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**DEPARTMENT OF VETERANS AFFAIRS**

**8320-01**

**38 C.F.R. Part 3**

**RIN 2900-AR25**

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

**AGENCY:** Department of Veterans Affairs.

**ACTION:** Interim final rule.

**SUMMARY:** The Department of Veterans Affairs (VA) is issuing this interim final rule to amend its adjudication regulations to establish presumptive service connection for three chronic respiratory health conditions, i.e., asthma, rhinitis, and sinusitis, to include rhinosinusitis, in association with presumed exposures to fine, particulate matter. These presumptions would apply to veterans with a qualifying period of service, i.e., who served on active military, naval, or air service in the Southwest Asia theater of operations during the Persian Gulf War (hereafter Gulf War), as well as in Afghanistan, Syria, Djibouti, or Uzbekistan, on or after September 19, 2001, during the Gulf War. This amendment is necessary to provide expeditious health care, services, and benefits to Gulf War Veterans who were potentially exposed to fine, particulate matter associated with deployment to the Southwest Asia theater of operations, as well as Afghanistan,

Syria, Djibouti, and Uzbekistan. The intended effect of this amendment is to address the needs and concerns of Gulf War Veterans and service members who have served and continue to serve in these locations as military operations in the Southwest Asia theater of operations have been ongoing from August 1990 until the present time. Neither Congress nor the President has established an end date for the Gulf War. Therefore, to provide immediate health care, services, and benefits to current and future Gulf War Veterans who may be affected by particulate matter due to their military service, VA intends to provide presumptive service connection for the chronic disabilities of asthma, rhinitis, and sinusitis, to include rhinosinusitis, as well as a presumption of exposure to fine, particulate matter. This will ease the evidentiary burden of Gulf War Veterans who file claims with VA for these three conditions, which are among the most commonly claimed respiratory conditions.

**DATES:** Effective Date: This interim final rule is effective on [insert date of publication in the *Federal Register*].

Applicability Date: The provisions of this interim final rule shall apply to all applications for service connection for asthma, rhinitis, and sinusitis based on service in the Southwest Asia theater of operations, as well as Afghanistan, Syria, Djibouti, or Uzbekistan, during the Persian Gulf War that are received by VA on or after [insert date of publication in the *Federal Register*], or that were pending before VA, the United States Court of Appeals for Veterans Claims, or the United States Court of Appeals for the Federal Circuit on [insert date of publication in the *Federal Register*].

Comment Date: Comments must be received on or before [insert date 60 days after publication in the *Federal Register*].

**ADDRESSES:** Comments may be submitted through [www.Regulations.gov](http://www.Regulations.gov) or mailed to, Compensation Service, 21C, 1800 G Street, NW, Suite 644A, Washington, D.C. 20006. Comments should indicate that they are submitted in response to “RIN 2900-AR25 – Presumptive Service Connection for Respiratory Conditions Due to Exposure to Particulate Matter”. Comments received will be available at [regulations.gov](http://regulations.gov) for public viewing, inspection or copies.

**FOR FURTHER INFORMATION CONTACT:** Jane Che, Director, VA Schedule for Rating Disabilities Program Office (210), Compensation Service, Veterans Benefits Administration (VBA), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 461-9700. (This is not a toll-free telephone number.)

**SUPPLEMENTARY INFORMATION:**

**I. National Academies of Science, Engineering, and Medicine (NASEM)<sup>1</sup> and National Research Council (NRC) Reports**

More than 3.7 million United States service members have participated in operations in Southwest Asia. During and after the initial Gulf War conflict, veterans began reporting a variety of health problems, as documented through the NASEM Gulf

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<sup>1</sup> Originally, the National Academy of Medicine was the Institute of Medicine (IOM). In 2015, the IOM was reconstituted as the National Academy of Medicine (NAM), a component of the National Academies of Sciences, Engineering, and Medicine (NASEM). The term NASEM is used in this rule to refer to reports published by IOM and NAM.

War and Health, Volumes 1 through 11. In addition, concerns continue to be raised by service members, veterans, veteran advocates, and Congress about possible adverse health consequences related to in-theater exposures to particulate matter, including smoke from open burn pits, and other airborne hazards. Several studies by NASEM have examined the possible contribution of air pollution to adverse health effects among U.S. military personnel serving in the Middle East or their descendants.<sup>2</sup>

**a. 2010 NRC Report, Review of the Department of Defense (DoD)  
Enhanced Particulate Matter Surveillance Program**

In February 2008 the Department of Defense issued the Department of Defense Enhanced Particulate Matter Surveillance Program (EPMSP) Final Report.<sup>3</sup> The purpose of the study was to provide information on the chemical and physical properties of dust collected at deployment locations. Aerosol and bulk soil samples were collected during a period of approximately one year at 15 military sites—including Djibouti, Afghanistan (Bagram, Khowst), Qatar, United Arab Emirates, Iraq (Balad, Baghdad, Tallil, Tikrit, Taji, Al Asad), and Kuwait (Northern, Central, Coastal, and Southern regions). The Enhanced Particulate Matter Surveillance Program Report found that exposures in the region may have exceeded military/national exposure guidelines, including EPA's 24-hr NAAQS for PM<sub>2.5</sub> (see p.4 and p. 8, Figure 4-1).

The National Research Council (NRC) of NASEM independently reviewed DOD's final report in Review of the Department of Defense Enhanced Particulate Matter

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<sup>2</sup> NASEM, Gulf War and Health Series: Volume 3: Fuels and Products of Combustion (2005), <https://doi.org/10.17226/11180> and Volume 11: Generational Health Effects of Serving in the Gulf War (2018), <https://doi.org/10.17226/25162>. NASEM, Respiratory Health Effects of Airborne Hazards Exposures in the Southwest Asia Theater of Military Operations (2020), <https://doi.org/10.17226/25837>.

<sup>3</sup> Department of Defense Enhanced Particulate Matter Surveillance Program (EPMSP) Final Report (2008), <https://apps.dtic.mil/sti/pdfs/ADA605600.pdf>.

Surveillance Program Report in 2010.<sup>4</sup> The NRC committee highlighted that the EPMS was one of the first large-scale efforts to characterize PM exposure in deployed military personnel. Despite the practical challenges of conducting this effort in an austere deployment environment, the NRC Report found the results of the EPMS can be viewed as providing sufficient evidence that deployed military personnel endured occupational exposure to a potential hazard to justify implementation of a comprehensive medical-surveillance program to assess PM-related health effects in military personnel deployed in the Middle East Theater.

The NRC committee noted the EPMS's approach and methodological techniques preclude comparison to existing literature on air sampling and limit a full understanding of PM chemical composition. The study also describes the challenges associated with conducting exposure-assessment/health surveillance studies, including related to: the need to have co-deployed medical/public health experts to conduct sampling; limitations in monitoring technologies in harsh environments for which they have not been validated and where they may overestimate concentrations due to bounce-off problems, limitations in DOD's health effects studies, difficulties in characterization of exposure of troops to multiple sources (dust storms, vehicle emissions, and emissions from burn pits), and potential confounding factors (such as smoking). This along with the infrequency of sampling as well as the lack of consideration of other ambient pollutants in the deployment environment make it challenging to fully ascertain the relationship between exposure data and health effects. Further complicating this interpretation are the paucity of exposure data from earlier

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<sup>4</sup> National Research Council, Review of the Department of Defense Enhanced Particulate Matter Surveillance Program Report (2010), <https://doi.org/10.17226/12911>.

conflicts, such as the first Gulf War, that limit understanding of potential chronic health effects.

Despite these limitations, the NRC committee found that the EPMSP results clearly documented that deployed Service Members deployed in the Middle East “are exposed to high concentrations of PM and that the particle composition varies considerably over time and space.” Further, the NRC Report committee concluded that “it is indeed plausible that exposure to ambient pollution in the Middle East theater is associated with adverse health outcomes.” The health outcomes noted may occur both during service (acute) as well as manifest years after exposure (chronic).

**b. 2011 NASEM Report, Long-Term Consequences of Exposure to Burn Pits in Iraq and Afghanistan**

To further address and investigate this service member exposures, VA requested that NASEM examine the long-term health consequences of service members’ exposure to open burn pits while serving in Iraq and Afghanistan. In NASEM’s report, Long-Term Consequences of Exposure to Burn Pits in Iraq and Afghanistan, published in 2011, NASEM concluded that particulate matter from regional sources was of potential importance.<sup>5</sup> The report also recommended that VA expand its research studies beyond burn pits to explore the role of a broader range of possible airborne hazards.

**c. 2020 NASEM Report Respiratory Health Effects of Airborne Hazards Exposures in the Southwest Asia Theater of Military Operations**

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<sup>5</sup> NASEM, Long-Term Health Consequences of Exposure to Burn Pits in Iraq and Afghanistan (2011), <https://doi.org/10.17226/13209>.

In September 2018, the VA Post Deployment Health Services (PDHS) requested NASEM to study the respiratory health effects of airborne hazards exposures in Southwest Asia. Specifically, VA requested NASEM to evaluate the extent to which the existing knowledge base informs the understanding of the potential adverse effects of in-theater military service on respiratory health; identify gaps in research that could feasibly be addressed for outstanding questions; review newly emerging technologies that could aid in these efforts, and identify organizations that VA might partner with to accomplish this work.

A NASEM committee was formed to undertake this review, which completed its work in early summer 2020. On September 11, 2020, NASEM published its findings and recommendations in the report, Respiratory Health Effects of Airborne Hazards Exposures in the Southwest Asia Theater of Military Operations.<sup>6</sup> The NASEM committee focused on “hazards associated with burn pit exposures; excess mortality, cancer, bronchial asthma, chronic bronchitis, sinusitis, constrictive bronchiolitis, and other respiratory health outcomes that are of great concern to veterans; and emerging evidence on respiratory health outcomes in service members from research such as the Millennium Cohort Study, Study of Active Duty Military for Pulmonary Disease Related to Environmental Deployment Exposures (STAMPEDE), National Health Study for a New Generation of U.S. Veterans, Comparative Health Assessment Interview (CHAI) Study, Pulmonary Health and Deployment to Iraq and Afghanistan Objective Study, Effects of Deployment Exposures on Cardiopulmonary and Autonomic Function Study, and research being conducted by the Department of Veterans Affairs (VA) War Related

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<sup>6</sup> NASEM, Respiratory Health Effects of Airborne Hazards Exposures in the Southwest Asia Theater of Military Operations (2020), <https://doi.org/10.17226/25837>.

Illness and Injury Study Center (WRIISC) Airborne Hazards Center of Excellence (AHCE) in New Jersey.”

The NASEM committee formulated a list of 27 respiratory health outcomes it deemed to be of concern to veterans in its review: rhinitis, sinusitis, sleep apnea, vocal cord dysfunction, asthma, chronic bronchitis, chronic obstructive pulmonary disease, constrictive bronchiolitis, emphysema, acute eosinophilic pneumonia, hypersensitivity pneumonitis, idiopathic interstitial pneumonia, idiopathic pulmonary fibrosis, pulmonary alveolar proteinosis, sarcoidosis, acute bronchitis, pneumonia, tuberculosis, chronic persistent cough, shortness of breath (dyspnea), wheeze, esophageal cancer, laryngeal cancer, lung cancer, oral/nasal/pharyngeal cancers, as well as changes in pulmonary function and mortality due to diseases of the respiratory system.

The NASEM committee also considered different types and sources of exposure in its review: exposures associated with military operations in the Southwest Asia theater such as open burn pits, emissions from the 2003 Al-Mishraq sulfur plant fire, fuels, oil-well fires, nerve agents, and depleted uranium; regional environmental exposures such as air pollution, particulate matter, biologic agents and allergens, the toxicity of sand and dust; and occupational exposures such as vapors, gases, dust, and fumes.

The summarized findings of the 2020 NASEM report found that: (1) of the 27 different respiratory systems and diseases, three respiratory symptoms, i.e., chronic persistent cough, shortness of breath (dyspnea), and wheezing, met the criteria for limited or suggestive evidence of an association with service in Southwest Asia whereas the remaining 24 conditions had inadequate or insufficient evidence to determine an

association; (2) deployment to the 1990-1991 Gulf War and changes in lung function were determined to have limited or suggestive evidence of no association; and (3) many of the studies that report on these conditions were weakened by bias due to self-selection of the participants and self-reported outcomes and exposures and/or lack of control for confounders such as cigarette smoking.

The 2020 NASEM report stated that, while there was inadequate or insufficient evidence to determine an association between respiratory health outcomes and deployment to Southwest Asia, the existing studies included were limited in the available data in exposure estimation; the availability of pertinent health, physiologic, behavioral, and biomarker data, especially data collected both pre-and post-deployment; the amount of time that passed since exposure; and use of additional or alternate sources of data that might enrich analyses. The NASEM committee recommended that a new approach was needed to allow researchers to better examine and respond to whether specific respiratory outcomes are associated with deployment.

**d. VA's Review and Analysis of the 2020 NASEM Report: Respiratory Health Effects of Airborne Hazards Exposures in the Southwest Asia Theater of Military Operations.**

VA adheres to established internal procedure requiring it to review and respond to the recommendations in NASEM reports as outlined in VA Directive 0215, *Management of Reports Issued by the National Academies of Sciences, Engineering, and Medicine*. This VA Directive establishes the process for developing responses to all NASEM

studies, whether legally mandated or not. VA is not obligated by statute to provide Congress with VA's response to the 2020 NASEM report.

Pursuant to the VA Directive process, VA convened a workgroup of VA subject matter experts (SMEs) in disability compensation, health care, infectious diseases, occupational and environmental medicine, public health, epidemiology, toxicology, and research. The workgroup convened in early spring of 2021 and was composed of subject matter experts from the Veterans Health Administration and the Veterans Benefits Administration. This workgroup was charged with analyzing the information presented by NASEM and informing the VA Secretary of its findings. The VA workgroup used the same management, coordination, and collaboration process in responding to NASEM reports that are undertaken and submitted because of legal mandates.

Upon review of the findings and recommendations of the 2020 NASEM report, the VA workgroup noted that NASEM focused its review on "airborne hazards encountered during service in Southwest Asia Theater of Military Operations and Afghanistan" but did not opine on the relevance of the literature regarding the potential impact of long-term general population or occupational exposure to ambient levels of particulate matter pollution in nor the mechanistic, animal and toxicologic studies. Other Federal agencies (i.e., the Environmental Protection Agency, Occupational Safety and Health Administration, and the National Institutes for Health) have explored those relationships in detail. In addition, VA conducted its own review of epidemiological studies of population exposures related to cough, wheeze, and shortness of breath (dyspnea). The practice per VA Directive 0215 is that the VA workgroup on NASEM reports reviews pertinent literature that has been published during the time following the

NASEM literature review and writing/publication of the report. VA identified the narrowed focus of the NASEM literature that omitted areas of inquiry that were felt to be relevant to a complete understanding of the hazards associated with respiratory outcomes.

While the 2020 NASEM report concluded there was inadequate or insufficient evidence of an association between airborne hazards exposures in the Southwest Asia theater and subsequent development of rhinitis, sinusitis, and asthma, the report did conclude that certain respiratory symptoms such as chronic persistent cough, shortness of breath (dyspnea), and wheeze did have limited or suggestive evidence of an association. Understanding the immediate needs and concerns of the Gulf War cohort and airborne exposures in service, VA reviewed the most commonly claimed chronic conditions related to airborne hazards for disability compensation benefits (as described further below) and found that asthma, sinusitis, and rhinitis were the most commonly claimed and granted respiratory conditions, and these conditions also most closely represented the symptomatology of chronic persistent cough, shortness of breath (dyspnea), and wheeze. Sleep apnea was noted as the top claimed and granted respiratory condition. However, VA has not identified literature to support inclusion of sleep apnea as a presumption at this time. VA is currently reviewing the other disabilities reviewed by NASEM in the 2020 report for consideration for potential presumptive service connection. VA will utilize a phased approach in reviewing these disabilities to explore additional studies and data.

**e. VA's Review of internal claims data**

In response to the 2020 NASEM report, VA analyzed respiratory claims data for veterans who were deployed to Southwest Asia theater of operations and other locations and compared this data to a similar cohort of veterans who served during the same period but who had never deployed. Based on a review of aggregate claims data (see table below), VA observed that the claims rates for rhinitis, sinusitis, and asthma in the combined Gulf War I and GWOT deployed cohorts were higher than the claims rates of similar non-deployed cohorts. In addition, the service-connection prevalence rates, (i.e., percentage of cohort population for which VA finds service connection) were higher for the deployed cohorts than the non-deployed cohorts.

Table 1: Aggregate Disability Claims Data By Cohort

	<i><b>GW 1 Deployed</b></i>	<i><b>GW 1-Era Non- Deployed</b></i>	<i><b>GWOT Deployed</b></i>	<i><b>GWOT- Era Non- Deployed</b></i>	<i><b>K2 Cohort (subset)</b></i>	<i><b>Totals Across Cohorts</b></i>
<i><b>Population Size</b></i>	750,205	2,615,287	2,450,344	2,599,446	15,670	8.4 M
<b>Rhinitis</b>						
<i># Claims</i>	16,684	26,094	276,609	91,063	1,564	410,810
<i>Claims Rate<sup>1</sup></i>	2.2%	1%	11.3%	3.5%	10%	4.9%
<i># Grants</i>	8,405	14,131	206,348	64,522	1,198	293,406
<i>Grant Rate<sup>2</sup></i>	49.3%	54.2%	74.6%	70.9%	76.6%	71%
<b>Sinusitis</b>						
<i># Claims</i>	22,787	37,740	195,747	65,863	1,206	322,137
<i>Claims Rate<sup>1</sup></i>	2.2%	1.4%	8%	2.5%	7.7%	3.8%
<i># Grants</i>	9,869	18,235	87,151	29,849	571	145,104
<i>Grant Rate<sup>2</sup></i>	43.3%	48.3%	44.5%	45.3%	47.3%	45%
<b>Asthma</b>						

<i># Claims</i>	<i>18,126</i>	<i>25,052</i>	<i>123,739</i>	<i>46,180</i>	<i>435</i>	<i>212,805</i>
<i>Claims Rate<sup>1</sup></i>	<i>2.4%</i>	<i>1%</i>	<i>5%</i>	<i>1.8%</i>	<i>2.8%</i>	<i>2.5%</i>
<i># Grants</i>	<i>7,453</i>	<i>12,910</i>	<i>62,971</i>	<i>25,209</i>	<i>210</i>	<i>108,543</i>
<i>Grant Rate<sup>2</sup></i>	<i>41.8%</i>	<i>51.5%</i>	<i>50.9%</i>	<i>54.6%</i>	<i>48.3%</i>	<i>51%</i>

VBA Corporate Data, as of April 2021.

<sup>1</sup>“Claims Rate” is the percentage of cohort who filed a claim for service connection.

<sup>2</sup>“Grant Rate” is percentage of claims granted service connection.

This increased volume of claims and the sheer number of grants within the deployed cohorts for these conditions was critical in determining that more scientific review was necessary.

**f. EPA’s 2019 Integrated Science Assessment for Particulate Matter**

The Environmental Protection Agency’s (EPA’s) Integrated Science Assessment (ISA) “is a comprehensive evaluation and synthesis of policy-relevant science aimed at characterizing exposures to ambient particulate matter (PM), and health and welfare effects associated with these exposures.” The evaluation of the science and the overarching conclusions of the ISA serves as the scientific foundation for the review of the primary (health-based) and secondary (welfare-based) National Ambient Air Quality Standards for Particulate Matter in the United States. EPA’s ISA is prepared through a structured and transparent process that includes review by a formal independent panel of scientific experts (specifically, the Clean Air Scientific Advisory Committee) and by

the public.<sup>7</sup> The ISA uses a formal causal framework to classify the weight of the evidence for health effects.

The EPA's causal framework and approach to evaluating the scientific evidence that informs the corresponding causality determinations is outlined in the "Preamble To The Integrated Science Assessments (ISA)" available at <https://cfpub.epa.gov/ncea/isa/recordisplay.cfm?deid=310244>. Within the ISAs, the EPA evaluates and integrates evidence across scientific disciplines to assess the causal nature of relationships between PM and health or welfare effects. Specifically, during the evaluation of the health effects evidence the focus is on assessing consistency of effects within a discipline, coherence of effects across disciplines, and whether there is evidence of biological plausibility, while also taking into consideration the exposures of studies. The 2019 PM ISAs, EPA concluded that there is a "likely to be causal relationship" between both short- (i.e., hours up to a month) and long-term (i.e., month to years) exposure to fine particulate matter and respiratory health effects. Their definition of a 'likely to be causal relationship' is as follows, "*Evidence is sufficient to conclude that a causal relationship is likely to exist with relevant pollutant exposures. That is, the pollutant has been shown to result in health effects in studies where results are not explained by chance, confounding, and other biases, but uncertainties remain in the evidence overall.*" (c.f., Table P-2). For long-term PM<sub>2.5</sub> exposure, the strongest evidence is for changes in lung function and lung function growth and asthma

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<sup>7</sup> See, e.g., Clean Air Science Advisory Committee (CASAC), CASAC Review of the EPA's Integrated Science Assessment for Particulate Matter (External Review Draft - October 2018) (Apr. 2019), available at [https://yosemite.epa.gov/sab/sabproduct.nsf/6CBCBCC3025E13B4852583D90047B352/\\$File/EPA-CASAC-19-002+.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/6CBCBCC3025E13B4852583D90047B352/$File/EPA-CASAC-19-002+.pdf).

development in children. For adults there is evidence of acceleration of lung function decline, but inconsistent evidence for asthma development. Additionally, there is very limited, and inconsistent evidence of respiratory effects in healthy populations for both short- and long-term PM2.5 exposure. The strongest evidence is from animal toxicological studies, but this is not consistent with epidemiologic and controlled human exposure studies.

**g. VA's comprehensive supplemental literature review**

VA's Health Outcomes Military Exposures (HOME) and the Airborne Hazards and Burn Pits Center of Excellence (AHBPCE) completed a literature review of asthma, sinusitis, and rhinitis that specifically considered literature on general population exposures to particulate matter in non-deployment settings. Additional relevant literature published after the 2020 NASEM report was identified, and the VA workgroup met to define search parameters and inclusion/exclusion criteria for literature review.

The VA workgroup utilized the PICOTS (Patient, Intervention/Exposure, Comparator, Outcomes, Timing, Setting) Framework (see below, Table 2-PICOTS Framework) to strengthen the evidence gathered, which was refined in consultation with the Director of the Veterans Affairs Central Office Library, who conducted the primary search. VA SMEs also performed a supplemental search to ensure completeness. To incorporate the full range of evidence, human and non-human studies were considered. "Human studies" refers to observational, case-control, cohort, and meta-analytic studies involving people. "Non-human studies" refers to experimental research not performed on people but includes in-vivo and in-vitro studies in animal models, cell lines, and

donated human tissue. Such research is particularly useful for determining if specific air pollutants or a mixture thereof is related to respiratory symptoms that might reasonably be seen as precursors to or analogous with the symptoms documented in humans (i.e., biological plausibility). Initial literature screening was performed by VA SMEs to ensure appropriateness for review as well as assignment to human and non-human categories.

Additional SMEs were recruited to critically evaluate the strengths and weakness of evidence using a semi-quantitative transparent approach that was based on the Grading of Recommendations Assessment, Development and Evaluation (GRADE) structure. Each reviewing SME was provided with instructions on the overall goals of the review, the PICOTS framework (below) as well as instructions on the scoring matrix with the GRADE structure. Each article was evaluated by at least two subject matter experts, and the aggregate results were reviewed by a panel of subject matter experts to derive consensus opinion.

Table 2 - PICOTS Framework:

<i>PICOTS Term</i>	<i>Human Studies</i>	<i>Non-Human Studies</i>
Patient Population OR Problem	Adults (18-50 years)	Relevant model systems (e.g., in-vitro, in-vivo)
Intervention OR Exposure	Chronic exposure to particulate matter (PM <sub>2.5</sub> ) air pollution	Acute/chronic exposure to PM <sub>2.5</sub> <sup>8</sup>
Comparator	No exposure (or fine PM levels < federal guidelines)	No exposure
Outcomes	ICD-9/10 codes <sup>9</sup> for respiratory conditions and/or biomarkers consistent with these conditions	Respiratory condition phenotypes and/or observed behaviors

<sup>8</sup> Particulate matter size of 2.5 microns (PM<sub>2.5</sub>)

<sup>9</sup> World Health Organization (WHO) authorized the publication of the International Classification of Diseases 10th Revision (ICD-10), which was implemented for mortality coding and classification from death certificates. The U.S. developed a Clinical Modification (CM) (ICD-10-CM) for medical diagnoses based on WHO's ICD-10. ICD-10-CM replaces ICD-9-CM, volumes 1 and 2.

Timing	Months to years	Days to months
Setting	All countries	Not applicable

The 2020 NASEM report reviewed different types of exposures such as open burn pits, emissions from the 2003 Al-Mishraq sulfur plant fire, fuels, oil-well fires, nerve agents, and depleted uranium; regional environmental exposures such as air pollution, particulate matter, biologic agents, and allergens, toxicity of sand and dusts; and occupational exposures such as vapors, gases, dusts, and fumes. The supplemental review focused on fine particulate matter (PM<sub>2.5</sub>), which is a mixture of solid particles and liquid droplets that have a mean aerodynamic diameter  $\leq 2.5$  microns.<sup>10</sup> The focus on PM<sub>2.5</sub> was intentional for the following reasons: 1) PM<sub>2.5</sub> is generated by a variety of sources including smoke from open burn pits, 2) the DoD's Enhanced Particulate Matter Surveillance Program objectively measured in-theater concentrations and documented concentrations of PM<sub>2.5</sub> that may have exceeded military and national exposure guidelines at deployment locations, and 3) its small diameter facilitates greater deposition into the lung and potential for harmful effects. It is recognized that the source of fine particles and their resultant chemical composition are important considerations beyond particle size that should be considered yet there is a paucity of these data.

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<sup>10</sup> See US EPA, Particulate Matter (PM) Basics, <https://www.epa.gov/pm-pollution/particulate-matter-pm-basics>.

Based on the observations from many veterans and studies that described particulates in Southwest Asia<sup>11</sup>, VA determined that the levels of particulate matter were high in Southwest Asia and could present a health risk to service members.

## **II. VA's Findings Post-2020 NASEM Report Review**

As previously noted, the VA Technical Working Group identified knowledge gaps from the 2020 NASEM report and felt additional review of the literature, of relevance to service members and veterans, was warranted. In first reviewing the EPA's 2019 ISA on PM<sub>2.5</sub>, it was noted that the literature reviewed included those articles published through 2017. In addition, the ISA included both children and adults and had a much broader scope. The VA's supplemental review was targeted to address these knowledge gaps. Ultimately, VA's conclusions on respiratory health effects were similar to those of the EPA's 2009 and 2019 ISAs. The VA committee acknowledges that: (1) there exists a range in the strength of association between PM<sub>2.5</sub> exposure and the respiratory conditions of interest, and (2) most of the population epidemiological studies are based upon the assumption that chronic respiratory symptoms are a function of long-term exposure and reductions in ambient concentration lead to resolution of short-term

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<sup>11</sup> E.g., [Summary - Review of the Department of Defense Enhanced Particulate Matter Surveillance Program Report - NCBI Bookshelf \(nih.gov\)](#); Lindsay T. McDonald et. al, Physical and elemental analysis of Middle East sands from recent combat zones, *Am J Ind Med.* 2020;63:980–987. *Inhalation Toxicology*, 2020, VOL. 32, NO. 5, 189–199. <https://doi.org/10.1080/08958378.2020.1766602>; Johann P. Engelbrecht et al., Characterizing Mineral Dusts and Other Aerosols from the Middle East — Part 1: Ambient Sampling and Part 2: Grab Samples and Re-Suspensions, *Inhalation Toxicology*, *International Forum for Respiratory Research* 2009;4:297-326 and 327-336, <https://www.tandfonline.com/doi/full/10.1080/08958370802464273> and <https://www.tandfonline.com/doi/full/10.1080/08958370802464299>.

responses, and thus are difficult to apply to the exposure scenario experienced by service members in SW Asia. Therefore, VA's own literature review is not a sufficient basis for concluding that such exposure scenarios would be expected to cause incident (or new-onset) asthma, sinusitis, and/or rhinitis secondary to exposure.

VA acknowledges that there are important differences between potential exposures experienced by deployed service members and the populations in the studies relied upon by the ISA, and that there are limitations in evidence specific to deployed service members, as discussed above. In the context of regulating potential service connection related to presumed exposure and benefits there is a strong role for policy decisions.<sup>12</sup> The Secretary's broad discretion weighs more strongly here than it would if the science related to the composition and duration of actual particulate matter and airborne hazard exposures of service members were more robust.

#### **a. Gulf War Service**

Based on the weight of the evidence considered as described above, VA presumes exposure to PM<sub>2.5</sub> for Gulf War veterans deployed in the Southwest Asia theater of operations, as defined in 38 C.F.R. 3.317(e)(2) including 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, and the Red Sea during the Persian Gulf War. Based on presumed PM<sub>2.5</sub>

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<sup>12</sup> See, e.g., VA, Diseases Associated With Exposure to Certain Herbicide Agents (Hairy Cell Leukemia and Other Chronic B-Cell Leukemias, Parkinson's Disease and Ischemic Heart Disease), 75 FR 53202 (where there was only limited/suggestive evidence of an association between Ischemic Heart Disease and service and the Secretary exercised his discretionary authority to grant a presumption of service connection).

exposures, VA is granting a presumption of service connection for the chronic respiratory conditions of asthma, sinusitis, and rhinitis, to include rhinosinusitis, for the service periods and manifestation timelines that follow.

**b. Service in Afghanistan, Syria, and Djibouti on or after September 19, 2001**

The presumption of PM<sub>2.5</sub> exposure will also include those deployed to Afghanistan, Syria, and Djibouti on or after September 19, 2001, the earliest date when service members were deployed in these locations. The literature and studies overwhelmingly show the prevalence of particulate matter due to the nature of the arid climate in these locations as well.<sup>13</sup> VA determined that the Southwest Asia theater of operations, Afghanistan, Syria, and Djibouti had similar arid or semi-arid climates with periods of high winds to suspend geologic dusts and regional pollutants, adhered to or a part of these dusts, though the composition of the PM varies in different regions. Therefore, VA is including Afghanistan, Syria, and Djibouti as qualifying locations for presumption of service connection based on presumed exposure to PM<sub>2.5</sub>.

VA's Airborne Hazards and Open Burn Pit Registry, which encourages veteran participation to help VA gather data and better understand the potential health effects of exposure to airborne hazards during military service, currently covers the Southwest Asia theater of operations, including Afghanistan, and will also expand the locations to

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<sup>13</sup> See Lindsay T. McDonald, Steven J. Christopher, Steve L. Morton & Amanda C. LaRue (2020) "Physical and elemental analysis of Middle East sands from recent combat zones," *Inhalational Toxicology*, 32:5, 189-199, available at <https://doi.org/10.1080/08958378.2020.1766602>. See UNEP, WMO, UNCCD (2016) "Global Assessment of Sand and Dust Storms," United Nations Environment Programme, Nairobi, 1-15, 21-24, available at [https://uneplive.unep.org/redesign/media/docs/assessments/global\\_assessment\\_of\\_sand\\_and\\_dust\\_storms.pdf](https://uneplive.unep.org/redesign/media/docs/assessments/global_assessment_of_sand_and_dust_storms.pdf).

include Syria and Uzbekistan. Expansion will be encouraged through periodic communications through the MyPay pay notifications with both active duty service members and veterans, and through press releases as well as through VA's Health Outcomes Military Exposures website

(<https://www.publichealth.va.gov/exposures/burnpits/index.asp>).

As the literature and studies overwhelmingly demonstrate the prevalence of particulate matter in these locations, VA is including Afghanistan, Syria and Djibouti in addition to the Southwest Asia theater of operations, as qualifying locations for the presumption of service connection and exposure to fine, particulate matter.

### **c. Service in Uzbekistan on or after September 19, 2001**

Furthermore, the VA workgroup recommended that the presumption of PM<sub>2.5</sub> exposure include those service members who were deployed to Uzbekistan in support of Operation Enduring Freedom. In March 2020, the Army Public Health Center issued, Environmental Conditions at Karshi Khanabad (K-2) Air Base, Uzbekistan, to provide information to service members and veterans on environmental exposures at the K-2 Air Base and the risk of potential long-term adverse health effects related to such deployment.<sup>14</sup> It noted that service members, mostly Army, Air Force and some Marines, were stationed at the air base Camp Stronghold Freedom from October 2001 to November 2005. This fact sheet referenced the results of three declassified assessments conducted by DoD, namely the Environmental Site Characterization and

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<sup>14</sup> Army Public Health Center, Environmental Conditions at Karshi Khanabad (K-2) Air Base, Uzbekistan, Fact Sheet 64-038-0617, [https://phc.amedd.army.mil/PHC%20Resource%20Library/EnvironmentalConditionsatK-2AirBaseUzbekistan\\_FS\\_64-038-0617.pdf](https://phc.amedd.army.mil/PHC%20Resource%20Library/EnvironmentalConditionsatK-2AirBaseUzbekistan_FS_64-038-0617.pdf) (accessed July 30, 2021).

an Operational Health Risk Assessment completed in 2001 and follow-up Post-Deployment Occupational and Environmental Health Site Assessments completed in 2002 and 2004. The collective findings of these assessments found the K-2 Air Base often had high levels of dust and other particulate matter in the air, depending upon the season and weather conditions, but also noted significantly high levels of dust during dust storms. The fact sheet concluded that there was inconclusive evidence that there is an increased risk of chronic respiratory conditions associated with military deployment to K-2 Air Base. It was noted that DoD was collaborating with VA and independent researchers to further evaluate the potential long-term health risks related to deployment exposures.

Based on these findings regarding particulate matter exposure at the K-2 Air Base, VA will presume PM<sub>2.5</sub> exposure for those service members who were deployed to Uzbekistan on or after September 19, 2001. VA acknowledges that this will cover a greater geographic area and time frame than the other studies annotated in this document. However, VA believes this is a veteran-centric approach that will enhance its operational efficiencies by simplifying the work necessary for claims adjudication.

VA will continue to collaborate with DoD as directed by E.O. 13982, "Care of Veterans with Service in Uzbekistan," executed on January 19, 2021, and published on January 25, 2021. This Executive Order requires that DoD conduct a study to assess the conditions at the K-2 Air Base, to identify any toxic substances that may have contaminated the Air Base, and to conduct an epidemiological study on potential health consequences for those deployed to K-2 Air Base. Once the studies have been

completed, VA will consider the results and findings from these studies in making determinations regarding diseases subject to presumptive service connection.<sup>15</sup>

**d. Manifestation period for chronic respiratory conditions of asthma, rhinitis, and sinusitis**

The VA workgroup also considered the onset of asthma, rhinitis, and sinusitis after service members separated from military service in the Southwest Asia theater of operations as well as Afghanistan, Syria, Djibouti, and Uzbekistan. The consensus of the VA workgroup was that the manifestation period for these three chronic respiratory conditions was generally five to 10 years after separation from service, supported by a review of claims data, and the human and epidemiological studies showed that manifestation of these respiratory conditions did not exceed 10 years. The VA Secretary will apply the liberal manifestation period of 10 years from separation from the last period of military service that includes a qualifying period of service. VA believes that a 10-year manifestation period for eligibility for presumptive service connection for the chronic respiratory conditions of asthma, rhinitis, and sinusitis, to include rhinosinusitis, would not only allow veterans time to seek healthcare treatment and/or diagnosis for such respiratory conditions after they leave military service but would expand eligibility to more Gulf War veterans if a longer manifestation period of 10 years was designated as opposed to a shorter manifestation period, e.g., five years, which would preclude certain veterans who develop and/or are diagnosed with a chronic respiratory condition

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<sup>15</sup> E.O. 13982, "Care of Veterans With Service in Uzbekistan," (January 19, 2021), <https://www.federalregister.gov/documents/2021/01/25/2021-01712/care-of-veterans-with-service-in-uzbekistan>.

outside of this timeframe. In consideration of the length of the military operations in the Gulf War and a large number of affected service members and veterans, the 10-year manifestation period more liberally provides these veterans with the healthcare, benefits, and services they have earned.

In addition, there is no minimum time limit required for the length of military deployment. There is no set guidance on deployment and this varies widely by service: some smaller units may deploy for two weeks or less for specialized missions (special operations, construction units), while larger units may deploy for three to six months in the case of the U.S. Air Force, while some Army units have deployed in extreme cases for up to 15 months. There is no average deployment time because of these extremes.

Current VA regulations governing presumptive service connection for certain diseases such as chronic diseases, diseases associated with exposure to certain herbicide agents, and others, generally require that the presumptive disease manifest to a compensable degree (i.e., 10-percent or more) within the applicable time limits. However, in other contexts, some adjudication regulations governing presumptive service connection, for example presumptions for certain diseases due to exposure to ionizing radiation in 38 C.F.R. 3.311 and mustard gas in 38 C.F.R. 3.316 , as well as for amyotrophic lateral sclerosis in 38 C.F.R. 3.318, do not require the associated disability to have manifested to a compensable degree or more. VA is opting against requiring a specific level or dose of exposure to particulate matter and is instead taking the more veteran-centric approach of presuming sufficient exposure based on service in these identified regions. This approach accounts for the fact that precise or specific information on individual veterans' exposures that is needed to support more granular

policy is generally not available. In addition, this approach is also consistent with some other presumptions of service connection. For example, VA does not require exposure dosage for Vietnam veterans who were presumed to have been exposed to a herbicide agent such as Agent Orange.

Thus, VA will not require that the chronic respiratory conditions of asthma, rhinitis, and sinusitis, to include rhinosinusitis, manifest to a compensable degree or more so that more Gulf War Veterans can meet the lower eligibility criteria for presumptive service connection for exposure to fine, particulate matter even at a non-compensable level, which could also make veterans eligible to receive VA health care services for that condition at no cost to themselves.

One of the VA Secretary's priorities is to address the needs of the Gulf War cohort and to address the imminent need for care, services, and benefits to these veterans that is long overdue. The VA Secretary has determined that, for the three most commonly claimed respiratory health conditions, waiting for the results of additional studies for more conclusive scientific evidence would unnecessarily delay the delivery of services and benefits to veterans who served in the Gulf War. Based on the critical need to provide immediate benefits such as disability compensation and healthcare services to veterans as well as the supplemental analysis conducted by VA on the 2020 NASEM report, the VA Secretary is establishing presumptive service connection and a presumption of exposure to fine, particulate matter for those veterans who were deployed to the Southwest Asia theater of operations as well as Afghanistan, Syria, Djibouti, or Uzbekistan and who are diagnosed with the chronic respiratory conditions of asthma, rhinitis, sinusitis, to include rhinosinusitis, as long as such conditions

manifested within 10 years after separation from the last period of military service that includes a qualifying period of service.

This regulation is based on the Secretary's broad authority under 38 U.S.C. 501(a) to "prescribe all rules and regulations which are necessary or appropriate to carry out the laws administered by the Department and are consistent with those laws, including— . . . regulations with respect to the nature and extent of proof and evidence . . . in order to establish the right to benefits under such laws." The Secretary may create presumptions for conditions based on exposure to particulate matter under Congress's broad delegation of general regulatory authority in 38 U.S.C. 501(a)(1), provided there is a rational basis for the presumptions. NOVA v. Sec'y of Veterans Affairs, 669 F.3d 1340, 1348 (Fed. Cir. 2012) ("A regulation is not arbitrary or capricious if there is a 'rational connection between the facts found and the choice made.'" (quoting Motor Vehicle Mfrs. Ass'n. of the U.S. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983))). For the reasons explained above, the Secretary has determined that such a rational basis exists for the chronic respiratory conditions of asthma, rhinitis, and sinusitis, to include rhinosinusitis.

### **III. Part 3 Adjudication Regulations Update**

VA is amending § 3.159, the regulation regarding VA's duty to assist claimants in developing their claims, specifically by adding new § 3.320 to the current subparagraph that addresses VA's duty to provide medical examinations or obtain medical opinions when it has been established that a veteran has a disease or symptoms of a disease

listed in the regulations governing presumptive conditions in §§ 3.309, 3.313, 3.316, and 3.317.

VA is adding new § 3.320 to address presumptive service connection based on exposure to particulate matter for Gulf War veterans. Specifically, in new paragraph (a)(1), this provision outlines that service connection will be granted for the listed diseases for a veteran with a qualifying period of service as long as such disease manifested to any degree (i.e., non-compensable would qualify) within 10 years from separation from the last period of military service that includes a qualifying period of service. This is based on the presumption that a veteran with a qualifying period of service was exposed to fine, particulate matter during that service. New subparagraph (a)(2) lists the three new chronic diseases for presumptive service connection as asthma, rhinitis, and sinusitis, to include rhinosinusitis. Chronic rhinosinusitis will be considered for presumptive service connection if claimed or diagnosed as related to particulate matter exposure. Since chronic rhinosinusitis is also a disease that affects the nasal cavity and paranasal sinuses similar to chronic sinusitis and rhinitis, VA will adjudicate claims for chronic rhinosinusitis under the Diagnostic Code (DC) for sinusitis in 38 C.F.R. 4.97, Schedule of ratings-respiratory system under DCs 6510-6514 as appropriate.

Moreover, these three diseases must not be seasonal or an acute allergic manifestation in nature, as pursuant to 38 C.F.R. 3.380, “[s]easonal and other acute allergic manifestations subsiding on the absence of or removal of the allergen are generally to be regarded as acute diseases, healing without residuals.”

In the event a claimant does not specifically claim one of the three presumptive diseases by name but references symptoms of a general medical condition such as “shortness of breath” or “respiratory issues” on claims forms or applications, VA will continue to process and adjudicate such claims to include on the basis of presumptive service connection due to exposure to particulate matter. VA will review and verify the claimant’s records, including records of deployment to a qualifying period of service and area. If confirmed, VA will schedule an examination (or medical opinion if/when necessary) to determine if the veteran has a diagnosis for any of the new presumptive diseases and will adjudicate the claim under new § 3.320 accordingly.

In addition, new paragraph (a)(3) provides the presumption that a veteran with a qualifying period of service was exposed to fine, particulate matter in service. And new paragraph (a)(4) establishes the qualifying period of service in Southwest Asia theater of operations as during the Persian Gulf War, as well as Afghanistan, Syria, Djibouti, or Uzbekistan on or after September 19, 2001 during the Persian Gulf War.

Lastly, new paragraph (b) provides the three circumstances under which presumptive service connection will not be granted. VA will not consider a disease to be service connected on a presumptive basis if there is affirmative evidence that shows: (1) the disease was not incurred or aggravated during a qualifying period of service; (2) the disease was caused by a supervening condition or event that happened between the most recent separation from a qualifying period of service and the onset of the disease; or (3) the disease was due to the veteran’s own willful misconduct. This new paragraph (b) is consistent with current regulations governing other conditions based on presumptive service connection such as exposure to ionizing radiation, exposure to

mustard gas, or based on Gulf War service and disabilities due to undiagnosed illness and medically unexplained chronic multi-symptom illnesses. See 38 C.F.R. 3.311(g), 3.316(b), and 3.317(a)(ii)(7) and (c)(4).

#### **IV. Review of Other Part 3 Adjudication Regulations**

On July 30, 2008, Congress passed Public Law 110-289, the Housing and Economic Recovery Act of 2008, of which section 2603 expanded eligibility of specially adapted housing benefits to veterans who are permanently and totally disabled due to severe burn injuries “as determined pursuant to regulations prescribed by the Secretary.” On December 18, 2009, VA published in the Federal Register (74 FR 67145) a proposed rule to amend §§ 3.809 and 3.809a, the provisions governing specially adapted housing and special home adaptation grants, respectively, to conform with Pub. L. 110-289. (RIN 2900-AN21) Particularly, VA proposed to add eligibility criteria of severe burn injuries to § 3.809a to be defined as (1) deep partial thickness burns that have resulted in contractures with limitation of motion of two or more extremities or of at least one extremity and the trunk, or (2) subdermal burns that have resulted in contracture(s) with limitation of motion of one or more extremities or the trunk. Although Pub. L. 110-289 did not specifically address non-dermatological severe burn injuries, VA proposed to add a third eligibility criteria of severe burn injury, defined as residuals of an inhalation injury. VA noted that “inhalation injuries can result from the same incidents that cause severe burns” and attributed the breathing of steam or “toxic

inhalants such as fumes, gases, and mists present in a fire environment. Toxic inhalants comprise a variety of noxious gases and particulate matter that are capable of producing local irritation, asphyxiation, and systemic toxicity.” See 74 FR at 67147. It was also noted that a significant number of individuals with burns to the skin also have inhalational injury, and the presence of inhalational injury is a determinant of mortality. VA concluded that this third eligibility criteria for inhalational injury was a logical outgrowth of section 2306 of P.L. 110-289 that added severe burn injury as a qualifying disability for special home adaptation grants as the law made no mention of inhalation injury.

Taken together, the fact that inhalation injury arose from legislation that only established severe burn injury as a qualifying injury for specially adapted housing and special home adaptation grants and that VA’s explanation for adding inhalation injury consistently describes such injury as attributable to combustion or fire environments and events that could cause severe burn injuries, VA concluded that the inhalation injury provision of § 3.809a would only apply to cases where veterans could also be exposed to possible severe burn injury (e.g., firefighting, escaping a burning building, etc.)

With regard to inhalation injuries for special home adaptation grants and PM exposure, VA concludes that the majority of these sources of particulate matter would not immediately put veterans in danger of suffering severe burn injury as particulate matter is ubiquitous in the environment. Therefore, VA will not automatically presume that anyone who is permanently and totally disabled due to a respiratory illness as a result of exposure to particulate matter will automatically qualify for special home adaptation grant (per 38 C.F.R. 3.809a) based on the eligibility criteria of inhalation

injury. Instead, the evidentiary record must show that the respiratory illness (or residuals) were due to an event where the possibility of severe burn injury may have occurred.

### **Administrative Procedure Act**

Pursuant to 5 U.S.C. 553(b)(B) and (d)(3), VA has found that there is good cause to publish this rule without prior opportunity for comment and to publish this rule with an immediate effective date. It is necessary to immediately implement this interim final rule in order to carry out the VA Secretary's decision to address the needs of service members and veterans who have been exposed to airborne hazards, i.e., particulate matter, due to their service in the Southwest Asia theater of operations, Afghanistan, Syria, Djibouti, or Uzbekistan. Delay in the implementation of this rule would be contrary to the public interest.

The new presumptions are entirely pro-claimant in nature. And because VA has a sufficient scientific basis to support the new presumptions, continuing to deny claims that could be granted under the presumption while rulemaking is ongoing would unnecessarily deprive veterans and beneficiaries of benefits to which they would otherwise be entitled and prolong their inability to timely receive benefits. Additionally, this could create risks to beneficiaries' welfare and health that would be exacerbated by any additional delay in implementation. Due to the complexity and the historical scientific uncertainty surrounding these issues of airborne hazard exposures and

disease, many veterans who will be affected by this rule have long borne the burden and expense of their disabilities while awaiting the results of research and investigation. Under these circumstances, imposing further delay on their receipt of benefits, potentially at the risk of their welfare and health, is contrary to the public interest.

Further, the Secretary's decision to extend certain VA-administered benefits to service members and veterans who have been exposed to airborne hazards, i.e., particulate matter, due to their service in the Southwest Asia theater of operations, Afghanistan, Syria, Djibouti, or Uzbekistan requires immediate effect to help them access these benefits without undue delay, particularly given that the COVID-19 pandemic, with its sustained adverse economic consequences, may have reduced or limited their personal resources. For veterans that are not otherwise eligible for health care, these presumptions could result in needed health care eligibility based on service connection. For this reason, delay in implementation of this rule would be contrary to the public interest.

5 U.S.C. 553(d) also requires a 30-day delayed effective date following publication of a rule, except for "(1) a substantive rule which grants or recognizes an exemption or relieves a restriction; (2) interpretative rules and statements of policy; or (3) as otherwise provided by the agency for good cause found and published with the rule." Pursuant to section 553(d)(3), the Secretary finds that there is good cause to make the rule effective upon publication, for the reasons discussed above.

For the foregoing reasons, and as explained in further detail in the interim final rule, the Secretary of Veterans Affairs is issuing this rule as an interim final rule with an immediate effective date. However, VA will consider and address comments that are

received within 60 days of the date this interim final rule is published in the Federal Register.

### **Executive Orders 12866 and 13563**

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

### **Regulatory Flexibility Act**

The Secretary hereby certifies that this interim final rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act (5 U.S.C. 601-612). The certification is based on the fact that only individuals, not small entities or businesses, will be affected. Therefore, pursuant to 5 U.S.C. 605(b), the initial and final regulatory flexibility analysis requirements of 5 U.S.C. 603 and 604 do not apply.

### **Unfunded Mandates**

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

### **Paperwork Reduction Act**

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

### **Catalog of Federal Domestic Assistance**

The Catalog of Federal Domestic Assistance program 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**

This regulatory action is a major rule under the Congressional Review Act, 5 U.S.C. 801-808, because it may result in an annual effect on the economy of \$100 million or more. 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 associated with the regulation. However, for the reasons explained above, VA has found that there is good cause to publish this rule with an immediate effective date, pursuant to 5 U.S.C. 808(2).

### **List of Subjects**

#### **38 C.F.R. Part 3**

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

### **Signing Authority**

Denis McDonough, Secretary of Veterans Affairs approved this document on July 12, 2021 and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs.

***Michael P. Shores,***  
Director,  
Office of Regulation Policy & Management,  
Office of the Secretary,  
Department of Veterans Affairs.

For the reasons stated in the preamble, the Department of Veterans Affairs amends 38 C.F.R. part 3 as set forth below:

**PART 3 – ADJUDICATION**

Subpart A – Pension, Compensation, and Dependency and Indemnity Compensation

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

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

2. Amend § 3.159 by revising paragraph (c)(4)(i)(B) to read as follows:

**§3.159 Department of Veterans Affairs assistance in developing claims.**

\* \* \* \* \*

(B) Establishes that the veteran suffered an event, injury or disease in service, or has a disease or symptoms of a disease listed in §§ 3.309, 3.313, 3.316, 3.317, and 3.320 manifesting during an applicable presumptive period provided the claimant has the required service or triggering event to qualify for that presumption; and

\* \* \* \* \*

3. Add § 3.320 to read as follows:

**§3.320 Claims based on exposure to particulate matter**

(a) *Service connection based on presumed exposure to particulate matter.* (1) Except as provided in paragraph (b) of this section, a disease listed in paragraph (a)(2) of this section shall be service connected even though there is no evidence of such disease during the period of service if it becomes manifest to any degree (including non-

compensable) within 10 years from the date of separation from military service that includes a qualifying period of service as defined in paragraph (a)(4) of this section.

(2) *Chronic diseases associated with exposure to particulate matter.* The chronic diseases referred to in paragraph (a)(1) of this section are the following:

(i) Asthma.

(ii) Rhinitis.

(iii) Sinusitis, to include rhinosinusitis.

(3) *Presumption of exposure.* A veteran who has a qualifying period of service as defined in paragraph (a)(4) 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.

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

(i) The Southwest Asia theater of operations, as defined in § 3.317(e)(2), during the Persian Gulf War as defined in § 3.2(i).

(ii) Afghanistan, Syria, Djibouti, or Uzbekistan on or after September 19, 2001 during the Persian Gulf War as defined in § 3.2(i).

(b) A disease listed in paragraph (a)(1) 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.