DEPARTMI **8320-01**

38 CFR Part 17

RIN 2900-AQ31

Elimination of Copayment for Opioid Antagonists and Education on Use of Opioid Antagonists

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: The Department of Veterans Affairs (VA) is amending its medical regulations that govern copayments to conform with recent statutory requirements. VA is eliminating the copayment requirement for opioid antagonists furnished to veterans who are at high risk of overdose of a specific medication or substance in order to reverse the effect of such an overdose. VA is also clarifying that no copayment is required for the provision of education on the use of opioid antagonists. This final rule is an essential part of VA's attempts to help veterans at high risk of overdose.

DATES: This rule is effective [insert date 30 days after date of publication in the FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Joseph Duran, Director of Policy and Planning. 3773 Cherry Creek North Drive, Denver, CO 80209. (303) 370–1637. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: On November 6, 2020, VA published a proposed rule in the Federal Register (85 FR 71020) that would eliminate the copayment requirement for opioid antagonists furnished to veterans who are at high risk of overdose of a specific medication or substance in order to reverse the effect of such an overdose and for the provision of education on the use of opioid antagonists. VA

provided a 60-day comment period, which ended on January 5, 2021. VA received 19 comments on the proposed rule.

In an effort to reduce the incidence of overdose among the veteran population, Congress, in two separate statutes, has required that VA must exempt from copayment (1) opioid antagonists furnished under chapter 17 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, and (2) education on the use of opioid antagonists to reverse the effects of overdoses of specific medications or substances. See Public Law 114–198, sec. 915 (July 22, 2016) and Public Law 114–223, Division A, sec. 243 (Sept. 29, 2016). These provisions were effective upon enactment and have already been implemented. These provisions assist veterans by eliminating copayments for life-saving medication and education on the use of such medication, with the goal of reducing the incidence of overdose deaths among the veteran population. This final rule amends two of VA's copayment regulations, 38 Code of Federal Regulations (CFR) 17.108 and 17.110, to accurately implement these changes in law. This final rule also adds an explanation of how VA would identify a veteran at high risk for overdose under the new provisions.

Positive Comments

Most commenters were in support of the proposed rule. One commenter stated that the rule would be a crucial part of VA's efforts to help veterans at an extreme risk of overdose. Another commenter stated that the rule is critical in creating cross-governmental cohesion in the fight against the opioid crisis in our veteran population, and it solidifies the message of a united front against the opioid crisis in our veteran community. The commenter suggested that adding a clear definition of who VA considers high risk is also an essential step in ensuring that any veteran needing these measures will have the availability of lifesaving opioid antagonists afforded to them. A commenter stated that the opioid crisis in the United State is getting worse every day

and it is VA's duty to eliminate copays for opioid antagonists and education on use of opioid antagonists. Another commenter stated that high-risk veterans should have adequate access to opioid antagonists and that veterans should also have access to counseling and educational information on the subject of opioid addiction.

A commenter stated that eliminating the copayment for opioid antagonists and the education on the use of opioid antagonists will relieve a veteran of those financial burdens while receiving treatment. The commenter added that veterans have sacrificed enough to protect the people of this country and it is our responsibility to provide proper health care and encourage healthy living. Eliminating the copayment will allow veterans to fight this battle with focus and determination and removing a stressor such as a copayment can increase the chances of a successful recovery.

A commenter was in favor of the rule and added that VA has several programs in place to help veterans manage pain that do not include the use of opioids. This same commenter stated that the use of naloxone rescue treatments is an option for opioid risk mitigation and that proper education on naloxone should be given with frequent observation of the veteran and documentation in the veteran's medical records. This commenter also stated that eliminating the copayment will allow a veteran to fight this battle with focus and determination. Treatment timeframe varies per situation, but when trying to heal the mind and body simultaneously, removing a stressor can increase the chances of a successful recovery.

Another commenter was in support of the proposed rule and stated that the rule will be impactful to veterans battling opioid use disorder. Several commenters stated that by waiving the requirement to pay a copayment to receive opioid antagonists or education on their use for qualifying veterans, VA is recognizing that costs can pose a barrier for veterans to health care accessibility and it is taking the right steps to alleviate those barriers. A commenter added that this rule is a statement by VA of support of

their at-risk patients and that it places the values of their patients' lives over the cost of this drug. Another commenter similarly stated that removing copayment requirements for veterans will likely result in increased access to these potentially life-saving medications. The commenter praised VA's efforts and believes that this rule will help reduce the incidence of overdose deaths among the veteran population.

A commenter stated that the proposed rule was a fine example of an executive agency ensuring compliance with Congressional direction.

VA thanks the commenters for their support of the rule. We are not making any changes based on these comments.

Comment on use of term opioid antagonist.

One commenter was in support of the rule but stated that VA should change the wording in the proposed rule from antagonist to something that is more relatable and not so demeaning to people who will interpret it the wrong way.

VA notes that the utilization of the term antagonist in the proposed rule is the correct medical term to describe the specific class of medications being authorized for provision to at risk veterans. An antagonist is a chemical that acts within the body to reduce the physiological activity of another chemical substance (such as an opioid). Since the term specifically describes this class of medication, VA is not making changes based on this comment.

Comments on education on opioid antagonists.

A commenter was in general support of the rule but indicated that the copayment for the outpatient visit should be eliminated regardless of whether the veteran's medical visit is solely for education on the use of opioid antagonists or the education is provided in conjunction with other types of care.

Under 38 United States Code (U.S.C.) 1710 and 38 CFR 17.108(c) VA is required to charge copayments for outpatient and inpatient health care services when

certain criteria are met. VA clarifies, in 38 CFR 17.108(c)(2), a veteran will only be charged one copayment per day even if there are multiple encounters. In accordance with section 1710(g)(3)(B) of title 38, United States Code, VA is exempting from the copayment requirement those outpatient health care visits whose sole purpose is to provide education on the use of an opioid antagonist. However, when the outpatient visit provides health care services in addition to the education on an opioid antagonist, VA must assess the veteran's copayment for the additional services in accordance with 38 U.S.C. 1710. VA emphasizes that the veteran will not be charged a separate copayment for the education but will be assessed one copayment for the entire encounter. VA notes this results in the same outcome as the veteran would have experienced if the veteran had not received education on the use of an opioid antagonist. VA is not making any changes based on this comment.

Comments on definition of at high risk veterans.

Several commenters were generally in support of the rule but were concerned that the rule only focused on veterans who VA classified as high risk. The commenters stated that all veterans, not just those with a diagnosed risk of opioid overdose, should be eligible for the waived copayment. A commenter stated that if a veteran needs the opioid antagonist, then costs should not be a concern whether they are high risk or not. The commenter added that the fact the veteran is in need of the antagonist is sufficient evidence the veteran is at high risk. Also, the commenter stated that while the proposed rule would be an improvement and would lead to more lives being saved, more aggressive action to expand the target population to all veterans would be warranted and welcomed by the American people.

VA defined a high risk veteran in the proposed rule as a veteran 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. VA also stated that, in the alternative, a high

risk veteran is one whose provider deems, based on their clinical judgment, that the veteran may benefit from ready availability of an opioid antagonist. VA believes this definition is broad enough to allow health care professionals the discretion to provide opioid antagonists and related education to any veteran who needs it without charging a copayment. In addition, VA has programs in place to assist veterans who are suffering financial hardship or who would face difficulties in making copayments; these efforts include measures to identify barriers for veterans at high risk due to substance use and to review the veteran's financial barriers and provide assistance as needed. VA is not making any changes based on this comment.

Another commenter stated that the proposed rule assumes that all those who are considered high risk would be appropriately identified to meet the requirements for the copayment waiver. The commenter added that this approach runs the risk of missing vulnerable individuals who may not fall within the parameters outlined by VA that are used to generate a high-risk status and thus, a waived copayment. The commenter recommended that VA expand the rule to capture not only those considered high-risk, but also those residing in highly impacted regions, such as rural communities. Another commenter similarly recommended including additional items in the definition of high risk, such as considering all veterans who requested opioid antagonists in geographical areas that see higher rates of opioid use and areas considered rural by the Federal Office of Rural Health Policy to be high risk. The commenter indicated that veterans in rural areas have limited access to health care and treatment centers, and delays in emergency medical services become critical when an accidental overdose occurs. The commenter added that VA should create the most inclusive definition possible and consider other, less obvious, circumstances veterans may face that could render them at "high risk" of opioid addiction. The commenter also stated that by utilizing a model

which casts a wider net for assistance, more veterans and those in their immediate circles are likely to benefit from these proposals.

As previously stated in this rulemaking, VA's definition of high risk veteran is broad enough to allow health care professionals the discretion to provide opioid antagonists and education on those medications to any veteran without charging a copayment. In addition, VA has developed numerous resources to support identification of patients at risk for overdose, including the VA Opioid Overdose Education and Naloxone Distribution (OEND) Risk Report (which includes patients with various opioid pharmacotherapy and Opioid Use Disorder risk factors); VA Stratification Tool for Opioid Risk Mitigation (STORM), which uses predictive analytics to identify patients prescribed opioids who are at high risk for overdose and/or suicide; and incorporating the Risk Index for Overdose or Serious Opioid-induced Respiratory Depression (RIOSORD) into multiple reports to assist with patient identification. VA clinicians provide patient-centered care that takes into account the complexity of conditions and circumstances with which patients present—including their work, home, support system, and community—when conducting risk assessments and developing treatment plans. Based on the broad definition for this rule, which allows clinicians to provide opioid antagonists and related education to any veteran they deem may benefit from ready availability of an opioid antagonist, VA is not making any changes to its definition of high risk in response to this comment.

Another commenter stated that opioid overdoses can occur even when someone is taking an opioid exactly as prescribed by their doctor, and even veterans who are not considered "high risk" can still die of an overdose or be left with long term brain damage. Therefore, the commenter concluded, it is imperative that all veterans taking opioids are educated on the dangers of opioid induced respiratory depression (OIRD) and are provided the monitoring technology to help keep them safe. The commenter

encouraged VA to utilize continuous physiologic monitoring with notifications for all patients using opioids, particularly during periods of sleep and rest. The commenter added that such monitoring has been shown to reduce opioid overdose deaths through earlier interventions and rapid response team activations when necessary. The commenter recommended that VA include the following in the list of factors that indicate that an individual is at high risk of overdose: individuals taking other sedating medications, including alcohol, marijuana, benzodiazepines and/or gabapentin; older adults; depression or mental health conditions; sleep apnea.

VA notes the specific modalities for treatment, such as monitoring for OIRD, are determined by the VA national program office responsible for developing guidance to VA staff overseeing the provision of care at the facility level. The establishment of such modalities are outside the scope of the proposed rulemaking. VA believes that the proposed definition of a high risk veteran is broad enough to grant health care professionals the discretion to identify veterans who such professionals consider to be high risk; the addition of the factors identified by the commenter would not enhance the proposed definition. Moreover, VA's aforementioned STORM model takes into consideration many of the factors described by the commenter that are available in VA data (e.g., substance use disorders, benzodiazepine and gabapentin prescriptions, age, mental health diagnoses, and sleep apnea). These factors are displayed in a VA-provider facing clinical dashboard for patients prescribed opioids as well as patients with opioid use disorders. VA is not making any changes based on these comments.

Comments on elimination of other types of copayments.

A commenter was generally in support of the rule but recommended the rule also eliminate any cost to veterans relating to substance use disorder counseling, rehabilitation, psychological treatment, and inpatient care. The commenter added that care coordination between providers must become an equal priority to prevent over-

prescription. In addition, the commenter stated that opioid antagonists should be treated as the last resort in reducing overdose deaths and not a course of treatment. The commenter stated the proposed rule should be only the first step in ensuring that high risk veterans face no obstacles in gaining access to the treatment that they need ahead of any possible overdose incident.

As previously stated in this rulemaking, section 915 of Public Law 114–198 and section 243 of Division A of Public Law 114–223 provide for the elimination of a copayment for the provision of opioid antagonists and for outpatient visits whose sole purpose is for the provision of education on the use of opioid antagonists. The elimination of copayments for substance use disorder counseling, rehabilitation, psychological treatment, and inpatient care are beyond the scope of the proposed rule. However, VA's implementation of opioid antagonist education emphasizes the importance of connecting patients, including those with opioid use disorder, with treatment (e.g., a standardized patient education brochure recommends considering seeking help for substance use disorder [SUD] treatment and includes a link to the VA SUD Program Locator). VA has also streamlined Prescription Drug Monitoring Program (PDMP) checks—incorporating an integrated Information Technology solution that allows providers to check for controlled substance prescriptions outside VA. This mechanism makes it easy for providers to check the PDMP for opioid prescriptions external to VA within the Computerized Patient Record System. VA also has programs in place to assist veterans experiencing financial hardship, including measures to identify barriers for veterans at higher risk due to SUD. VA is not making any changes based on this comment.

Comments on outreach

One commenter suggested that the rule should also ensure that VA provide outreach services to identify high-risk veterans, encourage educational outpatient visits,

and follow-up before or after both outpatient and inpatient visits for treatment and education. The commenter indicated that providing outreach services will increase the number of veterans who receive antagonist prescriptions, aid in tracking the most at risk of the high-risk population, aid in the dissemination of pain management alternatives, and overall reduce the risk of opioid misuse and overdose events. The commenter also stated that outreach has proven effective in several studies conducted all over the US for people suffering with Opioid Use Disorder and is a main factor is reducing repeat overdose events. The commenter stated that these outreach practices are already occurring in VA and should be folded into the regulation to ensure their continuation as outreach is an integral part of increasing the effectiveness of this rule's stated goal.

VA notes that this rulemaking is limited to the exemption of copayments for opioid antagonist education and dispensing of opioid antagonists to veterans identified by VA health care professionals as being at high risk of overdose. VA already has treatment programs and outreach programs in place for identification and treatment of veterans at risk of opioid use disorder. The provision of VA outreach programs for opioid use disorder is outside the scope of the proposed rulemaking, and VA generally seeks to avoid regulating outreach practices to allow for innovative approaches to be adopted to support safe and effective patient care. VA is not making any changes based on this comment.

Comments on the impact analysis.

A commenter had concerns regarding the impact analysis that accompanied the rulemaking. The commenter stated that the impact analysis projected a loss of revenue of more than $150,000 with increases for each year of this rule's existence due to the copayment exemptions. The commenter noted that the impact analysis did not state where this revenue stream would be diverted from internally and how this may impact other veteran services of equal or greater importance. The commenter queried whether

VA plans to apply for a grant under the Food, Drug, and Cosmetic Act (chapter 9 of title 21, U.S.C.) for the emergency treatment of opioid overdose, which can offset at least $200,000 of antagonist costs that is greater than the yearly projected loss of revenue from this rule.

VA believes the benefits of educating veterans on the risks of opioids and utilization of opioid antagonists during an overdose to potentially save a life outweighs any loss of revenue from VA copayments. VA anticipates no reduction or diversion of funds from other programs as a result of this rulemaking. VA has already been implementing this authority, and VA's budget requests already reflect the loss identified in the impact analysis. We are not making any changes based on this comment.

Based on the rationale set forth in the Supplementary Information to the proposed rule and in this final rule, VA is adopting the proposed rule with no changes.

Executive Orders 12866 and13563

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 not 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.

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). The adoption of the rule does not directly affect any small entities. There are no small entities involved with VA's process or adjustment of veteran's copayments for medications or services. The provisions of this rulemaking only apply to the internal operations of VA and to individual veterans.

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.

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.

Paperwork Reduction Act

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

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance program number and title for this final 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.

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

Denis McDonough, Secretary of Veterans Affairs, approved this document on September 10, 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**,*

Regulations 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 amends 38 CFR part 17 as set forth below:

PART 17 – MEDICAL

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

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

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2. Amend § 17.108 by revising paragraphs (e)(16) and (17) and adding paragraph (e)(18) to read as follows:

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

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(e) * * *

(16) In-home video telehealth care;

(17) Mental health peer support services; and

(18) An outpatient care visit solely for education on the use of opioid antagonists to reverse the effects of overdoses of specific medications or substances.

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4. Amend § 17.110 by adding paragraph (c)(12) to read as follows:

§ 17.110 Copayments for medication.

* * * * *

(c) * * *

(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.

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