free to move it to another location where the veteran may temporarily reside, such as another residence during an extended seasonal stay.

We will provide such equipment at the veteran's primary residence, as the veteran is usually also receiving professional care or assistance from a caregiver who must be at the residence at specific times, and which would involve use of the provided "home medical equipment." While we generally would provide "home medical equipment" to the veteran's primary residence, there may be instances when it may be provided to a veteran's non-primary residence, as is similar to the provision of "home exercise equipment." For example, a veteran may be authorized for a stair glider; however, his or her primary residence may be a single floor residence. The veteran may have another residence that has more than one floor, and it may be clinically determined that the provision of the stair glider at the non-primary residence is necessary as an active and direct component of the veteran's medical treatment or rehabilitation. We also would clarify that prior to any installation of "home medical equipment", the owner of the residence must agree to the installation of the equipment. We further would clarify that the definition of "home medical equipment" would exclude any requirement that VA will furnish such items in such a manner as to relieve any other person or entity of a contractual obligation to furnish these items or services to the veteran. This is because such items would not be needed as they have otherwise been provided for. For example, a veteran may have contracted with a residence or residential setting to furnish home medical equipment to the veteran.

The definition of "home medical equipment" would also exclude "medical alert devices," which, as discussed later in this proposed rule, we would define as devices designed to summon general safety assistance for a veteran, e.g. a device worn by an individual to summon medical assistance in the event of a fall or other incident, or to

provide a veteran's general medical information to others, e.g., medical identification bracelets. While we currently provide both medical alert devices and medical identification bracelets, those would not be provided under these proposed rules as these items would not be an active and direct component of a veteran's medical treatment or rehabilitation pursuant to proposed § 17.3230, described later in this rulemaking. Medical alert devices are passive and purely communicative devices, similar to cell phones, which are not used for specific medical treatment or rehabilitation and do not contribute directly to a veteran's medical treatment or rehabilitation and would therefore not be provided under this authority. Their purpose is to communicate about an unforeseeable future event, and they do not actively communicate clinical or medical information about a veteran nor do they communicate information that contributes directly to a veteran's medical treatment or rehabilitation pursuant to proposed § 17.3230, described later in this rulemaking. Although these may be used during an unforeseeable emergency to convey information about a veteran, they do not actively or directly medically treat or rehabilitate a veteran and any limitations the veteran may have, and thus are not "necessary" under this authority. Medical alert devices are also programmable to alert whomever the veteran chooses, and do not necessarily result in an alert or communication to a medical professional. These devices also do not necessarily result in an alert that the veteran is in need of medical assistance, as these devices can be used to alert an individual or entity of a general need for assistance. With the prevalence of, and access to, cell phones and other similar technologies that serve a similar function as medical alert devices in this context, we believe that most, if not all, veterans have access to the technology necessary to

alert individuals and/or entities when medical assistance is needed. Thus, while these devices could be considered beneficial to a veteran's treatment in limited circumstances, we do not consider the provision of these under this authority as reasonable. The definition of "medical alert devices" would not apply to alarms or other safety indicators on home medical equipment, such as an alarm to alert an individual if a ventilator is unplugged. Such alarms and indicators, therefore, could be provided as part of home medical equipment. These alarms and indicators that are part of medical equipment (such as a ventilator) do contribute directly to a veteran's treatment as part of the total function of the piece of medical equipment, unlike devices that serve a purely communicative function.

Similarly, medical identification bracelets would be excluded under this regulation as they are not a direct and active component of a veteran's medical treatment or rehabilitation, and therefore are not reasonable and necessary under this authority. Medical identification bracelets are entirely passive, do not actively communicate any information about a veteran, and merely provide information about the existence of a condition of a veteran. Although these may be used during an unforeseeable emergency to convey information about a veteran, they do not actively or directly medically treat or rehabilitate a veteran and any limitations the veteran may have, and thus are not "necessary" under this authority. While these devices could be considered beneficial to a veteran's treatment in limited circumstances, we do not consider the provision of these under this authority as reasonable for the same reasons stated above. We note that we currently provide these medical identification bracelets, however for the reasons discussed, they would be outside the scope of this authority

and would not be authorized to be provided pursuant to these proposed regulations.

We further note that after the publication of the final rulemaking, we would rescind VHA Directive 2009-007, Provision of Medical Identification (ID) Bracelets and Pendants, to ensure VA policy is consistent with the published final rules.

Lastly, we clarify that although certain home medical equipment might need to be installed in a home to ensure its proper functioning, such as a portable ramp or a hospital bed, such equipment must not amount to an improvement or structural alteration to a veteran's residence. Such improvements or alterations to homes are authorized by section 1717(a)(2) and 38 CFR 17.3100 et seq., and are not within the scope of these proposed regulations, as stated in the table in proposed § 17.3200(b). This clarification related to installation would be established in proposed § 17.3230 as discussed later in this rulemaking.

"Home respiratory equipment" would be defined as an item used to provide oxygen therapy or to support or enhance respiratory function. We note that home respiratory equipment would be distinguished from home medical equipment because we would permit the provision of additional pieces of respiratory equipment as medically necessary outside of a single home or residential setting, such as additional portable oxygen tanks when a veteran might need to travel. Examples of such equipment VA would provide to veterans include compressed oxygen, oxygen concentrators, and continuous positive airway pressure machines.

"Household appliances" would be defined as equipment for use in the home for performance of domestic chores or other domestic tasks, including but not limited to a

refrigerator, stove, washing machine, and vacuum cleaner. We believe this definition captures the common meaning and understanding of this term.

“Household furniture or furnishing” would be defined as an item commonly used to make a home habitable or otherwise used to ornament a home, including but not limited to tables, chairs, desks, lamps, cabinets, non-hospital beds, curtains, and carpet(s). We believe this definition captures the common meaning and understanding of this term.

“Implant” would be defined as any biological or non-biological material that is manufactured or processed to be placed into a surgically or naturally formed cavity on the human body; is covered with tissue, has the potential to be covered with tissue, or is permanently embedded in tissue; does not dissolve or dissipate within the body; and is not a living organ, embryonic tissue, blood, or blood product. VA provides implants as part of the prosthetics program, and this definition characterizes such implants consistently with VA’s current provision of implants, and to that extent would not reflect a change in the scope of benefits available to eligible veterans.

“Improvements or structural alterations” means a modification to a home or to an existing feature or fixture of a home, including repairs to or replacement of previously improved or altered features or fixtures. This term would be defined the same as it is defined in 38 CFR 17.3101 (i.e., a modification to a home or to an existing feature or fixture of a home, including repairs to or replacement of previously improved or altered features or fixtures). Such improvements or structural alterations are authorized by section 1717(a)(2) and 38 CFR 17.3100 et seq., and are not within the scope of these proposed regulations, as stated in the table in proposed § 17.3200(b).

“Medical alert device” would mean an item designed to summon general safety assistance for a veteran, or that provides a veteran’s general medical information to others. This definition would not include alarms or other safety indicators for home medical equipment. As previously discussed, this definition is necessary because “medical alert device” would be excluded from the term “home medical equipment.”

“Mobility aid” would be defined as an item that compensates for a mobility impairment and that is used to maintain or improve a veteran’s functional capabilities to be mobile. Examples of such equipment VA would provide to veterans include manual and motorized wheelchairs, canes, walkers, and equipment to assist veterans with reaching for or grasping items. We would exclude a service or guide dog from this definition because the provision of certain benefits for service or guide dogs is not within the scope of these proposed regulations as stated in the table in proposed § 17.3200(b). VA has published regulations concerning benefits for service and guide dogs at 38 CFR 17.148.

“Orthotic device” would be defined as an item fitted externally to the body that is used to support, align, prevent, or correct deformities or to improve the function of movable parts of the body. We believe this definition captures the common meaning and understanding of this term as well as its common meaning and use in the health care industry. Examples of such items VA would provide to veterans include leg braces, upper extremity splints and braces, and functional electrical stimulation devices such as Bioness® or WalkAide®.

“Primary residence” would be defined as the personal domicile or residential setting in which the veteran resides the majority of the year. We believe this definition

captures the common meaning and understanding of this term. While a person may maintain more than one residence, they may only have one primary residence at a time. This would include any residential setting the veteran owns, rents, or in which the veteran otherwise resides.

“Prosthetic device” would be defined as an item that replaces a missing or defective body part. We believe this definition captures the common meaning and understanding of this term as well as its common meaning and use in the health care industry. Examples of such items VA would provide to veterans include artificial limbs and artificial eyes. We note that certain prosthetic devices may not have mechanical or other functionality, but nonetheless could be considered medically necessary and not merely cosmetic in nature. For instance, certain artificial hands may not have mechanical functions to grasp objects, but the use of such devices equalizes weight distribution in the arm and across the body. As another example, artificial eyes would not function to restore or improve sight, but would provide necessary shape to an eye socket and prevent objects from entering the eye socket.

“Replacement item” would be defined as an item that is similar or identical to an item provided under proposed § 17.3230(a), and that takes the place of such an item. We believe this definition captures the common meaning and understanding of this term.

“VA-authorized vendor” would be defined as a vendor that has been authorized by VA to provide items and services under § 17.3230. We believe this definition is self-explanatory. This definition would be relevant to the discussion later in this proposed rule regarding the furnishing of items and services in proposed § 17.3240.

17.38. Medical benefits package and 17.3220. Eligibility.

Proposed § 17.3220 would clarify veteran eligibility for prosthetic and rehabilitative items and services provided under sections 1701(6)(F) and 1710(a). As explained previously in this rulemaking, VA is authorized under sections 1701(6)(F)(iii) and 1710(a) to provide those prosthetic and rehabilitative items and services that VA determines are medically necessary to assist a veteran to compensate for loss of mobility or loss of other functional abilities, where the veteran is otherwise receiving care or services under chapter 17 of title 38 U.S.C. Section 17.38(a)(1)(viii), in turn includes the provision of “durable medical equipment and prosthetic and orthotic devices” as part of VA’s “medical benefits package.” We would first revise § 17.38(a)(1)(viii) to use the term “prosthetic and rehabilitative items and services” as proposed in these regulations, and would cross reference this term with citations to the proposed regulations in this rulemaking so it is clear that such items and services under § 17.38(a)(1)(viii) are provided in accordance with proposed §§ 17.3200 through 17.3250.

We would also revise § 17.38(b) to reflect that prosthetic and rehabilitative items and services authorized in § 17.38(a)(1)(viii) are excluded from the “promote, preserve, or restore” standard under § 17.38(b). As previously discussed in this rulemaking, the standard of “promote, preserve, or restore” under §17.38(b) is not specific enough to distinguish when prosthetic and rehabilitative items should be provided because they are medically necessary, versus when an item or service would not be provided because it is only desired. Using a standard other than that of “promote, preserve, or

restore” would also be consistent with the authorizing statutes, sections 1701(6)(F) and 1710(a), requiring that VA provide those items and services that are necessary and reasonable. However, in a note to proposed § 17.3230, we would state that the exclusions in § 17.38(c) apply to the provision of items and services pursuant to § 17.3230.

Proposed § 17.3220 would then establish eligibility for prosthetic and rehabilitative items and services by requiring that veterans be enrolled in VA’s enrollment system under § 17.36 or exempt from such enrollment under § 17.37, and requiring that such veterans are otherwise receiving care under chapter 17 of title 38 U.S.C. These two eligibility criteria would be in proposed § 17.3220(a)-(b), respectively. Proposed § 17.3220(b) would further describe the concept of “otherwise receiving care” to include where a veteran is prescribed a prosthetic or rehabilitative item or service by a VA provider or an authorized non-Department provider. We believe that by receiving a prescription the veteran would be receiving care under chapter 17.

17.3230. Authorized items and services.

Proposed § 17.3230(a) would state that VA would provide veterans who are eligible under § 17.3220 with items and services that would be listed in proposed § 17.3230(a)(1)-(15) as described below. Proposed § 17.3230(a) would further state that VA will provide items and services listed in proposed § 17.3230(a)(1)-(15), if VA determines that the items or services serve as a direct and active component of the veteran’s medical treatment or rehabilitation, and do not merely support the comfort or convenience of the veteran. The statement in proposed §17.3230(a) that items and

services need to be a direct and active component of the veteran's medical treatment or rehabilitation and not merely for the comfort or convenience of the veteran is consistent with VA practice. As stated previously in this rulemaking, the more specific criteria related to medical necessity in proposed §17.3230(a) are needed because the "promote, preserve, or restore" criteria in §17.38(b) may be appropriate in terms of medical services generally, but are not specific enough to distinguish when prosthetic and rehabilitative items and services should be provided because they are medically necessary, versus when an item or service would not be provided because it is only desired. The items and services provided are intended to be limited to those that accommodate a veteran's medical treatment or rehabilitation. This would also be consistent with the authorizing statutes, sections 1701(6)(F) and 1710(a), requiring that VA provide those items and services that are necessary and reasonable. Proposed § 17.3230(a)(1) through (a)(15) would list the categories of items and services that have been and would continue to be provided by VA as prosthetic or rehabilitative items or services. Definitions of the items and services to be provided in proposed § 17.3230(a)(1) through (a)(15), as well as examples of such items, are provided in the discussion of proposed § 17.3210, and we do not reiterate that information generally below. We propose, however, additional criteria that must be met in proposed § 17.3230(a)(5) and (a)(6) for "home exercise equipment" and "home medical equipment," respectively. We reiterate from the discussion of the proposed definitions earlier in this rulemaking that proposed § 17.3230(a)(5) and (a)(6) would establish a restriction that both "home exercise equipment" and "home medical equipment" would only be provided for one location, generally the veteran's primary residence. This additional criterion that

such equipment would only be provided for one location is current VA practice and is reasonable because we believe it is adequate in most cases to provide this equipment at the veteran's primary residence, a term which is previously defined and discussed in this rulemaking. Relatedly, it is current VA practice to provide one piece of equipment; therefore, we believe it is also reasonable to provide that equipment to the veteran's primary residence, as that is the personal domicile or residential setting in which the veteran resides the majority of the year, and is where we believe the equipment will likely be used most routinely and regularly. If the veteran has more than one residence, the Department will provide the equipment to the veteran's primary residence. We note that to the extent the equipment is portable, an individual would be free to move it to another location where the veteran may temporarily reside, such as another residence during an extended seasonal stay. As indicated previously, there may be limited instances when "home exercise equipment" or "home medical equipment" may be provided at a non-primary residence based on a clinical determination. Prior to any installation of such equipment in the residence, the owner of the residence would have to agree to the installation of the equipment. Additionally, proposed § 17.3230(a)(6) would establish that home medical equipment must not require installation that amounts to a home improvement or structural alteration to a veteran's primary residence. Such improvements and alterations to homes are authorized by 38 U.S.C. 1717(a)(2) and controlled by other implementing regulations, as referenced in the table in proposed § 17.3200(b). Lastly, we would require an additional restriction in proposed § 17.3230(a)(2) and (a)(5) that "adaptive recreation equipment" and "home exercise equipment" be provided when such equipment would achieve the veteran's

rehabilitation goals as documented in the veteran's medical record. This is because these types of equipment are generally provided to achieve specific rehabilitation goals, while the other items and services provided under this section are not.

Proposed § 17.3230(a)(12) would authorize the repair of any item provided under proposed § 17.3230(a), unless cost or clinical reasons favor replacing the item. Even if not initially prescribed by VA, an item under proposed § 17.3230(a) could be repaired if the VA provider or authorized non-Department provider determines that the item is still medically necessary and writes an authorized prescription for the veteran. This is consistent with current VA practice, and is reasonable to ensure that veterans have necessary and properly functioning items.

Proposed § 17.3230(a)(13) would authorize the replacement of items provided under proposed § 17.3230 if the original items have been damaged, destroyed, lost, or stolen, or if replacement is clinically indicated. Proposed paragraph (a)(13) would establish that if items are serviceable and still meet the veteran's need, VA will not replace such items for the sole purpose of obtaining a newer model of the same or similar item. Proposed § 17.3230(a)(13) sets forth a reasonable restriction that would allow VA to provide replacement items as clinically indicated, for the benefit of all veterans to whom VA must provide these items and services.

We note that generally we would provide veterans with one item or service under this proposed rule. However, there may be instances when we would provide a veteran with a spare item. The provision of spare items would be authorized if it is clinically determined that a veteran would immediately require another identical or similar item. For example, the provision of a spare item may be clinically determined to be

immediately required if an item provided under the proposed regulations were to fail or require rotation (e.g., routine cleaning) as a component of proper use. VA may also provide an identical or similar item in the event of a failure of an item provided under these regulations if it is determined that it would otherwise be detrimental to the veteran's medical treatment or rehabilitation to not provide a spare item. This is current VA practice and is reasonable to ensure that veterans would have access to items that are necessary on a continuous basis if the veteran could not wait for repair or replacement, such as a spare wheelchair or spare prosthetic limb. VA's provision of items as explained above attempts to ensure that veterans have working, usable equipment when needed. We discuss the provision of spare items in a note at the end of proposed § 17.3230.

Additionally, VA's reimbursement of emergency care under 38 U.S.C. 1725 and 1728 ensures that VA may reimburse some veterans for needed repairs to equipment if such repairs cannot wait for prior VA authorization. For these reasons, and to be consistent with section 1728, we propose removing § 17.122, which authorizes the repair of prosthetic and similar items without prior authorization from VA if the expenses were incurred in the care of an adjudicated service-connected disability. Section 17.122 is not needed, as sections 1725 and 1728 would provide for VA payment of repairs without prior VA authorization as described above, and the other VA regulations that currently implement these sections (sections 17.120 et. seq and 17.1000 et. seq.) are sufficient to authorize payment. Further, we find no basis for treating reimbursement of the expenses of prosthetic repairs differently from the expenses of other types of "emergency care". In addition to removing § 17.122, we propose deleting from

§ 17.120 the following language, “(except prosthetic appliances, similar devices, and repairs),” because we do not see a need to treat the provision of these appliances, devices and repairs any differently from other emergency care provided under this section. Removing § 17.122 is needed as described above, and would clarify that the access to prosthetic repair services without prior authorization in medical emergencies for veterans would be authorized under sections 1725 and 1728 and their implementing regulations.

Proposed § 17.3230(a)(14) would authorize the provision of specialized clothing made necessary by the wearing of a prosthetic device. The provision of specialized clothing made necessary by the wearing of a prosthetic device is specifically identified as a medical service under section 1701(6)(F)(ii), and we would therefore include it in this proposed rule. We contrast this with the clothing allowance provided under § 3.810 and authorized by 38 U.S.C. 1162, which is intended to provide a clothing allowance only to veterans with certain service-connected disabilities, apart from the provision of medical services under section 1710. See 118 Cong. Rec. S. 20748, 20751 (1972) (legislative history related to the bill that would enact section 1162, explaining that a new clothing allowance would assist veterans to purchase non-specialized, regular clothing that may experience wear and tear due to use of a wheelchair or prosthetic device, separate from the benefit for specialized clothing due to the wearing of a prosthetic device that VA provided as a medical service).

Proposed § 17.3230(a)(15) would authorize training with and fitting of items as considered necessary. Training and fitting of prosthetic appliances is required by 38 U.S.C. 1714(a), is current VA practice, and is reasonable to ensure, to the extent

practicable, that veterans safely operate items and that items are properly maintained to promote their longevity. We would additionally remove current § 17.153 related to training and fitting of prosthetic and similar items, as it would be duplicative of proposed § 17.3230(a)(15).

Proposed § 17.3230(b) would establish that unless items provided under proposed § 17.3230(a) are loaned to a veteran, based on a clinical determination, such items become the property of the veteran once the veteran takes possession of those items. This would ensure that veterans have full use of, and responsibility for, items provided by VA, and will use them in the manner in which they are prescribed. If items will be loaned, a written agreement (which would include roles and responsibilities for the duration of the loan) with the veteran would be entered into to ensure that it is clear the veteran does not own the item, and that the veteran fully understands and agrees to the terms of the loan.

17.3240. Furnishing authorized items and services.

Proposed § 17.3240(a) would establish that VA will determine whether VA or a VA-authorized vendor will furnish authorized items and services under § 17.3230 to eligible veterans. When VA has the capacity or inventory, VA directly provides items and services to veterans. However, VA also may use, on a case-by case basis, VA-authorized vendors to provide greater access, lower cost, and/or a wider range of items and services. We would clarify in regulation that this administrative business decision 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 as part of our duty to administer this program in a legally sufficient, fiscally responsible manner.

Proposed § 17.3240(b) would establish that, except for emergency treatment reimbursable under 38 CFR 17.120 et. seq or 17.1000 et seq., prior authorization is required from VA for VA-authorized vendors to obtain reimbursement for furnishing items or services under § 17.3230 to veterans. Prior authorization may be obtained by contacting VA. Paragraph (b) will help ensure that the highest quality and most clinically appropriate device is provided, as prescribed by VA providers, and that items or services are not subject to potential alterations or substitutions by VA-authorized vendors without VA oversight.

17.3250. Veteran responsibilities.

Proposed 17.3250 would establish responsibilities of veterans who are provided prosthetic and rehabilitative items and services. Proposed § 17.3250(a) would establish that veterans must use items provided under proposed § 17.3230(a) in the manner for which they are prescribed, and consistent with the manufacturer's instructions and any training provided. This would ensure, to the extent practicable, veteran safety in using the item as well as the longevity of the item.

Proposed § 17.3250(b) would establish that, except for emergency care under 38 CFR 17.120 et. seq. or 38 CFR 17.1000 et seq., veterans must obtain prior authorization from VA if they want VA to reimburse a VA-authorized vendor for such items and services provided under § 17.3230. This would reinforce general VA oversight requirements already proposed in these regulations to ensure the highest quality and most appropriate item or service is provided, and would distinctly provide

notice to veterans and vendors that VA will not be responsible for the cost of items and services provided to veterans who are not preauthorized by VA or otherwise covered as emergency care.

Rescission of Use of Prosthetic Service Card and Related VA Policy

We note that after the publication of this rulemaking is final, we would rescind, in their entirety, VHA Handbooks 1173.06, 1173.1, 1173.10, 1173.2, 1173.3, VA Forms 10-2501 and 10-2520, and VA Form Letter 10-55; and develop new VHA policy to ensure VA's provision of prosthetics is consistent with the published final rules. Any references to the prosthetic service card would be excluded from future VHA policies and forms implementing these rules as further explained below.

As part of this plan, we specifically note that future VA policy would not include portions of existing VA policy that reference "prosthetic service cards" and establish limits on reimbursement or payment amounts for emergency repairs of prosthetic items through the use of a "prosthetic service card" to obtain repairs from VA-authorized vendors without prior authorization from VA. A "prosthetic service card" is a piece of paper (VA Form 10-2501) that VA has issued to veterans in the past for the purpose of providing a third party vendor with notice that VA would reimburse such vendor for the provision of certain repairs, up to certain amounts. VA Form 2520 in the past has been the invoice used by vendors to submit to VA requests for payment for repairs performed under the prosthetic service card. This prosthetic service card was intended to allow third party vendors to forego the normal process of contacting VA first for authorization, and instead submit an invoice to VA for the cost of repairs after they were completed.

The card was intended to be used if it was not feasible for a VA-authorized vendor to contact VA for authorization and the repair was immediately necessary, such as when a repair was needed after VA office hours. However, these prosthetic service cards have not been widely or consistently used by veterans or vendors for the purpose of obtaining VA approval of emergency repairs. First, veterans in many instances have lost their prosthetic service cards or have not carried the card on their person to be able to present to third party vendors. Second, even when presented with the card, many third party vendors have nonetheless contacted VA for authorization prior to providing repairs. The card itself is merely a piece of paper that provides notice that VA will reimburse a vendor for certain repairs up to certain amounts—it is not a pre-paid credit card or other means of providing immediate payment to a VA-authorized vendor (despite the description of the card as a “debit” card in VHA Handbook 1173.1). Even when the card has been used, third party vendors have still had to submit an invoice and other documentation to VA to get reimbursed for the repair. Therefore, use of the prosthetic service card has not typically been any less burdensome for third party vendors to receive payment from VA than if such vendors had contacted VA for authorization prior to the repair. The intent of the card was to decrease the burden for both veterans and third party vendors, but it has not functioned consistently in this manner. Additionally, the card does not appropriately reference sections 1725 and 1728 as the authorities to provide repairs without prior authorization, which creates problems where the card either does not recognize the applicable criteria in sections 1725 and 1728 (for instance, related to eligibility under sections 1725 and 1728), or

establishes criteria that may be inconsistent with 1725 and 1728 (for instance, the prosthetic service card contains a space for VA to set a limit on any repair costs).

Currently, references to the prosthetic service card (PSC) are located in paragraphs 3.tt, 8.a, 9.i, 9.h, 9.m of VHA Handbook 1173.1; paragraphs 4.a.(2)-a.(7), 4.b., 4.c.(1)-c.(7), and 6.c.(4) of VHA Handbook 1173.2; paragraphs 10.a.(1) and 10.c of VHA Handbook 1173.3; paragraphs 7.a. and 7.e. of VHA Handbook 1173.06; and paragraphs 3.i.(9) and 4.c. in VHA Handbook 1173.10. Paragraphs 3.tt and 9.h in VHA Handbook 1173.1 both define “VA Form 10-2501, Prosthetic Service Card (PSC).” Paragraph 8.a. in VHA Handbook 1173.1 references requests for payment of PSC (i.e. prosthetic service card) repairs. Paragraph 9.i in VHA Handbook 1173.1 defines “VA Form 10-2520, Prosthetic Service Card Invoice”, and paragraph 9.m. defines “VA Form Letter 10-55, Authority to Exceed Repair Costs of Prosthetic Appliances” as a letter of authorization forwarded to a provider of PSC (i.e. prosthetic service card) repairs when the cost of that repair exceeds the limit authorized by the PSC (i.e. prosthetic service card). In VHA Handbook 1173.2, paragraph 4.a.(2) requires that repairs be obtained by use of the prosthetic service card; paragraphs 4.a.(3)-a.(7) detail requirements that PSCs be provided by all prosthetic programs at field facilities, authority for equipment repairs and services using prosthetic service cards, monetary limits for prosthetic service cards, responsibility for payment of prosthetic service card invoices, and payment for repairs made without prior approval; paragraph 4.b. sets forth VA, vendor, and veteran responsibilities related to the administration of prosthetic service cards; paragraphs 4.c.(1)-c.(7) include prosthetic service card benefits limits, and the processes for prosthetic service card preparation and issuance, prosthetic service card

invoice preparation and issues, repairs authorization, and prosthetic service card revocation or cancellation; and paragraph 6.c.(4) requires repairs of artificial limbs, braces, wheelchairs, and other appliances on presentation by the veteran of a valid prosthetic service card.

Paragraph 10.a.(1) of VHA Handbook 1173.3 states that repairs may be obtained through commercial sources using VA Form 10-2501, and paragraph 10.c. of VHA Handbook 1173.3 encourages the use of prosthetic service cards for those veterans eligible for a prosthetic service card.

Paragraphs 7.a. and 7.e. of VHA Handbook 1173.06 authorize the use of prosthetic service cards for repairs to wheelchairs. Paragraphs 3.i.(9) and 4.c. in VHA Handbook 1173.10 authorize the use of prosthetic service cards for repairs to orthotic devices.

Lastly, VA Form 10-2501, VA Form 10-2520, and VA Form Letter 10-55 also reference prosthetic service cards. Currently, VA Form 10-2520 is an approved information collection under OMB Control Number 2900-0188, which is set to expire on October 31, 2017. On August 22, 2017, we issued a Federal Register (FR) Notice informing the public of the opportunity to comment on the proposed renewal of that information collection. 82 FR 39951. While we are requesting renewal of that collection, we now propose to eliminate VA Form 10-2520 under that existing collection for the reasons explained above as part of this proposed rule. Public comments on the discontinuance of VA Form 10-2520 should be submitted as part of this rulemaking for consideration by VA. While related, VA Form 10-2015 and VA Form Letter 10-55 are

not information collections, did not require OMB approval prior to issuance, and thus are not part of that Federal Register Notice.

As previously stated, to ensure consistency with the published final regulations, we would rescind all relevant and applicable handbooks, and develop a new VHA policy document or documents. Any references to prosthetic service cards in existing policies would be excluded from that future policy document or documents for the reasons mentioned above. We would also discontinue the use of the related forms and letters previously identified in this section. As part of this rulemaking, we welcome any public comments on these efforts as they relate to this rulemaking.

Although we would rescind the prosthetic service card and the policies and forms governing its use, there would remain, as explained previously, statutory and regulatory authority (38 U.S.C. 1725 and 1728, 38 CFR 17.120 et seq. and 17.1000 et seq.) to reimburse some vendors or veterans for the cost of some emergency, unauthorized repairs. VA could also obviate the need for veterans to obtain emergency repairs from vendors by providing spares for prosthetic and rehabilitative items under § 17.3230, as clinically appropriate.

Effect of Rulemaking

The Code of Federal Regulations, as proposed to be revised by this proposed rulemaking, 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 this proposed rulemaking if possible or, if not possible, such guidance would be superseded by this rulemaking.

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).

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. 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 and 13563

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Executive Order 12866 (Regulatory Planning and Review) defines a “significant regulatory action,” requiring review by the Office of Management and Budget (OMB) as “any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity,

competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.”

The economic, interagency, budgetary, legal, and policy implications of this regulatory action have been examined, and it has been determined not to be a significant regulatory action under Executive Order 12866. VA's impact analysis can be found as a supporting document at <http://www.regulations.gov>, usually within 48 hours after the rulemaking document is published. Additionally, a copy of the rulemaking and its impact analysis are available on VA's Web site at <http://www1.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 proposed rule 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.

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. Gina S. Farrisee, Deputy Chief of Staff, approved this document on October 11, 2017, for publication.

List of Subjects in 38 CFR part 17

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

Dated: October 11, 2017.

Janet Coleman,
Chief,
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. Amend § 17.38 by revising paragraph (a)(1)(viii) and revising paragraph (b).

The revisions read as follows:

§ 17.38. Medical Benefits Package.

(a) * * *

(1) * * *

(viii) Prosthetic and rehabilitative items and services as authorized under §§ 17.3200-3250, and eyeglasses and hearing aids as authorized under § 17.149.

* * * * *

(b) *Provision of the “medical benefits package”*. Care referred to in the “medical benefits package” (except for prosthetics and rehabilitative items and services authorized in paragraph (a)(1)(viii) of this section) will be provided to individuals only if it is determined by appropriate healthcare professionals that the care is needed to promote, preserve, or restore the health of the individual and is in accord with generally accepted standards of medical practice.

* * * * *

§ 17.120 [Amended].

3. Amend the introductory text of § 17.120 by removing “(except prosthetic appliances, similar devices, and repairs)”.

§ 17.122 [Removed].

4. Remove § 17.122.

5. Revise the undesignated center heading that precedes § 17.148 to read as follows:

SENSORY AND OTHER REHABILITATIVE AIDS

§§ 17.150 {Removed and reserved}.

§§ 17.153 [Removed and reserved].

6. Remove and reserve §§ 17.150 and 17.153.

7. Add an undesignated center heading and §§ 17.3200 through 17.3250, to read as follows:

PROSTHETIC AND REHABILITATIVE ITEMS AND SERVICES

§ 17.3200. Purpose and scope.

(a) Purpose. The purpose of §§ 17.3200 through 17.3250 is to establish eligibility and other criteria for the provision to veterans of the prosthetic and rehabilitative items and services, listed in § 17.3230, authorized as medical services under 38 U.S.C. 1701(6)(F) and 38 U.S.C. 1710(a).

(b) Scope. Sections 17.3200 through 17.3250 apply only to items and services listed in § 17.3230(a) and authorized as medical services under 38 U.S.C. 1701(6)(F) and 38 U.S.C. 1710(a). The provision of the items or services and payments in the table below are authorized in whole or in part by separate statutes and controlled by other implementing regulations:

Item or Service	Statute	Regulation(s)
Clothing allowance	38 U.S.C. 1162	38 CFR 3.810
Service and guide dog benefits	38 U.S.C. 1714(b) & (c)	38 CFR 17.148
Sensori-neural aids	38 U.S.C. 1707(b)	38 CFR 17.149
Patient lifts and other rehabilitative devices	38 U.S.C. 1717(b)	38 CFR 17.151

Devices for deaf veterans	38 U.S.C. 1717(c)	38 CFR 17.152
Equipment for blind veterans	38 U.S.C. 1714(b)	38 CFR 17.154
Automobile adaptive equipment	38 U.S.C. 3901 et seq.	38 CFR 17.155 et seq.
Home improvements and structural alterations	38 U.S.C. 1717(a)(2)	38 CFR 17.3100 et seq.

(Authority: 38 U.S.C. 501, 1162, 1701, 1707, 1710, 1714, 1717, 3901)

§ 17.3210. Definitions.

For the purposes of §§ 17.3200 through 17.3250:

Activities of daily living (ADLs) means specific personal care activities that are required for basic daily maintenance and sustenance, to include eating, toileting, bathing, grooming, dressing and undressing, and mobility.

Adaptive household item means a durable household item that has been adapted to compensate for, or that by design compensates for, loss of physical, sensory, or cognitive function and is necessary to complete one or more ADLs in the home or other residential setting. Adaptive household items include but are not limited to adaptive eating utensils, shower stools or chairs, hooks to assist in buttoning clothing, or shoe horns. This definition does not include household furniture or furnishings, improvements or structural alterations, or household appliances, unless a household appliance is necessary to complete an ADL in the home or other residential setting. VA will not furnish such items or services in such a manner as to relieve any other person or entity of a contractual obligation to furnish these items or services to the veteran.

Adaptive recreation equipment means an item that is designed to compensate for, or that by design compensates for, loss of physical, sensory, or cognitive function and is necessary for the veteran to actively and regularly participate in a sport,

recreation, or leisure activity to achieve the veteran's rehabilitation goals as documented in the veteran's medical record.

Cognitive device means an item that compensates for a cognitive impairment and that is used to maintain or improve a veteran's functional capabilities, including but not limited to technological equipment such as tablets and smart phones, and associated technological equipment, applications or software that can assist a veteran in maintaining daily scheduling of important tasks or navigating their surroundings (e.g., global positioning system, or GPS) .

Communication device means an item that compensates for a communication deficiency and allows participation in daily communication activities, including but not limited to picture or symbol communication boards and an electro larynx.

Durable means capable of, and intended for, repeat use.

Home exercise equipment means an item used in a home or residential setting that compensates for a loss of physical, sensory, or cognitive function and that is necessary for the veteran to actively and regularly participate in aerobic, fitness, strength, or flexibility activities to achieve the veteran's rehabilitation goals as documented in the veteran's medical record, when there is no other means for the veteran to exercise to achieve the veteran's rehabilitation goals. Such equipment includes but is not limited to an upper body ergometer and a functional electrical stimulation cycle.

Home medical equipment means an item that is a movable and durable medical device that is used in a home or residential setting to treat or support treatment of specific medical conditions. Such equipment includes but is not limited to hospital beds,

portable patient lifts, portable ramps, ventilators, home dialysis equipment, and infusion, feeding, or wound therapy pumps. This definition does not include household furniture or furnishings, improvements or structural alterations, household appliances, or medical alert devices. VA will not furnish home medical equipment in such a manner as to relieve any other person or entity of a contractual obligation to furnish these items or services to the veteran.

Home respiratory equipment means an item used to provide oxygen therapy or to support or enhance respiratory function, including but not limited to compressed oxygen, oxygen concentrators, and continuous positive airway pressure machines.

Household appliance means an item used in the home for performance of domestic chores or other domestic tasks, including but not limited to a refrigerator, stove, washing machine, and vacuum cleaner.

Household furniture or furnishing means an item commonly used to make a home habitable or otherwise used to ornament a home, including but not limited to tables, chairs, desks, lamps, cabinets, non-hospital beds, curtains, and carpet(s).

Implant means any biological or non-biological material that:

- (1) Is manufactured or processed to be placed into a surgically or naturally formed cavity on the human body;
- (2) Is covered with tissue, has the potential to be covered with tissue, or is permanently embedded in tissue;
- (3) Does not dissolve or dissipate within the body; and
- (4) Is not a living organ, embryonic tissue, blood, or blood product.

Improvements or structural alterations means a modification to a home or to an existing feature or fixture of a home, including repairs to or replacement of previously improved or altered features or fixtures.

Medical alert device means an item designed to summon general safety assistance for a veteran, or provides a veteran's general medical information to others. This definition does not include alarms or other safety indicators for home medical equipment.

Mobility aid means an item that compensates for a mobility impairment and that is used to maintain or improve a veteran's functional capabilities to be mobile. Mobility aids include but are not limited to manual and motorized wheelchairs, canes, walkers, and equipment to assist a veteran to reach for or grasp items. This definition does not include a service or guide dog.

Orthotic device means an item fitted externally to the body that is used to support, align, prevent, or correct deformities or to improve the function of movable parts of the body. Orthotic devices include but are not limited to leg braces, upper extremity splints and braces, and functional stimulation devices.

Primary residence means the personal domicile or residential setting in which the veteran resides the majority of the year.

Prosthetic device means an item that replaces a missing or defective body part. Prosthetic devices include but are not limited to artificial limbs and artificial eyes.

Replacement item means an item that is similar or identical to an item provided under § 17.3230(a), and that takes the place of such an item.

VA-authorized vendor means a vendor that has been authorized by VA to provide items and services under § 17.3230.

(Authority: 38 U.S.C. 501, 1701, 1710)

§ 17.3220. Eligibility.

A veteran is eligible to receive items and services described in § 17.3230 if:

(a) The veteran is enrolled under § 17.36 or exempt from enrollment under § 17.37; and

(b) The veteran is otherwise receiving care or services under chapter 17 of title 38 U.S.C. If a VA provider or an authorized non-Department provider prescribes an item or service for the veteran, the veteran is considered to otherwise be receiving care or services under chapter 17 of title 38 U.S.C.

(Authority: 38 U.S.C. 501, 1701(6)(F), 1710)

§ 17.3230. Authorized items and services.

(a) VA will provide veterans eligible under § 17.3220 with the following items and services, if VA determines that such items and services serve as a direct and active component of the veteran's medical treatment and rehabilitation and do not merely support the comfort or convenience of the veteran:

(1) Adaptive household items.

(2) Adaptive recreation equipment, when such equipment would achieve the veteran's rehabilitation goals as documented in the veteran's medical record.

(3) Cognitive devices.

(4) Communication devices.

(5) Home exercise equipment, where such equipment will only be provided for one location, the veteran's primary residence, unless it is clinically determined that the equipment should be provided at the veteran's non-primary residence instead of the veteran's primary residence. Prior to any installation of home exercise equipment, the owner of the residence must agree to the installation. Such equipment will only be provided to achieve the veteran's rehabilitation goals as documented in the veteran's medical record.

(6) Home medical equipment, and if required, installation that does not amount to an improvement or structural alteration to a veteran's residence. Such equipment will only be provided for one location, the veteran's primary residence, unless it is clinically determined that the equipment should be provided at the veteran's non-primary residence instead of the veteran's primary residence. Prior to any installation of home medical equipment, the owner of the residence must agree to the installation.

(7) Home respiratory equipment.

(8) Implants.

(9) Mobility aids.

(10) Orthotic devices.

(11) Prosthetic devices.

(12) Repairs to items provided under paragraph (a) of this section, even if the item was not initially prescribed by VA, but VA determines the repair to be necessary, unless VA determines to replace the item for cost or clinical reasons.

(13) Replacement items, if items provided under this section have been damaged, destroyed, lost, or stolen, or if replacement is clinically indicated, subject to

the following: items that are serviceable, and that still meet the veteran's need, will not be replaced for the sole purpose of obtaining a newer model of the same or similar item.

(14) Specialized clothing made necessary by the wearing of a prosthetic device;
and

(15) Training with and fitting of prescribed items as considered necessary.

(b) Unless an item provided under § 17.3230(a) is loaned to the veteran based on a clinical determination that a loan is more beneficial for the veteran, such items become the property of the veteran once the veteran takes possession of those items. If the determination is that the item will be loaned to a veteran, the veteran must agree to the terms of the loan in order to receive the item.

Note to Section §17.3230: Even though the items and services listed in this provision are included in the medical benefits package, this section governs determinations of need for them and not 38 CFR 17.38(b). The exclusions under 38 CFR 17.38(c) will apply to the items and services provided under this section. While VA will generally provide only one item under this section, the provision of spare items may be authorized based on a clinical determination of need using the criteria set forth in this section.

(Authority: 38 U.S.C. 501, 1701(6)(F), 1710, 1714(a))

§ 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 § 17.3210.

(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.

§ 17.3250. Veteran responsibilities.

(a) Veterans must use items provided under § 17.3230 in the manner for which they are prescribed, and consistent with the manufacturer's instructions and any training provided. Failure to do so may result in the item not being replaced under § 17.3230(a)(13).

(b) Except for emergency care under 38 CFR 17.120 et seq. or 17.1000 et seq., veterans obtaining items and services provided under § 17.3230 must obtain prior authorization from VA in order to obtain VA reimbursement for such items and services obtained from a VA-authorized vendor. VA will not be responsible for the cost of items and services provided that are not preauthorized by VA or that otherwise are not covered as emergency care under 38 CFR 17.120 et. seq. or 17.1000 et seq.

(Authority: 38 U.S.C. 501, 1701, 1710, 1725, 1728)

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