



DEPARTMENT OF VETERANS AFFAIRS

8320-01

38 CFR Part 17

RIN 2900-AP35

Tiered Pharmacy Copayments for Medications

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: The Department of Veterans Affairs (VA) adopts as a final rule, with changes, a proposal to amend its regulations concerning copayments charged to certain veterans for medication required on an outpatient basis to treat nonservice-connected conditions. Prior to this final rule, VA charged non-exempt veterans either \$8 or \$9 for each 30-day or less supply of medication, and that amount may have changed in future years. This rulemaking replaces those rates and establishes three classes of medications for copayment purposes, identified as Tier 1, Tier 2, and Tier 3. These tiers are defined further in the rulemaking and are distinguished in part based on whether the medications are available from multiple sources or a single source, with some exceptions. Copayment amounts are fixed and would vary depending upon the class of medication. The following medication copayment amounts are applicable on the effective date of this final rule: \$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. For non-exempt veterans these copayment amounts will result in lower out-of-pocket costs, thereby encouraging greater adherence to taking prescribed medications and reducing the risk of fragmented care that results when veterans use non-VA pharmacies to fill their prescriptions. The proposed rule was

published on January 5, 2016, and the public comment period closed on March 7, 2016. We received nine comments and respond to these comments here.

DATES: Effective Date: This rule is effective on February 27, 2017.

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SUPPLEMENTARY INFORMATION: Under 38 U.S.C. 1722A(a), VA must require veterans to pay at least a \$2 copayment for each 30-day supply of medication furnished on an outpatient basis for the treatment of a non-service-connected disability or condition, unless the veteran is exempt from having to pay a copayment because the veteran has a service-connected disability rated 50 percent or more, is a former prisoner of war, or has an annual income at or below the maximum annual rate of VA pension that would be payable if the veteran were eligible for pension. VA has the authority under 38 U.S.C. 1722A(b) to increase that copayment amount and establish a maximum annual copayment amount (a “cap”) through regulation. We have implemented this statute in 38 CFR 17.110. Both the copayment amount for certain priority groups, as well as an annual cap on those copayments, are addressed in 38 CFR 17.110(b).

On January 5, 2016, we proposed a new medication copayment formula, in order to address longstanding concerns that the regulatory formula VA had been using was

not competitive with non-VA retail copayment structures, lacked parity, may result in decreased medication adherence, and increased the likelihood of fragmented care due to price-shopping. 81 FR 196. The public comment period closed March 7, 2016, and we received nine comments, all of which were generally supportive. Several commenters expressed strong support for lowering the annual medication copayment amount. However, several commenters urged VA to make changes to different aspects of the proposed rule. The majority of the comments focused on the definition of multi-source medication. We address those comments, and make changes to the rulemaking as noted below.

The new regulatory formula established by this rule focuses on the type of medication being prescribed and would remove the automatic escalator provision, meaning that changes in copayments would only occur through subsequent rulemakings. Veterans exempt by law from copayments under 38 U.S.C. 1722A(a)(3) continue to be exempt. This VA rulemaking includes a definition of “medication” and “multi-source medication.” We also establish three classes of medications for copayment purposes: Tier 1 medications, Tier 2 medications, and Tier 3 medications. Tiers 1 and 2 includes multi-source medications, a term that is defined in § 17.110(b)(1)(iv). Tier 3 includes medications that retain patent protection and exclusivity and are not multi-source medications. Copayment amounts vary depending upon the Tier in which the medication is classified. A 30-day or less supply of Tier 1 medications has a copayment of \$5. For Tier 2 medications, the copayment is \$8, and for Tier 3 medications, the copayment is \$11. The rule also changes the annual cap for

medication copayments, lowering the cap to \$700 for all veterans who are required to pay medication copayments.

On September 16, 2015, VA published a final rule maintaining, through December 31, 2016, medication copayment amounts at the 2014 rate for certain priority groups (\$8 for veterans in priority groups 2–6 and \$9 for veterans in priority groups 7 and 8). See 80 FR 55544. VA anticipated at that time that necessary information technology (IT) structure changes would be in place by December 31, 2016, allowing the current rulemaking to have an effective date of January 1, 2017. However, those changes will not be ready for a full roll-out until February 27, 2017. The effective date of this final rule is February 27, 2017. VA published a separate rulemaking that will extend the current copayment freeze until the effective date of the present rulemaking. The end result is that the higher annual copayment cap of \$960 will be in effect through February 26, 2017, and the lower annual cap of \$700 will apply the following day. We believe it is unlikely that a veteran will pay more than \$700 in medication copayments during the short period of time before the lower annual cap goes into effect. However, in the event that any veteran exceeds the \$700 cap in this final rule, before the rule takes effect, VA will refund the amount in excess of the \$700 cap to the veteran.

Definition of the term “medication”

In paragraph (a) of proposed section 17.110, we proposed that for the purposes of this section, the term “medication” would mean prescription and over-the-counter medications as determined by FDA. One commenter noted that the term “medication” is not a regulatory term of art used by FDA and FDA does not determine whether an

item is medication. The commenter stated that the rule should instead refer to the regulatory approval authorities for drugs and biologics, section 505 of the Food Drug and Cosmetic Act (FDCA) for drugs, and section 351 of the Public Health Service Act (PHSA) for biologics. The commenter stated that citing these authorities would clarify that the term “medication” does not include medical supplies, nutritional items, and devices.

Section 505 of the FDCA is codified at 21 U.S.C. 355 (New drugs) and 355-1 (Risk evaluation and mitigation strategies). Citing the former would inappropriately limit the definition of “medication” to new drugs, and citing the latter would address only those instances where FDA determines that a risk evaluation and mitigation strategy is necessary to ensure that the benefits of a new drug outweigh the risks of the drug. While section 351 of the PHSA is applicable to the approval of all biologics, VA believes that it would be potentially confusing to the public if the rulemaking cited to statutory authority related to biologics but not for drugs. However, VA agrees with the commenter’s concern that medical supplies and devices are not specifically excluded from the definition of “medication.” We have amended the definition accordingly to exclude medical supplies and devices. We also specifically excluded oral nutritional supplements from the definition of “medication” because they are exempt from copayments. Oral nutritional supplements are commercially prepared nutritionally enhanced products used to supplement the intake of individuals who cannot meet nutrient needs by diet alone.

Definition of “multi-source medication”: General comments

One commenter stated that the definition of multi-source medication in § 17.110(b)(2)(A) is inappropriately broad, misaligned with the conventional use and understanding of the term, risks public confusion, and poses a potential risk to patient safety. The commenter stated that the term is typically used to describe only those drugs that FDA has determined to be therapeutically equivalent (i.e., pharmaceutically equivalent and bioequivalent), and that FDA’s definition is also consistent with Centers for Medicare and Medicaid Services’ regulatory use of the term “multiple source” for purposes of the Medicare and Medicaid programs.

Another commenter stated that the definition of “multi-source medication” “includes multiple categories of drugs defined separately under the Medicaid Drug Rebate Program in 42 U.S.C. 1396r-8(k)(7)(A) as ‘multiple source drug,’ ‘innovator multiple source drug,’ ‘non-innovator multiple source drug,’ and ‘single source drug.’” The commenter asserts that VA’s proposed definition of multi-source medication conflicts with these statutory definitions. Another commenter stated that the proposed definition of multi-source medication contributes to nonuniformity in federal regulations, noting that TRICARE regulations at 32 CFR 199.21(j) classify generic medications as multi-source products, and specifically define that term.

In response to these commenters, we note that our definition of multi-source medication is intentionally broad to differentiate medication that would fall under Tiers 1 and 2 from those in Tier 3 in the regulation. We determined that the use of a single term to describe medications that do not retain patent protection and exclusivity is appropriate because veterans receiving care from VA, not drug manufacturers, are

primarily affected by this rulemaking. VA considered several options on how to address the types of medications we include in the definition of multi-source medications in § 17.110(b)(1)(iv)(A). Our primary considerations were to ensure, first, that the types of medications were adequately defined and, second, that the rulemaking clearly states to which copayment tier each of these types of medications is assigned. It became evident during the drafting process that treating the types of medications currently described in § 17.110(b)(1)(iv)(A) as separately-defined terms was problematic, because adding multiple definitions could lead to confusion. VA believes that using a single term to refer to types of medication with a shared major characteristic is less confusing than referring to multiple separate definitions. The characteristic shared by each type of medication in current § 17.110(b)(1)(iv)(A) is that it is available from multiple sources. VA believes that using the term “multi-source medication” has a lower risk of confusing the public than does the use of separate terms like those suggested by the commenter. The various Medicaid definitions referred to by the commenters are necessary for administration of medication payments or reimbursement by Medicaid to states, retail or hospital pharmacies, other health care providers, and drug manufacturers. That degree of differentiation in definitions is unnecessary for tiered copayment purposes, and would lead to confusion in our veteran population. Likewise, adopting definitions of similar terms used by Medicaid would not be helpful to veterans, as the Medicaid definitions of terms were drafted to serve another purpose and were targeted to their specific audience. As one commenter stated, TRICARE regulations do classify generic drugs as multi-source products. However, as noted above, several classes of medications can properly be described as being multi-source. As the

definition of multi-source medication in this rulemaking relates solely to determining whether a particular medication should be in one of three tiers for purposes of VA medication copayments, we do not anticipate that nonuniformity of VA and other agencies' terms will be a problem. We make no changes based on these comments.

Two commenters stated that VA should clarify that the definition of “multi-source medication” applies only to VA’s copayment structure in order to avoid confusion given the use of similar terminology in other federal regulations. We specify in § 17.110(b)(1)(iv) that the definition of “multi-source medication” is for purposes of that section only. We make no changes based on these comments.

Definition of “multi-source medication”: Biosimilarity and interchangeability

In paragraph (b)(1)(iv)(A)(1)(ii) we proposed that the term “multi-source medication” would include a medication that has been and remains approved by FDA under section 351(k) of PHSA (42 U.S.C. 262), and 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). We received multiple, highly technical comments on this issue, which are summarized below. After the summary, we respond to the comments.

Several commenters stated that VA should clarify that it defers to FDA regarding both therapeutic equivalence for drugs and interchangeability for biological products. The commenters asserted that by defining multi-source medication to mean, in part, a medication that has been granted an I or B rating by FDA, VA would treat both biological products that FDA has determined to be interchangeable (I rated) and those

deemed biosimilar (B rated) exactly the same. The commenters stated that the proposed rule erroneously conflates entirely the two very distinct approval standards for these two very distinct categories of biological products.

Several commenters stated that the proposed rulemaking failed to recognize the significant differences between generic drugs and biosimilar products. The commenters noted that biosimilar products are not necessarily interchangeable. Whereas drugs typically have small molecule structures that can be completely defined and entirely reproduced, biologics are large-protein molecules that are generally more complex, and reproductions are unlikely to be shown to be structurally identical to the innovator product. In recognition of this difference, the Biologics Price Competition and Innovation Act of 2009 (BPCIA) established separate approval standards for biosimilar and interchangeable biological products, distinct from standards for generic drugs. Generic drugs must be the same as a previously approved Reference Product, and are approved for the same indications. In contrast, to receive FDA approval, biosimilar products must be demonstrated to be “highly similar,” but not identical, to the innovator product. Approved B rated biosimilar products have not been determined by FDA to be safe for substitution with the Reference Product. Biologics must meet additional criteria established by the FDA to be interchangeable, or I rated. One commenter urged VA to exclude biosimilar products that FDA has not determined to be interchangeable from the definition of multi-source medication. In the alternative, the commenter stated that VA should clarify that a biological product licensed by FDA as a biosimilar is not interchangeable absent an FDA determination of such.

Commenters noted that the BPCIA sets forth criteria for a biologic being rated as a biosimilar product, and two additional requirements for interchangeability. Only those biosimilar products that have met these two additional criteria are deemed by FDA to be interchangeable. Two commenters stated that FDA sets a higher standard for interchangeability of biological products and other related biosimilar products than it does for biosimilarity or therapeutic equivalence for smaller molecule drugs. The commenters stated that, in the absence of the robust data that FDA requires to make a determination regarding biosimilarity or interchangeability, VA could potentially place patients at significant risk.

One commenter stated that the proposed rulemaking encourages the use of the lowest cost biosimilar regardless of interchangeability and whether the biosimilar has been tested for the indication for which it is prescribed.

One commenter noted that there are some smaller molecule drugs that have not been determined by FDA to be therapeutically equivalent. The commenter stated that VA should consider the unique safety questions surrounding substitution of biological products, including those that have been determined to be biosimilar, especially with regard to immunogenicity.

One commenter stated that VA should clarify that B rated biological products have not been approved as interchangeable with the reference Product. FDA approval as an interchangeable biological product (I rated) requires the successful demonstration of an entirely separate and more rigorous set of standards. The commenter states that VA should clarify that the inclusion of B rated biologics in the definition of multi-source

medication does not imply that B rated biologics have been determined by FDA to be interchangeable.

We appreciate the complete analyses provided by the commenters on the topic of biosimilarity and interchangeability, and we have made changes to the regulation responsive to their concerns. Our reasoning follows.

The Purple Book lists biological products, including any biosimilar and interchangeable biological products licensed by FDA under the PHSA. The lists include the date a biological product was licensed under 351(a) of the PHSA and whether FDA evaluated the biological product for reference product exclusivity under section 351(k)(7) of the PHSA. The Purple Book enables a user to see whether a biological product licensed under section 351(k) of the PHSA has been determined by FDA to be biosimilar to or interchangeable with a reference biological product (an already-licensed FDA biological product). Biosimilar and interchangeable biological products licensed under section 351(k) of the PHSA are listed under the reference product to which biosimilarity or interchangeability was demonstrated.

The BPCIA was enacted as part of the Patient Protection and Affordable Care Act (Affordable Care Act) (Public Law 111-148) on March 23, 2010. The BPCIA amends the PHSA and other statutes to create an abbreviated licensure pathway for biological products shown to be biosimilar to or interchangeable with an FDA-licensed biological reference product (see sections 7001 through 7003 of the Affordable Care Act). Section 351(k) of the PHSA, added by the BPCIA, sets forth the requirements for an application for a proposed biosimilar product and an application or a supplement for a proposed interchangeable product. There are three relevant definitions in this statute.

Section 351(i) defines biosimilarity to mean that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components and that there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product.

To meet the standard for interchangeability, an applicant must provide sufficient information to demonstrate that the biological product is biosimilar to the reference product and can be expected to produce the same clinical result as the reference product in any given patient. Additionally, if the biological product is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between the use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch (see section 351(k)(4) of the PHSA). Interchangeable products may be substituted for the reference product by a pharmacist without the intervention of the prescribing health care provider (see section 351(i)(3) of the PHSA).

Reference product means the single biological product licensed under section 351(a) of the PHSA against which a biological product is evaluated in a 351(k) application (section 351(i)(4) of the PHSA).

The definition of multi-source medication in this rulemaking was crafted for only one purpose – to differentiate several classes of medication (including drugs and biologics) that can be termed either Tier 1 or 2 for medication copayment purposes. This definition does not equate an I rated product with one that is B rated by FDA. Nor does it conflict with or supersede a determination by FDA that a particular

drug is the therapeutic equivalent of another, or that two biologics are biosimilar. The Purple Book lists biological products, including any biosimilar and interchangeable biological products licensed by FDA, and the definition of multi-source medication at paragraph (b)(1)(iv)(A)(1)(ii) recognizes that fact and categorizes those already-licensed products for VA's purposes. We have added clarifying language to indicate that VA defers to FDA regarding both therapeutic equivalence for drugs and interchangeability for biological products.

We do not agree with the commenter concerned that the rulemaking encourages the use of the lowest cost biosimilar regardless of interchangeability and whether it has been tested for the indication for which it is prescribed. A VA health care provider makes decisions on prescribing specific medications based on the clinical need of the individual patient being treated for a given illness or condition. Prescribing decisions are generally limited to those medications included in the VA National Formulary, which is discussed in greater detail below. If a particular medication is not available, sound clinical practice is for the health care provider to select an alternate medication that is interchangeable or otherwise approved by the FDA for treatment of the illness or medical condition. Cost is only one of several factors considered when VA determines which medications are on the National Formulary. In general, individual prescribing choices are influenced by medication copayment charges only when the issue is raised by the veteran, and only in those instances where a clinically justifiable alternative is available. We make no changes based on this comment.

Definition of “multi-source medication”: Substitutability

In paragraph (b)(1)(iv)(A)(3) we proposed that the term “multi-source medication” would include a medication that has been and remains approved by the FDA pursuant to FDCA section 505(b)(1) or PHSa section 351(a); and 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).

One commenter expressed concerns that the proposed rule gives VA total discretion to determine whether two approved drugs or biological products are “substitutable.” The commenter stated that VA should defer to FDA’s determination of therapeutic equivalence and interchangeability when making decisions regarding substitutability of products.

The commenter also expressed concern that VA’s determination that products are substitutable may be misconstrued by the public as indicating that the products have been determined by FDA to be interchangeable or therapeutically equivalent when they are not.

One commenter stated that the portion of the proposed rulemaking addressing substitutability is written in a manner to suggest that there may be more treatment options, and thus there are competitive forces at play, when certain drugs and biologics have the “same active ingredient or ingredients, work . . . in the same way, and in a comparable amount of time.” The commenter argued that it is outside VA’s authority to determine when products are “substitutable” with one another. The commenter stated

that it is FDA's scientific determinations about therapeutic equivalence (for small molecule drugs) and interchangeability (for biologic products) that impact substitutability determinations.

VA agrees that FDA determinations regarding therapeutic equivalence and interchangeability are important considerations. However, substitutability is not the same as therapeutic equivalence or interchangeability. Whether one medication can be substituted for another is a clinical decision made by a health care provider, based on sound clinical judgment, and the decision should be evidence-based. A health care provider may decide to substitute one medication for another to treat a given medical condition for several reasons including, but not limited to, a comparison of relative side effects, contraindications, and potential adverse reactions; patient tolerance of one medication over another; a request by the patient; or an effort to decrease costs for the patient while achieving the same or similar benefits. Therapeutic equivalence and interchangeability may play a part in the decision-making process, dependent upon the range of treatment options available to the health care provider. When therapeutic equivalence and interchangeability are considerations, FDA determinations on these issues are highly relevant. We make no changes based on this comment.

Definition of "multi-source medication": Authorized generics

In paragraph (b)(1)(iv)(A)(4) we state that the term "multi-source medication" would also include a medication that is 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. The definition in paragraph (b)(1)(iv)(A)(4) is substantively identical to the definition of “authorized generic drug” found in FDA regulations at 21 CFR 314.3.

One commenter stated that this definition unfairly precludes drugs approved as brand drugs and marketed as generics (authorized generics) from being included as a multiple-source medication at the Tier 1 or 2 copayment amount if there is no generic source rated in the Orange Book or if a drug approved as a brand drug is not lower in cost than other generic sources.

For clarification, the FDA publication “Approved Drug Products with Therapeutic Equivalence Evaluations” is commonly known as the Orange Book. The Orange Book identifies drug products approved on the basis of safety and effectiveness by the FDA under the FDCA. The publication does not include drugs on the market approved only on the basis of safety covered by the ongoing Drug Efficacy Study Implementation review or pre-1938 drugs. The main criterion for the inclusion of any product is that the product is the subject of an application with an effective approval that has not been withdrawn for safety or efficacy reasons. In addition, the Orange Book contains therapeutic equivalence evaluations for approved generic drugs. Finally, the Orange Book lists patents that are purported to protect each drug.

The commenter stated that it is unfair to charge veterans more for an authorized generic drug simply because there is no marketed generic drug approved under section

505(j), or when VA's cost for a drug approved as a brand drug is only slightly higher than another generic source.

Nothing in this rulemaking precludes an authorized generic drug from inclusion in either Tier 1 or 2. Authorized generics are prescription drugs produced by brand pharmaceutical companies and marketed under a private label, at generic prices. Authorized generics compete with generic products in that they are identical to their brand counterpart in both active and inactive ingredients, while generic drugs are required to contain only the same active ingredient as the brand name. Pharmaceutical manufacturers typically launch an authorized generic when patent protection and exclusivity have expired, and the authorized generic competes in the marketplace against any generic equivalents approved by FDA.

The three classes of medications defined for copayment purposes, Tier 1, Tier 2, and Tier 3, are found in paragraph (b)(1)(iv)(B)-(D). Multi-source medications generally fall under either Tier 1 or 2; placement in either tier being governed by whether the medication meets all the criteria found at paragraph (b)(2) for Tier 1 placement. The only medications that would fall under Tier 3 are those 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. The definition of multi-source medication specifically includes authorized generic drugs at paragraph (b)(1)(iv)(A)(4). There is nothing in the criteria for inclusion in Tier 1 or 2 that would disqualify an authorized generic because no other generic equivalent had yet been approved by FDA.

The comment does highlight two elements of the Tier 3 definition that may cause confusion: patent protection and exclusivity. Tier 3 medication includes medications approved by FDA under a NDA that retains exclusivity. An authorized generic medication is manufactured by the original patent holder under a NDA, but is not marketed under the brand name. While an authorized generic medication may not retain exclusivity for patent purposes, the term “exclusivity” does come into play. Authorized generic medications are typically brought to the market during the 180-day exclusivity period during which a first filer of an Abbreviated New Drug Application (ANDA) under the Drug Price Competition and Patent Term Restoration Act (Public Law 98-417) can bring to market a generic version of the brand name drug. During this 180 day period no other manufacturer may market a generic version of the medication, other than the original patent holder who can market the authorized generic. To clarify the scope of Tier 3, we will amend the definition of Tier 3 to explicitly state that Tier 3 does not include authorized generic medications defined in paragraph (b)(1)(iv)(A)(4).

The commenter further stated that if the concern is that multiple source drug prices be competitive, the requirement should be that a drug approved as a brand drug be equivalent in cost to a generic version not lower in cost, particularly given generic drug pricing volatility. As noted above, the comment is based on an incorrect analysis of the definition of multi-source medication and what is included in each tier for copayment purposes. Authorized generic medications (which are generic versions of a medication that is marketed by the brand drug manufacturer) are not included in Tier 3. By definition, authorized generic medications are considered multi-source medication at paragraph (b)(1)(iv)(A)(4). A drug approved by the FDA as a brand drug is considered

under this rule in one of two ways, dependent on whether the drug is marketed as both a brand drug and authorized generic medication, or solely as a brand drug. In the latter case, the brand drug would be considered a Tier 3 medication, while in the former case the authorized generic medication would be either a Tier 1 or 2, and the brand drug would be Tier 3. This differentiation between an authorized generic medication and a brand drug is consistent with how many non-VA health insurers categorize these products. The commenter correctly states that generic drug pricing can be volatile. However, VA has been successful at stabilizing generic drug acquisition prices through a variety of government contract vehicles and therefore has minimized generic price volatility. Generic price volatility is not the primary determining factor in whether an authorized generic medication is Tier 1 or 2. We do not agree with the commenter that VA should require brand drug to be equivalent to either the authorized generic version of that drug, or other generic versions of that drug. Finally, the description of authorized generic medication in paragraph (b)(1)(iv)(A)(4) does not include a requirement that the medication be lower in cost; that requirement is in (b)(1)(iv)(A)(2)(iii) and is not applicable to authorized generic medication. We make no change based on this comment.

Tier structure

One commenter stated that, while the proposed rule is intended to align medication copayments charged by VA with commercial practice, the three-tiered system deviates further from established commercial practice than the current two-

tiered system. The commenter stated that the proposed three-tiered model will lead to confusion, and veterans may be less likely to fill needed prescriptions.

The primary purpose of this rulemaking is not to strictly align VA's medication copayment structure with commercial practice. Rather, it is to make medication copayments more affordable to the greatest number of affected veterans, while recognizing differences in costs of those medications to VA and the effect of that differential for veterans who may exercise a non-VA retail option. The previously utilized two-tiered system was inflexible and nonresponsive to changing conditions, and resulted in some veterans bearing a heavy financial burden to obtain necessary medication. We make no changes based on this comment.

One commenter was concerned that a single source drug or biologic for which there is no generic version is precluded from Tier 2, even where there is a therapeutic alternative that is also a single source drug or biologic. The commenter noted that single source drugs on the VA National Formulary may be clinically effective and cost effective compared to alternative treatments. The VA National Formulary is a listing of products (drugs and supplies) that must be available for prescription at all VA facilities. Only those products that actually have been approved by FDA under a NDA, ANDA, or biologics license, may be added to the National Formulary.

The commenter stated that many high use medications, such as oncology drugs and biologics, are for conditions for which no drug is available under another tier and which may not be on the VA formulary. The commenter asserted that the proposed tier structure will increase costs of these medications for veterans.

One commenter did not support the tiered copayment model, specifically Tier 3. The commenter argued that requiring higher copayments for Tier 3 medication penalizes veterans who benefit from newer medication, those who have no other option than using medication that retain patent protection and exclusivity to treat their medical condition. The commenter further stated that raising copayment amounts may force veterans to pick and choose which of several medications they will fill.

A medication is considered a therapeutic alternative if that medication differs chemically from the medication prescribed, but has the same therapeutic effect as the prescribed medication. An example is the various classes of calcium channel blockers that are prescribed to treat hypertension. One calcium channel blocking medication could be considered a therapeutic alternative to another, dependent upon case-specific factors. Placement of a medication into any of the three copayment tiers is not dependent on whether a therapeutic alternative exists. Rather, the issue is whether a particular medication is a multi-source or single source medication, and whether (in the case of a multi-source medication) the medication qualifies for Tier 1. The primary criteria for determining whether a medication is single source or multi-source is if it is 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). Using “therapeutic alternative” as the touchstone to determine whether a medication is single source would not be consistent with the common usage of that term, and would be difficult to administer since medications may sometimes be prescribed to treat several different medical conditions.

For one indication, medication X may be the therapeutic alternative to medication Y, and for another indication would be the therapeutic alternative to medication B.

Medication copayment amounts paid in non-VA pharmacies vary dependent upon whether the prescription is for a generic or brand name medication. The tiered copayment structure in this rulemaking follows the same pattern. What is commonly referred to as a brand name medication is equivalent to a medication that would fall under Tier 3. VA estimates that approximately 15 percent of billable prescriptions dispensed in a year will be in Tier 3, and that the total copayments for veterans prescribed Tier 3 medications will remain the same for many veterans and will decrease for a sizable portion. A reduction in the copayment cap provides a unique benefit to veterans who exclusively use Tier 3 medications. The total annual copayment costs for these veterans will not exceed \$700, whereas under the prior regulations the costs would be \$960, or more for those veterans in priority groups 7 or 8 that are not currently subject to a cap. So, while some veterans may still decide not to fill all of their prescriptions, we estimate that fewer will do so for financial reasons as a result of these changes.

We note that a veteran may request a waiver of medication copayment charges, as provided for in 38 CFR 17.105(c). That section states that the veterans must submit a form requesting a waiver, and that a hearing may be requested. We make no changes based on these comments.

Copayment amounts

Two commenters stated that this rule will still result in veterans being subject to copayments higher than they would have to pay in a non-VA pharmacy. One commenter argued that VA should offer the same copayment rates available in non-VA pharmacies.

In the impact analysis published concurrently with the proposed rule, VA considered the potential costs or savings to veterans as a result of this rulemaking. Based on a comparison of the current and proposed copayment amounts, we anticipate that most veterans would realize between a 10 and 50 percent reduction in their overall pharmacy copayment liability each year based on historic utilization patterns. By our estimates, 94 percent of copayment eligible veterans would experience no cost increase, and 80 percent would realize a savings of between \$1 and \$5 per 30-day equivalent of medications. While a small percentage of veterans may experience a small increase in medication copayments, a large majority will encounter no cost increase, or will realize savings, as a result of this rulemaking.

Medication copayment amounts vary widely between different non-VA pharmacies and under commercial health insurer policies, due to many factors. There is no standard non-VA medication copayment rate structure that can be used as a model for creating a copayment structure in VA. Uniformly adopting the lowest level of copayments found outside of VA would result in a copayment system that is not sustainable in the long term, and could possibly violate statutory requirements in 38 U.S.C. 1722A(a), which requires VA to charge a minimum copayment, with certain limited exceptions. VA believes that this rulemaking will result in copayment amounts

that will benefit the greatest number of veterans. We make no changes based on these comments.

One commenter stated that manufacturers may be providing VA with competitive prices to increase market share of a single source drug within a therapeutic class, and the lower cost to VA should be passed along to veterans through a lower tier copayment amount. Given the number of pharmaceutical manufacturers and suppliers VA contracts with, and the varying terms and lengths of these contracts, determining copayments amounts on an individual contract basis would be difficult from an administrative standpoint and could lead to uncertainty as to the amount an individual veteran would pay for a medication copayment. In addition, this could result in different copayments for the same medication where more than one manufacturer or supplier provides that medication. Under this rulemaking, VA does include acquisition cost as an element considered in determining whether a medication will be included in Tier 1. See paragraph (b)(2). We make no changes based on this comment.

Exemption from copayments

One commenter stated that if a large number of veterans are diagnosed with any one medical condition such as hypertension, medication to treat that condition should be considered service-connected and exempt from copayments. Another commenter stated that any veteran who has served in the military over 20 years, or served in a war or conflict, should be exempt from medication copayments. The commenter also stated that a pool of emergency funds should be set aside for use by veterans who are unable to afford medication copayments.

Exemptions from the medication copayment are controlled by statute. Under 38 U.S.C. 1722A(a)(3), the following veterans are exempt from the medication copayment: a veteran with a service-connected disability rated 50 percent or more; a veteran who is a former prisoner of war; and, a veteran whose annual income (as determined under 38 U.S.C. 1503) does not exceed the maximum annual rate of pension which would be payable to such veteran if such veteran were eligible for a VA pension. VA does not have the statutory authority to exempt other veterans from the medication copayment. While VA does not have the statutory authority to exempt other veterans from medication copayment charges, as noted above a veteran may request a waiver of such charges under 38 CFR 17.105(c). Service connection is not determined by whether a certain number of veterans have been diagnosed with a particular disease or condition. “Service-connected” means that the disability was incurred or aggravated in the line of duty while in active military, naval, or air service. 38 CFR 3.1(k). A finding that a disability is service connected means that the facts, shown by evidence, establish that a particular injury or disease resulting in disability was incurred coincident with service in the Armed Forces, or if preexisting such service, was aggravated therein. 38 CFR 3.303(a). Likewise, VA does not have the statutory authority to set aside appropriated funds for the use of individual veterans. We make no changes based on these comments.

Miscellaneous

One commenter stated that, unlike the Department of Defense, VA provides no opportunity for veterans, manufacturers, or the public to address the comparative

clinical benefits, and cost benefits or effectiveness of a drug or biologic under consideration for addition to the National Formulary. The commenter stated that VA should make the formulary decision-making process more transparent. The process VA utilizes to consider changes to the National Formulary is beyond the scope of the rulemaking, and we make no changes based on this comment.

One commenter asked for a clarification on how this rulemaking will impact contracting decisions for the National Contract covering short acting and human insulins, along with future contracting processes. Although changes in the prices of certain medications may affect certain future contracting actions, VA will continue to follow all federal contracting requirements and will make purchases accordingly.

Finally, we make a technical edit to paragraph (b)(1). This paragraph establishes the medication copayment amounts for each tier of medication. As drafted, each clause in paragraph (b)(1)(i) through (iii) reads “[f]or a 30-day supply or less of . . . medication, the copayment amount is . . .” This language could be misinterpreted to mean that no medication copayment is charged for medication amounts greater than 30 days. This would be inconsistent with the statutory mandate at 38 U.S.C. 1722A(a), that VA must require certain veterans to pay at least a \$2 copayment for each 30-day supply of medication furnished on an outpatient basis for the treatment of a non-service-connected disability or condition. In prior rulemakings we used the phrase “for each 30-day or less supply of medication” when establishing copayment amounts. Paragraph (b)(1) is edited to reflect that same language.

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

Effect of rulemaking

Title 38 of the Code of Federal Regulations, as revised by this final rulemaking, represents VA's implementation of its legal authority on this subject. Other than future amendments to this regulation or governing statutes, no contrary guidance or procedures are authorized. All existing or subsequent VA guidance must be read to conform with this rulemaking if possible or, if not possible, such guidance is superseded by this rulemaking.

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).

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). This final rule will generally be small business neutral. The rule will not affect pharmaceutical manufacturers, as it does not change the amount VA pays for medications to supply its pharmaceutical benefits program, only the amount VA collects from veterans as copayments. To the extent

there are effects on pharmaceutical companies, we believe it will most likely have a positive affect if VA is purchasing more medications and supplies from them. Similarly, VA does not believe that this rule will have a significant economic impact on small pharmacies. It is possible that some veterans will choose to fill their prescriptions within VA rather than from a community pharmacist, but we anticipate such a shift will not result in a significant economic impact on a substantial number of such entities. Therefore, under 5 U.S.C. 605(b), this rulemaking is exempt from the initial and final regulatory flexibility analysis requirements of sections 603 and 604.

Executive Order 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Executive Order 12866 (Regulatory Planning and Review) defines a “significant regulatory action,” requiring review by the Office of Management and Budget (OMB), unless OMB waives such review, as “any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) Create a serious

inconsistency or otherwise interfere with an action taken or planned by another agency; (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.”

The economic, interagency, budgetary, legal, and policy implications of this final rule have been examined, and it has been determined to be a significant regulatory action under Executive Order 12866 because it is likely to result in a rule that may have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities. VA's impact analysis can be found as a supporting document at <http://www.regulations.gov>, usually within 48 hours after the rulemaking document is published. Additionally, a copy of the rulemaking and its impact analysis are available on VA's Web site at <http://www.va.gov/orpm/>, by following the link for “VA Regulations Published From FY 2004 Through Fiscal Year to Date.”

Congressional Review Act

This final rule is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801, et seq.), which specifies that before a rule can take effect, the Federal agency promulgating the rule shall submit to each House of the Congress and to the Comptroller General a report

containing a copy of the rule along with other specified information. The required report and this rule have been submitted to Congress and the Comptroller General for review.

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 64.007, Blind Rehabilitation Centers; 64.008, Veterans Domiciliary Care; 64.009, Veterans Medical Care Benefits; 64.010, Veterans Nursing Home Care; 64.011, Veterans Dental Care; 64.012, Veterans Prescription Service; 64.013, Veterans Prosthetic Appliances; 64.014, Veterans State Domiciliary Care; 64.015, Veterans State Nursing Home Care; 64.018, Sharing Specialized Medical Resources; 64.019, Veterans Rehabilitation Alcohol and Drug Dependence; 64.022, Veterans Home Based Primary Care; and 64.024, VA Homeless Providers Grant and Per Diem Program.

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. Gina S. Farrisee, Deputy Chief of Staff, Department of Veterans Affairs, approved this document on October 3, 2016, for publication.

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.

Dated: December 2, 2016

Michael Shores
Acting Director,
Regulation Policy & Management
Office of the Secretary
Department of Veterans Affairs

For the reasons set out in the preamble, VA amends 38 CFR part 17 as follows:

PART 17 – MEDICAL

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

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

2. Amend § 17.110 by:

a. Revising paragraph (a).

b. Revising paragraphs (b)(1)(i) through (iii).

c. Adding paragraph (b)(1)(iv).

d. Revising paragraphs (b)(2) and (3), and adding a heading to paragraph (b)(4).

e. Adding paragraph (b)(5).

The revisions and additions read as follows:

§ 17.110 Copayments for medications.

(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) * * *

(1) * * *

(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.

(4) Veterans Choice Program. * * *

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

* * * * *

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