

## § 17.110

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§§ 17.108, 17.110, and 17.111 for any veteran of the Persian Gulf War who developed such mental illness other than psychosis:

(1) Within 2 years after discharge or release from the active military, naval, or air service; and

(2) Before the end of the 2-year period beginning on the last day of the Persian Gulf War.

(c) *No minimum service required.* Eligibility for care and waiver of copayments will be established under this section without regard to the veteran's length of active-duty service.

(Authority: 38 U.S.C. 501, 1702, 5303A)

[78 FR 28143, May 14, 2013]

### § 17.110 Copayments for medication.

(a) *General.* This section sets forth requirements regarding copayments for medications provided to veterans by VA. For purposes of this section, the term “medication” means prescription and over-the-counter medications, as determined by the Food and Drug Administration (FDA), but does not mean medical supplies, oral nutritional supplements, or medical devices. Oral nutritional supplements are commercially prepared nutritionally enhanced products used to supplement the intake of individuals who cannot meet nutrient needs by diet alone.

(b) *Copayments.* (1) *Copayment amount.* Unless exempted under paragraph (c) of this section, a veteran is obligated to pay VA a copayment for each 30-day or less supply of medication provided by VA on an outpatient basis (other than medication administered during treatment).

(i) For each 30-day or less supply of Tier 1 medications, the copayment amount is \$5.

(ii) For each 30-day or less supply of Tier 2 medications, the copayment amount is \$8.

(iii) For each 30-day or less supply of Tier 3 medications, the copayment amount is \$11.

(iv) For purposes of this section:

(A) *Multi-source medication* is any one of the following:

(1) A medication that has been and remains approved by the FDA—

(i) Under sections 505(b)(2) or 505(j) of the Food, Drug, and Cosmetic Act

(FDCA, 21 U.S.C. 355), and that has been granted an A-rating in the current version of the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the Orange Book); or

(ii) Under section 351(k) of the Public Health Service Act (PHSA, 42 U.S.C. 262), and that has been granted an I or B rating in the current version of the FDA's Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations (the Purple Book). FDA determines both therapeutic equivalence for drugs and interchangeability for biological products.

(2) A medication that—

(i) Has been and remains approved by the FDA pursuant to FDCA section 505(b)(1) or PHSA section 351(a);

(ii) Which is referenced by at least one FDA-approved product that meets the criteria of paragraph (b)(1)(iv)(A)(1) of this section; and

(iii) Which is covered by a contracting strategy in place with pricing such that it is lower in cost than other generic sources.

(3) A medication that—

(i) Has been and remains approved by the FDA pursuant to FDCA section 505(b)(1) or PHSA section 351(a); and

(ii) Has the same active ingredient or active ingredients, works in the same way and in a comparable amount of time, and is determined by VA to be substitutable for another medication that has been and remains approved by the FDA pursuant to FDCA section 505(b)(1) or PHSA section 351(a). This may include but is not limited to insulin and levothyroxine.

(4) A listed drug, as defined in 21 CFR 314.3, that has been approved under FDCA section 505(c) and is marketed, sold, or distributed directly or indirectly to retail class of trade with either labeling, packaging (other than repackaging as the listed drug in blister packs, unit doses, or similar packaging for use in institutions), product code, labeler code, trade name, or trademark that differs from that of the listed drug.

(B) *Tier 1 medication* means a multi-source medication that has been identified using the process described in paragraph (b)(2) of this section.

(C) *Tier 2 medication* means a multi-source medication that is not identified using the process described in paragraph (b)(2) of this section.

(D) *Tier 3 medication* means a medication approved by the FDA under a New Drug Application (NDA) or a biological product approved by the FDA pursuant to a biologics license agreement (BLA) that retains its patent protection and exclusivity and is not a multi-source medication identified in paragraph (b)(1)(iv)(A)(3) or (4) of this section.

(2) *Determining Tier 1 medications.* Not less than once per year, VA will identify a subset of multi-source medications as Tier 1 medications using the criteria below. Only medications that meet all of the criteria in paragraphs (b)(2)(i), (ii), and (iii) will be eligible to be considered Tier 1 medications, and only those medications that meet all of the criteria in paragraph (b)(2)(i) of this section will be assessed using the criteria in paragraphs (b)(2)(ii) and (iii).

(i) A medication must meet all of the following criteria:

(A) The VA acquisition cost for the medication is less than or equal to \$10 for a 30-day supply of medication;

(B) The medication is not a topical cream, a product used to treat musculoskeletal conditions, an antihistamine, or a steroid-containing medication;

(C) The medication is available on the VA National Formulary;

(D) The medication is not an antibiotic that is primarily used for short periods of time to treat infections; and

(E) The medication primarily is used to either treat or manage a chronic condition, or to reduce the risk of adverse health outcomes secondary to the chronic condition, for example, medications used to treat high blood pressure to reduce the risks of heart attack, stroke, and kidney failure. For purposes of this section, conditions that typically are known to persist for 3 months or more will be considered chronic.

(ii) The medication must be among the top 75 most commonly prescribed multi-source medications that meet the criteria in paragraph (b)(2)(i) of this section, based on the number of prescriptions issued for a 30-day or less

supply on an outpatient basis during a fixed period of time.

(iii) VA must determine that the medication identified provides maximum clinical value consistent with budgetary resources.

(3) *Information on Tier 1 medications.* Not less than once per year, VA will publish a list of Tier 1 medications in the FEDERAL REGISTER and on VA's Web site at [www.va.gov/health](http://www.va.gov/health).

(4) *Veterans Choice Program.* For medications furnished through the Veterans Choice Program under §§17.1500 through 17.1540, or the Veterans Community Care Program under §§17.4000 through 17.4040, the copayment amount at the time the veteran fills the prescription is \$0. VA will determine and assess the veteran's copayment amount at the end of the billing process, but at no time will a veteran's copayment be more than the amount identified in paragraphs (b)(1)(i) through (iii) of this section.

(5) *Copayment cap.* The total amount of copayments for medications in a calendar year for an enrolled veteran will not exceed \$700.

(c) *Medication not subject to the copayment requirements.* The following are exempt from the copayment requirements of this section:

(1) Medication for a veteran who has a service-connected disability rated 50% or more based on a service-connected disability or unemployability.

(2) Medication for a veteran's service-connected disability.

(3) Medication for a veteran whose annual income (as determined under 38 U.S.C. 1503) does not exceed the maximum annual rate of VA pension which would be payable to such veteran if such veteran were eligible for pension under 38 U.S.C. 1521.

(4) Medication authorized under 38 U.S.C. 1710(e) for Vietnam-era herbicide-exposed veterans, radiation-exposed veterans, Persian Gulf War veterans, post-Persian Gulf War combat-exposed veterans, or Camp Lejeune veterans pursuant to §17.400.

(5) Medication for treatment of sexual trauma as authorized under 38 U.S.C. 1720D.

(6) Medication for treatment of cancer of the head or neck authorized under 38 U.S.C. 1720E.

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(7) Medications provided as part of a VA approved research project authorized by 38 U.S.C. 7303.

(8) Medication for a veteran who is a former prisoner of war.

(9) A veteran who VA determines to be catastrophically disabled, as defined in 38 CFR 17.36(e).

(10) A veteran receiving care for psychosis or a mental illness other than psychosis pursuant to §17.109.

(11) Medication for a veteran who was awarded the Medal of Honor.

(12) Opioid antagonists furnished to a veteran who is at high risk for overdose of a specific medication or substance in order to reverse the effect of such an overdose.

(i) For purposes of this paragraph (c)(12), a veteran who is at high risk for overdose of a specific medication or substance in order to reverse the effect of such an overdose is a veteran:

(A) Who is prescribed or using opioids, or has an opioid use history, and who is at increased risk for opioid overdose as determined by VA; or

(B) Whose provider deems, based on their clinical judgment, that the veteran may benefit from ready availability of an opioid antagonist.

(ii) Examples of a veteran who is at high risk for overdose of a specific medication or substance in order to reverse the effect of such an overdose include, but are not limited to, the following:

(A) A veteran with an opioid or substance use disorder diagnosis;

(B) A veteran receiving treatment for an opioid or substance use disorder diagnosis, such as receiving opioid agonist therapy or inpatient, residential, or outpatient treatment for such diagnosis, or attending a support group for such diagnosis;

(C) A veteran with a history of prescription opioid misuse or injection opioid use;

(D) A veteran with a history of previous opioid overdose;

(E) A veteran who is taking an extended-release or long-acting prescription opioid;

(F) A veteran with household or community access to opioids who is at increased risk for overdose (*e.g.*, psychiatric disorder or high risk for suicide) as determined by VA; or

(G) A veteran predicted to be at high risk for overdose based on standardized assessments or predictive models (*e.g.*, Risk Index for Overdose or Serious Opioid-induced Respiratory Depression [RIOSORD]; Stratification Tool for Opioid Risk Mitigation [STORM]).

NOTE 1 TO PARAGRAPH (C)(12). The examples in paragraphs (c)(12)(ii)(A) through (G) of this section apply even if the veteran has had a period of abstinence from opioids (*e.g.*, due to treatment, detoxification, incarceration) because loss of tolerance can increase the risk for an overdose.

(13) Medication for an individual as part of emergent suicide care as authorized under 38 CFR 17.1200–17.1230.

(14) A veteran who meets the definition of Indian or urban Indian, as defined in 25 U.S.C. 1603(13) and (28), for medications provided on or after January 5, 2022. To demonstrate that they meet the definition of Indian or urban Indian, the veteran must submit to VA any of the documentation described in paragraphs (c)(14)(i) through (vi) of this section:

(i) Documentation issued by a federally recognized Indian Tribe that shows that the veteran is a member of the Tribe;

(ii) Documentation showing that the veteran, irrespective of whether they live on or near a reservation, is a member of a Tribe, band, or other organized group of Indians, including those tribes, bands, or groups terminated since 1940 and those recognized now or in the future by the State in which they reside, or who is a descendant, in the first or second degree, of any such member;

(iii) Documentation showing that the veteran is an Eskimo or Aleut or other Alaska Native;

(iv) Documentation issued by the Department of Interior (DOI) showing that the veteran is considered by DOI to be an Indian for any purpose;

(v) Documentation showing that the veteran is considered by the Department of Health and Human Services (HHS) to be an Indian under that Department's regulations; or

(vi) Documentation showing that the veteran resides in an urban center and meets one or more of the following criteria:

(A) Irrespective of whether they live on or near a reservation, is a member

of a Tribe, band, or other organized group of Indians, including those tribes, bands, or groups terminated since 1940 and those recognized now or in the future by the State in which they reside, or who is a descendant, in the first or second degree, of any such member;

(B) Is an Eskimo or Aleut or other Alaska Native;

(C) Is considered by DOI to be an Indian for any purpose; or

(D) Is considered by HHS to be an Indian under that Department's regulations.

(d) *Retroactive copayment reimbursement.* After VA determines the submitted documentation meets paragraph (c)(14) of this section and updates the veteran's record to reflect the veteran's status as an Indian or urban Indian, VA will reimburse veterans exempt under paragraph (c)(14) for any copayments that were paid to VA for medications provided on or after January 5, 2022, if they would have been exempt from making such copayments if paragraph (c)(14) had been in effect.

(The Office of Management and Budget has approved the information collection provisions in this section under control number 2900-0920)

[66 FR 63451, Dec. 6, 2001, as amended at 74 FR 69285, Dec. 31, 2009; 75 FR 32672, June 9, 2010; 75 FR 54030, Sept. 3, 2010; 76 FR 52274, Aug. 22, 2011; 76 FR 78826, Dec. 20, 2011; 77 FR 76867, Dec. 31, 2012; 78 FR 28143, May 14, 2013; 78 FR 79317, Dec. 30, 2013; 79 FR 57414, Sept. 24, 2014; 79 FR 63821, Oct. 27, 2014; 79 FR 65585, Nov. 5, 2014; 80 FR 55545, Sept. 16, 2015; 81 FR 88120, Dec. 7, 2016; 81 FR 89390, Dec. 12, 2016; 84 FR 7815, Mar. 5, 2019; 84 FR 26306, June 5, 2019; 86 FR 52076, Sept. 20, 2021; 88 FR 2536, Jan. 17, 2023; 88 FR 19872, Apr. 4, 2023; 88 FR 21478, Apr. 11, 2023]

#### § 17.111 Copayments for extended care services.

(a) *General.* This section sets forth requirements regarding copayments for extended care services provided to veterans by VA (either directly by VA or paid for by VA).

(b) *Copayments.* (1) Unless exempted under paragraph (f) of this section, as a condition of receiving extended care services from VA, a veteran must agree to pay VA and is obligated to pay VA a copayment as specified by this section. A veteran has no obligation to

pay a copayment for the first 21 days of extended care services that VA provided the veteran in any 12-month period (the 12-month period begins on the date that VA first provided extended care services to the veteran). However, for each day that extended care services are provided beyond the first 21 days, a veteran is obligated to pay VA the copayment amount set forth below to the extent the veteran has available resources. Available resources are based on monthly calculations, as determined under paragraph (d) of this section. The following sets forth the extended care services provided by VA and the corresponding copayment amount per day:

- (i) Adult day health care—\$15.
- (ii) Domiciliary care—\$5.
- (iii) Institutional respite care—\$97.
- (iv) Institutional geriatric evaluation—\$97.
- (v) Non-institutional geriatric evaluation—\$15.
- (vi) Non-institutional respite care—\$15.
- (vii) Nursing home care—\$97.

(2) For purposes of counting the number of days for which a veteran is obligated to make a copayment under this section, VA will count each day that adult day health care, non-institutional geriatric evaluation, and non-institutional respite care are provided and will count each full day and partial day for each inpatient stay except for the day of discharge.

(3) For hospital care and medical services considered non-institutional care furnished through the Veterans Choice Program under §§17.1500 through 17.1540, as well as extended care services furnished through the Veterans Community Care Program under §§17.4000 through 17.4040, the copayment amount at the time of furnishing such care or services by a non-VA entity or provider is \$0. VA will determine and assess the veteran's copayment amount at the end of the billing process, but at no time will a veteran's copayment be more than the amount identified in paragraph (b)(1) or (2) of this section.

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

- (1) *Adult day health care* is a therapeutic outpatient care program that