medical invoice reflecting the adjusted balance due after applying the sliding fee and/or catastrophic fee waiver. The invoice modified to reflect fee adjustments or waiver under the MHS MPWP will include notification of the requirement to transfer delinquent debts to the Department of the Treasury if, after any modification under the MHS MPWP, an unpaid invoice becomes delinquent.

(2) For disapproved applications, the DHA will issue a letter by U.S. mail to the patient's last known address reflecting the reason why the application was disapproved. The letter will inform the patient of the right to reapply should the patient's financial circumstances change.

(n) *Collection in installments.* Patients approved for a sliding scale fee reduction or catastrophic fee waiver shall have amounts collected in installments for a term not to exceed 72 months. Patients may choose to pay their balance in a lump sum payment.

(o) *Application for a 10 U.S.C. 1079b(b) waiver.* (1) *Basis for a waiver.* Waivers may be granted when—

(i) The patient has provided the DoD with a completed DD Form 2569 (even for patients who possess no valid health insurance) and applicable insurance payments have been applied;

(ii) The patient has previously submitted a completed application to the MHS MPWP (32 CFR 220.12(k)) and was provided any applicable discounts;

(iii) The patient provided additional information indicating that the MHS MPWP did not sufficiently mitigate severe financial harm; and

(iv) A DoD competent medical authority confirms in writing (on the DD Form 3201) that the care provided to the patient enhanced the KSAs of the DoD healthcare provider.

(v) If the above conditions are met, the Director of DHA may exercise discretionary authority to waive the medical invoice.

(2) *Method to request a waiver.* Patients must submit a completed DD Form 3201–1, ''Request for Medical Debt Waiver Military Health System Modified Payment and Waiver Program.'' All DoD invoices will include the address where a patient may submit a waiver request.

(3) *Response to a request for waiver.* Unless additional time is needed (*e.g.,* to verify a patient's documentation), the DoD shall make a decision on the request within 90 days. The DoD will provide a response in writing to the patient, as well as a copy of the medical invoice reflecting the balance due. Waivers that are approved under 10 U.S.C. 1079b(b) may require reporting to the IRS and issuance of a IRS Form 1099–C.

(p) *Debts transferred to Treasury that are subsequently processed through insurance.* In any instance where a debt is transferred to Treasury and a lower balance is assigned to a Treasury-managed debt due to a claim being subsequently processed through insurance, the DoD shall recall the debt back to the DoD for management actions and notify Treasury to delete the debt from its systems and reverse any adverse reporting that occurred against the debt.

(q) *Delinquent Accounts.* Delinquent accounts will be processed in accordance with the Debt Collection Improvement Act of 1996 and its implementing regulation 31 CFR parts 900–904 (Federal Claims Collection Standards).

(r) *Applications for MHS MPWP Received for Delinquent Accounts Transferred to the Department of the Treasury.* Individuals may still submit an application for the MHS MPWP after their account has been transferred to the Cross-Servicing Program (''Cross-Servicing'') of the Department of the Treasury, Bureau of the Fiscal Service; however, any reductions to the medical invoice from the MPWP may be subject to interest, penalties, and costs. When patients apply to the MHS MPWP after their accounts were transferred to Cross-Servicing, their debts will remain at Cross-Servicing unless and until the DoD determines that they are eligible for a reduction under the MHS MPWP. The DoD may recall the debt from Cross-Servicing after it determines that the debt is eligible for a reduction under the MHS MPWP. Patients may request reconsideration for the MHS MPWP when their financial circumstances appear to have significantly changed.

(s) *Reporting to IRS and Furnishing of IRS Forms 1099–C (Cancellation of Debt).* The DoD will report to IRS, and furnish to patients, IRS Forms 1099–C for all 10 U.S.C. 1079b(b) waivers issued during the previous calendar year where required by 26 U.S.C. 6050P. IRS reporting will not be done for portions of a bill which have been adjusted downwards due to insurance processing, or by assignment of a sliding fee/catastrophic fee waiver to the debt. The IRS Forms 1099–C will reflect amounts waived under the DHA Director's discretionary authority.

(t) *Refunds not permitted for amounts previously paid.* Except for circumstances specified in §§ 220.12(p) and 220.12(u)(3), financial relief under the MHS MPWP may only be granted for amounts still due by the patient; an application for financial relief cannot be used to obtain a refund for any amounts previously paid.

(u) *Claims involving tortfeasors and third-party payers.* No discount or waiver of fees under 10 U.S.C. 1079b shall be interpreted to be applicable to tortfeasors under the FMCRA, 42 U.S.C. 2651, or third-party payers under 10 U.S.C. 1095.

(1) For patients who indicate that their injury/disease was caused by a third party, DoD MTFs will follow procedures established under the Medical Affirmative Claims program.

(2) Patients who have a remaining balance after insurance remittances or recoveries from third-party tortfeasors may apply for relief of any remaining medical debt.

(3) Payments toward the medical debt that were made by the patient prior to settlement of the claim with the tortfeasor will be offset against any balances owed by the patient or may be refunded to the patient if no balance is owed.

Patricia L. Toppings,

OSD Federal Register Liaison Officer, Department of Defense.

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DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 3

RIN 2900–AR75

VA Adjudication Regulations for Disability or Death Benefit Claims Based on Toxic Exposure

AGENCY: Department of Veterans Affairs.

ACTION: Proposed rule.

SUMMARY: The Department of Veterans Affairs (VA) is proposing to amend its adjudication regulations to implement provisions of the Sergeant First Class Heath Robinson Honoring our Promise to Address Comprehensive Toxics Act of 2022 (PACT Act or Act). The statute amended procedures applicable to claims based on toxic exposure and modified or established presumptions of service connection related to toxic exposure. Pursuant to the Act, VA is proposing to remove the manifestation period requirement and the minimum compensable evaluation requirement from Persian Gulf War claims based on undiagnosed illness and medically unexplained chronic multisymptom illnesses. VA is also proposing to expand the definition of a Persian Gulf veteran; update the list of locations eligible for a presumption of exposure to

toxic substances, chemicals, or airborne hazards based on service during the Persian Gulf War; and add presumptions of service connection for 23 diseases associated with exposure to toxins. To implement additional provisions of the Act, VA is also proposing to codify the procedure for determining when medical examinations and nexus opinions are required for claims that cannot be considered on a presumptive basis and the evidence establishes participation in a toxic exposure risk activity (TERA). Additional provisions of the PACT Act will be addressed in separate, future rulemakings.

DATES: Comments must be received on or before December 2, 2024.

ADDRESSES: Comments must be submitted through *www.regulations.gov.* Except as provided below, comments received before the close of the comment period will be available at *www.regulations.gov* for public viewing, inspection, or copying, including any personally identifiable or confidential business information that is included in a comment. We post the comments received before the close of the comment period on *www.regulations.gov* as soon as possible after they have been received. VA will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the commenter will take actions to harm the individual. VA encourages individuals not to submit duplicative comments. We will post comments from multiple unique commenters even if the content is identical or nearly identical to other comments. Any public comment received after the comment period's closing date is considered late and will not be considered in the final rulemaking. In accordance with the Providing Accountability Through Transparency Act of 2023, a plain language summary (not more than 100 words in length) of this proposed rule is available at *www.regulations.gov,* under RIN 2900–AR75.

FOR FURTHER INFORMATION CONTACT: Sara Cohen, Lead Analyst, Regulations Staff (211C); Robert Parks, Chief, Regulations Staff (211C), 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 telephone number.)

SUPPLEMENTARY INFORMATION:

I. Background and Statutory Authority

The PACT Act expanded eligibility for health care and disability compensation benefits for veterans who were exposed to toxic substances during military service. The law established a presumption that veterans were exposed to certain substances, chemicals, and airborne hazards if they served in various specified locations during certain time frames. The law created a statutory framework for VA to provide medical examinations in order to obtain nexus opinions when a veteran submits a claim for compensation for a non-presumptive condition with evidence of a disability and evidence of participation in a toxic exposure risk activity (TERA) in service. The law also expanded the definition of ''Persian Gulf veteran'' under 38 U.S.C. 1117 to include six new locations, allowing veterans with service in those locations during the relevant time period to qualify for presumptions of service connection based on disability due to undiagnosed illness and medically unexplained chronic multisymptom illnesses (MUCMI). The PACT Act also created new 38 U.S.C. 1119, Presumptions of toxic exposure, which established a presumption of specific toxic exposures for certain covered veterans. The Act also created new 38 U.S.C. 1120, which established presumptions of service connection for 23 diseases that are associated with exposure to burn pits and other toxins. Although that section originally contained 24 diseases, lymphomatic cancer of any type was later removed as a technical amendment by Public Law 117–623, as the term ''lymphomatic cancer'' is not recognized by the medical and scientific community. However, lymphoma cancer of any type remains a covered disease presumptive to exposure to burn pits and other toxins under 38 U.S.C. 1120. The presumption of service connection under 38 U.S.C. 1120 applies to ''covered veterans'' under 38 U.S.C. 1119.

II. Proposed Changes to § 3.1 Definitions

VA is proposing to implement several portions of the PACT Act by adding new definitions to 38 CFR 3.1. VA is proposing to add the statutory definition of ''toxic exposure risk activity'' to 38 CFR 3.1, in new paragraph (bb). Section 303 of the PACT Act established 38 U.S.C. 1168, which governs medical nexus examinations based on TERA. 38 U.S.C. 1168(a) provides that if a veteran submits a claim for service-connected compensation with evidence of a disability and evidence of participation in a TERA during active military, naval, air, or space service, and such evidence is not sufficient to establish service connection for the disability, VA will provide the veteran with a medical examination and obtain a medical nexus opinion as to whether it is at least as likely as not that there is a nexus between the disability and the TERA. 38 U.S.C. 1168(c) states that ''the term ''toxic exposure risk activity'' has the meaning given that term in section 1710(e)(4) of this title.'' 38 U.S.C. 1710(e)(4) defines a ''toxic exposure risk activity'' as ''any activity that requires a corresponding entry in an exposure tracking record system (as defined in section 1119(c) of this title) for the veteran who carried out the activity; or that the Secretary determines qualifies for purposes of this subsection when taking into account what is reasonably prudent to protect the health of veterans.''

VA has determined that if a veteran's military service qualifies for a presumption of exposure, VA must concede participation in a TERA. Locations with a presumption of exposure include any recognized radiation risk activity locations (38 U.S.C. 1112 and 38 CFR 3.309(d)(3)(ii)); locations associated with herbicide exposure (38 U.S.C. 1116); the Persian Gulf (38 U.S.C. 1117); locations associated with exposure to burn pits (38 U.S.C. 1119); and at Camp LeJeune (38 CFR 3.307(a)(7)). If a veteran served in a location that qualifies for a presumption of exposure and submits a claim for a non-presumptive condition with evidence of a disability, a disability examination and medical opinion based on TERA must be requested, unless an exception under 38 U.S.C. 1168(b), as described below in section III, applies.

As required by the PACT Act, if an entry in an exposure tracking record system reflects an activity carried out by the veteran while on active duty, then the veteran will be considered to have participated in a TERA (38 U.S.C. 1710(e)(4)(C)). VA generally proposes to recognize participation in a TERA based on any entry in an exposure tracking record system (*e.g.,* the Individual Longitudinal Exposure Record (ILER)). However, there are circumstances where an ILER entry may show only a claimant's name and contain no deployment information nor show any potential toxic exposure. For an entry in an exposure tracking record system to constitute participation in a TERA, based on the statutory definition of such term (38 U.S.C. 1710(e)(4)(C)), the entry must correspond to an activity performed by the veteran. Because name-only entries do not contain any evidence of an activity performed by the veteran, VA proposes that these entries will not constitute participation in a

TERA, as name-only entries do not fall under the statutory definition of TERA.

VA also proposes that records in an exposure tracking record system from contractor or civilian service periods should not be accepted as participation in a TERA. For example, ILER records contain different component categories. These components include mixed deployment histories to include periods of Active Duty, Reserves, National Guard, civilian time, and contractor work. An examination and TERA medical opinion are required under 38 U.S.C. 1168(a) when there is evidence of a disability and evidence of participation in a TERA during active military, naval, air, or space service. Because contractor or civilian service periods are not considered active military service, deployments as a civilian or contractor listed in an exposure tracking record system should not be used to concede participation in a TERA for the purpose of triggering the examination requirements under 38 U.S.C. 1168(a).

VA also proposes to amend 38 CFR 3.1 by adding new paragraph (cc) defining the term ''exposure tracking record system.'' The term would be defined as in section 302 of the PACT Act, to mean any system, program, or pilot program used by the Secretary of Veterans Affairs or the Secretary of Defense to track how veterans or members of the Armed Forces have been exposed to various occupational or environmental hazards, including ILER, or successor system.

ILER is a joint Department of Defense (DoD) and VA web-based application that provides the ability to link a veteran to military exposures and/or deployments to improve the efficiency, effectiveness, and quality of health care, epidemiology, health effects research, and adjudication of benefits associated with exposures. The exposure data in ILER currently integrates information from multiple sources, including, but not limited to, the Defense Occupational and Environmental Health Readiness System—Industrial Hygiene (DOEHRS–IH), Armed Forces Health Surveillance Branch (AFHSB), Defense Manpower Data Center (DMDC), and Military Health System (MHS) Data Repository. ILER currently provides access to over six million unique veteran records and acts as a single access point to deployment history; including time, location, military and non-military deployment data, military occupational specialty (MOS), occupational hazard data, environmental hazards known or later found, monitoring performance in the area(s), diagnosis, treatment, and laboratory data. ILER has the capability of enabling a search by individual, location, exposure type, and health effect.

DOEHRS is the biggest source of information for ILER. DOEHRS contains information resulting from routine investigations for occupational and other health standards (similar to investigations for compliance with the Occupational Safety and Health Act, the Safe Drinking Water Act, or other investigations that may be conducted by the Environmental Protection Agency). Data stored in DOEHRS contains area sampling information and analysis for potentially hazardous conditions; specifically, this information includes analysis of recorded data. The surveillance data is linked by ILER through the DMDC to the names of individuals present at the time of the area sampling so that if an unsafe environment is identified, the correct service members can be identified for monitoring or treatment. Records identifying entries or exposures that exceeded permissible limits or are of concern, which may either be generally applicable occupational exposure limits or DoD-specific limits, are displayed in red. While TERA does not require exposures over any specific thresholds, evidence of exposures over permissible limits or are of concern are provided to the VA medical examiner to inform their medical opinion. All exposure information is recorded in DOEHRS (and available through ILER) and includes routine surveillance with normal environmental exposure as well as exposures that may have exceeded permissible limits. Sampling data is collected both from domestic sources as well as from forward operating bases.

Finally, VA also proposes to amend 38 CFR 3.1 by adding a definition of ''physical trauma'' in new paragraph (dd). This amendment is necessary to implement proposed changes to 38 CFR 3.159 and is discussed below in section III.

III. Proposed Changes to § 3.159 Department of Veterans Affairs Assistance in Developing Claims

VA proposes to amend 38 CFR 3.159 to implement the new medical nexus examination and exception authority created in 38 U.S.C. 1168 by section 303 of the PACT Act. Based on 38 U.S.C. 1168, if a veteran submits a claim for a disability that cannot be considered on a presumptive basis and evidence establishes that the veteran participated in a TERA, and the evidence of record is not sufficient to establish service connection for the disability, VA will obtain a medical examination and medical nexus opinion to determine if the veteran's claimed disability is at least as likely as not due to the veteran's TERA. Likewise, if a veteran submits a claim for a disability that is subject to a presumption of service connection, but the veteran did not have qualifying service in a location where VA has conceded toxic exposure, and evidence establishes that the veteran participated in a TERA, a medical examination and medical nexus opinion would be required if service connection could not otherwise be established. Additionally, VA would not obtain a medical examination and medical nexus opinion if the evidence did not establish that the veteran participated in a TERA because doing so would require the examiners to provide opinions based on speculation.

To implement the new medical nexus examination and exception authority created in 38 U.S.C. 1168 by section 303 of the PACT Act, VA is proposing to amend § 3.159(c)(4) by renumbering current paragraphs (c)(4)(iii) and (iv) as (c)(4)(v) and (vi), respectively. Additionally, VA proposes to amend the language in paragraph (c)(4)(i) by clarifying that the requirements apply except as provided in paragraph (c)(4)(iv). VA also proposes to include new paragraph (c)(4)(iii), which would outline when a medical examination and medical opinion must be provided for claims where the evidence establishes participation in a TERA.

Section 1168(b) of title 38 of the U.S.C. provides an exception to when medical examinations and nexus opinions are required for claims where there is evidence of participation in a TERA and the claim cannot be considered on a presumptive basis. The exception states that an examination is not required if the Secretary determines that there is no indication of an association between the claimed disability and the TERA. This exception provides VA with the authority to define when a medical examination and nexus opinion must be provided for claims where the evidence establishes participation in a TERA and will be utilized to minimize meritless examination requests. However, in all cases where the veteran submits competent medical or scientific evidence that indicates a possible association between their claimed disability and TERA, VA will provide an examination and medical nexus opinion.

The determination that there is no indication of an association between a disability and a TERA on a categorical basis will necessarily involve factors specific and unique to the disabilities and TERAs involved. And so, in interpreting the language of 38 U.S.C.

1168(b), VA is not proposing a single standard that would govern all such determinations going forward. However, at this time VA has determined that there is no indication of an association between the following disabilities and TERAs and is proposing to apply the exception at 38 U.S.C. 1168(b) in the following circumstances. As noted below, VA has also requested comment on whether there are any additional examination exceptions pursuant to section 1168(b), beyond those proposed below, that the agency should consider implementing.

First, VA proposes to apply the exception when a veteran submits a claim for service connection for a disability that resulted from physical trauma. VA would not automatically order a medical examination or medical nexus opinion if the veteran claims service connection for a disability that resulted from physical trauma unless the veteran submits competent medical or scientific evidence that indicates that the claimed disability may be associated with the in-service TERA. VA has determined that there is no indication of an association between disabilities due to physical trauma and TERAs because the etiology of these conditions is the physical trauma itself.

VA proposes to define physical trauma as ''a serious injury to the body.'' [1] VA notes that in this definition, VA intends the body to include the head and all members of the person. *See* Black's Law Dictionary 6th Ed. (1991) (defining body). The definition of physical trauma will include three main types: blunt force trauma, trauma due to repetitive use, and penetrating trauma.

VA proposes to define blunt force trauma to mean ''when an object or force strikes the body, often causing concussions, deep cuts, or broken bones.'' [2] Trauma due to repetitive use will be defined as occurring ''when repeated stress to the body's soft tissue structures, including muscles, tendons, and nerves, results in repetitive strain injuries.'' [3] Penetrating trauma will be defined to mean ''when an object pierces the skin or body, usually creating an open wound.'' [4] Penetrating trauma with embedded fragments will not fall under this exception. An embedded fragment is a piece of metal or other material (also referred to as shrapnel) that stays in the body after injury and can potentially lead to toxic exposure.[5] Therefore, if a veteran submits a claim for service connection for a disability due to embedded fragments and there is evidence of participation in a TERA, a medical examination and medical nexus opinion will be required.

To aid claims processors in identifying claims for conditions that fall under the physical trauma exception, VA proposes to publish and maintain a non-exhaustive list of conditions that may fall under the exception on the VA PACT Act website. However, VA notes that the list would not be binding on claims processors, who would still be required to make case-by-case determinations of whether a disability resulted from physical trauma based on the facts of the case. The VA ''The PACT Act and your VA benefits'' website is the primary site for all healthcare and benefits-related information on the PACT Act and provides the public with detailed information regarding these topics. Publishing the list on VA's PACT Act website provides VA the flexibility to update the list by the most efficient means based on the continually evolving science on health outcomes due to toxic exposure. This approach allows VA to provide updates to veterans and stakeholders in a timely manner. Although the specific website has not been created yet and so a link cannot be provided at this time, VA proposes to include a link to the VA PACT Act website in 38 CFR 3.159(c)(4)(iv) and would do so in the final rule. The VA PACT Act website can be found at: *https://www.va.gov/resources/the-pact-act-and-your-va-benefits/.* In addition, VA will provide notice in the **Federal Register** whenever updates are made to the non-exhaustive list of physical trauma exceptions.

VA is also proposing to apply the exception at 38 U.S.C. 1168(b) to any claim for service connection of a mental disorder under 38 CFR 4.130, Schedule of Ratings—Mental Disorders. VA would not automatically order a medical examination or medical nexus opinion if the veteran claims service connection for a mental disorder unless the veteran submits competent medical or scientific evidence that indicates there may be an association between their disability and the in-service TERA. VA has determined that there is no indication of an association between mental disorders and toxic exposures because currently available medical and scientific literature has not identified an association between mental disorders and toxic exposure.

The National Academies of Science, Engineering, and Medicine (NASEM) has been studying the health effects of serving in the Gulf War since 1993 and has published 13 reports in their Gulf War and Health series.[6] Over the last 25 years, NASEM has not found an association between toxic exposures during the Gulf War and mental disorders. In Gulf War and Health, Volume 10 (2016), NASEM was tasked with reviewing and evaluating the literature on health outcomes with higher incidence rates in Gulf War deployed veterans, including post-deployment mental disorders. NASEM determined that there was sufficient evidence of association between deployment to the Gulf War and several mental disorders, including posttraumatic stress disorder, generalized anxiety disorders, depression, and substance use disorder. However, this association was found to be due to combat exposure, and not associated with exposure to toxins.[7]

Although this decision is predicated on the currently available scientific evidence, section 507 of the PACT Act requires VA to partner with NASEM ''to assess possible relationships between toxic exposures experienced during service in the Armed Forces and mental health conditions, including chronic multisymptom illness, traumatic brain injury, posttraumatic stress disorder, depression, episodes of psychosis, schizophrenia, bipolar disorder, suicide attempts, and suicide deaths.'' The Act requires VA to submit a report detailing NASEM's findings not later than three years from the date of enactment of the Act. Depending on the results of this study, VA may revise its exceptions under 38 U.S.C. 1168(b).

VA is also proposing to apply the exception under 38 U.S.C. 1168(b) to claims for certain conditions that the VA Secretary has determined have no association with herbicide exposure when the only participation in a TERA

[1] National Institute of General Medical Sciences. Physical Trauma. Accessed at *https://www.nigms.nih.gov/education/fact-sheets/Pages/physical-trauma.aspx* on November 18, 2022.

[2] *Ibid.*

[3] O'Neil BA, Forsythe ME, Stanish WD. Chronic occupational repetitive strain injury. Can Fam Physician. 2001 Feb;47:311–6. PMID: 11228032; PMCID: PMC2016244.

[4] National Institute of General Medical Sciences. Physical Trauma. Accessed at *https://www.nigms.nih.gov/education/fact-sheets/Pages/physical-trauma.aspx* on November 18, 2022.

[5] Department of Veterans Affairs. Toxic Embedded Fragment Surveillance Center Information For Veterans. 2014. Accessed at *https://www.publichealth.va.gov/docs/exposures/TEFSC-veterans-fact-sheet.pdf* on October 11, 2022.

[6] VA Public Health. Gulf War Health and Medicine Division Reports. Accessed at *https://www.publichealth.va.gov/exposures/gulfwar/reports/health-and-medicine-division.asp* on October 25, 2022.

[7] National Academies of Sciences, Engineering, and Medicine. 2016. Gulf War and Health: Volume 10: Update of Health Effects of Serving in the Gulf War, 2016. Washington, DC: The National Academies Press. *https://doi.org/10.17226/21840.*

that is established relates to herbicide exposure. The Agent Orange Act of 1991, Public Law 102–4, provided that whenever the Secretary determined, based on sound medical and scientific evidence, that a positive association exists between exposure to an herbicide agent and a disease, the Secretary would publish regulations establishing presumptive service connection for that disease. If the Secretary determined that a presumption of service connection was not warranted, VA was required to publish a notice of that determination, including an explanation of the scientific basis for that determination.

Since 1994, NASEM has published 11 biennial reports in their Veterans and Agent Orange series, as required by the Agent Orange Act.[8] VA has published nine notices [9] explaining that presumptions of service connection are not warranted for a number of diseases addressed in NASEM's reports, due to the Secretary's determination that there is not a positive association between herbicide exposure and the diseases evaluated. VA has determined that there is no indication of an association between these certain conditions and herbicide exposure. Thus, VA is proposing to exclude these conditions from warranting a medical examination and medical opinion under 38 U.S.C. 1168(b) when the only relevant TERA is herbicide exposure. And therefore, VA would not automatically order a medical examination or medical nexus opinion if a veteran claims service connection for an excluded condition when the only participation in a TERA that is established relates to herbicide exposure, unless the veteran submits with, or during the course of the claim, competent medical or scientific evidence [10] that indicates there may be an association between their disability and herbicide exposure. This exception would not apply to claims for the excluded conditions if participation in a TERA other than herbicide exposure was established.

VA has reviewed the list of conditions that the Secretary determined did not warrant establishment of presumptive service connection, published in the most recent **Federal Register** notice (79 FR 20308), but has made several changes for purposes of the exception under 38 U.S.C. 1168(b). Conditions that are not considered disabilities for VA rating purposes, such as laboratory findings, have been removed. Conditions that have been determined to be presumptive to herbicide exposure and added to 38 U.S.C. 1112(c) since publication of the **Federal Register** notice have been removed. In addition, VA reviewed currently available scientific evidence regarding any associations with the conditions on the list and herbicide exposure. VA finds there is sufficient scientific evidence warranting removal of renal cancer from the previously published TERA exceptions list.[11] VA's review of currently available scientific evidence did not identify sufficient evidence of an association between the remaining conditions on the list and herbicide exposure. Several conditions were listed using vague and non-specific medical terminology, such as ''eye problems'' and ''bone conditions.'' ''Eye problems'' has been changed to ''diseases of the eye.'' ''Bone conditions'' has been changed to ''osteoporosis'' because osteoporosis was the only bone condition considered in the most recent Veterans and Agent Orange report.

The list of conditions published in the **Federal Register** and recognized as not warranting a presumption of service connection based on herbicide exposure also included ''cancers at other unspecified sites (other than those as to which the Secretary has already established a presumption.)'' VA determined that excluding all other cancers for which there is not an established presumption was too broad and may result in a veteran being denied a VA examination in error. This determination is based on the fact that toxic exposure research has advanced dramatically since the initial list was published in the **Federal Register**, and VA cannot conclusively say that there is no indication of an association between herbicide exposure and *all* other cancers not already established by presumption.

Pursuant to the exception at 38 U.S.C. 1168(b), VA proposes to exclude the following conditions when the only participation in a TERA that is established relates to herbicide exposure: (1) Cancers of the oral cavity (including lips and tongue), pharynx (including tonsils), and nasal cavity (including ears and sinuses); (2) cancers of the pleura, mediastinum, and other unspecified sites within the respiratory system and intrathoracic organs; (3) cancers of the digestive organs (esophageal cancer; stomach cancer; colorectal cancer (including small intestine and anus), hepatobiliary cancers (liver, gallbladder, and bile ducts), and pancreatic cancer); (4) bone and connective tissue cancer; (5) melanoma; (6) nonmelanoma skin cancer (basal cell and squamous cell); (7) cancers of the reproductive organs (cervix, uterus, ovary, breast, testes, and penis; not including prostate); (8) cancers of the brain and nervous system (including eye); (9) endocrine cancers (including thyroid and thymus); (10) leukemia (other than all chronic B-cell leukemias including chronic lymphocytic leukemia and hairy cell leukemia); (11) neurobehavioral disorders (cognitive and neuropsychiatric); (12) neurodegenerative diseases (including amyotrophic lateral sclerosis (ALS) but not including Parkinson's disease and Parkinsonism); (13) chronic peripheral nervous system disorders (other than early-onset peripheral neuropathy); (14) asthma; (15) chronic obstructive pulmonary disease; (16) farmer's lung; (17) gastrointestinal, metabolic, and digestive disorders; (18) immune system disorders (immune suppression, allergy, and autoimmunity); (19) circulatory disorders (other than hypertension, ischemic heart disease, and stroke); (20) endometriosis; (21) hearing loss; (22) diseases of the eye; and (23) osteoporosis.

VA proposes to apply the exception under 38 U.S.C. 1168(b) to claims for disabilities that manifested during military service or with an etiology not associated with toxic exposure. This exception will apply to conditions that manifested during service for which a medical nexus opinion would not be needed to decide service connection on

[8] VA Public Health. Health and Medicine Division Reports on Agent Orange. Accessed at *https://www.publichealth.va.gov/exposures/agentorange/publications/health-and-medicine-division.asp* on October 25, 2022.

[9] 59 FR 341, published January 4, 1994, Disease Not Associated With Exposure to Certain Herbicide Agents; 61 FR 41442, published August 8, 1996, Disease Not Associated With Exposure to Certain Herbicide Agents. August 8, 1996; 64 FR 59232, published November 2, 1999, Diseases Not Associated With Exposure to Certain Herbicide Agents; 67 FR 45600, published June 24, 2002, Diseases Not Associated With Exposure to Certain Herbicide Agents; 68 FR 27630, published May 20, 2003, Diseases Not Associated With Exposure to Certain Herbicide Agents; 75 FR 32540 published June 8, 2010, Health Effects Not Associated With Exposure to Certain Herbicide Agents; 75 FR 81332, published December 27, 2010, Determinations Concerning Illnesses Discussed in National Academy of Sciences Report: Veterans and Agent Orange: Update 2010;77 FR 47924, published August 10, 2012, Determinations Concerning Illnesses Discussed in National Academy of Sciences Report: Veterans and Agent Orange: Update 2010; 79 FR 20308, published April 11, 2014, Determinations Concerning Illnesses Discussed in National Academy of Sciences Report: Veterans and Agent Orange: Update 2012.

[10] Competent medical or scientific evidence is typically provided by one who is qualified to provide such evidence, due to training, education, or experience in that particular field. *See Parks* v. *Shinseki,* 716 F.3d 581,585 (2013).

[11] Andreotti, G., Beane Freeman, L.E., Shearer, J.J., Lerro, C.C., Koutros, S., Parks, C.G., Blair, A., Lynch, C.F., Lubin, J.H., Sandler, D.P., & Hofmann, J.N. (2020). Occupational Pesticide Use and Risk of Renal Cell Carcinoma in the Agricultural Health Study. *Environmental health perspectives, 128*(6), 67011. *https://doi.org/10.1289/EHP6334.*

a direct basis (evidence of chronicity or continuity is of record) and to claims where the evidence of record indicates that the claimed condition has an etiology that is not associated with toxic exposure (to include post-service event).

VA also proposes to apply the exception under 38 U.S.C. 1168(b) to claims where the only established participation in a TERA is based on an entry in an exposure tracking record system that does not correspond to an activity performed by the veteran that could result in potential in-service exposure to toxic substances, chemicals, or airborne hazards. Claims processors should apply a liberal standard to determine participation in a TERA. VA generally proposes to recognize participation in a TERA based on any entry in ILER, except for contractor and civilian service records and where only the veteran's name appears. However, there are circumstances where an entry in the ILER database may show, for example, only a post-military service health record or physical injuries. Such entries do not show the veteran was in proximity to, or in the environment of, toxic substances, chemicals, and/or airborne hazards, and so such entries cannot corroborate potential exposure to toxic substances, chemicals, or airborne hazards. Such entries would be sufficient to establish participation in a TERA, but where the relevant entry provides no indication of a potential toxic exposure during military service, VA has determined that there would be no indication of an association between the claimed disability and such entry. In such scenarios, VA proposes that it will not provide an examination and opinion, pursuant to the exception in section 1168(b).

VA further proposes that in order to corroborate a potential exposure to toxic substances, chemicals, and/or airborne hazards, the entries in an exposure tracking record system that establish the veteran's participation in a TERA must show that the veteran was in proximity to, or in an environment which contained, toxic substances, chemicals, and/or airborne hazards. The proximity should not be considered in terms of actual distance, but whether the conditions, circumstances, and hardships of service placed the claimant in a potentially toxic environment. Examples of service in proximity to, or in an environment which contained, a toxic substance, chemical, or airborne hazard include, but are not limited to, service in the following locations: Congressionally recognized radiation risk locations (38 U.S.C. 1112, 1154); locations associated with herbicide exposure (38 U.S.C. 1116); the Persian Gulf (38 U.S.C. 1117; Pub. L 111–275, section (d)); locations associated with exposure to burn pits (38 U.S.C. 1120); at Camp Lejeune (38 CFR 3.307(a)(7); and any locations determined by the Secretary pursuant to 38 U.S.C. 1119 (c)(1)(B)(ix). Claims processors should also recognize veterans may participate in a TERA based on their proximity to environmental hazards such as asbestos, benzene, PFAS, or other accepted environmental substances that pose risk to human health, regardless of location or service era. For example, between 2001 and 2005, the U.S. occupied an old Soviet-era airbase, Karshi-Khanabad (K2) in Uzbekistan, near Tajikistan.[12] The veterans who served at K2 were exposed to jet fuel as a result of a leaking Soviet era underground jet fuel distribution system; [13] volatile organic compounds found in air samples; [14] particulate matter and dust; [15] depleted uranium from non-U.S. ammunition destroyed in fires; [16] asbestos roofing tiles and lead based paint; [17] and lead in water samples,[18] which VA would consider TERAs for this population. VA invites public comment on what should be considered toxic exposure risk activity, and how VA should determine whether a veteran participated in the same.

VA also proposes to apply the exception under section 1168(b) where the only participation in a TERA that is established is based on entries in an exposure tracking record system that are self-reported records that cannot be substantiated. That is, the self-reported records are inconsistent with the information available and circumstances of the veteran's service or provide insufficient information to permit reasonable verification. For example, if the only participation in a TERA that is established is based on a veteran's statement in a post-service health assessment or an Agent Orange examination registry that they believe an herbicide exposure occurred, the record must corroborate that the veteran served in proximity to, or in an environment in which, an herbicide was present.

VA proposes that an unsubstantiated report is one VA cannot prove or otherwise accept to be true. (See unsubstantiated definition ''not proven to be true''. *https://www.merriam-webster.com/dictionary/unsubstantiated,* reviewed January 11, 2024.) Unsubstantiated would also be considered unsupported by any facts or evidence, unfounded by the evidence, or lacking in foundation. This also includes circumstances where the report in an exposure tracking record system, such as in an Agent Orange registry exam in ILER, is inconsistent with the circumstances of service based on the totality of the claimant's record. Such scenarios could include, for example, inaccurate information about a veteran's military occupational specialty or reporting service in an unverifiable location.

VA has determined that there is no indication of an association between participation in a TERA that is based on an entry in an exposure tracking record system that is based on uncorroborated assertions of exposure or unsubstantiated reports and disabilities. VA notes that it would not be possible for an examiner to provide a medical opinion on the relationship between a disability and participation in a TERA that cannot be corroborated or substantiated, as doing so would require speculation on the examiner's part. Although a veteran's own statements may have evidentiary value in VA adjudications, in instances where self-reported records are inconsistent with the information available and circumstances of the veteran's service, or provide insufficient information to permit reasonable verification, such records do not reasonably provide any

[12] ''Military Deployment Periodic Occupational and Environmental Monitoring Summary (POEMS): Karshi-Khanabad Airbase, Uzbekistan: 2001 to 2005,'' Department of Defense, *https://ph.health.mil/PHC%20Resource%20Library/U_UZB_Karshi-Khanabad%20POEMS%202001-2005_Public%20Release%20Review.pdf.*

[13] ''Environmental Conditions at Karshi-Khanabad (K–2) Air Base Uzbekistan,'' Army Public Health Center, *https://ph.health.mil/PHC%20Resource%20Library/EnvironmentalConditionsatK-2AirBaseUzbekistan_FS_64-038-0617.pdf* ; ''Transmittal of Deployment Occupational and Environmental Health Site Assessment, Karshi-Khanabad Airbase, Karshi, Uzbekistan,'' Department of the Army, *https://ph.health.mil/PHC%20Resource%20Library/ehse-k2-08-doeh-assessment.pdf;* ''Final Report, Environmental Assessment—Hardened Aircraft Shelters, Stronghold Freedom, Karshi Khanabad Airfield, Uzbekistan, 6 June—20 July 2002,'' *https://ph.health.mil/PHC%20Resource%20Library/ehse-k2-05-enviro-assessment-aircraft-shelters.pdf.*

[14] ''Transmittal of Deployment Occupational and Environmental Health Site Assessment, Karshi-Khanabad Airbase, Karshi, Uzbekistan,'' Department of the Army.

[15] ''Environmental Conditions at Karshi-Khanabad (K–2) Air Base Uzbekistan,'' Army Public Health Center.

[16] ''Transmittal of Deployment Occupational and Environmental Health Site Assessment, Karshi-Khanabad Airbase, Karshi, Uzbekistan,'' Department of the Army.

[17] ''Transmittal of Deployment Occupational and Environmental Health Site Assessment, Karshi-Khanabad Airbase, Karshi, Uzbekistan,'' Department of the Army.

[18] ''Transmittal of Deployment Occupational and Environmental Health Site Assessment, Karshi-Khanabad Airbase, Karshi, Uzbekistan,'' Department of the Army.

indication of an association between a claimed disability and toxic exposure risk activity.

The exceptions to the medical examination and medical opinion requirements under 38 U.S.C. 1168(b) will be applied on a case-by-case basis and require individualized determinations. In all cases, where there is reasonable doubt as to whether the exception applies, such doubt will be resolved in favor of the veteran, and a medical examination and medical opinion will be provided (38 CFR 3.102).

As noted, VA also invites public comment on whether additional exceptions under 1168(b) are warranted. For example, the agency invites comment on the appropriateness of an exception that would apply if a veteran has not affirmatively indicated the presence of a TERA.

VA proposes to list all medical examination and nexus opinion exceptions for claims based on TERA under 38 CFR 3.159(c)(4)(iv).

In the interest of implementing the PACT Act as soon as possible following enactment of the law, VA published Notification of Sub-regulatory Guidance in the **Federal Register** on December 22, 2022 (87 FR 78543). The notification includes as an attachment VBA Letter 20–22–10, which provides sub-regulatory guidance for claims processors adjudicating disability compensation claims and appeals for veterans and survivors impacted by the PACT Act prior to implementation of the Act in regulation. Regarding section 303 of the PACT Act, the policy letter outlines the procedures for determining when participation in a TERA will be conceded. The Policy Letter can be found as an attachment to the notification and can be viewed and downloaded at *Regulations.gov*.

IV. Proposed Changes to § 3.317 Compensation for Certain Disabilities Occurring in Persian Gulf Veterans

Section 3.317(a) governs presumptive service connection for certain qualifying chronic disabilities based on service in the Southwest Asia theater of operations during the Gulf War. The controlling statute, 38 U.S.C. 1117, was established in 1994, in response to large numbers of Gulf War veterans returning from the Southwest Asia theater of operations with unexplained symptoms of fatigue, skin rash, muscle and joint pain, headache, loss of memory, shortness of breath, and gastrointestinal and respiratory symptoms, which could not be diagnosed or clearly defined. Congress recognized that veterans who deployed during the Gulf War were exposed to toxic substances, chemicals, and airborne hazards. However, at the time, there was a lack of scientific evidence linking toxic exposure during Gulf War service to undiagnosed illnesses and MUCMIs. Congress also recognized that VA did not have the authority to provide compensation for these claims because the claimed conditions could not be attributed to a known diagnosis (Pub. L. 103–446, title I, sec. 102).

In response to these issues, Congress enacted the Veterans' Benefits Improvements Act of 1994, Public Law 103–446. The law added 38 U.S.C. 1117, authorizing the Secretary of Veterans Affairs to compensate any Persian Gulf veteran suffering from a chronic disability resulting from an undiagnosed illness or MUCMI that became manifest either during active duty in the Southwest Asia theater of operations during the Persian Gulf War or to a degree of 10 percent or more within a presumptive period, as determined by the Secretary, following service in the Southwest Asia theater of operations during the Persian Gulf War.

Implementing that statute, 38 CFR 3.317 prohibits compensation for disabilities that, through medical history, physical examination, and laboratory tests, are determined to result from any known clinical diagnosis. Disabilities resulting from a known clinical diagnosis receive consideration for service connection under other regulations governing direct service connection or aggravation (38 CFR 3.303, 3.306, 3.310).

Section 405 of the PACT Act amended 38 U.S.C. 1117, Compensation for disabilities occurring in Persian Gulf War veterans, by removing the manifestation requirements for claims based on undiagnosed illnesses and MUCMIs and instead allows compensation to be paid for qualifying chronic disabilities that become manifest to any degree at any time. Section 405 also amended the definition of a Persian Gulf veteran contained in 38 U.S.C. 1117(f) to include veterans with service in six additional locations: Afghanistan, Israel, Egypt, Turkey, Syria, and Jordan.

Therefore, VA is proposing to amend 38 CFR 3.317(a)(1) to remove the requirement that an undiagnosed illness or MUCMI must manifest either during active military, naval, or air service in the Southwest Asia theater of operations, or to a degree of 10 percent or more not later than December 31, 2026. VA proposes to amend 38 CFR 3.317(a)(1) to state that a qualifying chronic disability under this section may manifest to any degree at any time, provided that such disability, by history, physical examination, and laboratory tests, cannot be attributed to any known clinical diagnosis.

Based on section 405 of the PACT Act, VA also proposes to amend 38 CFR 3.317(e)(1) to update the definition of a Persian Gulf veteran. Currently, 38 CFR 3.317(e)(1) defines a Persian Gulf veteran as ''a veteran who served on active military, naval, or air service in the Southwest Asia theater of operations during the Persian Gulf War.'' The PACT Act amended 38 U.S.C. 1117(f) to define a Persian Gulf veteran as ''a veteran who served on active duty in the Armed Forces in the Southwest Asia theater of operations, Afghanistan, Israel, Egypt, Turkey, Syria, or Jordan, during the Persian Gulf War.'' Therefore, VA proposes to add these six new locations to the definition of a Persian Gulf veteran under 38 CFR 3.317(e)(1).

VA recently announced its plans to take steps to consider Veterans who served in Uzbekistan as Persian Gulf Veterans, therefore making undiagnosed illness and medically unexplained chronic multi-symptom illness (also known as Gulf War Illness) presumptive conditions for those Veterans. VA invites public comment on that issue, as well as whether VA should also add Somalia, Djibouti, Lebanon, and Yemen as covered locations in the definition of a Persian Gulf veteran under 38 CFR 3.317(e)(1) based on exposure in these locations to toxic substances similar to those that were present in currently covered locations, such as fine particulate matter ($PM_{2.5}$).

Further, because 38 CFR 3.317(c)(3)(ii) defines the qualifying service for infectious diseases in terms of § 3.317(e), it is necessary to amend paragraph (c)(3)(ii) to correctly limit the scope of its application to the Southwest Asia theater of operations during the Gulf War period as well as on or after September 19, 2001, in Afghanistan. VA acknowledges that there is overlap in 38 CFR 3.317 with regard to locations currently covered for undiagnosed illnesses, MUCMIs and infectious diseases. VA seeks comment as to whether the following countries should be considered for inclusion under infectious diseases in 38 CFR 3.317(c): Djibouti, Lebanon, Somalia, Uzbekistan, Yemen, Israel, Egypt, Turkey, Syria or Jordan. VA is proposing amendments to the manifestation requirements and the definition of a Persian Gulf veteran under § 3.317 described above to implement the statutory changes imposed by the PACT Act.

V. Proposed Changes to § 3.320 Claims Based on Exposure to Fine Particulate Matter

VA proposes to amend 38 CFR 3.320 to implement portions of sections 302 and 406 of the PACT Act. VA promulgated 38 CFR 3.320 to establish presumptions of service connection for certain chronic diseases based on presumed exposure to fine particulate matter ($PM_{2.5}$) during service in the Southwest Asia theater of operations during the Persian Gulf War, and service in Afghanistan, Syria, Djibouti, or Uzbekistan, on or after September 19, 2001, during the Persian Gulf War. These presumptions were based on VA's review and analysis of several reports that focused on airborne hazards in the Southwest Asia theater of operations during the Persian Gulf War. The primary reports that informed VA's decision were NASEM's 2020 report, Respiratory Health Effects of Airborne Hazards Exposures in the Southwest Asia Theater of Military Operations,[19] and NASEM's 2011 report, Long-Term Consequences of Exposure to Burn Pits in Iraq and Afghanistan.[20] VA's decision was also informed by NASEM's 2010 report, Review of the Department of Defense Enhanced Particulate Matter Surveillance Program, which noted the difficulties associated with conducting exposure assessments in deployment environments. However, the report concluded that service members deployed to the Middle East ''are exposed to high concentrations of PM and that the particle composition varies considerably over time and space.'' [21]

PM air pollution includes smoke, fumes, soot, and particles from natural sources such as dust, pollen, sea salt, and forest fires. Incomplete combustion of organic and inorganic material in burn pits results in high volumes of toxic PM in the air that includes metals, benzene, and other toxic compounds.[22] When VA identified the qualifying periods of service under 38 CFR 3.320, the three main considerations were (1) whether burn pits were used in the location, (2) the $PM_{2.5}$ levels, and (3) desert climate. Further, VA relied on the Secretary's general rulemaking authority at 38 U.S.C. 501(a) when we established 38 CFR 3.320.

Again, taking into account the three considerations noted above, VA is proposing to remove the references to qualifying periods of service and incorporate the definition of ''covered veteran'' from section 302 of the PACT Act into 38 CFR 3.320. Section 302 of the PACT Act created new 38 U.S.C. 1119, Presumptions of toxic exposure, and defines a ''covered veteran'' as a veteran who served in the following eligible locations: Bahrain, Iraq, Kuwait, Oman, Qatar, Saudi Arabia, Somalia, and the United Arab Emirates on or after August 2, 1990, and Afghanistan, Djibouti, Egypt, Jordan, Lebanon, Syria, Yemen, and Uzbekistan on or after September 11, 2001. VA is additionally proposing to extend the current regulatory presumption of exposure to $PM_{2.5}$ to the five new locations listed in 38 U.S.C. 1119 that are not currently recognized under § 3.320: Somalia, Egypt, Jordan, Lebanon, and Yemen.

All new locations added by section 302 of the PACT Act have documented burn pit use. In 2021, DoD provided Congress with a list of locations within U.S. Central Command where open burn pits have been used since 2001. The U.S. Central Command's Area of Responsibility consists of 21 nations that stretch from Northeast Africa across the Middle East to Central and South Asia [23] and is the only combatant command that conducts open burn pit operations.[24] Egypt, Jordan, Lebanon, and Yemen were included as locations with open, active burn pits. Somalia was not included on the list. However, there is evidence of burn pit use in Somalia prior to 1993, when service members were deployed in support of Operation Show Care.[25] Additional deployments occurred in 1992, 1995, 2012, and 2022; the latter being a ''small persistent-presence.'' [26] Available data in ILER provides evidence that service members deployed to Somalia were exposed to significant amounts of fugitive dust from airfields, residential fires and burn pit smoke, and that this contributed to elevated PM levels.

Additionally, all new locations added by section 302 of the PACT Act have similar arid desert climate conditions. DoD's 2008 Enhanced Particulate Matter Surveillance Program studied the chemical and physical properties of dust at 15 deployment sites in the Middle East, Central Asia, and Northeast Africa. The study found that Military Exposure Guideline (MEG) values for $PM_{2.5}$ were exceeded at all 15 sites for the entire one-year sampling period. The study also demonstrated how ''short-term dust events—exacerbated by dirt roads, agricultural activities, and disturbance of the desert floor by motorized vehicles—all contribute to exceedance of both PM_{10} and $PM_{2.5}$ mass exposure guidelines and standards.'' [27] Finally, DoD's report also stated that PM levels in the Middle East are as much as ten times greater than the levels at both urban and rural southwestern U.S. air monitoring sites.

Dust storms and high windblown dust concentrations are one of many environmental hazards experienced during deployment to locations within U.S. Central Command. Windblown dust in these locations is considered an airborne hazard because it combines with elemental carbon and metals that arise from transportation and industrial activities.[28] While dust in these locations can be toxic based on transportation and industrial activities alone, open air burn pits increase the concentration of toxins in $PM_{2.5}$.

All new section 1119 locations have a history of annual $PM_{2.5}$ levels that exceed military and EPA air quality standards. Not only do they exceed air quality standards, average $PM_{2.5}$ concentrations have been increasing in North Africa and the Middle East since 1990, while Europe and North America have experienced decreasing trends in average $PM_{2.5}$ concentrations.[29] Based on evidence of burn pit use, $PM_{2.5}$ levels

[19] National Academies of Sciences, Engineering, and Medicine 2020. *Respiratory Health Effects of Airborne Hazards Exposures in the Southwest Asia Theater of Military Operations.* Washington, DC: The National Academies Press. *https://doi.org/10.17226/25837.*

[20] Institute of Medicine 2011. *Long-Term Health Consequences of Exposure to Burn Pits in Iraq and Afghanistan.* Washington, DC: The National Academies Press. *https://doi.org/10.17226/13209.*

[21] National Research Council 2010. *Review of the Department of Defense Enhanced Particulate Matter Surveillance Program Report.* Washington, DC: The National Academies Press. *https://doi.org/10.17226/12911.*

[22] American Cancer Society. Military Burn Pits and Cancer Risk. 2022. Accessed at *https://www.cancer.org/healthy/cancer-causes/chemicals/burn-pits.html* on October 10, 2022.

[23] U.S. Central Command. Area of Responsibility. Accessed at *https://www.centcom.mil/AREA-OF-RESPONSIBILITY/* on September 29, 2022.

[24] Department of Defense. Open Burn Pit Report to Congress. 2019. Accessed at *https://www.acq.osd.mil/eid/Downloads/Congress/Open%20Burn%20Pit%20Report-2019.pdf* on October 1, 2022.

[25] Center of Military History, United States Army. *United States Forces, Somalia After Action Report and Historical Overview: The United States Army in Somalia, 1992–1994. https://www.history.army.mil/html/documents/somalia/index.html.*

[26] CRS Report R42738, *Instances of Use of United States Armed Forces Abroad, 1798–2022, https://crsreports.congress.gov/product/pdf/R/R42738/38.*

[27] Jiandong Wang et al., *Historical Trends in $PM_{2.5}$-Related Premature Mortality during 1990–2010 across the Northern Hemisphere.* Environmental Health Perspectives. 2017. 125:3. CID: *https://doi.org/10.1289/EHP298;* Melanie S. Hammer et al., *Global Estimates and Long-Term Trends of Fine Particulate Matter Concentrations (1998–2018).* Environ. Sci. Technol. 2020, 54, 7879–7890. *https://doi.org/10.1021/acs.est.0c01764.*

[28] Institute of Medicine 2011. *Long-Term Health Consequences of Exposure to Burn Pits in Iraq and Afghanistan.* Washington, DC: The National Academies Press. *https://doi.org/10.17226/13209.*

[29] Department of Defense. Enhanced Particulate Matter Surveillance Program (EPMSP) Final Report. 2008. *https://apps.dtic.mil/sti/pdfs/ADA605600.pdf.*

that exceed military and EPA air quality standards, and their arid desert climate conditions that exacerbate $PM_{2.5}$ levels, VA finds there is sufficient evidence to extend the presumption of exposure to $PM_{2.5}$ under 38 CFR 3.320 to Somalia, Egypt, Jordan, Lebanon, and Yemen.

Additionally, under 38 U.S.C. 1119(b)(2)(A), VA is required to establish and maintain a list that contains an identification of one or more such substances, chemicals, and airborne hazards as the Secretary, in collaboration with the Secretary of Defense, may determine appropriate for purposes of section 1119. VA proposes to add $PM_{2.5}$ as the first airborne hazard recognized as warranting a presumption of exposure under 38 U.S.C. 1119(b)(1). As discussed above, in 2021, VA established a presumption of exposure to $PM_{2.5}$ for veterans who served in the Southwest Asia theater of operations, Afghanistan, Syria, Djibouti, or Uzbekistan when it promulgated 38 CFR 3.320. Adding $PM_{2.5}$ as the first airborne hazard recognized under 38 U.S.C. 1119(b)(2)(A) will allow VA to merge the current presumption of exposure (38 CFR 3.320) with the PACT Act presumptions of service connection without having to maintain a separate presumption of exposure to $PM_{2.5}$ for the population currently eligible under 38 CFR 3.320. It avoids VA having to maintain two separate presumptions of exposure ($PM_{2.5}$ and the PACT Act (sec 406) presumption of exposure to ''burn pits and other toxins'') with almost identical covered populations. A major aim of the PACT Act was to streamline VA's decision-making process related to toxic exposure to provide faster decisions to veterans. Merging the current presumption of exposure to $PM_{2.5}$ with the PACT Act presumptions of service connection supports this aim and would improve efficiency and consistency of rating decisions.

Further, under this approach, VA would still be able to study additional health outcomes that may warrant a presumption of *service connection* based on $PM_{2.5}$ exposure. This includes reviewing body systems other than the respiratory system, as this was the main focus of VA's initial PM research. VA's presumption of exposure to $PM_{2.5}$ was rigorously analyzed through VA's established presumption process in 2021, and based on the current section 302 requirements, VA has now identified $PM_{2.5}$ as an exposure that was ubiquitous to the entire Gulf War theater of operations. VA's Health Outcomes and Military Exposures (HOME) office, in collaboration with DoD, will continue to study and evaluate the substances, chemicals, and airborne hazards experienced by deployed Gulf War Veterans. Based on these efforts, VA may add additional substances, chemicals, and airborne hazards to the list in future rulemaking.

As discussed above, in locations that rely on open burning of waste, the PM air pollution in that location will contain toxic combustion emissions. Open burning is the ''burning of any matter in such a manner that products of combustion resulting from the burning are emitted directly into the ambient or surrounding outside air without passing through an adequate stack, duct or chimney.'' [30] The Environmental Protection Agency (EPA) defines ''ambient air'' as ''that portion of the atmosphere, external to buildings, to which the general public has access.'' (40 CFR 50.1(e)). Because $PM_{2.5}$ is a form of ambient air pollution and open burning of waste emits toxic combustion emissions into the ambient air, VA considers exposure to $PM_{2.5}$ as encompassing exposure to burn pit smoke. As a result, VA will no longer maintain a separate presumptive regulation based on PM exposure, but 38 CFR 3.320 will now cover presumptions of exposure for various toxic substances, chemicals, and airborne hazards. This change will supersede the procedural concession of burn pit exposure in VA's M21–1 Adjudication Procedures Manual. Concession of burn pit exposure is now covered under the presumption of exposure to toxic substances, chemicals, and airborne hazards.

The new definition of a ''covered veteran'' in section 1119 does not include all areas historically included in the Southwest Asia theater of operations. The new definition omits the neutral zone between Iraq and Saudi Arabia, the Gulf of Aden, the Gulf of Oman, the Persian Gulf, the Arabian Sea, and the Red Sea. However, VA is proposing to maintain the current definition of the Southwest Asia theater of operations under the authority of 38 U.S.C. 501, as this definition was based on Executive Order 12744 of January 21, 1991, which designated the combat zone of the Persian Gulf War. Doing so would allow individuals with service in those locations omitted from the definition of ''covered veteran'' to still qualify as covered veterans under the regulation.

Section 406 of the PACT Act established new 38 U.S.C. 1120, Presumption of service connection for certain diseases associated with exposure to burn pits and other toxins, which added a presumption of service connection for 23 diseases. This presumption applies to covered veterans as defined in 38 U.S.C. 1119(c), as described above. Because VA is proposing to amend 38 CFR 3.320 to now govern not only claims based on $PM_{2.5}$ exposure, but also claims based on exposure to toxic substances, chemicals, and additional airborne hazards, VA proposes to add the following presumptive diseases from 38 U.S.C. 1120(b) to 38 CFR 3.320: (1) asthma; (2) head cancer of any type; (3) neck cancer of any type; (4) respiratory cancer of any type; (5) gastrointestinal cancer of any type; (6) reproductive cancer of any type; (7) lymphoma cancer of any type; (8) kidney cancer; (9) brain cancer; (10) melanoma; (11) pancreatic cancer; (12) chronic bronchitis; (13) chronic obstructive pulmonary disease; (14) constrictive bronchiolitis or obliterative bronchiolitis; (15) emphysema; (16) granulomatous disease; (17) interstitial lung disease; (18) pleuritis; (19) pulmonary fibrosis; (20) sarcoidosis; (21) chronic sinusitis; (22) chronic rhinitis; and (23) glioblastoma. VA notes that although section 406 of the PACT Act included lymphomatic cancer of any type in the list of presumptions, that term was removed from 38 U.S.C. 1120 pursuant to section 5124(a) of Public Law 117–263, as it was not a term recognized by the scientific and medical community Therefore, VA will not include lymphomatic cancer of any type in the list of presumptions included in regulation. However, ''lymphoma cancer of any type'' remains a presumptive condition for covered Gulf War veterans under 38 U.S.C. 1120.

Section 406 of the PACT Act established ''reproductive cancer of any type'' as a disease presumed to be associated with exposure to burn pits and other toxins (38 U.S.C. 1120(b)(2)(E)). The phrase reproductive cancer is not defined in the PACT Act or elsewhere in statute. As an initial matter, we propose to interpret reproductive cancer as including breast cancer. Breasts are generally considered a secondary sex characteristic, and breast tissue has unique attributes that are responsive to reproductive hormones, including estrogen and testosterone. Breast disorders may cause reproductive-related impacts. And breast cancer has been considered a reproductive cancer in other contexts,

[30] Estrellan, C.R. and Iino, F. (2010) Toxic Emissions from Open Burning. Chemosphere, 80, 193–207. *https://doi.org/10.1016/j.chemosphere.2010.03.057.*

including by the U.S. Department of Health and Human Services.[31]

Further, when determining whether to include all breast cancers, VA considered the similarities between the epidemiology, treatment, and psychosocial effects of breast cancer in males compared to females. Mutational signatures found in cancer cells show extensive core similarities between male and female breast cancer, supporting a view that these cancers have common etiologic processes. In addition, risk factors for breast cancer in men are the same as or analogous to risk factors for breast cancer in women.[32] Given the marked similarity of male and female breast cancer across a range of factors, especially common risk factors and mutational signatures, the Secretary has determined that VA policy should apply equally to veterans with breast cancer regardless of sex or gender. Based on the Secretary's decision, VA is proposing that all breast cancers be considered reproductive cancer of any type under 38 U.S.C. 1120 and be eligible for presumptive service connection for covered veterans.

Following VA's review of eligible reproductive cancers under the PACT Act, VA has also determined that it is reasonable to interpret ''reproductive cancer of any type'' as including cancer of the urethra and cancer of the paraurethral glands. The urethra is the tube that carries urine from the bladder to outside the body. In women, the urethra is about 1½ inches long and is just above the vagina. In men, the urethra is about 8 inches long, and goes through the prostate gland and the penis to the outside of the body. In men, the urethra also carries semen.[33] Because it transports seminal fluid, the urethra is a part of the reproductive system in males. In female human anatomy, paraurethral glands (also known as the Skene glands or lesser vestibular glands) are located around the lower end of the urethral meatus.[34] The paraurethral glands are located in the vestibule of the vulva, around the lower end of the urethra. Two ducts lead from the paraurethral glands to the vulvar vestibule, to the left and right of the urethral opening, from which they are structurally capable of secreting fluid. One purpose of the paraurethral glands is to secrete a fluid that helps lubricate the urethral opening.[35]

Because the paraurethral glands and the male prostate act similarly by secreting prostate-specific antigen (PSA), which is an ejaculate protein produced in males, and of prostate-specific acid phosphatase, some medical authorities refer to the paraurethral glands as the ''female prostate''.[36] They are homologous to the male prostate (developed from the same embryological tissues).

The Secretary has determined that VA policy should apply equally to Veterans filing claims for service connection regardless of sex, sexual orientation, gender, and/or or gender identity. Therefore, VA is proposing that urethral cancers, to include cancer of the paraurethral glands, be considered reproductive cancer of any type under 38 U.S.C. 1120 and be eligible for presumptive service connection for covered veterans.

Finally, section 406 adds a distinction after listing asthma as a presumptive condition under 38 U.S.C. 1120. The PACT Act specifies that asthma must be ''diagnosed after service of the covered veteran as specified in section 1119(c).'' This means the presumption only applies when asthma is diagnosed after service. Per 38 CFR 3.303(d), presumptive periods are not intended to limit service connection to diseases diagnosed after service when the evidence warrants direct service connection. The presumptive regulations are intended as liberalizations applicable when the evidence would not warrant service connection without their aid. Therefore, requiring that asthma be diagnosed after service in order for a presumption of service connection to apply conflicts with the basic principle of presumptive service connection. Therefore, VA will implement the PACT Act presumption for asthma without the qualifying language that requires the condition to be diagnosed after the covered service in section 1119(c).

VA notes that new sections 1119 and 1120 provide a service-connection pathway distinct from that provided under section 1117 (undiagnosed illness and MUCMI). Therefore, VA is proposing to codify new sections 1119 and 1120 under 38 CFR 3.320 rather than 38 CFR 3.317.

VA is proposing to change the heading of 38 CFR 3.320 to replace the term ''fine particulate matter'' with ''toxic substances, chemicals, and airborne hazards.'' This change is needed to make clear that under this proposal, 38 CFR 3.320 would no longer be specific to a single exposure ($PM_{2.5}$) but would govern all claims based on exposure to toxic substances, chemicals, and airborne hazards for covered veterans. VA is proposing to describe the presumption of exposure in paragraph (a), describe the presumptions of service connection in paragraph (b), provide the definition of covered veteran in paragraph (c), and keep the existing exceptions in paragraph (d).

Finally, section 406 of the PACT Act does not require that any of the listed diseases manifest to a specific level or within a specific presumptive period for presumptions of service connection under 38 U.S.C. 1120. VA is proposing to codify 38 U.S.C. 1120 under § 3.320 as described above as required by the PACT Act.

VI. Severability

The purpose of this section is to clarify the agencies' intent with respect to the severability of provisions of this proposed rule. Each provision that the agency has proposed is capable of operating independently. If any provision of this proposed rule is determined by judicial review or operation of law to be invalid, that partial invalidation will not render the remainder of this proposed rule invalid. Likewise, if the application of any portion of this proposed rule to a particular circumstance is determined to be invalid, the agencies intend that the rulemaking remain applicable to all other circumstances.

VII. Effective Date and Applicability

Section 406 of the PACT Act prescribed phased-in and criteria-based applicability dates for 11 of the 23 new presumptive conditions. All claims

[31] Reproductive Cancers, HHS Office of Population Affairs, available at *https://opa.hhs.gov/reproductive-health/reproductive-cancers,* last accessed June 1, 2023.

[32] Fentiman IS. The endocrinology of male breast cancer. Endocr Relat Cancer. 2018 Jun;25(6):R365–R373. doi: 10.1530/ERC–18–0117. PMID: 29752333; Davey M.G., Davey C.M., Bouz L., Kerin E., McFeetors C., Lowery A.J., Kerin M.J., Relevance of the 21-gene expression assay in male breast cancer: A systematic review and meta-analysis. *Breast.* 2022;64:41–46; Valentini V., Silvestri V., Bucalo A., Conti G., Karimi M., Di Francesco L., Pomati G., Mezi S., Cerbelli B., Pignataro M.G., Nicolussi A., Coppa A., D'Amati G., Giannini G., Ottini L. Molecular profiling of male breast cancer by multigene panel testing: Implications for precision oncology. Front Oncol. 2023 Jan 6;12:1092201. doi: 10.3389/fonc.2022.1092201.

[33] National Cancer Institute. *https://www.cancer.gov/types/urethral/patient/urethral-treatment-pdq.*

[34] Dorland, W.A. Newman 1864–1956. *Dorland's Illustrated Medical Dictionary.* 29th ed. Philadelphia, Saunders, 2000.

[35] Pastor Z., Chmel R., (2017). ''Differential diagnostics of female ''sexual'' fluids: a narrative review''. International Urogynecology Journal. 29 (5): 621–629. doi:10.1007/s00192–017–3527–9. PMID 29285596. S2CID 5045626.

[36] Bullough, Vern L.; Bullough, Bonnie (2014). Human Sexuality: An Encyclopedia. Routledge. p. 231. ISBN 978–1135825096; Diane Tomalty, Olivia Giovannetti et al.: Should We Call It a Prostate? A Review of the Female Periurethral Glandular Tissue Morphology, Histochemistry, Nomenclature, and Role in Iatrogenic Sexual Dysfunction. In: Sexual Medicine Reviews. Volume 10, Issue 2, April 2022, page 183–194.

based on section 406 will be effective on the date of enactment of the Act; however, section 406 would stagger the dates that VA would be required to effectuate payment of compensation. The Act provides an exception to the phased-in applicability dates for veterans meeting certain priority criteria. Specifically, new presumptions under section 406 are applicable on the date of enactment of the Act for claims for dependency and indemnity compensation (DIC) and for veterans whom the Secretary determines are terminally ill, homeless, under extreme financial hardship, more than 85 years old, or capable of demonstrating other sufficient cause. For claimants not meeting one of the priority-based criteria, the applicability date of the presumption would be established as one of the following staggered dates: October 1, 2022, October 1, 2023, October 1, 2024, October 1, 2025, and October 1, 2026. As stated above, these phased-in applicability dates apply to 11 of the 23 new presumptive conditions under 38 U.S.C. 1120.

However, the Secretary has determined that the text of the PACT Act provides VA with authority to treat all new presumptions in section 406 of the PACT Act as immediately applicable, and the Secretary has chosen to exercise this authority. The Secretary has determined that all veterans presenting a claim for disability compensation for which service connection could be established based on the presumptions in section 406 are ''capable of demonstrating other sufficient cause,'' entitling those veterans to an applicability date concurrent with the date of enactment of the PACT Act. While the Secretary recognizes that Congress enumerated phased-in applicability dates, Congress also provided an extremely broad ''catch-all'' at the end of categories of cases that would justify immediate applicability of an otherwise phased-in presumption. This final category is textually broad and left undefined, providing the Secretary with significant discretion to expand the universe of cases for which otherwise phased-in presumptions under section 406 can be treated as immediately applicable. In making this determination, the Secretary considered first and foremost the health and economic needs of veterans, and specifically the serious nature of exposure to toxins in combat zones and the associated health effects from such exposures. Additionally, while phased-in applicability dates intuitively might help manage the significant increase in claims inventory that will result from the Act, VA estimates that phased-in applicability dates would result in between 900,000 and 1.5 million veterans having to wait up to four years for a decision on their claim, whereas acceleration of the applicability dates would avoid making veterans wait years. Further, rather than the administrative complexity and claimant confusion that would inevitably be created by having to hold many thousands of claims pending arrival of the phased-in applicability dates, immediate applicability ensures a simple, streamlined policy that will be easy for veterans and their families to understand and for VA to implement with consistency and efficiency.

For these reasons, the Secretary has determined to treat all presumptions in the PACT Act as applicable upon enactment and is proposing to add a new paragraph (e) to § 3.320 to reflect this determination.

VIII. Public Participation

Interested persons or organizations are invited to participate in this rulemaking by submitting written comments, recommendations, and data on any topic covered in this proposal. In addition, VA invites comments specifically on the following questions related to this rulemaking:

(1) What other factors and/or types of evidence should be considered when determining if participation in a TERA should be conceded?

(2) Are there additional TERA examination exceptions that should be implemented? If so, what are some examples of exceptions that should be considered? For example, the agency invites comment on the appropriateness of an exception that would apply if a veteran has not affirmatively indicated the presence of a TERA.

(3) Considering that the definition of TERA has an impact on the provision of medical examinations and nexus opinions under 38 U.S.C. 1168 and the provision of health care pursuant to 38 U.S.C. 1710(e)(4)(C), what additional activities or factors should the Secretary consider when determining what qualifies as TERA?

(4) Would it be appropriate to require that the veteran affirmatively assert the existence of a TERA in order for their claim to be considered under 38 U.S.C. 1168/TERA procedure?

VA welcomes comments from the public on all aspects of this proposed rule. This information will be utilized by VA to enhance our sub-regulatory guidance, inform the final rule, and improve consistency and transparency in our decision-making. All comments received by the closing date will be considered prior to final action.

IX. Revise Remainder of 38 CFR 3.1

Because VA is amending 38 CFR 3.1, VA is also required to bring the authority citations for the entirety of the regulation into compliance with 1 CFR 21.43. For § 3.1, VA is proposing to revise § 3.1(d), (j), (m), (r), (s), (t), (x), (y), (aa)(1) and (2) to amend the authority citations. These are not substantive changes, but rather changing the placement of the authority in regulation. Although VA is also making changes to §§ 3.159, 3.317, and 3.320, VA is addressing the changes to authority to § 3.159 in a separate rulemaking, and there are no authority changes required for §§ 3.317 or 3.320.

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 of September 30, 1993 (Regulatory Planning and Review), and Executive Order 13563 of January 18, 2011 (Improving Regulation and Regulatory Review). 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 associated with this rulemaking can be found as a supporting document at *www.regulations.gov.*

Regulatory Flexibility Act (RFA)

The Secretary hereby certifies that this proposed rule would not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act (5 U.S.C. 601–612). The factual basis for this certification is that no small entities or businesses provide Federal compensation or pension

benefits to veterans, and such entities or businesses therefore would be unaffected by the proposed rule. 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 proposed rule would have no such effect on State, local, and Tribal governments, or on the private sector.

Paperwork Reduction Act (PRA)

Although this proposed rule contains a collection of information under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521), there are no provisions associated with this rulemaking constituting any new collection of information or any revisions to the current collection of information. The collection of information for 38 CFR 3.1, 3.159, 3.307, 3.309, 3.311, 3.317, 3.320, is currently approved by the Office of Management and Budget (OMB) and has a valid OMB control number of 2900–0747 and 2900–0886.

List of Subjects in 38 CFR Part 3

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

Signing Authority

Denis McDonough, Secretary of Veterans Affairs, approved and signed this document on September 19, 2024, 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 Department of Veterans Affairs proposes to amend 38 CFR 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), unless otherwise noted.

■ 2. Amend § 3.1 by:
■ a. Revising paragraphs (d) introductory text, (j), (m), (r), (s), (t), (x), (y) introductory text, and (aa)(1) and (2); and
■ 3. Adding paragraphs (bb) through (dd).

The revisions and additions read as follows:

§ 3.1 Definitions.

* * * * *

(d) *Veteran* means a person who served in the active military, naval, air, or space service and who was discharged or released under conditions other than dishonorable under 38 U.S.C. 101(2).

* * * * *

(j) *Marriage* means a marriage valid under the law of the place where the parties resided at the time of marriage, or the law of the place where the parties resided when the right to benefits accrued under 38 U.S.C. 103(c)).

* * * * *

(m) In line of duty, per 38 U.S.C. 105, means an injury or disease incurred or aggravated during a period of active military, naval, air, or space service unless such injury or disease was the result of the veteran's own willful misconduct or, for claims filed after October 31, 1990, was a result of his or her abuse of alcohol or drugs. A service department finding that injury, disease or death occurred in line of duty will be binding on the Department of Veterans Affairs unless it is patently inconsistent with the requirements of laws administered by the Department of Veterans Affairs. Requirements as to line of duty are not met if at the time the injury was suffered or disease contracted the veteran was:

* * * * *

(r) *Date of receipt* means the date on which a claim, information or evidence was received in the Department of Veterans Affairs, except as to specific provisions for claims or evidence received in the State Department (§ 3.108), or in the Social Security Administration (§§ 3.153, 3.201), or Department of Defense as to initial claims filed at or prior to separation. However, the Under Secretary for Benefits may establish, by notice published in the **Federal Register**, exceptions to this rule, using factors such as postmark or the date the claimant signed the correspondence, when he or she determines that a natural or man-made interference with the normal channels through which the Veterans Benefits Administration ordinarily receives correspondence has resulted in one or more Veterans Benefits Administration offices experiencing extended delays in receipt of claims, information, or evidence from claimants served by the affected office or offices to an extent that, if not addressed, would adversely affect such claimants through no fault of their own (38 U.S.C. 512(a), 5110).

(s) *On the borders thereof* means, with regard to service during the Mexican border period, the States of Arizona, California, New Mexico, and Texas, and the nations of Guatemala and British Honduras (38 U.S.C. 101(30)).

(t) *In the waters adjacent thereto* means, with regard to service during the Mexican border period, the waters (including the islands therein) which are within 750 nautical miles (863 statute miles) of the coast of the mainland of Mexico (38 U.S.C. 101(30)).

* * * * *

(x) *Service pension* is the name given to Spanish-American War pension. It is referred to as a service pension because entitlement is based solely on service without regard to nonservice-connected disability, income and net worth. (38 U.S.C. 1512, 1536).

(y) *Former prisoner of war.* The term *former prisoner of war* means a person who, while serving in the active military, naval, air, or space service, was forcibly detained or interned in the line of duty by an enemy or foreign government, the agents of either, or a hostile force under 38 U.S.C. 101(32).

* * * * *

(aa) * * *

(1) As used in 38 U.S.C. 103 and implementing regulations, fraud means an intentional misrepresentation of fact, or the intentional failure to disclose pertinent facts, for the purpose of obtaining, or assisting an individual to obtain an annulment or divorce, with knowledge that the misrepresentation or failure to disclose may result in the erroneous granting of an annulment or divorce; and

(2) As used in 38 U.S.C. 110 and 1159 and implementing regulations, fraud means an intentional misrepresentation of fact, or the intentional failure to disclose pertinent facts, for the purpose of obtaining or retaining, or assisting an individual to obtain or retain, eligibility for Department of Veterans Affairs

benefits, with knowledge that the misrepresentation or failure to disclose may result in the erroneous award or retention of such benefits.

(bb) *Toxic exposure risk activity* means:

(1) Any activity that requires a corresponding entry in an exposure tracking record system for the veteran who carried out the activity; or

(2) Any activity that the Secretary determines qualifies for purposes of this section when taking into account what is reasonably prudent to protect the health of veterans.

(cc) *Exposure tracking record system* means:

(1) Any system, program, or pilot program used by the Secretary of Veterans Affairs or the Secretary of Defense to track how veterans or members of the Armed Forces have been exposed to various occupational or environmental hazards; and

(2) Includes the Individual Longitudinal Exposure Record, or successor system.

(dd) *Physical trauma* means a serious injury to the body. The three types of physical trauma are as follows:

(i) Blunt force trauma—when an object or force strikes the body, often causing concussions, deep cuts, or broken bones;

(ii) Trauma due to repetitive use—when repeated stress to the body's soft tissue structures, including muscles, tendons, and nerves, results in repetitive strain injuries; and

(iii) Penetrating trauma—when an object pierces the skin or body, usually creating an open wound. Penetrating trauma due to embedded fragments (to include shrapnel) does not fall under this definition.

(Authority: 38 U.S.C. 101, 103, 105, 110, 501, 512, 1159, 1168, 1512, 1536, 1742, 5110)

■ 4. Amend § 3.159 by:

■ a. Revising paragraphs (c)(4)(i) and (ii);

■ b. Redesignating paragraphs (c)(4)(iii) and (iv) as paragraphs (c)(4)(v) and (vi), respectively; and

■ c. Adding new paragraphs (c)(4)(iii) and (iv).

The revisions and additions read as follows:

§ 3.159 Department of Veterans Affairs assistance in developing claims.

* * * * *

(c) * * *

(4) *Providing medical examinations or obtaining medical opinions.* (i) Except as provided in paragraphs (c)(4)(iii) and (iv) of this section, in a claim for disability compensation, VA will provide a medical examination or obtain a medical opinion based upon a review of the evidence of record if VA determines it is necessary to decide the claim. A medical examination or medical opinion is necessary if the information and evidence of record does not contain sufficient competent medical evidence to decide the claim, but:

(A) Contains competent lay or medical evidence of a currently diagnosed disability or persistent or recurrent symptoms of disability;

(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

(C) Indicates that the claimed disability or symptoms may be associated with the established event, injury, or disease in service or with another service-connected disability.

(ii) Paragraph (c)(4)(i)(C) of this section could be satisfied by competent evidence showing post-service treatment for a condition, or other possible association with military service.

(iii) Except as provided in paragraph (c)(4)(iv) of this section, when a claim that cannot be considered on a presumptive basis is received, VA will provide a medical examination and medical nexus opinion if the evidence of record does not contain sufficient competent medical evidence to establish service connection, but only if the claim:

(A) Contains competent lay or medical evidence of a current disability; and

(B) Establishes that the veteran participated in a toxic exposure risk activity as defined in § 3.1(bb).

(iv). The Secretary has determined that there is no indication of an association between toxic exposure risk activities and the disabilities, conditions, and circumstances listed in paragraphs (c)(4)(iv)(A) through (D) of this section. A VA examination and medical nexus opinion will not be required for claims that cannot be considered on a presumptive basis and evidence establishes that the veteran participated in a toxic exposure risk activity if evidence shows:

(A) The disability is the result of physical trauma as defined in § 3.1(dd); or

(B) The claimed condition is a mental disorder; or

(C) The disability manifested during military service or has an etiology not associated with toxic exposure; or

(D) The only participation in a toxic exposure risk activity that is established relates to herbicide exposure and the veteran claims any of the following conditions:

(*1*) Cancers of the oral cavity (including lips and tongue), pharynx (including tonsils), and nasal cavity (including ears and sinuses);

(*2*) Cancers of the pleura, mediastinum, and other unspecified sites within the respiratory system and intrathoracic organs;

(*3*) Cancers of the digestive organs (esophageal cancer; stomach cancer; colorectal cancer (including small intestine and anus), hepatobiliary cancers (liver, gallbladder, and bile ducts), and pancreatic cancer);

(*4*) Bone and connective tissue cancer;

(*5*) Melanoma;

(*6*) Nonmelanoma skin cancer (basal cell and squamous cell);

(*7*) Cancers of the reproductive organs (cervix, uterus, ovary, breast, testes, and penis; not including prostate);

(*8*) Cancers of the brain and nervous system (including eye);

(*9*) Endocrine cancers (including thyroid and thymus);

(*10*) Leukemia (other than all chronic B-cell leukemias including chronic lymphocytic leukemia and hairy cell leukemia);

(*11*) Neurobehavioral disorders (cognitive and neuropsychiatric); Neurodegenerative diseases (including amyotrophic lateral sclerosis (ALS) but not including Parkinson's disease and Parkinsonism);

(*12*) Chronic peripheral nervous system disorders (other than early-onset peripheral neuropathy);

(*13*) Asthma;

(*14*) Chronic obstructive pulmonary disease;

(*15*) Farmer's lung;

(*16*) Gastrointestinal, metabolic, and digestive disorders;

(*17*) Immune system disorders (immune suppression, allergy, and autoimmunity);

(*18*) Circulatory disorders (other than hypertension, ischemic heart disease, and stroke);

(*19*) Endometriosis;

(*20*) Hearing loss;

(*21*) Diseases of the eye; and

(*22*) Osteoporosis.

(E) The exceptions under paragraphs (c)(4)(iv)(A) through (D) of this section will not apply if the veteran submits competent scientific or medical evidence that indicates that the claimed disability or condition may be associated with the in-service toxic exposure risk activity.

(F) The only participation in a toxic exposure risk activity that is established is based on an entry in an exposure tracking record system, as defined in § 3.1(cc), that does not corroborate a veteran's potential exposure to toxic substances, chemicals, or airborne hazards during military service.

(G) The only participation in a toxic exposure risk activity that is established is based on an entry in an exposure tracking record system, as defined in § 3.1(cc), that is based on the veteran's report of exposure to toxic substances, chemicals, or airborne hazards that cannot be substantiated.

* * * * *

■ 4. Amend § 3.317 by revising the section heading and paragraphs (a)(1), (c)(3)(ii), and (e)(1) to read as follows:

§ 3.317 Presumption of service connection for certain undiagnosed illnesses and medically unexplained chronic multi-symptom illnesses occurring in Persian Gulf veterans.

(a) * * *

(1) Except as provided in paragraph (a)(7) of this section, VA will pay compensation in accordance with 38 U.S.C. chapter 11, to a Persian Gulf veteran who exhibits objective indications of a qualifying chronic disability that became manifest to any degree at any time, provided that such disability, by history, physical examination, and laboratory tests, cannot be attributed to any known clinical diagnosis.

* * * * *

(c) * * *

(3) * * *

(ii) For purposes of this paragraph (c), the term *qualifying period of service* means service in the Southwest Asia theater of operations during the Gulf War or a period of active military, naval, or air service on or after September 19, 2001, in Afghanistan.

* * * * *

(e) *Service.* For purposes of this section:

(1) The term *Persian Gulf veteran* means a veteran who served on active military, naval, or air service in the Southwest Asia theater of operations, Afghanistan, Israel, Egypt, Turkey, Syria, or Jordan, during the Persian Gulf War.

* * * * *

■ 5. Revise § 3.320 to read as follows:

§ 3.320 Presumptive service connection based on exposure to toxic substances, chemicals, and airborne hazards.

(a) *Presumption of exposure.* A covered veteran as defined in paragraph (c) of this section, and required by 38 U.S.C. 1119(b), shall be presumed to have been exposed to the following toxic substances, chemicals, and airborne hazards during such service, unless there is affirmative evidence to establish that the veteran was not exposed to any such toxic substances, chemicals, and airborne hazards during that service.

(1) Fine particulate matter.

(2) [Reserved]

(b) *Presumption of service connection.* Except as provided in paragraph (d) of this section, the following diseases becoming manifest in a covered veteran, as defined in paragraph (c) of this section, shall be considered to have been incurred in or aggravated during active military, naval, air, or space service, notwithstanding that there is no record of evidence of such disease during the period of such service.

(1) Asthma.

(2) Head cancer of any type.

(3) Neck cancer of any type.

(4) Respiratory cancer of any type.

(5) Gastrointestinal cancer of any type.

(6) Reproductive cancer of any type.

(7) Lymphoma cancer of any type.

(8) Kidney cancer.

(9) Brain cancer.

(10) Melanoma.

(11) Pancreatic cancer.

(12) Chronic bronchitis.

(13) Chronic obstructive pulmonary disease.

(14) Constrictive bronchiolitis or obliterative bronchiolitis.

(15) Emphysema.

(16) Granulomatous disease.

(17) Interstitial lung disease.

(18) Pleuritis.

(19) Pulmonary fibrosis.

(20) Sarcoidosis.

(21) Chronic sinusitis.

(22) Chronic rhinitis.

(23) Glioblastoma.

(c) *Covered veteran.* For purposes of this section, the term covered veteran means any veteran who:

(1) On or after August 2, 1990, performed active military, naval, air, or space service while assigned to a duty station in, including airspace above:

(i) The Southwest Asia theater of operations as defined in § 3.317(e)(2); or

(ii) Somalia; or

(2) On or after September 11, 2001, performed active military, naval, air, or space service while assigned to a duty station in, including airspace above:

(i) Afghanistan;

(ii) Djibouti;

(iii) Egypt;

(iv) Jordan;

(v) Lebanon;

(vi) Syria;

(vii) Yemen; or

(viii) Uzbekistan.

(d) *Exceptions.* A disease listed in paragraph (b) of this section shall not be presumed service connected if there is affirmative evidence that:

(1) The disease was not incurred or aggravated during active military, naval, air, or space service; or

(2) The disease was caused by a supervening condition or event that occurred between the veteran's most recent departure from active military, naval, air, or space service and the onset of the disease; or

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

(e) *Special applicability date provision.* The Secretary has determined that all veterans presenting a claim for disability compensation for which service connection could be established based on the presumptions in section 406 of Public Law 117–168 are ''capable of demonstrating other sufficient cause,'' entitling those veterans to an applicability date for the presumptions concurrent with the date of enactment of Public Law 117–168.

(Authority: 38 U.S.C. 501, 1119, 1120)

[FR Doc. 2024–21852 Filed 9–30–24; 8:45 am]

BILLING CODE 8320–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R02–OAR–2024–0083; FRL–11767–01–R2]

Finding of Failure To Attain the Primary 2010 1-Hour Sulfur Dioxide Standard for the San Juan and Guayama-Salinas Nonattainment Areas; Approval and Conditional Approval of Air Quality State Implementation Plans; Puerto Rico; Attainment Plan for the 2010 1-Hour Sulfur Dioxide Standard for the San Juan and Guayama-Salinas Nonattainment Areas

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing two actions related to attainment of the 2010 primary 1-hour sulfur dioxide (SO_2) National Ambient Air Quality Standard (NAAQS or ''standard''). First, the EPA is proposing to determine that the San Juan and Guayama-Salinas SO_2 Nonattainment Areas (NAAs) failed to attain the 2010 primary 1-hour SO_2 NAAQS by the applicable attainment date of April 9, 2023, based upon a technical analysis of various evidence