DEPARTMENT OF VETERANS AFFAIRS **8320-01**

38 CFR Part 3

RIN 2900-AR25

Presumptive Service Connection for Respiratory Conditions Due to Exposure to Fine Particulate Matter

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: This rulemaking adopts as final, with changes, an interim final rule that amended the Department of Veterans Affairs (VA) adjudication regulations governing presumptive service connection based on presumed exposures to fine particulate matter. The amendment was necessary to provide health care, services, and benefits to Gulf War Veterans who were exposed to fine particulate matter associated with deployment to the Southwest Asia theater of operations, as well as Afghanistan, Syria, Djibouti, and Uzbekistan. The amendment eased the evidentiary burden of Gulf War Veterans who file claims with VA for asthma, rhinitis, and sinusitis, to include rhinosinusitis.

DATES: Effective date: This rule is effective [insert 60 days after date of publication in the FEDERAL REGISTER].

Applicability date: The provisions of this final rule shall apply to all applications for benefits that are received by VA on or after the effective date of this final rule or that are pending before VA, the United States Court of Appeals for Veterans Claims, or the United States Court of Appeals for the Federal Circuit on the effective date of this final rule.

FOR FURTHER INFORMATION CONTACT: Jane Allen, Policy Analyst; Robert Parks, Chief, Part 3 Regulations Staff (211), Compensation Service (21C), Veterans Benefits

Administration, Department of Veterans Affairs, 810 Vermont Avenue, NW, Washington, DC 20420, 202-461-9700. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: On August 5, 2021, VA published an interim final rule in the Federal Register (86 FR 42724) to amend its adjudication regulations to establish presumptive service connection for asthma, rhinitis, and sinusitis, to include rhinosinusitis, in association with presumed exposure to fine particulate matter. These presumptions apply to veterans who served on active military, naval, air, or space service in the Southwest Asia theater of operations during the Persian Gulf War (hereinafter Gulf War), as well as in Afghanistan, Syria, Djibouti, or Uzbekistan, on or after September 19, 2001. VA provided a 60-day comment period which ended on October 4, 2021. VA received comments from the National Veterans Legal Services Program, National Law School Veterans Clinic Consortium, Stronghold Freedom Foundation, Disabled American Veterans, Veterans of Foreign Wars, Wounded Warrior Project, and nineteen individuals. Nine of the comments received expressed general support of the rule. VA has made limited changes based on the comments, as discussed below.

I. Asthma, Obstructive Sleep Apnea, and Respiratory Illnesses Under 38 CFR 3.317

VA received one comment suggesting that asthma, obstructive sleep apnea, and other respiratory illnesses should be considered medically unexplained chronic multisystem illnesses under 38 CFR 3.317, Compensation for certain disabilities occurring in Persian Gulf veterans. This commenter stated that evidence is not required to prove that an illness is associated with a veteran's service in Southwest Asia for claims under 38 U.S.C. 1117 and 38 CFR 3.317. However, this rulemaking and the interim final rule address regulations governing presumptive service connection for respiratory conditions based on presumed exposures to fine particulate matter. The rulemaking does not

address 38 CFR 3.317 or whether certain conditions may be considered medically unexplained chronic multisymptom illnesses. Further, as explained in the interim final rule, the Secretary relied on the broad authority under 38 U.S.C. 501(a) when establishing section 3.320. Section 3.320 and the presumptions it established are not based on the same authority that underlies section 3.317, to include 38 U.S.C. 1117 and 1118. Therefore, this comment is outside the scope of the rulemaking, and VA makes no change based on it.

II. Service in Afghanistan Under 38 CFR 3.317(a) and (b)

One commenter expressed concern that VA considers veterans who served in Afghanistan to be exposed to infectious diseases and fine particulate matter in the same manner as other veterans in Southwest Asia, however, excludes their service from the exposures and illnesses under paragraph (a) and (b) of 38 CFR 3.317. However, as explained above, this rulemaking and the interim final rule address regulations governing presumptive service connection for respiratory conditions based on presumed exposures to fine particulate matter and do not address 38 CFR 3.317.

Paragraphs (a) and (b) of 38 CFR 3.317 regulate claims for compensation due to undiagnosed illnesses and medically unexplained chronic multisymptom illnesses. The rule establishing 38 CFR 3.317 (a) and (b) (75 FR 59968) was based on a National Academies of Sciences, Engineering, and Medicine (NASEM) review focused primarily upon health effects of exposure to hazards associated with service in the Southwest Asia theater of operations, as that area was defined for purposes of the 1991 Gulf War. See Executive Order 12744 (Jan. 12, 1991). Afghanistan is not located in Southwest Asia and therefore was not included as a qualifying location under 38 CFR 3.317(a) and (b). However, section 405 of the Sergeant First Class Heath Robinson Honoring our Promise to Address Comprehensive Toxics Act of 2022, Pub. L. 117-168, (PACT Act) expanded the definition of a Persian Gulf veteran by adding Afghanistan, Israel, Egypt,

Turkey, Syria, and Jordan as eligible locations under 38 U.S.C. 1117. Thus, individuals with service in Afghanistan are no longer excluded from the exposures and illnesses under paragraph (a) and (b) of 38 CFR 3.317 due to the PACT Act. But implementing that provision of the PACT Act is beyond the scope of this rule, and VA plans to address that statutory change in a separate rulemaking. Therefore, VA makes no changes based on this comment.

III. Effective Dates

Three commenters inquired about effective dates and stated that claims for the three new presumptive conditions should be granted retroactive effective dates in the same manner as claims under *Nehmer v. United States Department of Veterans Affairs*. *Nehmer* was a class-action lawsuit against VA by Vietnam veterans and their survivors, who alleged that VA had improperly denied their claims for service-connected compensation for disabilities allegedly caused by exposure to the herbicide Agent Orange in service. *See Nehmer* v. *U.S. Department of Veterans Affairs,* No. CV-86-6161 TEH (N.D. Cal.). 38 CFR 3.816 regulates effective date rules required by *Nehmer* and defines a *Nehmer* class member as "a Vietnam veteran who has a covered herbicide disease; or a surviving spouse, child, or parent of a deceased Vietnam veteran who died from a covered herbicide disease." 38 CFR 3.816(b). VA notes that the effective date provisions of the *Nehmer* court order and section 3.816 apply only to claims based on exposure to herbicides in the Republic of Vietnam during the Vietnam era and are therefore inapplicable to this final rule.

Further, as stated in the interim final rule, this rule applies to claims received by VA on or after the effective date of the rule and to claims pending before VA on that date. This will ensure that VA adheres to the provisions of its change-of-law regulation, 38 CFR 3.114, which states, "[w]here pension, compensation, dependency and indemnity compensation . . . is awarded or increased pursuant to a liberalizing law, or a

liberalizing VA issue approved by the Secretary or by the Secretary's direction, the effective date of such award or increase shall be fixed in accordance with the facts found, but shall not be earlier than the effective date of the act or administrative issue." Section 3.114 reflects ordinary statutory effective date principles that VA is bound to apply in cases outside the scope of *Nehmer*. *See* 38 U.S.C. 5110. Specifically, the law requires that the effective date for an award of benefits pursuant to an Act or administrative issue "shall not be earlier than the effective date of the Act or administrative issue." 38 U.S.C. 5110(g).

Therefore, VA makes no changes based on these comments.

IV. Exposures in Other Locations

One commenter inquired whether the interim final rule included exposure to fine particulate matter in other locations, specifically in Germany. 38 CFR 3.320 was based on scientific and medical studies that focused on the respiratory effects of fine particulate matter for Veterans who served in the Southwest Asia theater of operations, Afghanistan, Syria, Djibouti, and Uzbekistan during the Gulf War. As stated in the interim final rule, veterans began reporting a variety of respiratory health issues during and after the initial Gulf War conflict. As a result, Congress mandated that VA study the health outcomes of veterans deployed to the Southwest Asia theater of operations. VA then requested NASEM to study the evidence regarding respiratory health outcomes in veterans of the Southwest Asia conflicts. The results of that study form the basis for this rulemaking. As Germany was not a location considered in the study, it cannot be included as a qualifying location under 38 CFR 3.320. VA makes no changes based on this comment.

V. Eligible Locations in Southwest Asia

One commenter questioned whether eligible locations in Southwest Asia, Afghanistan, Syria, Djibouti, or Uzbekistan will be limited to specific bases or combat

outposts. The simple answer is no. A qualifying period of service for presumptive service connection based on exposure to fine particulate matter is defined as service in the Southwest Asia theater of operations during the Gulf War, or in Afghanistan, Syria, Djibouti or Uzbekistan on or after September 19, 2001, during the Gulf War. The Southwest Asia theater of operations refers to Iraq, Kuwait, Saudi Arabia, the neutral zone between Iraq and Saudi Arabia, Bahrain, Qatar, the United Arab Emirates, Oman, the Gulf of Aden, the Gulf of Oman, the Persian Gulf, the Arabian Sea, the Red Sea, and the airspace above these locations. 38 CFR 3.317(e)(2). The eligible locations listed under 38 CFR 3.320 are more expansive than specific bases or combat outposts. VA makes no changes based on this comment.

VI. Combat Presumption

One commenter stated that VA failed to consider that for "veterans who claim that their condition is a result of their combat service in Southwest Asia, their [*sic*] becomes an evidentiary burden shift that requires the VA to show affirmative evidence proving that the claimed presumptive condition did not manifest during service in Southwest Asia, the VA must confirm if an event after service caused the veteran's condition, or the VA must confirm if the claimed condition was directly caused as a result of the veteran's own willful misconduct or while under the influence of drugs or alcohol." The commenter suggested that claims based on combat service for asthma, rhinitis, and sinusitis, to include rhinosinusitis, already have a presumption in place that is equally advantageous to veterans as the new 38 CFR 3.320. VA disagrees with this suggestion.

There are three basic elements required to establish service connection: (1) a current disability, (2) an injury or disease that was incurred or aggravated during service, and (3) a causal relationship between the injury or disease and the veteran's

current disability. Several presumptions have been created to ease the burden of providing evidence of these three elements.

Consideration of combat service is directed by 38 CFR 3.304(d), which provides a reduced evidentiary burden for combat veterans in proving an in-service illness or injury (Element #2). *See Collette v. Brown*, 82 F.3d 389, 392-93 (Fed. Cir. 1996). However, the reduced evidentiary burden provided by 38 CFR 3.304(d) should not be confused with the presumption provided by 38 CFR 3.320. 38 CFR 3.320 eases the evidentiary burden of proving exposure to fine particulate matter in service (Element #2) and additionally addresses the requirement to demonstrate causation (Element #3). Claims for service connection based on combat must still show "a causal relationship between the present disability and the injury, disease, or aggravation of a preexisting injury or disease incurred during active duty." *See Shedden v. Principi*, 381 F.3d 1163, 1167 (Fed. Cir. 2004). We also note that while the presumptions in section 3.320 should, in the vast majority of cases, obviate the question of whether a given disease or injury was incurred in combat, to the extent rare cases genuinely implicate both regulations, VA sees no reason why they cannot operate to benefit the same veteran. As the presumption under the new 38 CFR 3.320 addresses different and additional aspects of establishing entitlement to service connection than 38 CFR 3.304(d), VA makes no changes based on this comment.

VII. Presumptive Service Connection for Vietnam Veterans Exposed to Asbestos

One commenter proposed that VA establish presumptive service connection for Vietnam Veterans who served aboard World War II era ships and were exposed to asbestos. As previously explained, this rulemaking is based on current medical and scientific evidence related to the respiratory health effects of fine particulate matter for veterans who served in the Southwest Asia theater of operations during the Gulf War, or in Afghanistan, Syria, Djibouti or Uzbekistan on or after September 19, 2001, during the

Gulf War. As this comment is beyond the scope of our rulemaking, VA makes no changes based on this comment.

VIII. Allergic Rhinitis

One commenter asked whether veterans who are currently service connected for allergic rhinitis with a 0 percent evaluation can file an appeal based on this amendment and what the criteria would be. Veterans who are already service connected and seek an increased evaluation because their condition has worsened should submit a claim for increased evaluation on VA Form 21-526EZ, Application for Disability Compensation and Related Compensation Benefits. VA makes no changes based on this comment.

Another commenter inquired whether claims for allergic rhinitis would warrant a VA examination to determine if this condition was in fact "chronic rhinitis" and therefore eligible for presumptive service connection. Generally, pursuant to 38 CFR 3.159(c)(4), VA will assist a claimant in obtaining an examination if it is necessary to decide the claim. An examination may serve the purpose of obtaining medical evidence relevant to establishing entitlement to benefits, such as information about diagnosis, onset, and etiology, or may be necessary to develop adequate information for rating purposes. Applying the criteria from 38 CFR 3.159(c)(4) to the substantive criteria of the version of section 3.320 implemented by the interim final rule, an examination is warranted in claims under 38 CFR 3.320(a)(2) when three criteria are met: 1) the veteran claims a qualifying condition listed at 38 CFR 3.320(a)(2)(i)-(iii) (or signs or symptoms of a qualifying condition under 38 CFR 3.320(a)(2)), 2) the veteran's military records show a qualifying period of service under 38 CFR 3.320(a)(5), and 3) evidence shows that the veteran's qualifying condition manifested within 10 years from the date of last discharge. However, as explained below, VA is removing the 10-year manifestation period, and so that criterion is no longer necessary for an examination to be warranted. Allergic rhinitis

is a covered condition under 38 CFR 3.320 as long as the condition is chronic in nature and not an acute manifestation. VA makes no changes based on this comment.

IX. Chronicity Should be Presumed

One commenter recommended that VA explicitly state that chronicity is presumed to be innate to asthma, rhinitis, and sinusitis, to include rhinosinusitis. The paragraph heading at 38 CFR 3.320(a)(2) is "*Chronic diseases associated with exposure to fine particulate matter*." 38 CFR 3.320 makes clear that the diseases associated with exposure to fine particulate matter are chronic in nature. However, as explained in the interim final rule notice, diseases that are seasonal or acute allergic manifestations in nature are not covered diseases as, pursuant to 38 CFR 3.380, "[s]easonal and other acute allergic manifestations subsiding in the absence of or removal of the allergen are generally to be regarded as acute diseases, healing without residuals." Therefore, VA makes no changes based on this comment.

X. Additional Respiratory Conditions Should be Included under 38 CFR 3.320

One commenter stated that VA failed to provide a reasonable explanation as to why asthma, rhinitis, and sinusitis, to include rhinosinusitis, were approved for presumptive service connection and not all 27 health outcomes listed in NASEM's 2020 report, Respiratory Health Effects of Airborne Hazards Exposures in the Southwest Asia Theater of Military Operations. As explained in the interim final rule, NASEM's report identified 27 of the most prevalent respiratory health outcomes experienced by Gulf War veterans. Of the 27 respiratory health outcomes, only three respiratory symptoms met the criteria for limited or suggestive evidence of an association with service in Southwest Asia: chronic persistent cough, shortness of breath (dyspnea), and wheezing. The remaining 24 conditions, including asthma, rhinitis, and sinusitis, had inadequate or insufficient evidence to determine an association.

To respond to the findings in NASEM's 2020 report, VA convened a workgroup of VA subject matter experts in disability compensation, health care, infectious diseases, occupational and environmental medicine, public health, epidemiology, toxicology, and research. The VA workgroup reviewed the most claimed chronic conditions related to airborne hazards for disability compensation benefits and found that asthma, sinusitis, and rhinitis were the most claimed and granted (on the basis of direct service connection) respiratory conditions, and these conditions also most closely represented the symptomatology of chronic persistent cough, shortness of breath (dyspnea), and wheeze. The VA workgroup then analyzed respiratory claims data comparing veterans who were deployed to Southwest Asia with veterans who had never been deployed. The VA workgroup found that the claim rates and service connection prevalence rates for asthma, rhinitis, and sinusitis were higher than for non-deployed veterans.

VA recognizes that there are limitations in evidence specific to deployed service members and a range in the strength of association between fine particulate matter exposure and the 27 respiratory health outcomes. However, section 501(a)(1) of title 38, United States Code, provides that "[t]he Secretary has authority to prescribe all rules and regulations which are necessary or appropriate to carry out the laws administered by [VA] and are consistent with those laws, including . . . regulations with respect to the nature and extent of proof and evidence and the method of taking and furnishing them in order to establish the right to benefits under such laws." This broad authority includes the establishment of a presumption of service connection and exposure under specified circumstances, provided there is a rational basis for the presumptions. For the reasons noted above and in the interim final rule, including the review of NASEM's 2020 report, review of internal claims data, and a comprehensive supplemental literature review, the Secretary has determined that there was a rational basis to support a presumption of service connection when there is proof of qualifying service (38 CFR 3.320(a)(5)) and

the subsequent development of asthma, rhinitis, or sinusitis, to include rhinosinusitis. However, the Secretary also determined that there was not a rational basis at this time to support creating a presumption of service connection for the remaining 24 health outcomes listed in NASEM's 2020 report. VA makes no changes based on this comment.

Multiple commenters also suggested that VA should create presumptions for additional conditions. For example, one commenter suggested that secondary health concerns for individuals diagnosed with asthma or severe sinusitis should be reviewed and added to 38 CFR 3.320. VA recognizes that chronic respiratory conditions can lead to numerous secondary health effects. However, for the reasons explained above and in the interim final rule, the Secretary determined that at this time there was a reasonable basis to support creating presumptions of service connection for only the three listed conditions. VA makes no changes based on this comment.

Another commenter specifically requested that VA create a presumption of service connection for chronic obstructive pulmonary disorder (COPD), chronic bronchitis, obstructive sleep apnea, and emphysema. The commenter stated that COPD, chronic bronchitis, obstructive sleep apnea, and emphysema involve symptoms of chronic persistent cough, shortness of breath, and wheezing and have increased claim rates that are comparable to or exceed those for asthma, rhinitis, and sinusitis. Another commenter questioned why obstructive sleep apnea was not added as a presumptive condition. For the reasons provided below, VA makes no changes based on these comments.

The complexity of the etiologic factors associated with obstructive sleep apnea were considered when establishing new presumptions under 38 CFR 3.320. Unlike asthma, sinusitis, and rhinitis, obstructive sleep apnea can be related to anatomic risk factors, such as craniofacial profile, structural abnormalities (e.g., pharyngeal wall

instability) and neck circumference. Furthermore, obesity and high body mass index are the strongest risk factors for obstructive sleep apnea.[1]

Additionally, provisions of the PACT Act added presumptions related to Gulf War service for additional respiratory conditions, including COPD, chronic bronchitis, and emphysema. Incorporation of provisions of this Act relevant to this regulation will be the subject of separate and future rulemakings.

Further, we note that section 202 of the PACT Act created a new process for establishing presumptions of service connection based on toxic exposure. Under the new process, VA is required to publish notice in the Federal Register, no less than once per year, to notify the public of the formal evaluations of environmental exposures and adverse health outcomes that the Secretary plans to conduct. With each notice published in the Federal Register, VA will seek public comment and hold an open meeting for members of the public to ensure that the public participates in the decision-making process (38 U.S.C. §§ 1171-1174). VA welcomes comments and contributions from the public on future notices.

XI. 10-Year Manifestation Period

VA received nine comments that either objected to or requested revision of the 10-year manifestation period requirement. VA found that several comments identified factors that were not considered in our initial analysis. Based on the substantive comments received, summarized below, VA will amend 38 CFR 3.320(a)(2) to remove

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[1] Abbasi A, Gupta SS, Sabharwal N, Meghrajani V, Sharma S, Kamholz S, Kupfer Y. A comprehensive review of obstructive sleep apnea. Sleep Sci. 2021 Apr-Jun;14(2):142-154. doi: 10.5935/1984-0063.20200056. PMID: 34381578; PMCID: PMC8340897.
Sutherland K, Keenan BT, Bittencourt L, Chen NH, Gislason T, Leinwand S, Magalang UJ, Maislin G, Mazzotti DR, McArdle N, Mindel J, Pack AI, Penzel T, Singh B, Tufik S, Schwab RJ, Cistulli PA; SAGIC Investigators. A Global Comparison of Anatomic Risk Factors and Their Relationship to Obstructive Sleep Apnea Severity in Clinical Samples. J Clin Sleep Med. 2019 Apr 15;15(4):629-639. doi: 10.5664/jcsm.7730. PMID: 30952214; PMCID: PMC6457518.

the requirement that asthma, sinusitis, and rhinitis manifest within 10 years from the date of the most recent separation from military service.

VA received one comment that questioned whether the 10-year manifestation period starts following the most recent period of service, even if qualifying service in the defined locations did not occur during that period of service, or whether the manifestation period begins at the end of the period of service during which actual qualifying service took place, even if there is a later, separate period of active service during which no qualifying service took place. Another commenter stated that the 10-year manifestation period was poorly defined.

Several commenters recommended that the 10-year manifestation period be extended beyond 10 years. One commenter noted they had suffered symptoms of respiratory illness since their discharge in 2006 but did not receive a formal diagnosis until 2020, more than 10 years since discharge. The commenter felt that they would not be eligible for presumptive service connection based on the 10-year manifestation period.

Several commenters objected to the 10-year manifestation period stating that many veterans do not seek treatment and self-treat with over-the-counter medications, making it difficult to produce medical records in support of their claim. One commenter noted that symptoms of asthma, rhinitis, and sinusitis that would warrant a non-compensable rating may not require treatment from a medical provider, and veterans may not seek medical treatment until their symptoms increase in severity and self-treatment of the disability is no longer sufficient. Several commenters also stated that veterans who served during the Gulf War were not aware that there was a possible connection between their symptoms and their service, as the scientific studies on the effects of fine particulate matter did not exist at the time; therefore, they may not have collected and maintained medical records in support of their claims.

Two commenters stated that the 10-year manifestation period for asthma, rhinitis, and sinusitis, to include rhinosinusitis, was not based on evidence establishing their development and should therefore be removed.

One commenter recommended elimination of the 10-year manifestation period and stated that for the majority of the diseases for which VA has recognized a presumption due to exposure to toxic substances, VA has not required that the disease manifest itself within any specific period of time after exposure.

One commenter stated that VA should not impose a manifestation period unless and until it provides the public with adequate notice and an opportunity to comment on a proposed manifestation period after publicly disclosing and providing all the scientific evidence it reviewed and considered. The commenter further stated that VA not citing every study used in its decision-making is a failure in Administrative Procedure Act required notice.

One commenter disagreed with the 10-year manifestation period starting after the veteran's most recent discharge, even if that discharge did not include a qualifying period of service, as long as there was a previous deployment to a qualifying location. The commenter recommended that the 10-year manifestation period begin at the date of discharge that included deployment to a qualifying location.

VA appreciates the substantive comments received on the interim final rule. Upon further evaluation, and weighing the evidence and claims data available against the substantive comments received, VA will amend 38 CFR 3.320(a)(2) to remove the 10-year manifestation requirement under 38 CFR 3.320(a)(2). While claims data was given significant weight in VA's initial determination, VA acknowledges that sufficient consideration was not given to the difficulties veterans may face in documenting the onset of their disease. In addition, section 405 of the PACT Act removed the manifestation period requirement under 38 U.S.C. 1117 (codified at 38 CFR 3.317). As

stated above, incorporation of provisions Pub. L. 117-168 will be the subject of separate and future rulemaking.

XII. Cause-and-Effect Standard

One commenter urged VA to reject a cause-and-effect standard in deciding whether to adopt a presumption of service connection and recommended a statistical association test as the most appropriate standard to use. In addition, the commenter urged VA to apply a statistical association test consistently when creating new presumptions. VA notes that it did not employ a cause-and-effect standard in determining to establish the presumptions of service connection for asthma, rhinitis, and sinusitis, to include rhinosinusitis. We note that the PACT Act created a new process for establishing presumptions of service connection based on toxic exposure. As stated above, implementation of provisions in Pub. L. 117-168 will be the subject of separate and future rulemaking. Therefore, VA makes no changes based on this comment.

XIII. Definition of Qualifying Period of Service

One commenter suggested that VA revise the language describing qualifying periods of service because the current wording may be misinterpreted as excluding Gulf War Veterans who served prior to September 19, 2001. The commenter noted that including the definition of the Southwest Asia theater of operations and the definition of the Gulf War within 38 CFR 3.320 would improve clarity. VA agrees with this recommendation and will amend 38 CFR 3.320 to include new paragraph (a)(6). 38 CFR 3.320(a)(6) will provide the definition of the Southwest Asia theater of operations, also found at 38 CFR 3.317(e)(2), and the definition of the Gulf War, also found at 38 CFR 3.2(i). This addition will clarify the intent of the regulation.

Additionally, VA is amending the definition of the qualifying periods of service in paragraph (a)(5) by adding space service to the list of types of service as it was inadvertently omitted from the interim final rule.

XIV. Clarifications/Future Reviews

One commenter asked that VA clarify that this rule in no way precludes future rules providing presumptive service connection for health conditions resulting from Gulf War service that are not respiratory in nature. While this rulemaking is based on current medical and scientific evidence related to the respiratory health effects of fine particulate matter on veterans who served during the Gulf War, VA will continue to review new scientific evidence as it develops relating to all health effects resulting from exposure to fine particulate matter. This rulemaking does not limit the future establishment of presumptive service connection for conditions related to respiratory or other body systems.

One commenter requested that VA notify stakeholders promptly regarding the progress of its ongoing review of health outcomes related to exposure to fine particulate matter, its expected timetable, the steps it is taking and will take as part of the review, and the opportunities for additional public comment that will be provided. VA appreciates the comments and valuable feedback it receives from its stakeholders and will continue to participate in notice-and-comment rulemaking (as appropriate) on future presumptive conditions.

VA appreciates all comments submitted in response to the interim final rule. Based on the rationale stated in the interim final rule and in this document, the final rule is adopted with changes as noted.

Administrative Procedure Act

VA has considered all comments submitted in response to the interim final rule and does not consider any to be objecting to the rule. Rather, the comments received have suggested ways in which the rule could be refined or liberalized. And for the reasons set forth in the foregoing responses to those comments, VA has made changes. Accordingly, based upon the authorities and reasons set forth in the interim

final rule, VA is adopting the provisions of the interim final rule as a final rule with the changes as described above.

Executive Orders 12866, 13563 and 14094

Executive Order 12866 (Regulatory Planning and Review) directs 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 14094 (Executive Order on Modernizing Regulatory Review) supplements and reaffirms the principles, structures, and definitions governing contemporary regulatory review established in Executive Order 12866 and Executive Order 13563. The Office of Information and Regulatory Affairs has determined that this rulemaking is a significant regulatory action under Executive Order 12866, section 3(f)(1), as amended by Executive Order 14094. The Regulatory Impact Analysis (RIA) associated with this rulemaking can be found as a supporting document at www.regulations.gov.

Regulatory Flexibility Act

The Regulatory Flexibility Act, 5 U.S.C. 601-612, is not applicable to this rulemaking because notice of proposed rulemaking is not required. 5 U.S.C. 601(2), 603(a), 604(a). On August 5, 2021, VA published an interim final rule in the Federal Register (86 FR 42724). This Final rule adopts the Interim Final rule without changes.

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).

Assistance Listing

The Assistance Listing program numbers and titles for this rule are 64.101, Burial Expenses Allowance for Veterans; 64.102, Compensation for Service-Connected Deaths for Veterans' Dependents; 64.104, Pension for Non-Service-Connected Disability for Veterans; 64.105, Pension to Veterans, Surviving Spouses, and Children; 64.109, Veterans Compensation for Service-Connected Disability; and 64.110, Veterans Dependency and Indemnity Compensation for Service-Connected Death.

Congressional Review Act

Under the Congressional Review Act, this regulatory action may result in an annual effect on the economy of $100 million or more, 5 U.S.C. 804(2), and so is subject to the 60-day delay in effective date under 5 U.S.C. 801(a)(3). In accordance with 5 U.S.C. 801(a)(1), VA will submit to the Comptroller General and to Congress a copy of this Regulation and the Regulatory Impact Analysis (RIA) associated with the Regulation.

List of Subjects in 38 CFR Part 3

Administrative practice and procedure, Claims, Disability benefits, Health care, Pensions, and Veterans.

Signing Authority

Denis McDonough, Secretary of Veterans Affairs, approved and signed this document on August 25, 2023, 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.

Jeffrey M. Martin,

Assistant Director,

Office of Regulation Policy & Management,

Office of General Counsel,

Department of Veterans Affairs.

For the reasons stated in the preamble, the interim final rule amending 38 CFR part 3, which was published at 86 FR 42724, is adopted as final with the following changes:

PART 3—ADJUDICATION

1. The authority citation for part 3 continues to read as follows:

Authority: 38 U.S.C. 501(a), unless otherwise noted.

Subpart A - Pension Compensation and Dependency and Indemnity Compensation

2. Revise § 3.320 to read as follows:

§ 3.320 Claims based on exposure to fine particulate matter.

(a) *Service connection based on presumed exposure to fine particulate matter—*

(1) *General.* Except as provided in paragraph (b) of this section, a disease listed in paragraphs (a)(2) and (3) of this section shall be service connected even though there is no evidence of such disease during the period of military service.

(2) *Chronic diseases associated with exposure to fine particulate matter.* The following chronic diseases will be service connected if manifested to any degree (including non-compensable) at any time following separation from a qualifying period of military service as defined in paragraph (a)(5) of this section.

(i) Asthma.

(ii) Rhinitis.

(iii) Sinusitis, to include rhinosinusitis.

(3) *Rare cancers associated with exposure to fine particulate matter.* The following rare cancers will be service connected if manifested to any degree (including non-compensable) at any time following separation from a qualifying period of military service as defined in paragraph (a)(5) of this section.

(i) Squamous cell carcinoma of the larynx.

(ii) Squamous cell carcinoma of the trachea.

(iii) Adenocarcinoma of the trachea.

(iv) Salivary gland-type tumors of the trachea.

(v) Adenosquamous carcinoma of the lung.

(vi) Large cell carcinoma of the lung.

(vii) Salivary gland-type tumors of the lung.

(viii) Sarcomatoid carcinoma of the lung.

(ix) Typical and atypical carcinoid of the lung.

(4) *Presumption of exposure.* A Veteran who has a qualifying period of service as defined in paragraph (a)(5) of this section shall be presumed to have been exposed to fine, particulate matter during such service, unless there is affirmative evidence to establish that the veteran was not exposed to fine, particulate matter during that service.

(5) *Qualifying period of service.* The term *qualifying period of service* means any period of active military, naval, air, or space service in:

(i) The Southwest Asia theater of operations during the Persian Gulf War.

(ii) Afghanistan, Syria, Djibouti, or Uzbekistan on or after September 19, 2001, during the Persian Gulf War.

(6) *Definitions*. (i) The term *Southwest Asia theater of operations means* Iraq, Kuwait, Saudi Arabia, the neutral zone between Iraq and Saudi Arabia, Bahrain, Qatar, the United Arab Emirates, Oman, the Gulf of Aden, the Gulf of Oman, the Persian Gulf, the Arabian Sea, the Red Sea, and the airspace above these locations, as defined in § 3.317(e)(2).

(ii) The term *Persian Gulf War* means August 2, 1990, through date to be prescribed by Presidential proclamation or law, as defined in § 3.2(i).

(b) *Exceptions.* A disease listed in paragraphs (a)(2) and (3) of this section shall not be presumed service connected if there is affirmative evidence that:

(1) The disease was not incurred during or aggravated by a qualifying period of service; or

(2) The disease was caused by a supervening condition or event that occurred between the Veteran's most recent departure from a qualifying period of service and the onset of the disease; or

(3) The disease is the result of the Veteran's own willful misconduct.

(Authority: 38 U.S.C. 501(a))

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