U.S.C. 115(d)(1)(C)(i).'' [21] This proposed language seems to suggest that the DLC and MLC believe there are types of voluntary licenses, authorizing DMPs to make and distribute permanent downloads, that would *not* apply to the exclusion of the blanket license. It is not entirely clear to the Office what is meant by this aspect of the proposal, but the Office observes that section 115(d)(1)(C) says ''[a] voluntary license for covered activities entered into by or under the authority of 1 or more copyright owners and 1 or more digital music providers, or authority to make and distribute permanent downloads of a musical work obtained by a digital music provider from a sound recording copyright owner pursuant to an individual download license, shall be given effect in lieu of a blanket license under this subsection with respect to the musical works (or shares thereof) covered by such voluntary license or individual download authority.'' [22]

Beyond the DLC's proposal, the Office invites comments more generally on how to address, or whether the Office should address, the pass-through license issue that has been raised, including whether a different approach should be taken. One potential alternative approach the Office seeks comment on could be for the Office to adopt a rule providing that any failure to comply with the previously adopted reporting requirements in 37 CFR 210.24(b)(8), 210.25(b)(6), 210.27(c)(5), or 210.28(c)(5) with respect to individual download licenses or voluntary pass-through licenses may not be construed as material noncompliance with the statute or regulations, but rather would be considered to be harmless errors, if appropriate alternative information—perhaps the information the DLC proposed—is timely reported instead. This would mean that in such cases, the harmless error provisions in place for notices of license (§ 210.24(e)), notices of nonblanket activity (§ 210.25(e)), and SNBL-submitted reports of usage (§ 210.28(k)) would apply to protect the DMP or SNBL; the statutory default provision in 17 U.S.C. 115(d)(4)(E)(i)(III) would similarly protect a DMP from being in default under the blanket license with respect to its reports of usage.

List of Subjects in 37 CFR Part 210

Copyright, Phonorecords, Recordings.

[21] *See* DLC & MLC *Ex Parte* Letter Dec. 9, 2020 add. B at 2, 3, 10.

[22] 17 U.S.C. 115(d)(1)(C).

Interim Regulations

For the reasons set forth in the preamble, the Copyright Office amends 37 CFR part 210 as follows:

PART 210—COMPULSORY LICENSE FOR MAKING AND DISTRIBUTING PHYSICAL AND DIGITAL PHONORECORDS OF NONDRAMATIC MUSICAL WORKS

■ 1. The authority citation for part 210 continues to read as follows:

Authority: 17 U.S.C. 115, 702.

■ 2. Add § 210.30 to read as follows:

§ 210.30 Temporary exception to certain reporting requirements about certain permanent download licenses.

(a) Subject to paragraph (b) of this section, where a requirement of § 210.24(b)(8), § 210.25(b)(6), § 210.27(c)(5), or § 210.28(c)(5) has not been satisfied with respect to an individual download license or voluntary pass-through license, such failure shall not:

(1) Render an otherwise compliant notice of license, notice of nonblanket activity, or report of usage invalid; or

(2) Provide a basis for the mechanical licensing collective to reject an otherwise compliant notice of license, serve a notice of default on an otherwise compliant blanket licensee, terminate an otherwise compliant blanket license, or engage in legal enforcement efforts against an otherwise compliant significant nonblanket licensee.

Note 1 to paragraph (a): Paragraph (a) of this section is a transitional exception that shall cease to apply in accordance with such further regulations as the Copyright Office may adopt.

(b) After paragraph (a) of this section is no longer applicable, the mechanical licensing collective may take such action(s) against a beneficiary of paragraph (a) of this section as had been prohibited by paragraph (a) when it was applicable, if an amendment adopted by the Copyright Office to a requirement of § 210.24(b)(8), § 210.25(b)(6), § 210.27(c)(5), or § 210.28(c)(5) with respect to individual download licenses or voluntary pass-through licenses is not complied with by such a beneficiary within 45 calendar days after the effective date of such an amendment, or an alternate date subsequently adopted by the Office, whichever is later. Any deadline otherwise applicable to any such action by the mechanical licensing collective shall be tolled with respect to a beneficiary of paragraph (a) of this section until the conclusion of such 45-day or alternate period.

(c) For purposes of this section, a *voluntary pass-through license* is a voluntary license obtained by a licensor of sound recordings to make and distribute, or authorize the making and distribution of, permanent downloads embodying musical works through which a digital music provider or significant nonblanket licensee has obtained authority from such licensor of sound recordings to make and distribute permanent downloads of musical works embodied in such sound recordings.

Dated: December 16, 2020.

Shira Perlmutter,

Register of Copyrights and Director of the U.S. Copyright Office.

Approved by:

Carla D. Hayden,

Librarian of Congress.

[FR Doc. 2020–28505 Filed 12–23–20; 8:45 am]

BILLING CODE 1410–30–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 17

RIN 2900–AP46

Prosthetic and Rehabilitative Items and Services

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: This rulemaking adopts as final, with changes, proposed amendments to VA's regulations governing the provision of prosthetic and rehabilitative items and services as medical services to veterans. This rulemaking establishes a new section for the provision of prosthetic and rehabilitative items and services, clarifies eligibility for such items and services, and defines the types of prosthetic and rehabilitative items and services available to eligible veterans.

DATES: This rule is effective on January 27, 2021.

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; *penny.nechanicky@va.gov;* (202) 461–0337. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION:

Background

On October 16, 2017, VA published a proposed rule in the **Federal Register** (82 FR 48018) to revise VA's regulations governing the provision of prosthetic and rehabilitative items and services to eligible veterans. The proposed rule set forth revisions to reorganize and update

the regulations on prosthetic and rehabilitative items, and define the types of items and services available to eligible veterans. The proposed rule also put forward the elimination of existing prosthetics regulations at § 17.150 of title 38, Code of Federal Regulations (CFR) and the establishment of entirely new sections at §§ 17.3200 through 17.3250. VA provided a 60-day comment period for the public to respond to the proposed rule. The comment period for the proposed rule ended on December 15, 2017, and VA received 305 comments.

Based on a review of the public comments received on the proposed rule, VA drafted and published a Supplemental Notice of Proposed Rulemaking (SNPRM) in the **Federal Register** (83 FR 61137) on November 28, 2018. The SNPRM provided clarification about provisions of the proposed rulemaking, included additional proposed amendments to § 17.3240 as proposed, and provided a 30-day comment period for the public to respond to the SNPRM and summit comments. The comment period for the SNPRM ended on December 28, 2018, and VA received 8 comments on the SNPRM. The SNPRM also provided notice regarding certain communications between VA and external parties regarding the proposed rule, and a summary of those communications were added to the public docket of the rulemakings.

We appreciate the comments we received on the proposed rule and SNPRM, and have considered them when adopting this rulemaking as final.

Several comments commended and supported revisions to the regulations identified in the proposed rule and the SNPRM. VA appreciates these comments for their support of these rules. All of the issues raised by the comments that concerned at least one portion of the rule can be grouped together by similar topic, and we have organized our discussion of the comments accordingly. For the reasons set forth in the proposed rule, in the SNPRM, and in further detail below, we are adopting the proposed rule as modified by the SNPRM and with additional changes as final.

Medical Alert Devices and Medical Identification Bracelets

Several comments opposed the proposed elimination of the provision of medical alert devices. One comment stated that emergency assistance through cell phones is limited among the elderly population, which may not have cell phones and may have limited ability in making a cell phone call and identifying their location. This comment noted that the Freedom Alert device allows for easier and quicker notification of a medical emergency to emergency services or a family member than a cell phone, in particular because the device can be used to answer a call, and would also reduce costs of emergency services. Additionally, this comment suggested that the Freedom Alert device would be a small investment that would allow many veterans to remain in their homes, thus reducing the costs for institutionalized care, home health aide care, and assisted living. Another comment also noted that life alerts do not directly provide medical information, but rather allow a veteran to stay in their home with some safety measure versus having to be placed in a facility which is more costly. One comment also opined that these devices should not be eliminated as veterans may not have alternative technology or financial resources available to them. Additional comments noted other benefits of providing these devices, including that the device can: Be used to answer phone calls; be programmed to contact family first (thus reducing emergency response costs); allow those with limited dexterity to push a simple button; ensure the well-being of veterans and reduce anxiety; be used as a substitute for cell phones in rural areas with unreliable cell service; and prevent exacerbation of serious falls or health conditions. Comments also noted that eliminating these devices under this regulation would reduce quality of life and pose potential risk to veterans to everyday hazards, medical complications, and life-threatening situations; and comments further asserted that if a treating physician requests such a device, it should be provided.

Similarly, some comments opposed elimination of the provision of medical identification bracelets pursuant to the proposed rule. A comment opined that no longer providing such items would reduce a veteran's quality of life and may result in those who need monitoring or who have communication limitations being unable to convey medical issues. This inability to communicate medical information can affect an individual's peace of mind and emotional and mental functioning. Additionally, in response to the SNPRM, another comment expressed high concern about the elimination of medical identification bracelets, as veterans have been provided these bracelets for years, and these bracelets help veterans receive better care and better outcomes in emergencies when a veteran may not be able to communicate about conditions, allergies, etc. This comment also noted that in a survey of VA clinicians, 97 percent of them believed VA should continue to provide medical identification bracelets to veterans.

We agree with the comments that medical alert devices as well as medical identification bracelets can be an important component of ensuring prompt medical response to emergency situations a veteran may encounter outside a hospital or clinic environment. However, when such devices and bracelets are purely communication devices that do not actively or directly treat or rehabilitate a veteran's health condition or limitation, they do not meet the direct and active component standard as described in the proposed rule. Medical identification bracelets particularly are entirely passive and do not actively communicate any information about a veteran, but merely provide a source of information about the existence of a condition of a veteran. Although many of the comments identified general benefits of providing medical alert devices and identification bracelets, such comments also failed to provide examples of how these devices would meet the direct and active component standard, and one comment averred that these devices do not contribute directly to an individual's treatment or rehabilitation. However, there were also some comments that did provide examples of benefits in providing these devices that may, in fact, rise to the level of meeting the direct and active component test. For example, some comments noted that some individuals need to be safe in their homes due to medical conditions, it may be possible for a clinician to determine that a medical alert device is the appropriate item to directly and actively contribute to the treatment of that medical condition. Therefore, in response to comments, we now revise the definition of the term home medical equipment in § 17.3210 as proposed to remove the restriction on medical alert devices, and we further delete the proposed definition of medical alert device as it will no longer be needed. This revision will allow the prescribing clinician to assess a medical alert device under the same direct and active component standard as all other prosthetic and rehabilitative items and services. We note that this change will permit a clinician to assess clinical needs on a case by case basis as with all other types of home medical equipment as provided in the definition under § 17.3210 as

revised in this final rule, this change does not ensure that medical alert devices will be prescribed merely if they are requested or thought needed by a veteran. This change also does not reverse VA's rationale as stated in the proposed and supplemental proposed rules for not prescribing or approving the furnishing of these items in any case in which they serve merely in a monitoring or preventive function, as opposed to actively and directly contributing to treatment. When such devices and bracelets are purely communication devices that do not actively or directly treat or rehabilitate a veteran's health condition or limitation, they would not meet the direct and active component standard established in this rule and therefore would not be provided.

As a result of this change, VA will ensure that applicable Veterans Health Administration (VHA) policy or guidance is revised or rescinded accordingly. For example, VHA Directive 2009–007, Provision of Medical Identification (ID) Bracelets and Pendants, provides that medical identification bracelets or pendants containing pertinent medical information (allergies or diagnoses) must be available, upon appropriate request from VA clinicians through VHA's Prosthetics Service, for veteran patients whose pertinent medical information would be valuable to emergency medical care providers. Although VA's proposed rule stated that VA would rescind VHA Directive 2009–007, upon this final rule being effective, we will instead revise VHA Directive 2009–007 to clarify that medical alert devices and medical identification bracelets will be made available to veterans under the direct and active component standard as with all other prosthetic and rehabilitative items and services. We note that the direct and active component standard is explained more fully in the next section of this final rule that addresses comments on the proposed changes to § 17.38 and § 17.3230.

Section 17.38, Medical Benefits Package and § 17.3230, Authorized Items and Services

We received multiple comments to the proposed revisions to current § 17.38 and criteria in new proposed § 17.3230. To aid in summarizing and responding to these comments, we first provide the following background and summary of what was proposed. The medical benefits package at § 17.38 defines medical services that are available from VA to eligible veterans. Paragraph (a) of § 17.38 addresses the hospital, outpatient, and extended care services that constitute the medical benefits package, and prosthetic devices are included in the medical benefits package at § 17.38(a)(1)(viii). We proposed amending § 17.38(a)(1)(viii) to state that the medical benefits package includes prosthetic and rehabilitative items and services as authorized under proposed §§ 17.3200 through 17.3250, to reference the new proposed criteria in §§ 17.3200 through 17.3250, versus extensive and likely confusing additional revisions to § 17.38 that would apply only to prosthetic and rehabilitative items and services. Current § 17.38(b) provides that care referred to in the medical benefits package at § 17.38(a) will be provided by VA 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. We proposed amending the introductory sentence to § 17.38(b) to exclude prosthetics and rehabilitative items and services from the requirements in § 17.38(b) (specifically, not subject to the promote, preserve, or restore standard in § 17.38(b)), and proposed a different standard in proposed § 17.3230(a) that VA would provide prosthetic and other rehabilitative devices where VA determines that such items and services serve as a direct and active component of a veteran's medical treatment and rehabilitation and do not merely support the comfort or convenience of the veteran.

In addition to the background above, we will summarize and discuss below those comments that related to proposed revisions to § 17.38 and to § 17.3230(a) as proposed in two general categories: (1) Those comments related more directly to VA's standards in determining medical necessity for prosthetic and rehabilitative items and services; and (2) those comments related more directly to VA's practices and continued provision of prosthetic and rehabilitative items and services.

Comments Related to VA's Standards in Determining Medical Necessity for Prosthetic and Rehabilitative Items and Services

We received several comments that generally opposed VA's consideration of medical necessity in its determination to provide prosthetic and rehabilitative items and services, and one comment specifically objected to the proposed rule's interpretation of 38 U.S.C. 1701(6)(F)(i)–(iii) to find that prosthetic and rehabilitative items are considered medical services to require VA to consider medical necessity. At least one comment also stated that because non-VA programs and studies have struggled with defining medical necessity, VA should not consider medical necessity in the provision of prosthetic and rehabilitative items and services, and further stated that considering medical necessity is contrary to VA's policy, mission, and public statements.

We first address those comments that generally opposed VA's consideration of medical necessity in its determination to provide prosthetic and rehabilitative items and services. We reiterate from the proposed rule that VA is required to consider medical necessity in the provision of prosthetic and rehabilitative items and services, as 38 U.S.C. 1710(a) provides that VA shall furnish, or is authorized to furnish, hospital care and medical services that the Secretary determines to be needed.

In response to another comment, we note that the term medical services is further defined in 38 U.S.C. 1701(6)(F) to include: (i) Wheelchairs, artificial limbs, trusses, and similar appliances; (ii) special clothing made necessary by the wearing of prosthetic appliances; and (iii) such other supplies or services as VA determines to be reasonable and necessary, where VA has interpreted section 1701(6)(F)(i)–(iii) to authorize the provision of prosthetic and rehabilitative items generally. To address the comment that objected to the proposed rule's interpretation of section 1701(6)(F) to find that prosthetic and rehabilitative items are considered medical services to require VA to consider medical necessity, we reiterate from the proposed rule that VA has interpreted section 1701(6)(F)(iii) to authorize the provision of other supplies and services if 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) because such other supplies and services are similarly required to assist a veteran to compensate for the loss of mobility or loss of other functional abilities. 82 FR 48019. 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.

We next address the comment that asserted VA struggles with defining medical necessity and therefore should not consider it when determining whether to provide prosthetic or rehabilitative items or services, and that further asserted consideration of medical necessity is contrary to VA's practice, mission, or messaging. We reiterate from the proposed rule that durable medical equipment and prosthetic and orthotic devices are expressly listed as medical services available to eligible veterans as part of VA's medical benefits package in § 17.38(a)(1)(viii). When VA promulgated § 17.38, we explained that the promote, preserve, or restore standard in § 17.38(b) would be used to determine whether health care and services available under § 17.38(a) were medically needed for a veteran. *See* 63 FR 37300. VA's assessment of medical need for prosthetic and rehabilitative items and services is clearly stated in § 17.38(a)(1)(viii) and (b) and is longstanding VA practice.

We received other comments that did not object to VA's consideration of medical necessity per se in providing prosthetic and rehabilitative items and services, but that opposed replacement of the promote, preserve, or restore standard in current § 17.38(b) with the direct and active component standard in § 17.3230(a) as proposed. We note that a few of these comments did not indicate an understanding that the current promote, preserve, or restore standard already required VA to consider medical necessity in the provision of medical services generally, so we again clarify that it has been longstanding VA practice to use the promote, preserve, or restore standard under § 17.38(b) when determining medical necessity for care and services provided in the medical benefits package under § 17.38(a), to include prosthetic and rehabilitative items under § 17.38(a)(1)(viii). We reiterate from the proposed rule that VA has found it necessary, however, to more specifically characterize medical necessity in the context of providing prosthetic and rehabilitative items and services through establishing the more specific direct and active component standard in § 17.3230(a) as proposed. 82 FR 48019. The direct and active component standard in § 17.3230(a) as proposed is more appropriately descriptive of VA's assessment of veterans' medical need for prosthetic and rehabilitative items and services because these items and services are durable medical equipment, which is a unique category of care under § 17.38(a) that functions as an extension of the direct provision of clinical treatment from a provider to a veteran. The extended use of reusable, durable medical equipment by a veteran as part of their treatment or rehabilitation warrants additional considerations on VA's part to ensure such equipment is not merely beneficial but is also medically necessary.

Although we believe the direct and active component standard in § 17.3230(a) as proposed provides for the appropriate assessment of medical necessity in the context of prosthetic and rehabilitative items and services, we have reconsidered the exclusion of prosthetic and rehabilitative items and services from the requirements in § 17.38(b) based on public comments. Based on comments, we now find that the direct and active component test in § 17.3230(a) as proposed should supplement the promote, preserve, and restore standard as well as all other requirements in § 17.38(b). We therefore now remove the parenthetical exception for prosthetics and rehabilitative items and services from § 17.38(b) as proposed, to leave the reading of § 17.38(b) as it is in its current state with regard to the application of the promote, preserve, or restore standard to all care and services available under § 17.38(a), to include prosthetic and rehabilitative items and services under § 17.38(a)(1)(viii). To further ensure it is clear that VA considers both the promote, preserve, and restore standard under § 17.38(b) as well as the supplemental direct and active component standard in § 17.3230(a) as proposed when assessing medical need, we now revise § 17.3230(a) as proposed to clearly reference the assessment of medical need under § 17.38(b). Section 17.3230(a) will now state that VA will provide veterans with prosthetic and rehabilitative items and services if VA determines that such items and services are needed under § 17.38(b), serve as a direct and active component of the veteran's medical treatment and rehabilitation, and do not solely support the comfort or convenience of the veteran. We note that revisions to § 17.38(a)(1)(viii) as proposed indicated that prosthetic and rehabilitative items and services will be available as authorized by §§ 17.3200 through 17.3250, and we are retaining that language in this final rule to ensure it is clear that the prescription of prosthetic and rehabilitative items is subject not only to the promote, preserve, or restore standard in § 17.38(b), but also subject to the direct and active component standard in § 17.3230(a) as proposed. We additionally revise the reference to ''§§ 17.3200–.3250'' in § 17.38(a)(1)(viii) as proposed, to remove the dash and insert the word through, to indicate the range of applicable sections from §§ 17.3200 through 17.3250. To further ensure consistency between the medical necessity standards in §§ 17.38(b) and 17.3230, we are revising and moving the language in the note at the end of § 17.3230 as proposed to further clarify that § 17.3230 supplements determinations of need for items and services listed in § 17.3230(a) in addition to the requirements in § 17.38(b). The revised language in the former note at the end of § 17.3230 as proposed will now be lcoated in § 17.3230(a)(2), and we will renumber § 17.3230(a) as proposed to § 17.3230(a)(1), and renumber § 17.3230(a)(1) through (15) as proposed to § 17.3230(a)(1)(i) through (xv), respectively. We are also revising § 17.3240(a)(1) as proposed to remove the phrase that indicated items will be prescribed based on the veteran's clinical needs and replace it with a clearer reference to the clinical needs assessments in § 17.3230(a) (which are the needs assessment under both §§ 17.38(b) and 17.3230(a)). Lastly, we are removing extraneous language that alludes to a specific item or service listed in § 17.3230(a)(1) through (15) as being separately or additionally assessed for necessity, as this would be duplicative of the clarifications and revisions explained above. Specifically, we are revising § 17.3230(a)(12) and (15) as proposed to remove such extraneous language. However, we reiterate from the proposed rule that an item under § 17.3230(a) could be repaired if it is determined that the item meets the needs assessment in § 17.3230(a). 82 FR 48018, 48024. The same logic follows for § 17.3230(a)(15) with regards to fitting and training, that such fitting and training for an item will be provided as long as such item is found to meet the needs assessment under § 17.3230(a).

Because the proposed rule did not indicate that the direct and active component test in § 17.3230(a) should supplement, versus replace, the requirements in § 17.38(b), we now provide an example of VA's assessment of both the medical necessity standards under §§ 17.38(b) and 17.3230(a) as proposed and made final in this rulemaking. In this example, a provider who is treating a veteran may determine that a number of clinical approaches are medically necessary to treat a veteran's sleep apnea by assisting the veteran to

maintain a less obstructed airway while sleeping, such as lifestyle changes (losing weight or quitting smoking), or treatment for nasal allergies or other upper respiratory ailments or illnesses. Under the medical benefits package in § 17.38(a), the veteran could receive weight management and smoking cessation counseling, and could be prescribed allergy medications as needed, where all of these care and services meet the promote, preserve, or restore standard in § 17.38(b). None of these care and services would be considered prosthetic or rehabilitative items under § 17.38(a)(1)(viii), and the assessment of clinical need would be fully met under the § 17.38(b) promote, preserve, or restore standard. This veteran's provider, however, may also determine that a continuous positive airway pressure (CPAP) machine would be necessary for the veteran to maintain an unobstructed airway while sleeping. A CPAP machine is a durable piece of equipment that would be considered a prosthetic or rehabilitative item under § 17.38(a)(1)(viii). As such, the provider would assess medical need under the requirements in § 17.38(b) and could specifically find the standard under § 17.38(b)(3) to be met because the CPAP machine could be found to restore the daily functional level of the veteran's airway that has been obstructed due to illness or injury. The provider would then also assess the CPAP machine under the direct and active component standard in § 17.3230(a) as proposed and could find this standard to be met because the CPAP machine delivers air pressure through a mask to directly and actively assist a veteran to maintain an unobstructed airway while sleeping. A CPAP machine would also meet the requirement under § 17.3230(a) as proposed as not being solely for the comfort or convenience of the veteran.

We believe the considerations under § 17.3230(a) as proposed establish additional context that is necessary when assessing medical need for prosthetic and rehabilitative items and services, where the promote, preserve, or restore standard in § 17.38(b) by itself may not provide adequate context. In the example above of the veteran with sleep apnea, for instance, a durable item could be provided under § 17.38(b)(1) because it promotes health, even if it merely makes the act of sleeping seem subjectively easier for a veteran but does not directly address the medical issue of an obstructed airway while sleeping. A white noise machine is a durable item that may tend to make a veteran with sleep apnea feel that it is easier to fall or stay asleep, but a white noise machine does not address the medical issue of the veteran's obstructed airway while sleeping. Without the additional consideration of the direct and active component standard in § 17.3230(a), it could be possible for a white noise machine to be provided under the standard in § 17.38(b)(1) because it promotes health by enhancing the quality of life or daily functional level of a veteran.

The additional consideration that prosthetic and rehabilitative items and services must be a direct and active component of treatment in § 17.3230(a) as proposed helps ensure that VA only furnishes durable items that are medically necessary. This is consistent with current and longstanding VA practice that requires all prescriptions for prosthetic and rehabilitative items to include a medical justification that draws a nexus between the item and the function it will perform for that condition. As we will respond more directly in this rule in relation to the comfort and convenience language from § 17.3230(a) as proposed, this nexus between an item and its function to medically address a condition does not mean that items may not be both beneficial and necessary; but, there must be a medical need for an item, and the additional considerations in § 17.3230(a) as proposed help ensure that is the case.

Several comments further opposed elimination of the promote, preserve, or restore standard due to concern that the direct and active component standard could reduce services to veterans, eliminate most quality of life items, and reduce veterans' quality of life. As clarified above, the direct and active component standard in § 17.3230(a) as proposed will supplement and not replace VA's assessment of medical need under § 17.38(b). Although it is the case that the direct and active component standard will not support VA's provision of comfort or convenience items that are not medically required, this additional standard should not result in any reduction of medically necessary items or services currently being provided to veterans. Most items currently provided will continue to be provided so long as they are determined by VA health care providers or authorized non-VA providers to be medically necessary using both the promote, preserve, and restore standard under § 17.38(b) and the direct and active component standard in § 17.3230(a) as proposed.

For the reasons stated in the proposed rule and above, we adopt as final the direct and active component standard and other language in § 17.3230(a) as proposed with some revisions. We reiterate that removing the parenthetical exception from the proposed revision to § 17.38(b), as well as the additional revisions to § 17.3230(a) and the note at the end of § 17.3230 (to reference § 17.38(b)) will clarify that we are supplementing rather than replacing the promote, preserve, or restore standard in § 17.38(b).

Comments Related to VA Practices and Continued Provision of Prosthetic and Rehabilitative Items and Services

One comment opined that there is no reason to change the standards and criteria for providing prosthetic and rehabilitative items and services if we intend to continue current practices. We clarify that we are only changing our regulations to conform with current practice; these regulations will convey more clearly to the public how we administer these benefits and clarify our current practices for the public. In those cases where regulatory language does not accurately reflect current practice, we should update it to reflect the standard we use so that the public is informed of and understands the standards, criteria, and requirements that VA uses to provide these benefits.

Comments also raised concerns that prosthetics representatives could deny a prescribed item or service if they determine it to be more of a comfort or quality of life item and not a medically necessary item. One comment stated that prosthetics representatives may lack necessary training, which could result in denial of a physician-recommended item or service because the item is viewed as convenient rather than medically necessary. It was also recommended that we remove the language in proposed § 17.3230 that stated that items or services must not merely support the comfort or convenience of the veteran as this would ensure that veterans are not inappropriately denied medically-indicated items because someone not trained in prosthetics and rehabilitation may view a prescribed item as convenient rather than medically necessary. To address these comments, VA is not precluded from providing medically necessary prosthetic and rehabilitative items and services that are additionally beneficial to the veteran or support the comfort and convenience of the veteran. However, VA will not provide prosthetic and rehabilitative items and services merely because they support the veteran's comfort or convenience *only.* Prosthetic and rehabilitative services or items may be medically necessary, and incidentally or

directly support the comfort and convenience of the veteran. In response to this comment, we have not removed the comfort and convenience language as we believe it is important and necessary to include in the regulation as it is reflective of our current practices. However, we have removed the word merely that was in proposed § 17.3230(a) and have replaced it with the word solely in order to reflect that an item or service will not be provided exclusively for comfort or convenience. We believe this addresses any potential confusion and more accurately reflects our intent.

To more specifically address the concern raised in the comment related to the input of prosthetic representatives, we note that prosthetics representatives give deference to the prescription written by a VA health care provider or an authorized non-VA health care provider. In the instance that a prosthetic representative may question whether a prescribed item or service meets the direct and active component standard in § 17.3230(a), the prosthetics representative would discuss such concerns with the provider. As long as the item or service is prescribed as medically necessary under the standards in both §§ 17.38(b) and 17.3230(a), it will be provided if it can be procured; and it may be the case that in such instances a level of comfort and convenience is concomitantly obtained. Indeed, comfort and convenience are valid clinical considerations in many decisions about which item or service will best meet a veteran's clinical needs.

In sum, VA will continue to support the holistic care of our Veterans. The decision about what item will best meet the Veteran's needs will be determined jointly by clinicians and veterans, which will result in a prescription for an item. The clinician will continue to consider how a specific item may be optimized to meet the veteran's unique needs like other diagnosed medical conditions and preserve functional independence. For example, VA wheeled mobility clinics will continue to partner with veterans, conduct comprehensive evaluations of veterans, and consult with clinicians across disciplines to identify and prescribe the wheeled mobility device that will best meet a veteran's needs. This could be a basic powered wheelchair, one that is optimized for transportation in a given urban environment, or an all-terrain powered wheelchair that could allow the veteran to navigate natural obstacles that the veteran encounters on a daily basis. The direct and active component standard in § 17.3230(a) will not restrict VA's ability to provide this equipment.

One comment stated that the regulations do not distinguish between service-connected versus non service-connected veterans, as the former traditionally have been able to choose their provider in limited circumstances pursuant to VA policy. While we note that the policy documents referred to by the comment do distinguish between service-connected and non-service connected veterans, the policy documents do not provide an all-inclusive list of factors that should be considered when providing prosthetic or rehabilitative services, such as the veteran's clinical needs, and it was our intent that VA clinical providers would be involved in the decision on how the veteran's needs can be best met. Authorities such as 38 U.S.C. 1703 previously distinguished between these groups of veterans, but this authority was amended by the VA Maintaining Internal Systems and Strengthening Integrated Outside Networks (MISSION) Act of 2018, Public Law 115–182, and as amended, section 1703 no longer recognizes a distinction between service-connected and non service-connected care. We see no valid reason to continue to distinguish between these groups of veterans with regard to the provision of prosthetic and rehabilitative items and services, particularly as we believe there are compelling reasons to be consistent in how we determine whether VA or an authorized non-VA vendor will provide the prescribed item or service, as explained in this paragraph and in the SNPRM. See 83 FR 61139–61142.

One comment raised concerns that proposed § 17.3230(a)(2), which would provide that VA furnishes adaptive recreation equipment when such equipment would achieve the veteran's rehabilitation goals as documented in the veteran's medical record, would limit access to rehabilitative items such as sport-specific wheelchairs. The comment noted that participation in sports is part of a veteran's rehabilitation goals and overall health. We acknowledge that the needs of veterans are unique, and the veteran is involved in the decision on the appropriate item to be prescribed based on his or her unique needs and to ensure his or her clinical needs are met. We specifically note that rehabilitation goals, developed jointly by the veteran and clinician, will be considered when determining the appropriate item or service to be provided to the veteran pursuant to these regulations. As long as the sports-related item meets the medical necessity standards set forth in §§ 17.38(b) and 17.3230(a), we do not believe that any additional requirements in § 17.3230(a)(2) such as documentation of goals in a medical record will prevent provision of such items.

Another comment supported VA for including adaptive recreation equipment in the list of equipment VA will provide under these regulations, but suggested VA clarify that the medical need for such equipment may be identified within inpatient and outpatient settings. We note that there is nothing in the regulation limiting the determination of the medical need for prosthetic and rehabilitative items and services to inpatient or outpatient care or that the determination needs to be made within a certain timeframe. The determination that a prosthetic or rehabilitative item or service is medically needed can be made at any time by VA. As long as the equipment meets the medical necessity standards in §§ 17.38(b) and 17.3230(a), it will be provided regardless of whether the veteran is in an inpatient or outpatient setting. We also note that a veteran's medical needs and rehabilitation goals can change over time, and these regulations would not limit VA's ability to prescribe a new piece of equipment based on a change in the veteran's medical needs.

Another comment raised concerns that the definition of adaptive recreation equipment in § 17.3210 as proposed was too restrictive and that it could negatively impact veterans' quality of life. The comment referred to the language in the preamble that states that such equipment will not be provided merely to support a veteran's participation in an activity only for personal enjoyment. This comment explained that if a medical professional determines that such equipment is needed for medical or therapeutic reasons, prosthetics personnel can deny the appliance by determining it is for personal enjoyment. Similar to the explanation in prior discussion of this rulemaking on the issue of the comfort or convenience language in § 17.3230(a), VA is not precluded from providing adaptive recreation equipment if such equipment is additionally beneficial to the veteran or supports a veteran's participation in an activity for personal enjoyment. VA clinicians work closely with veterans to identify recreation activities and needed adaptive recreation equipment that are consistent with the veteran's individualized rehabilitation goals. While considering physical rehabilitation needs, the clinician and veteran simultaneously consider quality of life opportunities that are uniquely presented by

recreation, like personal enjoyment and fulfillment, and socialization with friends, family, and fellow veterans. However, VA will not provide adaptive recreation equipment solely because the equipment supports the veteran's participation in an activity for personal enjoyment. This equipment authorized under § 17.3230(a)(2) will be provided only if it meets the medical necessity requirements under §§ 17.38(b) and 17.3230(a).

We note that the provision of adaptive recreation equipment is one component of a comprehensive VA approach to reach out to veterans and encourage their participation in recreational and leisure activities, led by the VA Recreation Therapy Service. This service embraces a philosophy of health promotion and disease prevention facilitated by qualified clinicians to enhance physical, cognitive, emotional, social, and leisure development that support each veteran's self-directed, self-determined, and fully independent participation in their chosen life pursuits. The VA recreation therapist's role is not to focus solely on the medical diagnosis, but to improve and enrich bio-psycho-social functioning through active therapy and meaningful therapeutic activities to maintain or improve functional independence and life quality. VA also regularly conducts National Veteran Sports Programs and Special Events, in which we encourage veterans to participate and focus on their specific abilities, rather than disabilities. Additionally, VA connects veterans to the community of recreational resources via the VA Adaptive Sports Grant program to engage in activities that promote independent veteran participation in activities designed for personal enjoyment.

We do not make changes to the definition of the term adaptive recreation equipment based on the comments above, but we do revise § 17.3230(a)(2) to remove all language after the term adaptive recreation equipment, as this language is duplicative of the definition of adaptive recreation equipment in § 17.3210.

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. We stated that 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. One comment stated that the definition of and references to replacement item should include that the item will be of similar value. We address this comment in terms of the cost of a replacement item because cost is an objective comparison to the item being replaced, versus the subjective and broader comparison of value. When considering whether to replace an item, VA considers the veteran's clinical needs and whether the replacement item would meet the medical necessity standards in §§ 17.38(b) and 17.3230(a). If the replacement item is the same as the previously prescribed and provided item, then we would expect the cost of the replacement item would be the same or very similar to the original item. The focus will be on what replacement item would be most appropriate to provide to meet the veteran's clinical needs, and the most appropriate item may not be the same item previously prescribed and consequently may not be the same cost as the item previously prescribed.

Proposed § 17.3230(a)(14) would authorize the provision of specialized clothing made necessary by the wearing of a prosthetic device, while paragraph (a)(6) would authorize VA to provide certain home medical equipment. One comment suggested that VA not purchase items, such as socks, shoes, heating pads, and scales, that can be purchased at retail stores. While many of these described items may be available for purchase at retail stores, VA will provide those items pursuant to this rulemaking as long as the provision of such items meets the medical necessity standards under §§ 17.38(b) and 17.3230(a) and the items are one of the types of items expressly identified under proposed § 17.3230. That a retail store may carry such items would not preclude VA from providing an item to a veteran if the criteria and requirements in the regulation are met, similar to VA's provision of prescription drugs that are available over the counter under § 17.38(a)(1)(iii). The provision of such items would be within VA's authority. We further note that eligibility for the provision of specialized clothing made necessary by the wearing of a prosthetic device is not the same as the clothing allowance provided under 38 CFR 3.810 and authorized by 38 U.S.C. 1162, which is intended to provide a clothing allowance to veterans with certain service-connected disabilities.

Section 17.3240 Furnishing Authorized Items and Services

We proposed in § 17.3240(a) that VA would 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. As stated in the preamble of the proposed rule, the intent of the language in § 17.3240(a) as proposed was to establish that when VA has the capacity or inventory, VA directly provides items and services to veterans, but that 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. The intent of § 17.3240(a) as proposed was to clarify in regulation that whether VA or a VA-authorized vendor provides a prosthetic item is an administrative business decision that 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 its duty to administer this program in a legally sufficient, fiscally responsible manner.

We received over 280 comments concerning proposed § 17.3240, and the vast majority of these comments (228) addressed the same issues in nearly identical language. The main arguments in these comments included the following: VA would have sole discretion in determining how prosthetic and orthotic care is delivered to veterans; this rulemaking would eliminate veterans' choice of provider; it would contradict long-standing practice and policy of VA regarding a veteran's choice of provider (particularly relating to prosthetic limbs); it would disregard the history of cooperation between VA and contracted providers as well as veterans' clinical needs; and it would directly conflict with public statements made by VA regarding veterans' choice in health care. It was also argued that this decision on how to provide prosthetic and orthotic care to veterans is not an administrative decision, but rather a clinical one. We note that these concerns were primarily raised in reference to the provision of prosthetic limbs (also referred to as artificial limbs).

In the SNPRM published on November 28, 2018, we clarified and explained our current practices for the general provision of prosthetic and rehabilitative items and services, and specifically, the provision of prosthetic limbs. See 83 FR 61137. In the SNPRM, we also addressed many of the concerns discussed above regarding the comments to the proposed rule. We also note that the SNPRM addressed other concerns raised in response to the proposed rule. These other concerns

that the SNPRM addressed included that this proposed rule would be inconsistent with the Veterans Access, Choice, and Accountability Act of 2014, Public Law 113–146 (Choice Act), with VA policy and with current practices; that it would alter current practices; that it may implicate other community care authorities (*i.e.,* 38 U.S.C. 1703 and 8153); and that we did not cite to or reference the authority for § 17.3240.

In response to public comments on the proposed rule, the SNPRM revised § 17.3240(a) as proposed to 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, which we believed was responsive to the concerns related to clinical decision making and retaining veteran input clarified that this is current VA practice. See 83 FR 61141. The SNPRM also revised § 17.3240(a) as proposed to state that 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, and further that the 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. We believed these additional revisions made in the SNPRM to § 17.3240(a) as originally proposed further supported and clarified current VA practice concerning how VA makes the administrative decision regarding who furnishes a prosthetic item to a veteran (*i.e.,* VA or a VA-authorized vendor), for the benefit of both veterans and VA-authorized vendors. See 83 FR 61141.

In response to the SNPRM, we received 8 comments, many of which raised the same concerns previously raised in response to the language in § 17.3240(a) as originally proposed. In response to these same concerns as raised in comments to § 17.3240(a) as originally proposed, we reiterate from above that the revisions made in the SNPRM clarified that current VA practice does consider clinical need and consider veteran input, but also that VA retains control over the administrative decision of whether to provide the prosthetic item directly to the veteran or have it provided by a VA-authorized vendor. See 83 FR 61139–61143. We address below other comments we received to the SNPRM.

In response to the SNPRM, one comment commended VA for the emphasis on clinical consultation between the veteran and VA providers in § 17.3240 and the supporting explanation provided within the SNPRM. One comment expressed an expectation that in applying § 17.3240, a veteran's prosthetic needs will outweigh any concern with nationwide consistency when items are clinically recommended. We acknowledge that prosthetic and rehabilitative items and services will be prescribed based on a determination that such item or service is medically necessary under the direct and active component standard, and that medical need will outweigh other concerns such as nationwide consistency. This prioritization of medical need is consistent with current practice.

In the SNPRM, we did not specifically address the concern raised in the 228 comments that this rulemaking would disregard the history of cooperation between VA and contracted providers. Related to this set of comments, one comment stated that through these regulations, VA will restrict a veteran's ability to receive care from non-VA contractors. We now state that this rulemaking does not disregard this history of cooperation, as we intend to continue to contract and work with non-VA providers to provide the most appropriate and high-quality care, and we acknowledge that VA alone cannot meet every veteran's prosthetic and rehabilitative needs. VA has over 600 contracts with non-VA providers that are utilized to meet the clinical needs of veterans, and we intend to continue to utilize such contracts. As explained in the SNPRM, veterans will continue to receive care from authorized non-VA providers, and this determination is based upon the clinical needs of the veteran, as well as additional considerations (*e.g.,* VA capacity and availability, geographic availability, cost) which will vary on a case by case basis. See 83 FR 61137–61142. These determinations will be made for routine, non-urgent, and non-emergent needs for durable medical equipment and medical devices. This will ensure that veterans' needs are met with the most appropriate and highest quality items and services in a consistent manner throughout VA and ensure that VA complies with Federal acquisition requirements. Id. As noted in the SNPRM revision to § 17.3240(a)(2), we consider veterans' clinical needs when determining whether to provide artificial limbs and all other items and services under § 17.3230(b) internally or via authorized community vendors.

Several comments raised concerns that § 17.3240 is inconsistent with the Choice Act. In the SNPRM, we addressed this concern, and incorporate in this final rule our related response from the SNPRM. See 83 FR 61139–61140. We further note that, effective June 6, 2019, VA was no longer authorized to furnish care and services under section 101 of the Choice Act. Consequently, we consider these comments to be moot.

One comment specifically stated that § 17.3240(b) should not prevent a provider authorized under the Choice Act to provide care to a veteran from providing all items and services related to the care being furnished. Similarly, another comment opined that once care is authorized in the community, all care should be authorized without additional authorization being needed. VA treated prescriptions from authorized community providers under the Veterans Choice Program, and treats prescriptions under the Veterans Community Care Program, the same way that a prescription from an internal VA provider would be managed. As explained in the SNPRM, if VA authorized a community provider to furnish care to a veteran pursuant to the Choice Act and it was determined that a prosthetic or rehabilitative item or service is needed, VA would review the prescribed item or service to determine whether the prescribed item is within the scope of the authorized community care; this requirement applies as well to the Veterans Community Care Program. As long as the prescribed item or service meets the medical necessity standards in §§ 17.38(b) and 17.3230(a) and is otherwise authorized pursuant to §§ 17.3230 through 17.3250, then VA will provide the item to the veteran either directly or through a VA-authorized vendor. If the prescription is lacking sufficient justification, VA will attempt to contact the prescribing clinician and may consult with internal VA clinicians with subject matter expertise if necessary. If the prescribing clinician or a consulted VA clinician is able to provide the needed justification, then VA will provide the item to the veteran either directly or through a VA-authorized vendor. If the prescribing provider does not respond or otherwise provide the necessary justification, then VA is not authorized to purchase the item for the veteran. In such an instance, VA will ensure that the veteran is seen by a provider who can determine whether the initially prescribed item or another item or service is needed. We further note that

in VA's regulations implementing the Veterans Community Care Program, VA stated it would pay for prescriptions written by eligible entities or providers for covered veterans that have an immediate need for durable medical equipment and medical devices that are required for urgent or emergent conditions, and that VA would fill prescriptions written by such entities and providers for covered veterans for durable medical equipment and medical devices that are not required for urgent or emergent conditions. See 38 CFR 17.4025(b)(3) and (4). To ensure consistency with these community care regulations, we now revise § 17.3240(a)(1) to similarly state that VA providers or eligible entities and providers as defined in 38 CFR 17.4005 will prescribe items and services based on the veteran's clinical needs and will do so in consultation with the veteran. We further revise § 17.3240(a)(2) and (3) to reflect that once an item or service is authorized under paragraph (a)(1), VA will either fill a prescription directly or will pay for such prescriptions to be furnished through a VA-authorized vendor. Lastly, to ensure these regulations are consistent with VA's community care regulations, we revise § 17.3240(b) to include mention of emergency care available under 38 CFR 17.4020(c) and urgent care under 38 CFR 17.4600, and revise § 17.3220(b) to also expressly include eligible entities and providers as defined in 38 CFR 17.4005. We believe these provisions address the issues raised by this comment. Incorporating the provisions promulgated separately (RIN 2900–AQ46, Veterans Community Care Program, and RIN 2900–AQ47, Urgent Care) and already subject to public comment will ensure that VA's programs are consistently operated.

The revisions to §§ 17.3220 and 17.3240 as proposed and described above we believe clarify that VA would determine whether the item or service could be provided, and that VA would separately determine whether it is furnished by VA or a VA-authorized vendor. If a VA provider prescribed an item or service, and VA authorized and contracted with a community prosthetist for the item or service, that prosthetist would only provide the prescribed item or service. If a community prosthetist suggests additional or different items or services those items or services must be further reviewed and authorized by VA, and VA would additionally determine whether it will furnish the item directly or through a VA-authorized vendor. Similarly, if a an eligible entity or provider under 38 CFR 17.4005 prescribes items or services, because VA will have entered into a contract, agreement, or other arrangement for care from such a provider, any prescribed items or services would be reviewed and authorized by VA, and VA would then determine whether it will furnish the items or services directly or through a VA-authorized vendor. This is consistent with Federal and VA acquisition requirements, the Veterans Community Care Program, and our current business practices to require community providers to complete a secondary authorization request or a request for service form for additional or continued care to include all prosthetic item and service requests (except in the case of items or services needed in emergent or urgent circumstances). Because we believe that this requirement for VA-authorized vendors to receive authorization from VA, prior to such vendors furnishing items or services to veterans, is clear within the terms of the contracts, agreements, or other arrangements for care VA forms with such vendors, we further amend § 17.3240(b) as proposed to remove the last sentence that states prior authorization must be obtained from VA by contacting any VA medical facility. We believe the revisions to §§ 17.3220 and 17.3240 described above assist to clarify that in all cases, VA either itself furnishes items or services or provides them through a VA-authorized vendor as long as VA finds that the prescription meets the medical necessity standards in §§ 17.38(b) and 17.3230(a) and otherwise meets the requirements set forth in § 17.3200 through 17.3250.

Comments to both the proposed rule and SNPRM opposed VA retaining sole authority in § 17.3240 to determine whether VA or an authorized VA vendor will provide the authorized item or service under these regulations, and that veterans should maintain this right. As we explained in the SNPRM, the veteran will be involved in the decision of what item or service will be prescribed in order to meet their needs, but VA retains the authority over the determination of how the item or service will be provided. This is because VA needs to ensure that veterans' needs are met with the most appropriate and highest quality items and services in a consistent manner throughout VA, that VA does so in a manner that complies with Federal and VA acquisition requirements, and that VA is also being fiscally responsible in the provision of these items and services. See 83 FR 61138–61142. As previously explained, VA has already regulated these general conditions in § 17.4025(b)(3) and (4) as part of the Veterans Community Care Program.

One comment stated that § 17.3240 could result in a prosthetics representative hundreds of miles away making a decision on how the item or service is provided without knowing what is best for the veteran. As explained in the SNPRM, the decision regarding what item or service will be provided is a clinical decision, and the decision of how that item or service is provided is a separate decision that is based on clinical and administrative factors. 83 FR 61137, 61138–61142. Both decisions take into account the best interests of the veteran, and VA clarified the clinical and administrative factors it considers when determining how to furnish an item in proposed § 17.3240(a)(2) as revised by the SNPRM. 83 FR 61137, 61141. As long as the prescribed item or service is authorized pursuant to these regulations and meets the medical necessity standards in §§ 17.38(b) and 17.3230(a), the VA prosthetics representative will honor the prescription and procure the prescribed item or service. 83 FR 61137, 61138. This rule will not permit a VA decision of how an item or service is furnished without considering what is best for a veteran, and we do not make changes based on this comment.

One comment suggested VA revise the regulation as proposed to codify VA's consideration of a non-VA provider's input in determining what to authorize. We reiterate from the discussion above that VA clinicians do consider a non-VA provider's input when VA reviews prescriptions from non-VA providers, and that the revision of § 17.3240 as proposed to specifically reference non-VA eligible entities and providers makes this clear without further revisions to the regulations as proposed.

One comment argued that under these regulations, a veteran has no role in the decision of who they see or who provides the prescribed item. As we explained in the SNPRM, the veteran, in consultation with his or her clinician, is directly involved in the decision of what item or service is prescribed. See 83 FR 61137–61139. In the SNPRM, we modified the language of proposed § 17.3240 to incorporate the veteran's input in this decision, and now adopt that language as final in this rulemaking. VA retains the authority to make the determination of how the item or service is provided in order to ensure that veterans' clinical needs are met with the most appropriate and highest quality items and services in a consistent manner throughout VA, and that we comply with Federal and VA

acquisition requirements in providing such items and services. See 83 FR 61138. We further note that in the provision of artificial or prosthetic limbs, if VA decides that the veteran should receive the item or service from a community prosthetist, the veteran, in consultation with his or her VA clinician or amputee clinic (or eligible entities and providers as defined in 38 CFR 17.4005), would in most cases be able to select a vendor that has an existing agreement with VA and is able to meet the veteran's clinical needs.

At least two comments opined that non-VA providers should be utilized to prescribe prosthetic and rehabilitative items and services as VA does not have the necessary expertise to meet the needs and requirements of veterans to ensure they receive appropriate care. Other comments stated that non-VA providers should be utilized to ensure appropriate, available, quality, timely, and convenient care. Another comment opined that decreased access to non-VA providers would result in sub-optimal care, leading to unnecessary pain, less mobility, depression, and unemployment among veterans. Comments also noted that veterans will have to travel long distances to VA facilities if not given a choice to utilize non-VA providers, or claimed VA's historical issues with time constraints, availability, and administrative deficiencies presented obstacles to justify use of non-VA providers. Similar to our response above, we intend to continue to contract and work with non-VA providers to enable VA to provide the needed items and services in a timely, appropriate, convenient, or quality manner in specific cases. As we explained in the proposed rule, VA 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. 82 FR 48025. In the SNPRM, we further explained that the determination of whether VA or a VA-authorized vendor will furnish authorized items or services will be based on, but not limited to, such factors as the veteran's clinical needs, VA capacity and availability, geographic availability, and cost. 83 FR 61141–61143. We clarify here that these determinations are only about the furnishing of items or services (such as fitting a prosthetic) and not the clinical care that establishes the medical necessity of such items and services. The eligibility for receipt of that clinical care in the community by covered veterans is controlled by the Veterans Community Care Program established in regulation at 38 CFR 17.4000 through 17.4040. We enter into contracts, agreements, and other arrangements with non-VA providers for both clinical care and furnishing items and services and will continue to do so on a case-by-case basis and as clinically needed, to ensure that veterans' clinicals needs are met in an appropriate, timely, convenient, and high-quality manner.

We note that VA provides high-quality and timely in-house care in the area of artificial limbs. VA has modernized the way that veterans access and receive amputation care services. Currently VA offers same-day service to veterans at all of the 145 sites that offer orthotic and prosthetic services. Veterans may also schedule their amputation care services directly with the amputee clinics, rather than through a referral from another clinical service, facilitating more timely provision of care. This ultimately results in the care plan for amputee veterans being created on the day that the veteran contacts VA. We also note VA has engaged in several activities to ensure that veterans receive the best prosthetic care possible from VA. Since 2009, through the Extremity Trauma and Amputation Center of Excellence (EACE), we have collaborated with the Department of Defense (DoD) to conduct research and foster innovation to improve prosthetics for wounded servicemembers and veterans. EACE allows VA and DoD to collaborate and study extremity trauma care to ensure that prosthetics are made more comfortable and better fitting. Since 2008, we also have implemented the Amputation System of Care (ASoC) within VA to enhance quality and consistency of care provided to veterans with limb loss. ASoC is designed to provide the latest practices in medical care, prosthetic technology, and rehabilitation management to support veterans in reaching the highest level of functional independence. We note that ASoC is similar to DoD's amputation care program, which ensures consistency during the transition from DoD to VA health care. In addition to these systems, we also have prosthetic and orthotic laboratories across VA. Prosthetic and orthotic laboratories have artificial limb fabrication and repair equipment, and allow for on-site evaluation, fitting, maintenance, and long-term care of prosthetic and orthotic needs. As of the publication of this final rule, VA currently has 84 such laboratories across the country. This allows veterans to receive on-site and specialized care at their local facilities in a timely manner.

Similarly, another comment opined that non-VA providers augment VA care by providing cutting-edge technology and advanced labs. VA often leads in providing such technology when clinically appropriate for artificial limbs and any other class of device that may clinically benefit veterans, including breakthrough devices newly cleared by the United States Food and Drug Administration to be marketed. VA is able to provide items that may be unavailable from the private sector due to the cost of a given device and limitations of private insurance coverage. With regard to artificial limbs and components, VA is a leader in clinical research. As mentioned above, we also have prosthetic and orthotic labs that allow us to provide timely and appropriate care to veterans. Additionally, through EACE, we also continue research to find innovative ways to meet the prosthetic needs of veterans.

One comment opined that VA is unable to handle combat amputees and is only able to handle amputees due to vascular issues. We acknowledge that the vast majority of the amputees we treat are those who had an amputation due to disease processes. However, this is reflective of the veteran amputee population as only a small percentage of the veteran population with amputations has an amputation of traumatic etiology. We do provide amputee care to both populations. Webster JB, Poorman CE, Cifu DX. *Department of Veterans Affairs Amputation System of Care: 5 years of accomplishments and outcomes.* J Rehabil Res Dev. 2014;51(4):vii–xvi. VA collaborates with DoD via sharing agreements, joint education programs, and other initiatives, specifically to provide the care for newly-separated reserve and active duty servicemembers, as well as veteran combat amputees. A VA Office of Inspector General report found that within 5 years of military separation, 99 percent of servicemembers with combat-related amputations transitioned their care to VA. *Health care Inspection: Prosthetic limb care in VA facilities,* Report No. 11–02138–116. Washington, DC, March 8, 2012.

We note that VA has unique experience in providing care to amputee veterans. For example, we have seen over 80,000 veterans with amputations for amputee services since 2013. Between 2008 and 2013, VA performed an average of 7,669 new amputation procedures annually. See Webster JB, *et al. Department of Veterans Affairs Amputation System of Care: 5 years of accomplishments and outcomes,* cited above. In fiscal year 2019 VA saw 96,518 veterans with amputations, with

46,214 of these veterans having at least one major limb amputation (*i.e.,* amputation at or proximal to the wrist or ankle). Of those 96,518 veterans, 39,291 of them were service-connected for an amputation-related disability while 2,375 veterans were service-connected for a combat-related amputation disability. Due to the large number of veterans with amputations that we see for care within our system, we have unique expertise that allows us to provide specialized care to meet these veterans' clinical needs.

A related comment noted that § 17.3240 as proposed does not address the unique clinical needs of veterans, in particular amputees. As explained in the SNPRM, we are trying to ensure consistency with the provision of all prosthetic and rehabilitative items and services across VA, and therefore do not expressly or explicitly distinguish between veterans based on their clinical needs in the regulations. However, the proposed rules were drafted in a manner to allow clinicians to determine, based on each veteran's unique clinical needs, those items or services to be provided and how such items or services will be provided.

At least one comment stated that choice of provider is an important quality assurance mechanism. The comment noted that veterans can determine quality versus VA making that determination. One comment additionally noted that the fact that VA contracts with non-VA providers indicates that non-VA providers meet or exceed a required level of quality. We reiterate from earlier in this rulemaking that revisions to § 17.3240(a) as proposed will account for consultation with a veteran when VA or non-VA providers prescribe items or services for veterans, although this does not necessarily address the issue of a veteran's choice of provider. We note that in terms of VA providers, VA can address issues of provider choice with veterans internally without any changes to these regulations. In terms of non-VA providers (*i.e.,* eligible entities and providers as defined in 38 CFR 17.4005, per revised § 17.3240(a)(1)), such providers are available to veterans to choose from under VA community care regulations at 38 CFR 17.4030, to the extent that community providers meet the criteria of § 17.4030 and to the extent the veteran is a covered veteran and meets one or more of the eligibility criteria in § 17.4010. Particularly, we note that § 17.4030(c)(2) requires VA to assess the qualifications of the community provider to furnish care or services, such that a contractual relationship between a community provider and VA does not equate with an assumption on VA's part of the quality of the provider; VA must still determine whether the community provider would be able to provide the services that would meet the veteran's unique clinical needs. Thus, even though a veteran may want to choose a certain community provider because they have a relationship with that community provider or for other reasons, it does not mean that the community provider has the specific expertise needed in all instances. VA retains ultimate authority to ensure that the veteran's clinical needs can be met in an appropriate and high-quality manner.

Another comment opined that if VA does not allow veterans to choose their provider, VA will mass produce prosthetics, and in particular will do so using the computer-aided design and manufacturing (CAD–M) production method. As a result, this comment explained that veterans would receive uncomfortable prosthetics that do not work well. We note that VA does not mass produce artificial limbs, and our providers work to ensure that the artificial limbs fit each veteran properly. VA also has no such plan to mass produce artificial limbs or components using any known production method. VA fabricates customized artificial limbs based on the individualized needs of each veteran and that veteran's personal goals. Most VA prosthetists make the artificial limb by hand and make a plaster bandage of the limb shape. We do not generally make the limb by CAD–M.

Another comment asked that VA clarify in the final rule the mechanisms it will use to determine and ensure that the clinical needs of veterans drive the decision-making of the agency in determining whether VA will directly provide the prescribed item or service or whether VA will use an authorized vendor. As a general rule, VA internal agency processes are not reflected in VA regulations. We will develop policies that implement the rule to ensure that clinicians and prosthetics representatives make this determination based on the veteran's clinical needs, and we do not make changes based on this comment.

A comment also raised a concern that VA may consider cost savings ahead of the provision of optimal, timely, efficient care, which would harm veterans. This comment requested that we clarify in this final rule that when cost is factored into the determination of who will provide the authorized item or service, the veteran will receive the prescribed item of the same quality, caliber, and effectiveness regardless of who furnishes it. This comment also urged VA to afford a veteran's preferences greater weight in instances in which cost is the sole administrative factor considered and the veteran's preferences do not align with VA's determination. We agree with these comments and believe that the amendments to § 17.3240 as proposed in the SNPRM sufficiently prioritize the clinical needs of each veteran over other factors, including cost. We clarify that the clinical needs of the veteran are critical to prescribing the correct item. Generally, VA will provide the exact item described in the prescription. If the item must be procured from a VA-authorized vendor, VA complies with Federal acquisition regulations and VA acquisition regulations, which require VA to enter into and utilize national and regional contracts when appropriate. In the instance that the fabrication of an item like an artificial limb requires a skilled clinician to work with the veteran on an ongoing basis, then we noted in § 17.3240(a)(2) as proposed in the SNPRM that VA will consider the veteran's clinical needs and other factors in addition to cost.

Additionally, a comment requested that as VA develops and implements the VA MISSION Act of 2018, it does so in a meaningful way that is designed to limit disruption or delay in the delivery of care that does not impose undue financial and administrative burdens on VA authorized vendors. As we explained in the SNPRM, the VA MISSION Act of 2018 was enacted on June 6, 2018, and section 101 of this Act revised section 1703 of title 38, U.S.C., when VA's implementing regulations became effective June 6, 2019. As we have previously discussed, these regulations expressly address how VA will pay for or fill prescriptions written by eligible entities or providers for covered veterans for durable medical equipment and devices at 38 CFR 17.4025(b)(3) and (4); similar regulations also apply to the urgent care benefit regulated by VA at 38 CFR 17.4600(e)(3). We do not believe that VA-authorized vendors will experience any undue financial or administrative burdens as a result of VA's implementation of the new Veterans Community Care Program or the urgent care benefit, but VA will continue to work to ensure that its processes do not cause undue disruption or delay in the delivery of care. As previously stated, we have also revised this final rule to account for the regulations implementing the changes made by

section 101 of the VA MISSION Act of 2018.

Section 17.3250 Veteran Responsibilities

We proposed that § 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.

In proposed § 17.3250(b) we stated that, except for emergency care under 38 CFR 17.120 through 17.132 or 38 CFR 17.1000 through 17.1008, 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 that are not otherwise covered as emergency care.

One comment stated that proposed § 17.3250(b) was too restrictive, as veterans should not be required to obtain pre-approval on an item or service obtained from a VA-authorized vendor as this could cause delays, lead to lapses in care, and be detrimental to treatment. This comment and others also raised similar concerns about pre-approvals for repairs or replacement services and opposed elimination of § 17.122 and the related revision of § 17.120. As previously mentioned above, VA may authorize a veteran to receive an item or service in the community for numerous reasons. If an item or service has been prescribed and VA has authorized a vendor to provide that item or service, no further approval is needed unless the vendor determines that a different item or service is necessary. This would require further VA approval as a new prescription would be needed. This would be consistent with our practices and with Federal and VA acquisition regulations, as VA has to authorize items and services prior to their being provided. We do not find that VA's review and approval of prescriptions or review of different requested items or services creates undue delay, lapses in care, or is detrimental to a veteran's treatment. Absent emergent cases, VA's review and approval of prescriptions from non-VA providers, or requests for items or services from VA-authorized vendors that differ from what VA providers prescribed, is necessary to consider the unique needs of each veteran. We note that in emergent cases, VA could reimburse a veteran for emergency care pursuant to 38 U.S.C. 1725 or 1728 and 38 CFR 17.120 through 17.132, or 38 CFR 17.1000 through 17.1008. As previously noted, §§ 17.4025(b)(3) and 17.4600(e)(3) also authorize payment for prescriptions for durable medical equipment and medical devices that are required for urgent or emergent conditions. We find that, although these other authorities have their own criteria, they would also address situations in which a veteran needed an item or service due to an emergency.

Similarly, repairs and replacements by a vendor must also have prior authorization from VA before such items and services can be provided. When VA contracts for items and services, a scope of work is generated, which specifically identifies the items and services for which VA is contracting. Prior to performing work for which a vendor can be reimbursed, VA must comply with the Federal Acquisition Regulation and create a purchase order or establish a contract for such work. As a result, VA cannot provide a blanket authorization for a vendor to provide any repairs and replacements in addition to the item or service prescribed. A new authorization for a vendor to provide repairs or replacements would be required. To the extent that there is an emergent or urgent situation, prior authorization would not be required under one of the authorities described above. We believe that these authorities would address the situation in which a veteran needed a repair or replacement due to an emergency or urgent situation, and we would be able to pay or reimburse for that care consistent with those authorities. Thus, VA has determined that § 17.122 is unnecessary, although we clarify in this rulemaking that we will remove § 17.122 but also mark it reserved for future use of the section number as needed. VA could also obviate the need for veterans to obtain emergency repairs from vendors by providing spare items or devices for prosthetic and rehabilitative items under § 17.3230, as clinically appropriate.

One comment stated that moving emergency repairs from under § 17.120 to § 17.3250 would cause confusion, and that if this change is made, outreach and education to veterans on this change should be provided. VA believes that consolidating all information on the provision of prosthetic and rehabilitative items and services within the scope of this rulemaking under one set of regulations, at §§ 17.3200 through 17.3250, will provide a centralized location for veterans to look for information on the provision of these items and services. As a result, we believe this will lead to less confusion. We will be providing information to veterans once this rulemaking becomes final to ensure that veterans are educated and informed on how these items and services including emergency repairs will be provided.

We make no changes to the regulations based on these comments.

Elimination of the Prosthetics Service Card

We noted in discussion of the proposed rule that VA intended to stop use of the prosthetics service card (VA Form 10–2501) when the final rule is published. 82 FR 48026. We stated that the prosthetics service card is often not used for its intended purpose, is not universally utilized by veterans and VA vendors, and would not be necessary after publication of the final rule.

One comment opposed elimination of the prosthetics service card as it would result in veterans not being allowed to have immediate non-emergent repairs completed without prior approval by VA. This comment raised concerns that VA would not be able to provide timely pre-approval and that it is unclear whether an estimate for pre-approval would be needed or whether a list of VA authorized vendors would be provided. The comment also expressed concern about this adding another level of bureaucracy before an item can be repaired. As we explained in the preamble of the proposed rule, prosthetics service cards were intended to be used in emergency situations. However, these cards have not been widely used or consistently used for this purpose. As we noted, many veterans have lost these cards or have failed to provide them to third party vendors; many vendors still contact VA for authorization prior to making repairs; and these cards merely provide notice that VA will reimburse repairs up to a certain amount. We have found that third party vendors still submit invoices and documentation to VA for reimbursement for repairs. As a result, we are eliminating use of the prosthetics service card. Non-emergency repairs will be authorized pursuant to §§ 17.3230 and 17.3240. As we noted above, pre-approval is required to

comply with Federal and VA acquisition regulations. Additionally, as explained in § 17.3240(b), prior authorization is not required for emergency care under 38 CFR 17.120 through 17.132, 38 CFR 17.1000 through 17.1008, and 38 CFR 17.4020(c), or urgent care under 38 CFR 17.4600.

We make no changes to the regulation based on this comment.

Comments Received on Miscellaneous Issues

Several comments generally opposed the changes. Some of these comments, which included issues with VA leadership, are beyond the scope of these regulations, and we are not making any edits based on these comments. One comment opined that the drafter of the comment should be involved in the development of VA handbooks, directives, and other policies that will implement these regulations. We note that this comment is outside the scope of these regulations, and we are not making any edits based on this comment. In response to the SNPRM, one comment raised several other issues, including implementation of the VA MISSION Act of 2018, the recommendation that VA consider how to incentivize more community-based physical therapists and physical therapist assistants to work with VA, and that Veterans Integrated Service Networks should include a therapist on the leadership team to provide therapy-services relations guidance and expertise. These are also outside the scope of these regulations, and we are not making any edits based on these comments.

One comment expressed concerns with veterans' ability to receive cochlear implantation through these regulations. While we do reference implants in this regulation, hearing aids and other hearing technology, including cochlear implants, are outside the scope of these regulations as they are covered by a separate regulation, 38 CFR 17.149. Additionally, this comment suggested that VA provide training and updates on current cochlear implant candidacy practices and outcomes to align with best practices. This is also outside the scope of these regulations, but we have provided this comment to the appropriate VA program office to consider.

One comment suggested that the clothing allowance should be abolished or awarded for artificial limbs only. We note that clothing allowance is provided pursuant to separate authorities, 38 U.S.C. 1162 and 38 CFR 3.810, as explained in proposed § 17.3200, and thus is not covered by this rulemaking. This comment is beyond the scope of these regulations, and we are not making any edits based on this comment.

One comment opined that the proposed rule may have violated the Administrative Procedure Act (APA) due to ambiguities in the discussion of the proposed rule concerning the intent of proposed § 17.3240, no explanation or citation for the discretionary authority for proposed § 17.3240 or on how VA would exercise this authority, the lack of discussion in the proposed rule regarding existing law and policy and how that will change under § 17.3240, and the failure to address non-VA care authorities or prosthetics procurement authority in the proposed rulemaking. We note that these issues were addressed in the SNPRM, as we explained the intent of proposed § 17.3240; described our authority for that section and our exercising of that authority; and discussed current laws (including non-VA care authorities such as VA MISSION Act of 2018 and Choice Act) as well as VHA policies concerning the provision of prosthetic and rehabilitative items and services and how these regulations are impacted by the laws and how they will impact the referenced policies. See 83 FR 61139–61143. Elements of VA's Veterans Community Care Program that affect the prescription of prosthetic items and services were subject to notice and comment rulemaking (see RIN 2900–AQ46 and RIN 2900–AQ47), and elements of those rules are incorporated here for consistency. We are not making any edits based on this comment.

Non-Substantive Revisions That Are Not Based on Comments

We are making certain revisions to provisions from the proposed rule that are not based on comments, and that are non-substantive in nature.

We add a section list, immediately following the undesignated center heading that reads Prosthetic And Rehability Items and Services, to identify each of the §§ 17.3200 through 17.3250 with their corresponding section header.

We revise § 17.3200(a) as proposed to add the phrase ''[t]his section and §§ 17.3210'' through 17.3230 are applicable as proposed, to better distinguish reference to § 17.3200.

We revise § 17.3200(b) as proposed to add the phrase ''[t]his section and §§ 17.3210'' through 17.3230 are applicable as proposed, to better distinguish reference to § 17.3200. We additionally revise § 17.3200(b) as proposed to add the phrase ''to be provided'' after the first use of the term ''authorized'', so that the first sentence of § 17.3200(b) now reads ''[s]ections 17.3200 through 17.3250 apply only to items and services listed in § 17.3230(a) and authorized to be provided as medical services under 38 U.S.C. 1701(6)(F) and 38 U.S.C. 1710(a).'' We lastly revise § 17.3200(b) to add more specific reference to the accompanying table as proposed, to identify the table as table 1, to add to the table a corresponding title to read ''Table 1 to Paragraph (b),'' and in table 1 to correct the ''*et seq.*'' citation format to include, instead, a citation through the end of the applicable section numbers for the automobile adaptive equipment and home improvement and structural alterations regulatory citations.

We revise § 17.3220(a) as proposed to remove, from the reference to § 17.37, the dash between § 17.37(a) and (c), and insert the word ''through'' in its place to better distinguish the range of applicable paragraphs. We revise § 17.3220(b) as proposed to correct the citation to § 17.4005 with a section symbol versus reference to ''38 CFR.''

We revise § 17.3240(a)(1) as proposed to correct the citation to § 17.4005 with a section symbol versus reference to ''38 CFR.'' We revise § 17.3240(a)(2) as proposed to correct the reference to paragraph (a)(1) of § 17.3240. We revise § 17.3240(a)(3) as proposed to correct the reference to paragraph (a)(2) of § 17.3240. We revise § 17.3240(b) as proposed to correct citations to §§ 17.120, 17.1000, 17.4020(c), and 17.4600 with section symbols versus reference to ''38 CFR,'' and to correct the ''*et seq.*'' citation format to include, instead, a citation through the end of the applicable section numbers for §§ 17.120 through 17.132 and 17.1000 through 17.1008.

We revise § 17.3250(a) as proposed to add a reference to § 17.3240, as § 17.3240 also relates to the provision of items and services set forth in these regulations. We also revise § 17.3250 (a) as proposed to replace the phrase ''in the manner for which they are prescribed'' with the phrase ''as they are prescribed'', as we believe this language is more easily understood.

We revise § 17.3250(b) to correct citations to §§ 17.120, 17.1000, 17.4020(c), and 17.4600 with section symbols versus reference to ''38 CFR,'' and to correct the ''*et seq.*'' citation format to include, instead, a citation through the end of the applicable section numbers for §§ 17.120 through 17.132 and 17.1000 through 17.1008. We additionally revise § 17.3250(b) to remove from the last sentence the phrase ''that otherwise are'', as this language is extraneous and does not add

to the provisions in § 17.3250(b). We additionally revise the last sentence of § 17.3250(b) to reference emergency care under 38 CFR 17.4020(c) and urgent care under 38 CFR 17.4600, to be consistent with the first sentence of § 17.3250(b) and be consistent with § 17.3240(b) as revised.

External Communications Discussed in SNPRM

In the SNPRM, we described communications VA had with external parties after the comment period for the proposed rule had closed. See 83 FR 61142. We briefly described a roundtable that was held on July 25, 2018, which VA attended. We noted that the concerns that were raised at the roundtable that related to the proposed rule at RIN 2900–AP46 were similar to those raised during the public comment period for that proposed rule. In the SNPRM, we stated that we addressed these concerns within the SNPRM. 83 FR 61142. In response to the SNPRM, at least one comment noted that we did not address issues raised concerning the proposed rule and medical alert devices and medical identification bracelets that were discussed at the roundtable. We acknowledge and clarify now that we misstated when we explained that we addressed in the SNPRM all the concerns of the roundtable. While we addressed, in the SNPRM, some of the concerns that were raised during the roundtable, we did not address all of the concerns, such as medical alert devices and medical identification bracelets. However, we note that in this final rulemaking, we have addressed the remaining concerns that were raised during the roundtable. We are not making any edits based on this comment.

We lastly note that we make one technical and nonsubstantive revision to § 17.38(b) as proposed, to indicate that the term ''healthcare'' as proposed will be printed as two words to read ''health care'', as is consistent with a majority of VA's other medical regulations. We also make one technical and nonsubstantive revision to § 17.3220(a) as proposed to clarify that veteran eligibility may occur if a veteran is exempt from enrollment under § 17.37(a) through (c), and not under § 17.37 more generally.

Based on the rationale set forth in the proposed rule, the SNPRM, and in this document, VA is adopting the provisions of the proposed rule as a final rule with changes as noted above.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507) requires that VA consider the impact of paperwork and other information collection burdens imposed on the public. Under 44 U.S.C. 3507(a), an agency may not collect or sponsor the collection of information, nor may it impose an information collection requirement unless it displays a currently valid Office of Management and Budget (OMB) control number. See also 5 CFR 1320.8(b)(2)(vi).

This final rule contains no new and/or revised provisions constituting a collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). However, as stated in the proposed rule, we noted that after the final rule is published, VA would request to rescind several VHA handbooks and several VA forms, to include VA Form 10–2520, which is an approved collection under OMB Control Number 2900–0188. We proposed to rescind this form, which is an invoice used by vendors to submit to VA requests for payment for repairs performed pursuant to the prosthetic service cards. Prosthetic service cards have not been widely or consistently used by veterans or vendors, these cards have typically been lost, and third-party vendors still submit separate invoices for reimbursement. We reiterate from earlier in this rule that although we received one comment in opposition to rescinding this form, we will not keep this form because we find that many vendors do not use it as an assurance of pre-approval for emergency repairs. Instead, VA-authorized vendors still contact VA for authorization prior to making repairs and still submit invoices and documentation to VA for reimbursement of repairs, thereby negating the concept that this form functions as an emergency approval for repairs. Therefore, upon publication of this final rule, VA will request to rescind this form through VA's Paperwork Reduction Act Clearance Officer.

Regulatory Flexibility Act

The Secretary hereby certifies that this final rule will 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. There will be no material changes to the types of items and services available to veterans or veteran eligibility for such items and services. Therefore, pursuant to 5 U.S.C. 605(b), the initial and final regulatory flexibility analysis requirements of 5 U.S.C. 603 and 604 do not apply.

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. The Office of Information and Regulatory Affairs has determined that this final rule is not a significant regulatory action under Executive Order 12866.

VA's regulatory impact analysis can be found as a supporting document at *http://www.regulations.gov*, usually within 48 hours after the rulemaking document is published. Additionally, a copy of the rulemaking and its impact analysis are available on VA's website at *http://www.va.gov/orpm* by following the link for VA Regulations Published from FY 2004 through FYTD.

This final rule is not an E.O. 13771 regulatory action because this rule is not significant under E.O. 12866.

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 final rule will 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; 64.029—Purchase Care Program; 64.041—VHA Outpatient Specialty Care.

Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs designated this rule as not a major rule, as defined by 5 U.S.C. 804(2).

List of Subjects in 38 CFR Part 17

Administrative practice and procedure, Alcohol abuse, Alcoholism, Claims, Day care, Dental health, Drug abuse, Government contracts, Grant programs—health, Grant programs—

veterans, Health care, Health facilities, Health professions, Health records, Homeless, Medical and Dental schools, Medical devices, Medical research, Mental health programs, Nursing homes, Reporting and recordkeeping requirements, Travel and transportation expenses, Veterans.

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. Brooks D. Tucker, Assistant Secretary for Congressional and Legislative Affairs, Performing the Delegable Duties of the Chief of Staff, Department of Veterans Affairs, approved this document on October 1, 2020, for publication.

Luvenia Potts,

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

For the reasons stated in the preamble, we amend 38 CFR part 17 as follows:

PART 17—MEDICAL

■ 1. The authority citation for part 17 is amended by adding entries for §§ 17.3200 through 17.3250 in numerical order to read in part as follows:

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

* * * * *

Section 17.3200 also issued under 38 U.S.C. 1162, 1701, 1707, 1710, 1714, 1717, 3901.
Section 17.3210 also issued under 38 U.S.C. 1701, 1710.
Section 17.3220 also issued under 38 U.S.C. 1701(6)(F), 1710.
Section 17.3230 also issued under 38 U.S.C. 1701(6)(F), 1710, 1714(a).
Section 17.3250 also issued under 38 U.S.C. 1701, 1710, 1725, 1728.

* * * * *

■ 2. Amend § 17.38, revise paragraph (a)(1)(viii) and in paragraph (b) introductory text, remove the word ''healthcare'' and add in its place the phrase ''health care'' to read as follows:

§ 17.38 Medical Benefits Package.

(a) * * *

(1) * * *

(viii) Prosthetic and rehabilitative items and services as authorized under §§ 17.3200 through 17.3250, and eyeglasses and hearing aids as authorized under § 17.149.

* * * * *

§ 17.120 [Amended]

■ 3. Amend § 17.120 introductory text by removing ''(except prosthetic appliances, similar devices, and repairs)''.

§ 17.122 [Removed and Reserved]

■ 4. Remove and reserve § 17.122.

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

Sensory and Other Rehabilitative Aids

§§ 17.150 and 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

Sec.

§ 17.3200 Purpose and scope.

(a) *Purpose.* The purpose of this section and §§ 17.3210 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.* This section and §§ 17.3210 through 17.3250 apply only to items and services listed in § 17.3230(a) and authorized to be provided 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 table 1 to this paragraph (b) are authorized in whole or in part by separate statutes and controlled by other implementing regulations:

TABLE 1 TO PARAGRAPH (B)

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 through 17.159
Home improvements and structural alterations	38 U.S.C. 1717(a)(2)	38 CFR 17.3100 through 17.3130

§ 17.3210 Definitions.

For the purposes of §§ 17.3200 through 17.3250:

Activities of daily living (ADL) 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 veterans 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, or household appliances. 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.

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.

§ 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(a) through (c); 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 eligible entity or provider as defined in § 17.4005 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.

§ 17.3230 Authorized items and services.

(a)(1) VA will provide veterans eligible under § 17.3220 with the following items and services if VA determines that such items and services are needed under § 17.38(b), serve as a direct and active component of the veteran's medical treatment and rehabilitation, and do not solely support the comfort or convenience of the veteran:

(i) Adaptive household items.

(ii) Adaptive recreation equipment.

(iii) Cognitive devices.

(iv) Communication devices.

(v) 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.

(vi) 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.

(vii) Home respiratory equipment.

(viii) Implants.

(ix) Mobility aids.

(x) Orthotic devices.

(xi) Prosthetic devices.

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

(xiii) 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.

(xiv) Specialized clothing made necessary by the wearing of a prosthetic device.

(xv) Training with and fitting of prescribed items.

(2) Paragraph (a)(1) of this section supplements the requirement in § 17.38(b) for a determination of need but only with respect to the provision of items and services listed in paragraph (a)(1) of this section. The exclusions under § 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.

(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.

§ 17.3240 Furnishing authorized items and services.

(a)(1) VA providers, or eligible entities and providers as defined in § 17.4005, will prescribe items and services in accordance with § 17.3230(a) and will do so in consultation with the veteran.

(2) Once the item or service is prescribed under paragraph (a)(1) of this section, VA will either fill such prescriptions directly or will pay for such prescriptions to be furnished through a VA-authorized vendor.

(3) The determination under paragraph (a)(2) of this section of whether a prescription will be filled by VA directly or will be furnished by a VA-authorized vendor 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 under §§ 17.120 through 17.132, §§ 17.1000 through 17.1008, or § 17.4020(c), or urgent care under § 17.4600, 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.

§ 17.3250 Veteran responsibilities.

(a) Veterans must use items provided under §§ 17.3230 and 17.3240 as 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 §§ 17.120 through 17.132, §§ 17.1000 through 17.1008, or § 17.4020(c), or urgent care under § 17.4600, 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 not covered as emergency care under §§ 17.120 through 17.132, §§ 17.1000 through 17.1008, or § 17.4020(c), or urgent care under § 17.4600.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[EPA–HQ–OAR–2019–0282; FRL–10014–50–OAR and FRL–10019–02–OAR]

RIN 2060–AM75

Reclassification of Major Sources as Area Sources Under Section 112 of the Clean Air Act; Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; correction.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is correcting a final rule that appeared in the **Federal Register** on November 19, 2020, and will become effective on January 19, 2021. The EPA finalized the amendments to the General Provisions that apply to National Emission Standards for Hazardous Air Pollutants (NESHAP). This action corrects inadvertent typographical errors and redundant text in the **Federal Register**. The corrections described in this action do not affect the substantive requirements of the final rule implementing the plain language reading of the ''major source'' and ''area source'' definitions of section 112 of the Clean Air Act.

DATES: This final rule is effective on January 19, 2021.

FOR FURTHER INFORMATION CONTACT: For questions about this final action, contact Elineth Torres, Sector Policies and Programs Division (D205–02), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–4347; fax number: (919) 541–4991; and email address: *torres.elineth@epa.gov*.

SUPPLEMENTARY INFORMATION: The EPA is making the following corrections to the final rule, Reclassification of Major Sources as Area Sources Under Section 112 of the Clean Air Act (also refered as final Major MACT to Area or MM2A rule) as published in the **Federal Register** on November 19, 2020 (85 FR 73854).

The EPA is correcting inadvertent typographical errors and redundant text included in the regulatory text of six NESHAP subparts amended by the final MM2A rule. As described in the preamble to the final MM2A rule, the EPA finalized amendments to the NESHAP General Provision applicability tables for most of the NESHAP subparts to account for the final amendments to the General Provisions included in the final MM2A rule.

With this action, the EPA is correcting the following errors in FR Document Number (FR Doc) 2020–22044 in the issue of November 19, 2020. These corrections do not change the requirements finalized in the MM2A rule.

- At 85 FR 73894, second column, 40 CFR part 63, subpart EE. The final MM2A rule instruction 37 amended Table 1 to subpart EE by revising the entry for 40 CFR 63.9(b)(2), however, there is no such entry on Table 1 to subpart EE. In this action, instruction 37 is corrected to read ''adding in numerical order entries for §§ 63.1(c)(6) and 63.9(k) . . .'' and amendatory text is corrected by removing the entry for 40 CFR 63.9(b)(2) from Table 1 to Subpart EE of Part 63—Applicability of General Provisions to Subpart EE.
- At 85 FR 73897, third column, 40 CFR part 63, subpart DDD. The final MM2A rule instruction 51 amended Table 1 to subpart DDD to add an entry for 40 CFR 63.1(c)(6), however this addition is unnecessary as Table 1 to subpart DDD has another entry including that provision. In this action, instruction 51 is corrected to read ''. . . by adding in numerical order an entry for § 63.9(k) . . .'' and the amendatory text is corrected by removing the entry for 40 CFR 63.1(c)(6) from Table 1 to Subpart DDD of Part 63—Applicability of General Provisions (40 CFR part 63, subpart A) to Subpart DDD of Part 63.
- At 85 FR 73899, first column, 40 CFR part 63, subpart NNN. The final