DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 17

RIN 2900–AQ30

Modifying Copayments for Veterans at High Risk for Suicide

AGENCY: Department of Veterans Affairs.

ACTION: Proposed rule.

SUMMARY: The Department of Veterans Affairs (VA) proposes to amend its medical regulations that govern copayments for VA outpatient medical care and medications (to include outpatient medical care and medications provided by VA directly or community care obtained by VA through contracts, provider agreements or sharing agreements) by effectively eliminating the copayment for outpatient care and reducing the copayment for medications dispensed to veterans identified by VA as being at high risk for suicide. These copayment changes would be applied until VA determines that the veteran is no longer at high risk for suicide.

DATES: Comments must be received by VA on or before March 7, 2022.

ADDRESSES: Comments may be submitted through *www.Regulations.gov.* Comments received will be available at *regulations.gov* for public viewing, inspection or copies.

FOR FURTHER INFORMATION CONTACT: David Carroll, Ph.D., Executive Director, Office of Mental Health and Suicide Prevention (11MHSP), Department of Veterans Affairs, Veterans Health Administration, 810 Vermont Ave. NW, Washington, DC 20420; (202) 461–4058. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION:

I. Background

Under 38 U.S.C. 1710(g), VA is required to set the copayment amount for outpatient medical care provided to veterans who are eligible for such care by reason of 38 U.S.C. 1710(a)(3). In general, this applies to veterans enrolled in priority groups 7 and 8, which includes veterans with no compensable service-connected disability and veterans who have an annual income exceeding the applicable threshold. 38 CFR 17.36. VA regulates the copayment amount for outpatient medical care in 38 CFR 17.108(c). Under existing regulations, VA charges certain veterans $15.00 for each primary care outpatient visit and $50.00 for each specialty care outpatient visit. 38 CFR 17.108(c)(2). Across the broad continuum of mental health services, mental health care may be classified for billing purposes as primary care, such as an outpatient general mental health appointment, or as specialty care, such as a neuropsychological assessment.

Section 1722A(a)(1) of title 38 of the U.S. Code states that the Secretary shall require a veteran to pay the United States $2 for each 30-day supply of medication furnished to such veteran under this chapter on an outpatient basis for the treatment of a non-service-connected disability or condition. In general, this applies to veterans enrolled in priority groups 2 through 8 (38 CFR 17.36) and excludes veterans with a service-connected disability rated 50 percent or more, veterans who are former prisoners of war, veterans whose annual income does not exceed the applicable threshold, and veterans awarded the medal of honor. VA regulates the copayment amount for medications in 38 CFR 17.110(c). Section 1722A(a)(1) also states that if the amount supplied is less than a 30-day supply, VA may not reduce the copayment amount. While VA is not permitted to require a veteran to pay an amount in excess of the cost to VA, 38 U.S.C. 1722A(b) authorizes the Secretary to increase the copayment amount in effect under subsection (a) to cover the agency's costs for medications by regulation. However, the Secretary is not authorized to reduce the medication copayment below $2 for each 30-day supply.

VA regulations set forth the categories of veterans who are exempt from copayment requirements as required by law for inpatient and outpatient medical care (38 CFR 17.108(d)–(f)), as well as medication (38 CFR 17.110(c)).

II. Need for the Proposed Rule

VA has identified suicide prevention as a top clinical priority. Implementation of evidence-based clinical practice guidelines is one strategy VA has embraced to improve mental health care and access to suicide prevention resources available to veterans by reducing variation in practice and systematizing best practices. Jointly issued by VA and the Department of Defense (DoD), the VA/DoD Clinical Practice Guideline for the Assessment and Management of Patients at Risk for Suicide (2019) (CPG) recommends health care professionals increase the frequency of outpatient mental health encounters to provide more intense care and preventive services for veterans who are determined to be at high risk for suicide, as these evidence-based enhancements have shown to reduce the risk of suicide. *See, e.g.,* CPG pp. 23–25. *https://www.healthquality.va.gov/guidelines/MH/srb/VADoDSuicideRiskFullCPGFinal5088212019.pdf.*

However, VA understands that the increase in outpatient visits may be a financial burden and a detriment to certain veterans who must pay a copayment, as an increase in outpatient visits results in increased numbers of copayments. Healthcare research has provided extensive evidence that copayments can be barriers to healthcare for vulnerable patients. For example, as summarized in the CPG, scientific and clinical literature supports the principle that copayment rates can be barriers to medication adherence and access to clinical services. *See, e.g.,* (No author listed). Impact of Copays in Vulnerable Populations, American Journal of Managed Care, Vol. 12 No. 13 Nov. 2006, S359–363; and, Simon GE, VonKorff M, Durham ML. Predictors of outpatient mental health utilization by primary care patients in a health maintenance organization, American Journal of Psychiatry, Vol. 151 No. 6 Jun. 1994, 908–913. Currently, there is no exemption from outpatient care copayments for veterans who are at risk for suicide, and such veterans have to pay a $15.00 or $50.00 copayment for each outpatient visit (depending on whether the visit qualifies as primary care or specialty care).

In addition, VA internal reporting documents, such as issue briefs, have revealed that there are substantial numbers of suicides and suicide attempts among veterans that result from overdoses of medications that are prescribed by VA providers on an outpatient basis. The CPG includes a strong recommendation to prescribe medication in less than 30-day supplies for veterans at high risk of suicide in order to prevent fatal or medically serious overdoses. *See* CPG p. 24. The clinical necessity to prescribe medication in less than 30-day supplies for veterans who are at high risk for suicide would likely arise, for medications that are potentially dangerous or lethal in the event of overdose, either by themselves or in combination with other medications being used by a veteran. VA understands that providing less than a 30-day supply would necessarily require more prescriptions, which may cause an economic burden to veterans who must pay a copayment for each prescription. In order to address both the necessity of prescribing medication in less than 30-day supplies for veterans at high risk of suicide and the consequent financial burden of issuing

multiple prescriptions, each with fewer doses, for the same 30-day period, VA believes that current 38 CFR 17.110 should be amended to allow for lesser copayment amounts for medications prescribed for a veteran at high risk of suicide.

III. Provisions of the Proposed Rule

VA seeks to revise two sections of our medical regulations, § 17.108 regarding copayments for inpatient hospital care and outpatient medical care and § 17.110 regarding copayments for medication to modify copayments for veterans who are determined by VA to be at high risk of suicide. As §§ 17.108 and 17.110 apply to care and medication obtained by VA through contracts, providers agreements, and sharing agreements, not just care and medication provided directly by VA, the proposed revisions below would apply to outpatient care and medication provided directly by VA as well as outpatient care and medication provided by community providers. The determination of whether a veteran is at high risk of suicide is a clinical decision made by VA clinicians that is based upon the following essential features: (1) A recent suicide attempt or preparatory behaviors, (2) suicidal ideation with intent to die resulting in inpatient hospitalization, or (3) active threats to harm oneself, seeking access to means, or talking or writing about death, dying, or suicide when the actions are out of character for the person.

In general, electronic flags and triggers are used in the electronic health record to alert a provider to a variety of clinical needs and prevention opportunities. VA restricts the use of the alert to address immediate clinical safety issues. VA has implemented such tools in several areas, including alerting VA providers through patient record flags to a veteran's suicide risk. For purposes of readability, we will use the term ''alert'' in this document rather than referring to an electronic flag or trigger. The CPG at Sidebar 2a. Essential Features from Risk Stratification Table—Acute Risk (p. 23) lists essential features for a high acute risk of suicide as: Suicidal ideation with intent to die by suicide; and an inability to maintain safety, independent of external support/help. The CPG lists common warning signs such as: A plan for suicide; recent attempt and/or ongoing preparatory Behaviors; acute major mental illness (*e.g.,* major depressive episode, acute mania, acute psychosis, recent/current drug relapse); and, exacerbation of a personality disorder (*e.g.,* increased borderline symptomatology). In addition, various psychosocial factors are associated with risk for suicide and suicide attempts. These include recent life events such as losses (especially employment, careers, finances, housing, marital relationships, physical health, and a sense of a future), and chronic or long-term problems such as relationship difficulties, unemployment, and ongoing or pending legal issues.

In addition, there are warning signs that empirically have been shown to be temporally related to the acute onset of suicidal behaviors (*e.g.,* within hours to a few days). These signs should warn the clinician of acute risk for the expression of suicidal behaviors, especially in those individuals with other risk factors. *See, e.g.,* Rudd MD, Berman AL, Joiner TE, et al. Warning signs for suicide: Theory, research and clinical applications. Suicide and Life Threatening Behavior; Volume 36 Issue 3, 255–62 (2006). Three of these warning signs carry the highest likelihood of short-term onset of suicidal behaviors and require immediate attention, evaluation, referral, or consideration of hospitalization. These warning signs are: (1) Threatening to hurt or kill self; (2) looking for ways to kill self; seeking access to pills, weapons or other means; and, (3) talking or writing about death, dying or suicide. See VA Suicide Risk Assessment Guide. *https://www.mentalhealth.va.gov/docs/suicide_risk_assessment_reference_guide.pdf.*

Once a veteran is determined to be at high risk for suicide by a VA clinician, VA suicide prevention staff, as a matter of VA policy, places an alert in the veteran's electronic health record indicating that the veteran is at high risk for suicide. VA suicide prevention staff then conducts a periodic review in all cases where a high-risk of suicide alert has been added to the electronic health record to determine whether the alert will remain active or be discontinued.

We note that community care providers do not have direct access to the veteran's electronic health record, which is maintained by VA, and therefore cannot add an alert into that record. VA intends to engage community care providers and urge them to communicate to VA any finding that a veteran patient is believed to be at high risk of suicide so that VA can determine if a veteran is at high risk of suicide, as appropriate.

A. § 17.108 Copayments for Inpatient Hospital Care and Outpatient Medical Care

Section 17.108 establishes the copayment amounts for inpatient hospital care and outpatient medical care. Paragraph (c) of that section lists the copayments for outpatient care. We propose to add a new paragraph (c)(5), which would reduce to zero the outpatient copayment amount for veterans that VA determines to be at high risk for suicide.

We propose that this copayment level would align with the use of the high risk of suicide alert in the veteran's electronic health record. Therefore, it would begin once the veteran is determined to be at high risk for suicide by a VA clinician and an alert is placed in the veteran's electronic health record. This copayment level would remain in place until the veteran is no longer at high risk for suicide. VA would no longer consider a veteran to be at high risk for suicide when an alert in the veteran's electronic health record indicating that the veteran is at high risk for suicide has been inactivated or removed by VA suicide prevention staff.

VA has interpreted 38 U.S.C. 1710(g)(1) to mean that VA has the discretion to establish the applicable outpatient visit copayment amount by regulation, even if such amount is zero. 77 FR 13195, 13196. Therefore, if finalized as proposed, VA would effectively eliminate the outpatient visit copayment for veterans when veterans are at high risk for suicide by establishing the outpatient visit copayment amount as zero. This copayment level would begin once the veteran is determined to be at high risk for suicide and would remain in place until the veteran is no longer at high risk for suicide. By proposing elimination of copayments for all outpatient care it is VA's intent to remove any financial deterrents or barriers that a veteran may have against agreeing to an increase in the frequency of outpatient care when they are at high risk of suicide. VA believes this proposed change will assist VA in preventing suicide among veterans who are at high risk for suicide by providing a CPG-informed intervention without introducing new barriers to care, such as financial burdens. See, *e.g.,* National Academy of Science, Institute of Medicine. Reducing Suicide: A National Imperative (2002).

The proposed copayment reduction would be for all outpatient care, and not just limited to mental health care, for these veterans who are at high risk of suicide. VA believes that active and increased engagement in all medical care, not just mental health care, is a protective factor against suicide. See Department of Veterans Affairs, Veterans Health Administration. National Veteran Suicide Prevention Annual Report (2002); National

Academy of Science, Institute of Medicine. Reducing Suicide: A National Imperative (2002). Mental health care is integrated into health care provided across the full range of VA medical services, and mental health care cannot reasonably and accurately be parsed out by provider type (*e.g.,* some oncologists, who ordinarily screen for and treat cancer, also screen for depression and suicide risk) or setting type (*e.g.,* some patients receive the bulk of their mental health care, including risk assessments and medication adjustments, in primary care settings). VA believes that eliminating copayments for all outpatient care supports provision of ongoing mental health screenings in clinical settings by various VA health care professionals.

In addition, we propose revising paragraph (c)(1) by adding a reference to new proposed paragraph (c)(5). Current paragraph (c)(1) states that ''[e]xcept as provided in paragraphs (d), (e), or (f) of this section, a veteran, as a condition for receiving outpatient medical care provided by VA (provided either directly by VA or obtained by VA by contract, provider agreement, or sharing agreement), must agree to pay VA (and is obligated to pay VA) a copayment as set forth in paragraph (c)(2) or (c)(4) of this section.'' We would revise this paragraph to instead refer to ''a copayment as set forth in paragraph (c)(2), (c)(4) or (c)(5) of this section.''

B. § 17.110 Copayments for Medication

Section 17.110 establishes the copayment amounts for medications. Under this proposed rule, a veteran would pay the copayment amount of only $2 for a 30-day or less supply of medication while such veteran is determined to be at high risk for suicide. We propose to add a new paragraph (b)(6) to Section 17.110 to state that veterans who VA determines to be at high risk for suicide will pay a $2 medication copayment for all medications for each 30-day or less supply of a medication. We also propose that the initiation and duration of this medication copayment level would be the same as that established for outpatient copayments in proposed § 17.108(c)(5). In other words, this copayment level would begin when the veteran is determined to be at high risk for suicide and would remain in place until the veteran is no longer considered to be at high risk for suicide. Also, VA would no longer consider a veteran to be at high risk for suicide when the alert in the veteran's electronic health record indicating that the veteran is at high risk for suicide is inactivated or removed.

VA has three classes of medications, identified as Tier 1, Tier 2, and Tier 3. Copayment amounts are fixed and vary depending upon the class of medication as follows: $5 for a 30-day or less supply of a Tier 1 medication, $8 for a 30-day or less supply of a Tier 2 medication, and $11 for a 30-day or less supply of a Tier 3 medication. Currently, there is no exemption from medication copayments for veterans who are at high risk for suicide, and such veterans would have to pay a much higher amount in copayments if they are being prescribed medication more frequently but with less supply (*e.g.,* in increments of two weeks or less) and still paying a full copayment for each prescription filled. However, VA has consistently interpreted 38 U.S.C. 1722A(a) to mean that VA has discretion to determine the appropriate copayment amount for medication furnished on an outpatient basis, as long as that amount is at least $2. *See, e.g.,* 74 FR 69283 (December 31, 2009); 75 FR 32668 (June 9, 2010); 81 FR 88117 (December 7, 2016).

Under this proposed regulation, if VA were to prescribe a veteran medication on, for example, a weekly basis, the veteran would pay a $2 copayment every week and would ultimately pay a total of $8 in copayments for a month's supply of medication regardless of tier. By contrast, under the current regulations and in the same scenario, for a Tier 1 medication (pursuant to 38 CFR 17.110(b)(1)), the veteran would pay $5 in copayment every week and would ultimately pay a total of $20 in copayments for a month's supply of medication, or $44 for a Tier 3 medication.

Under the proposed rule, VA would adjust the copayment for medications once the veteran is determined to be at high risk for suicide and would remain in place until the veteran is no longer at high risk for suicide. The copayment reduction would be for all medications, regardless of tier, for these veterans who are at high risk of suicide. This is because many medications, psychiatric or non-psychiatric, may be non-lethal when taken alone, but lethal when combined with other medication in an overdose. Also, it would be impractical for VA to identify every potentially dangerous medication combination for purposes of this copayment reduction.

VA believes that establishing a flat $2 medication copayment, regardless of tier, for veterans determined to be at high risk for suicide serves several purposes. Applying a flat copayment amount to all prescribed medications means that there is no financial disincentive to the veteran continuing with medications that are prescribed to treat medical conditions other than for mental health, such as ongoing chronic medical conditions. In addition, veterans sometimes request that a clinician prescribe a Tier 1 or 2 medication to treat a diagnosed condition rather than a Tier 3 medication recommended by the clinician in order to decrease medication copayments. Adopting a flat medication copayment regime ensures that therapeutic options are not limited by concerns for medication copayment amounts for these veterans determined to be at high risk of suicide. Finally, as noted, a flat medication copayment of $2 helps ensure that veterans determined to be at high risk for suicide are not financially penalized because medications are prescribed in less than 30-day increments.

Therefore, if finalized as proposed, VA would reduce the copayment amount for medications for veterans at a high risk for suicide as a way to remove any deterrents or barriers that a veteran may have to agreeing to an increased number of prescriptions when providers find it clinically necessary to reduce the amount of certain medications prescribed at one time (*i.e.,* from a 30-day supply to a less than 30-day supply). This will better enable VA to reduce lethality of medications at hand and reduce the risk of medication-related suicide attempts among veterans who are at high risk for suicide.

Paperwork Reduction Act

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

Regulatory Flexibility Act

The Secretary hereby certifies that this proposed rule would not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act (5 U.S.C. 601–612). This proposed rule would only affect individual veterans who receive VA health care. The proposed rule focuses on the copayment amount that must be paid by a veteran who has been determined to be at high risk of suicide. It does not impact payments made to non-VA entities or health care providers, and does not create any administrative or transition burdens for third parties that might qualify as a small entity under the Regulatory Flexibility Act. Billing for copayment amounts is administered solely by VA. 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 and 13563

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. The Office of Information and Regulatory Affairs has determined that this rule is a significant regulatory action under Executive Order 12866. The Regulatory Impact Analysis associated with this rulemaking can be found as a supporting document at *www.regulations.gov.*

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any one year. This proposed rule would have no such effect on State, local, and tribal governments, or on the private sector.

Assistance Listing

The Assistance Listing program numbers and titles for this proposed rule are as follows: 64.009, Veterans Medical Care Benefits; 64.012, Veterans Prescription Service; 64.019, Veterans Rehabilitation Alcohol and Drug Dependence; 64.041, VHA Outpatient Specialty Care; 64.045, VHA Outpatient Ancillary Services; 64.047, VHA Primary Care; 64.048, VHA Mental Health Clinics.

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

Denis McDonough, Secretary of Veterans Affairs, approved this document on June 8, 2021, 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.

Consuela Benjamin,

Regulation Development Coordinator, Office of Regulation Policy & Management, Office of General Counsel, Department of Veterans Affairs.

For the reasons stated in the preamble, the Department of Veterans Affairs proposes to amend 38 CFR part 17 as set forth below:

PART 17—MEDICAL

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

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

* * * * *

■ 2. Amend § 17.108 by revising paragraph (c)(1) and adding paragraph (c)(5) to read as follows:

§ 17.108 Copayments for inpatient hospital care and outpatient medical care.

* * * * *

(c)(1) Except as provided in paragraphs (d), (e), or (f) of this section, a veteran, as a condition for receiving outpatient medical care provided by VA (provided either directly by VA or obtained by VA by contract, provider agreement, or sharing agreement), must agree to pay VA (and is obligated to pay VA) a copayment as set forth in paragraph (c)(2), (c)(4) or (c)(5) of this section.

* * * * *

(5) The copayment for outpatient medical care furnished to a veteran who VA determines to be at high risk for suicide is zero dollars ($0). This copayment level will begin once the veteran is determined to be at high risk for suicide and will remain in place until the veteran is no longer at high risk for suicide.

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■ 3. Amend § 17.110 by adding paragraph (b)(6) to read as follows:

§ 17.110 Copayments for medication.

* * * * *

(b) * * *

(6) *Veterans at high risk for suicide.* Veterans who VA determines to be at high risk for suicide will be charged a $2 medication copayment amount for all medications for each 30-day or shorter supply of a medication. The initiation and duration of this medication copayment level are the same as those established for outpatient copayments in § 17.108(c)(5).

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[EPA–HQ–OAR–2005–0155; FRL–8391–03–OAR]

RIN 2060–AV44

National Perchloroethylene Air Emission Standards for Dry Cleaning Facilities Technology Review; Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; correction.

SUMMARY: On December 27, 2021, the U.S. Environmental Protection Agency (EPA) proposed amendments to the National Emission Standards for Hazardous Air Pollutants (NESHAP) for dry cleaning facilities using perchloroethylene (PCE) as the cleaning solvent (PCE Dry Cleaning NESHAP). The proposed amendments addressed the results of the technology review for the PCE Dry Cleaning NESHAP, in accordance with section 112 of the Clean Air Act (CAA). This action is being issued to correct a typographical error which stated that we would hold a virtual public hearing if anyone contacted us requesting a public hearing on or before January 11, 2022 (*i.e.,* 15 days after publication of the proposed rule). However, that same notice also said that if requested, the virtual hearing would be held on January 11, 2022. Logistically, we cannot have the same date for both actions because we need to know several days ahead of time whether stakeholders request a hearing so that we have sufficient time to plan accordingly and make all the necessary arrangements. For most proposed rules, the EPA states that if anyone contacts us requesting a public hearing on or before a date five days after publication of the proposed rule, that the EPA will hold such public hearing on a date 15 days after publication of such rule. To correct this error, in this correction notice, EPA states that if anyone contacts us requesting a public hearing on or before January 10, 2022 the virtual hearing will be held on January 20, 2022. As