DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 3

RIN 2900–AS27

Presumptive Service Connection for Leukemias, Multiple Myelomas, Myelodysplastic Syndromes, and Myelofibrosis Due to Exposure to Fine Particulate Matter

AGENCY: Department of Veterans Affairs.

ACTION: Interim final rule.

SUMMARY: The Department of Veterans Affairs (VA) is issuing this interim final rule (IFR) to amend its adjudication regulations to establish presumptive service connection for acute leukemias, chronic leukemias, multiple myelomas, myelodysplastic syndromes (MDS), and myelofibrosis due to exposure to Particulate Matter 2.5 ($PM_{2.5}$). The new presumptions would apply to veterans who served on active military, naval, air, or space service in the Southwest Asia theater of operations or Somalia during the Persian Gulf War (hereafter Gulf War) on or after August 2, 1990, and in Afghanistan, Syria, Djibouti, Uzbekistan, Egypt, Jordan, Lebanon, and Yemen during the Gulf War on or after September 11, 2001.

DATES:

Effective date: This interim final rule is effective January 10, 2025.

Comment date: Comments must be received on or before March 11, 2025.

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 an individual. VA encourages individuals not to submit duplicative comments; however, 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 interim final rule is available at *www.regulations.gov,* under RIN 2900–AS27.

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SUPPLEMENTARY INFORMATION:

I. Background

On August 10, 2022, the President signed into law the Sergeant First Class Heath Robinson Honoring our Promise to Address Comprehensive Toxics Act of 2022 (PACT Act). Public Law 117–168. The PACT Act provided a process for VA to establish presumptive service connection based on toxic exposures. 38 U.S.C. 1171–1174. The PACT Act also added a presumption of service connection for certain diseases associated with exposure to burn pits and other toxins (BPOT) in 38 U.S.C. 1120. This presumption applies to veterans who served in locations listed in 38 U.S.C. 1119(c)(1).

One of VA's priorities is to address the long overdue needs of the Gulf War cohort and to address the need for these veterans to receive timely care, services, and benefits. VA has reviewed both medical and scientific literature and has found sufficient evidence to conclude that a positive association exists between exposure to $PM_{2.5}$ and acute and chronic leukemias and multiple myelomas. Accordingly, VA has determined that presumptions of service connection for these diseases and two precursors to acute myeloid leukemia (AML), MDS and myelofibrosis, are warranted for certain Gulf War veterans.

In this IFR, VA adds 38 CFR 3.320b to its adjudicatory regulations to presume service connection for acute leukemias, chronic leukemias, multiple myelomas, MDS, and myelofibrosis for certain Gulf War veterans. VA adds these as presumptive conditions in 38 CFR 3.320b by IFR so that any veteran with these diseases and who served in a prescribed location need not wait for benefits.

II. Scientific Background

a. Exposure to Fine Particulate Matter

On August 5, 2021, VA promulgated 38 CFR 3.320 to establish presumptions of service connection for certain chronic diseases based on exposure to $PM_{2.5}$ during service in the Southwest Asia theater of operations during the Persian Gulf War, or service in Afghanistan, Syria, Djibouti, or Uzbekistan, on or after September 19, 2001, during the Persian Gulf War. 86 FR 42724, 42733 (2021) (interim final rule); *see* 88 FR 60341 (2023) (adopting the interim final rule with changes). VA based these presumptions on review and analysis of airborne hazards in the Southwest Asia theater of operations during the Persian Gulf War, by examining the National Academies of Science, Engineering, and Medicine's (NASEM) 2020 report, Respiratory Health Effects of Airborne Hazards Exposures in the Southwest Asia Theater of Military Operations; [1] NASEM's 2011 report, Long-Term Health Consequences of Exposure to Burn Pits in Iraq and Afghanistan; [2] and NASEM's 2010 report, Review of the Department of Defense (DoD) Enhanced Particulate Matter Surveillance Program.[3] *See* 86 FR at 42725–42726. The 2010 report concluded that Service members deployed to the Middle East ''are exposed to high concentrations of PM[2.5].'' [4] *See* 86 FR at 42725. Toxic compounds present in burn pit fumes include $PM_{2.5}$.[5] This airborne pollution includes smoke from oil well fires; sand; dust; mechanical fumes from aircraft, vehicle, and ship engines; wood; plastic; rubber; metals; munitions; chemicals; and food and human waste.[6] 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.[7]

When promulgating 38 CFR 3.320 in August 2021, to determine the qualifying periods of service, VA primarily considered (1) whether burn

[1] 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* (hereafter ''Respiratory Health Effects of Airborne Hazards'').

[2] 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* (hereinafter ''NASEM 2011 Report'').

[3] 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* (hereinafter ''NRC'').

[4] NRC, *supra.*

[5] Wang X, Doherty TA, James C. *Military burn pit exposure and airway disease: Implications for our Veteran population.* Ann Allergy Asthma Immunol. 2023 Dec;131(6):720–725. doi: 10.1016/j.anai.2023.06.012. *https://pmc.ncbi.nlm.nih.gov/articles/PMC10728339/.*

[6] *Id.*

[7] American Cancer Society. Military Burn Pits and Cancer Risk. 2022. *https://www.cancer.org/healthy/cancer-causes/chemicals/burn-pits.html.*

pits were used in the location, (2) the $PM_{2.5}$ levels, and (3) desert climates according to 86 FR at 42725–42729. However, in August 2022, the PACT Act created new 38 U.S.C. 1119, ''Presumptions of toxic exposure,'' with different qualifying periods of service. Section 1119(c) 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's new presumptions in 38 CFR 3.320b will include the locations in current 38 CFR 3.320(a)(5), and the locations listed in 38 U.S.C. 1119(c) (including Egypt, Jordan, Lebanon, Somalia, and Yemen). This approach conforms with the information available regarding 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.[8] 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 [9] and is the only combatant command that conducts open burn pit operations.[10] Egypt, Jordan, Lebanon, and Yemen were included as locations with open, active burn pits.[11] Somalia was not included on the list. However, there is evidence of burn pit use in Somalia when service members were deployed in support of Operation Show Care in 1993.[12] Additional deployments occurred in 1992, 1995, 2012, and 2022.[13]

Additionally, all the locations listed in 38 U.S.C. 1119(c) 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.[14] 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.[15] 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.[16] Finally, DoD's report also stated that $PM_{2.5}$ 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.[17]

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.[18] Although dust in these locations can be toxic based on transportation and industrial activities alone, open air burn pits increase the concentration of toxins in $PM_{2.5}$.

As discussed above, in locations that rely on open burning of waste, the $PM_{2.5}$ 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.'' [19] 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 that can have many different components from many different sources (for example, sand, dust, and smoke) and open burning of waste emits toxic combustion emissions into the ambient air; VA considers burn pit smoke to be a contributor to $PM_{2.5}$.

The 38 U.S.C. 1119(c) 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.[20] For consistency with the statutory start date for service in 38 U.S.C. 1119(c)(1)(B) locations (including Afghanistan, Syria, Djibouti, and Uzbekistan) back to September 11, 2001, new 38 CFR 3.320b will presume exposure to $PM_{2.5}$ for those countries back to September 11, 2001.

b. The PACT Act Process

The PACT Act presumption determination process consists of four phases. The Ongoing Exploratory Surveillance Phase includes collaborating with VA partners, to include Veterans Service Organizations (VSOs) and other stakeholders, to identify, monitor, and investigate potential toxic exposures and adverse health effects. 38 U.S.C. 1172(a). The Research and Assessment Phase involves collecting information, evidence, and data regarding a particular toxic exposure and adverse health effect, and potentially conducting a scientific study and analysis of the data. 38 U.S.C. 1172(c). Based on the findings, VA's Military Environment Exposures Sub-Council (MEESC) may recommend that the Secretary initiate a formal evaluation of the issue. 38 U.S.C. 1172(d).

If the Secretary adopts that recommendation, the Formal Evaluation Phase begins. 38 U.S.C. 1173. In this phase, a technical working group is convened to conduct an evaluation of the evidence and research collected in the prior phases as well as claims data and potentially other factors, to render a conclusion on the strength of the evidence and to provide a recommendation to the Secretary with respect to a presumption. *Id.* If the Secretary decides to accept a recommendation to establish a presumption, the Rulemaking and Implementation Phase then begins. 38 U.S.C. 1174.

c. Ongoing Exploratory Surveillance Phase

On July 26, 2023, VA published a notice soliciting public comment on its plan to assess the scientific literature

[8] See Letter from Office of Under Secretary of Defense to the U.S. House of Representatives Committee on Appropriations (May 7, 2021), available on the rulemaking docket at *www.regulations.gov* (hereafter ''Defense Letter'').

[9] U.S. Central Command. Area of Responsibility. *https://www.centcom.mil/AREA-OF-RESPONSIBILITY/.*

[10] Department of Defense. Open Burn Pit Report to Congress. 2019. *https://www.acq.osd.mil/eie/Downloads/Congress/Open%20Burn%20Pit%20Report-2019.pdf.*

[11] See Defense Letter, *supra.*

[12] 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.*

[13] . CRS Report R42738, Instances of Use of United States Armed Forces Abroad, 1798–2022, *https://crsreports.congress.gov/product/pdf/R/R42738/38;* Stimson Center, US Security Assistance to Somalia, *https://www.stimson.org/2023/us-security-cooperation-with-somalia/.*

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

[15] *Id.*

[16] *Id.*

[17] *Id.*

[18] NASEM 2011 Report, *supra.*

[19] 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.*

[20] EPMSP Report, *supra.*

and historical claims data regarding multiple myelomas, acute leukemias, and chronic leukemias associated with specific military environmental exposures. 88 FR 73094. On November 7, 2023, VA's Health Outcomes Military Exposures (HOME) office held a public listening session and briefed VSOs and Congressional staffers on the plan to study leukemias and multiple myelomas. Most comments were in favor of assessing the scientific literature and historic claims data regarding multiple myelomas, acute leukemias, and chronic leukemias. 89 FR 33471.

d. Research and Assessment Phase

In November 2023, Veterans Health Administration (VHA) HOME and Veterans Benefits Administration's (VBA) Military Exposure Team (MET) (hereafter ''the committee'') began collaboration to evaluate two distinct types of information (peer-reviewed scientific literature and VBA claims data) to determine the strength of the evidence supporting an association between exposure to $PM_{2.5}$ in the Southwest Asia theater of operations or Somalia on or after August 2, 1990, or in Afghanistan, Egypt, Jordan, Lebanon, Syria, Yemen, Djibouti, or Uzbekistan on or after September 11, 2001 and chronic and acute leukemias and multiple myelomas. The committee considered this issue because blood and bone marrow cancers were not included as presumptions in the PACT Act. The committee followed the Patient, Exposure, Comparator, Outcomes, Timing, Setting (PECOTS) framework to guide a literature search and identify relevant articles for review—and identified 319 peer-reviewed publications that met the search criteria, of which 154 were deemed relevant.[21]

To assist in reviewing the relevant articles, the committee engaged experts including military exposure epidemiologists from VHA and the Department of Defense, VA scientists, VA oncologists/hematologists, board-certified occupational and environmental medicine (OEM) physicians, and a senior medical advisor from the Commissioned Corps of the U.S. Public Health Service.[22] Of the 154 relevant publications, 42 met the desired grade quality of high or moderate quality based on the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) guidelines.[23] Of the moderate and high quality peer-reviewed scientific publications, 74% showed a positive association between exposure to $PM_{2.5}$ and development of acute and chronic leukemias and multiple myelomas.[24] The committee concluded with a recommendation that the Secretary initiate a formal evaluation of the matter.[25]

e. Formal Evaluation Phase

On November 20, 2024, the Secretary initiated a formal evaluation on chronic and acute leukemias and multiple myelomas and their possible association with exposure to $PM_{2.5}$ pollution in the Southwest Asia theater of Operations.[26] At the same time, the Secretary also directed a formal evaluation on other blood cancers.[27]

Under 38 U.S.C. 1173(b), a formal evaluation shall be based on the review of available scientific literature, including human, toxicological, animal, and methodological studies, and other factors, and must consider claims data including claim rate, grant rate, and service connection prevalence. It can also consider the level of disability and mortality caused by the health effects related to the case of toxic exposure being evaluated; the quantity and quality of the information available and reviewed; the feasibility of and period for generating relevant information and evidence; whether such health effects are combat- or deployment-related; the ubiquity or rarity of the health effects; and any time frame during which a health effect must become manifest.

A formal evaluation shall review scientific evidence in a manner that conforms to principles of scientific and data integrity; be free from suppression or distortion of scientific or technological findings, data, information, conclusions, or technical results; evaluate the likelihood that a positive association exists between an illness and a toxic exposure while serving in the active military, naval, air, or space service; and determine whether the evidence supports a finding of a positive association between the toxic exposure and the illness. 38 U.S.C. 1173(c).

Here, the formal evaluation team (hereinafter ''the team'') reviewed the methods and findings of the committee's report from the Research and Assessment phase.[28] The team included the HOME policy team, and hematologists/oncologists, epidemiologists, a toxicologist, and VBA Compensation Service personnel who were not part of the scientific assessment.[29] The team assessed that the committee's report had three major components and was consistent with robust scientific methods.[30] First, the team noted that masters' trained biomedical librarians, not part of the scientific assessment committee, had followed a PECOTS framework to complete an expansive structured literature search. Second, the team noted that the committee had critically reviewed the papers of moderate and high-grade quality based on the GRADE structure.[31] Third, the team noted that the committee had reviewed VBA claims data on leukemias and multiple myelomas from March 2003–March 2023 for both deployed and non-deployed Gulf War Era veterans, including 1990–1991 Gulf War veterans, Global War on Terror veterans, and Karshi-Khanabad Veterans.[32]

The team emphasized that the 74% of the moderate and high-quality peer-reviewed scientific publications reviewed by the committee, as discussed above, consistently showed a positive relationship between exposure to $PM_{2.5}$ and development of leukemias and multiple myelomas. The team noted that the VBA claims data provided a complementary perspective to the evidence in the scientific literature and showed trends among veterans with deployment to countries with recognized high levels of $PM_{2.5}$ and burn pit pollution. Notably, veterans deployed to the relevant countries were granted a higher proportion of claims (53% vs. 42% for non-deployed), which supports the correlation between $PM_{2.5}$ and higher risk of service-related diagnoses of these conditions. The data also showed that the deployed cohort filed more claims than non-deployed

[21] Report to the Secretary of Veterans Affairs on the Relationship Between Exposure to Fine Particulate Matter ($PM_{2.5}$) in the Southwest Theatre of Operations or Somalia on or After August 2, 1990, or in Afganistan, Egypt, Jordan, Lebanon, Syria, Yemen, Djibouti, or Uzbekistan on or After September 11, 2001 and Chronic and Acute Leukemias and Multiple Myleomas, November 2024 (hereafter ''Committee report''), is attached to this rulemaking, available at *www.regulations.gov*.

[22] *Id.*

[23] *Id.*

[24] *Id.*

[25] *Id.*

[26] Secretary's Memorandum, signed November 20, 2024, is attached to this rulemaking, available at *www.regulations.gov*.

[27] *Id.*

[28] Formal Evaluation of the Report to The Secretary of Veterans Affairs on The Relationship Between Exposure to Fine Particulate Matter ($PM_{2.5}$) in the Southwest Theatre of Operations or Somalia on or after August 2, 1990, or In Afghanistan, Egypt, Jordan, Lebanon, Syria, Yemen, Djibouti, or Uzbekistan on or After September 11, 2001, and Acute Leukemias, Chronic Leukemias, and Multiple Myelomas, December 6, 2024 (hereafter ''Formal Evaluation Report'') is attached to this rulemaking, available at *www.regulations.gov*.

[29] *Id.*

[30] *Id.*

[31] *Id.*

[32] *Id.*

veterans, and also filed claims at a younger age, suggesting earlier onset of deployment related conditions. The team highlighted these data findings as supporting the link between PM exposure and increased risk for hematological cancers.[33]

As an additional validation step, the team analyzed a sample of ten papers considered by the scientific review to be high-quality studies that reported positive associations between exposure to $PM_{2.5}$ and chronic leukemias, acute leukemias, and multiple myelomas. The team confirmed that, taken as a body of literature, the evidence suggested that environmental exposure to $PM_{2.5}$ is positively associated with acute and chronic leukemias and multiple myelomas. In sum, groups of people that had measured, documented exposure to $PM_{2.5}$ had a higher risk of developing leukemias and multiple myelomas than those who did not have a measured, documented exposure to $PM_{2.5}$.[34]

The team did note certain limitations in the data, including that PM is diverse and depends on many factors. PM air pollution can include smoke, fumes, soot, and other products of combustion, as well as particles from natural sources, including dust and sand. Further, the team noted that, of the 42 papers deemed to provide high or moderate quality evidence, none were done on military Service members or in the environments in which Service members were deployed to the Southwest Asia theater of operations or Somalia on or after August 2, 1990, or in Afghanistan, Egypt, Jordan, Lebanon, Syria, Yemen, Djibouti, or Uzbekistan. The studies relied upon were conducted in other parts of the world, studied firefighters, those exposed to ambient air pollution or specific pollutants, and individuals exposed to the possibly unique PM exposures at the WTC. Nevertheless, the team found that the argument that exposure to PMs creates risk for acute and chronic leukemias and myelomas is biologically plausible and remains regardless of the differences in location or particulates.[35]

Despite these limitations, the team concluded that the evidence meets the ''sufficient'' category in 38 U.S.C. 1173(c)(2), where the evidence is sufficient to conclude a positive association existed. 38 U.S.C. 1173(c)(2)(A). This is the strongest category of positive association under the PACT Act's presumptive decision-making process. 38 U.S.C. 1173(c)(2)(A). Based on the positive association demonstrated, the formal evaluation team recommended—in its December 6, 2024, formal evaluation report—that the Secretary initiate rulemaking to establish acute leukemias, chronic leukemias, and multiple myelomas as presumptive service-connected conditions for veterans who served in the Southwest Asia theater of Operations or Somalia on or after August 2, 1990, or in Afghanistan, Egypt, Jordan, Lebanon, Syria, Yemen, Djibouti, or Uzbekistan on or after September 11, 2001.[36]

Regarding the formal evaluation for other blood cancers, on December 5, 2024, the MEESC recommended that the formal evaluation team continue to research these conditions (Polycythemia Vera, MDS, Essential (Hemorrhagic) Thrombocythemia, Chronic Myeloproliferative Disease, Myelofibrosis, Histiocytosis, and Mastocytosis) and provide a formal evaluation report to the Secretary by March 20, 2025, *i.e.,* within 120 days of the formal evaluation initiation, in accord with 38 U.S.C. 1173(d).[37] The MEESC noted that there were over 60,000 studies on polycythemia vera and millions of studies on myeloproliferative neoplasms[38] and, with respect to mechanistic studies that may establish biological plausibility, more investigation was needed.[39]

To aid an evaluation of the MEESC's recommendation on these ''other blood cancers,'' the Office of the Secretary of Veterans Affairs requested additional information concerning the survivability of those seven diseases. On December 9, 2024, HOME provided the Secretary an information paper on the issue.[40] In summary, two of the seven other blood cancers (MDS and myelofibrosis) may progress to acute myeloid leukemia (AML), and veterans whose disease so progresses often have a very poor prognosis.

The Secretary considered the formal evaluation report on acute leukemias, chronic leukemias, and multiple myelomas; the MEESC's recommendation to continue the formal evaluation on other blood cancers; and the additional information on survivability provided by HOME. On December 13, 2024, the Secretary directed VA to initiate rulemaking to establish acute leukemias, chronic leukemias, and multiple myelomas, and precursors MDS and myelofibrosis, as presumptive service-connected conditions related to exposure to $PM_{2.5}$ in the Southwest Asia theater of operations or Somalia on or after August 2, 1990, or in Afghanistan, Egypt, Jordan, Lebanon, Syria, Yemen, Djibouti, or Uzbekistan on or after September 11, 2001.[41]

Though much of the evidence supporting the Secretary's decision has already been chronicled above, we also provide additional information on each of the conditions below:

1. Leukemias

As noted above, the formal evaluation team reviewed the report generated by the scientific assessment committee, evaluated the methods, findings, and conclusions, and validated the conclusions.[42] Among the pertinent findings, the team cited the EPA's determination that there is suggestive evidence of a relationship between long-term exposure to $PM_{2.5}$ and cancers.[43]

Of the PM components detected in air samples taken at Joint Base Balad Iraq in 2007 and 2009, some volatile organic compounds with documented associations with leukemias and other hematopoietic cancers, such as benzene and 1,3-butadiene, were measured at levels that exceed safety thresholds.[44] The team also highlighted several high-quality papers that reported positive associations between exposure to $PM_{2.5}$ and chronic leukemias and acute leukemias, which supported the findings that $PM_{2.5}$ exposure placed individuals at increased risk for leukemias.[45]

The team concluded there is sufficient evidence supporting the conclusion that veterans deployed in the relevant areas

[33] *Id.*

[34] *Id.*

[35] *Id.*

[36] Formal Evaluation Report, *supra.*

[37] MEESC Memorandum, dated December 5, 2024, is attached to this rulemaking, available at *www.regulations.gov.*

[38] A myeloproliferative neoplasm is ''A type of disease in which the bone marrow makes too many red blood cells, platelets, or certain white blood cells.'' National Cancer Institute Dictionaries, myeloproliferative neoplasm, *https://www.cancer.gov/publications/dictionaries/cancer-terms/def/myeloproliferative-neoplasm.*

[39] *Id.*

[40] HOME Information Paper, dated December 9, 2024, is attached to this rulemaking, available at *www.regulations.gov.*

[41] Secretary's Memorandum, signed December 13, 2024, is attached to this rulemaking, available at *www.regulations.gov.*

[42] Formal Evaluation Report, *supra.*

[43] *Id;* see also Environmental Protection Agency Integrated Science Assessment (ISA) for Particulate Matter (2019), *https://www.epa.gov/isa/integrated-science-assessment-isa-particulate-matter* (finding the relationship ''likely to be causal''); World Health Organization, International Agency for Research on Cancer, Monographs on the Evaluation of Carcinogenic Risks to Humans Volume 109, 2015. *https://publications.iarc.fr/Book-And-Report-Series/Iarc-Monographs-On-The-Identification-Of-Carcinogenic-Hazards-To-Humans/Outdoor-Air-Pollution-2015* (finding that PM was carcinogenic to humans and detailing the mechanistic process by which PM initiates mutations).

[44] *Id.*

[45] *Id.*

develop leukemia earlier in their lives than those who did not deploy.[46] Among other findings, the studies cited show $PM_{2.5}$ exposure plays a major role in the process of activating or maintaining gene expression, leading to the development of leukemia.[47] Exposure to benzene, which may be absorbed by particulates as a result of burn pits, significantly increases the risk of developing leukemia.[48] Additional associative environmental causes are soot [49] and toxic metals,[50] which are known airborne hazards.[51] Further, excessive exposure to carcinogens due to inhalation of PM, such as fire, smoke, dust, and burning debris, leads to increased rates of leukemia.[52] Moreover, pollutants at the World Trade Center (WTC) recovery site were similar to $PM_{2.5}$, and the workers who engaged in onsite recovery efforts developed hematological cancers, including myeloma, leukemia, and lymphoma at a higher rate than those who did not.[53] The studies cited also show that the higher the exposure to $PM_{2.5}$ in the year prior to diagnosis, the more likely a leukemia diagnosis would occur.[54]

$PM_{2.5}$ exposure is of concern for those deployed to the Southwest Asia theater of operations and other known BPOT locations. VA has already examined studies by NASEM on the contribution of air pollution to adverse health effects among U.S. Service Members serving in the Middle East.[55] 86 FR at 42725–42726. Thus, VA has determined that it will consider chronic and acute leukemias for this population to be associated with exposure to $PM_{2.5}$. Accordingly, VA concludes it is appropriate to add chronic leukemias and acute leukemias to 38 CFR 3.320b.

2. Multiple Myelomas

Similar to leukemia, the scientific committee and formal evaluation team found strong scientific evidence linking exposure to $PM_{2.5}$ to the development of multiple myelomas.[56] The studies cited show that exposure to coal dust, coke dust, crude petroleum, iron, lubricants, and solvents found in $PM_{2.5}$ was a probable carcinogen causing multiple myelomas.[57] Another study noted higher than normal diagnoses of multiple myelomas occurred in WTC responders. These responders were exposed to a complex mix of pollutants, including benzene and polycyclic aromatic hydrocarbons, asbestos, paint and solvent vapors, aromatic hydrocarbons, polychlorinated biphenyls, pesticides, microscopic shards of glass, polychlorinated biphenyls, other organochlorines, dioxins, furans, engine exhaust, and metals, which previous studies had associated with higher rates of multiple myelomas.[58] The dust carrying $PM_{2.5}$ at the WTC recovery site was potent in inducing change in multiple myeloma cells, increasing risk for the disease.[59] First responders were diagnosed with multiple myelomas at a higher rate than the general population.[60] An excess number of cases of multiple myeloma were observed among first responders, in particular among those younger than 45 years of age.[61] The environmental etiology at the WTC may be similar to exposure to pollutants, including $PM_{2.5}$.[62] Another study showed that both men and women who lived near a waste incineration plant had increased rates of multiple myelomas compared to those who did not.[63]

For these reasons, VA concludes that the evidence is sufficient to warrant a presumption of multiple myelomas due to $PM_{2.5}$ for the affected population. As stated above, VA recognizes the adverse health effects of $PM_{2.5}$ exposure on U.S. Service Members serving in the Middle East. VA concludes it is appropriate to add multiple myelomas to 38 CFR 3.320b.

3. Myelodysplastic Syndromes (MDS) and Myelofibrosis

MDS and myelofibrosis are rare blood cancers that can progress to AML, a condition which will be presumptive under this rule. In addition to the presumptions above, VA has examined MDS and myelofibrosis and concluded that these diseases warrant presumptive service connection because they can progress to AML, and veterans whose disease so progresses often have a very poor prognosis.[64]

Approximately 30% to 40% of individuals with MDS will eventually progress to AML [65] and ''often have a very poor prognosis.'' [66] The majority of

[46] *Id.*

[47] G. Visani et al., ''Environmental nanoparticles are significantly over-expressed in acute myeloid leukemia,'' Leukemia Research, Volume 50, 2016–11–01, *https://www.clinicalkey.com/#!/content/playContent/1-s2.0-S0145212616301916?returnurl=https:%2F%2Flinkinghub.elsevier.com%2Fretrieve%2Fpii%2FS0145212616301916%3Fshowall%3Dtrue&referrer=https:%2F%2Fpubmed.ncbi.nlm.nih.gov%*.

[48] Demers PA, Heyer NJ, Rosenstock L. Mortality among firefighters from three northwestern United States cities. Br J Ind Med. 1992 Sep;49(9):664–70. doi: 10.1136/oem.49.9.664. PMID: 1390274; PMCID: PMC1039313. *https://pmc.ncbi.nlm.nih.gov/articles/PMC1039313* (hereinafter ''Demers Mortality among firefighters''); Andrea Micheli et.al, Risk of death for hematological malignancies for residents close to an Italian petrochemical refinery: a population-based case-control study, *https://link.springer.com/article/10.1007/s10552-014-0468-1*.

[49] Jenny N. Poynter et al., ''Chemical exposures and risk of acute myeloid leukemia and myelodysplastic syndromes in a population-based study,'' International Journal of Cancer, 140–1, 2017, *https://pmc.ncbi.nlm.nih.gov/articles/PMC5245124*.

[50] Maro Ohanian et al., ''A heavy metal baseline score predicts outcome in acute myeloid leukemia,'' American Journal of Hematology, Volume 95, Issue 4, 2020, *https://onlinelibrary.wiley.com/doi/10.1002/ajh.25731*.

[51] Formal Evaluation Report, *supra.*

[52] Jiehui Li et al., ''Association between World Trade Center exposure and excess cancer risk,'' JAMA, Volume 308, 2012, *https://jamanetwork.com/journals/jama/fullarticle/1486831* (hereinafter ''Li World Trade Center Exposure''); Demers Mortality among firefighters, *supra.*

[53] Samara Solan et al., ''Cancer incidence in World Trade Center Rescue and Recovery Workers, 2001–2008,'' Environmental Health Perspectives, Volume 121,6, 2013, *https://pmc.ncbi.nlm.nih.gov/articles/PMC3672914*.

[54] Robin C. Puett et al., ''Relationship of leukaemias with long-term ambient air pollution exposures in the adult Danish population,'' British Journal of Cancer, Volume 123, 12, 2020, *https://pmc.ncbi.nlm.nih.gov/articles/PMC7722932/*.

[55] NASEM, Gulf War and Health Series: Volume 3: Fuels and Products of Combustion (2005), *https://doi.org/10.17226/11180* and Volume 11: Generational Health Effects of Serving in the Gulf War (2018), *https://doi.org/10.17226/25162;* Respiratory Health Effects of Airborne Hazards, *supra.*

[56] Committee Report, *supra;* Formal Evaluation Report, *supra.*

[57] Sunita Ghosh et al., Multiple myeloma and occupational exposures: a population-based case-control study *https://pubmed.ncbi.nlm.nih.gov/21654434/*; B. Charbotel et al., ''Occupational exposures in rare cancers: A critical review of the literature,'' Critical Reviews in Oncology and Hematology, Volume 90, Issue 2, *https://www.clinicalkey.com/#!/content/playContent/1-s2.0-S104084281300259X* (hereafter ''Occupational exposures in rare cancers'').

[58] Jacqueline Moline, et.al. Multiple Myeloma in World Trade Center Responders: A Case Series, *https://journals.lww.com/joem/fulltext/2009/08000/multiple_myeloma_in_world_trade_center_responders_.7.aspx* (hereafter ''Moline, Multiple Myeloma'').

[59] Kai Wu, et al. Proteomic Characterization of the World Trade Center dust-activated mdig and c-myc signaling circuit linked to multiple myeloma, *https://pmc.ncbi.nlm.nih.gov/articles/PMC5105131/* (hereinafter ''Wu'').

[60] *Id.*

[61] Moline, Multiple Myeloma, *supra.*

[62] Wu, *supra.*

[63] Eugenia Marine Barjoan et al., ''Cancer incidence in the vicinity of a waste incineration plant in the Nice area between 2005 and 2014,'' Environmental Research, Volume 188, 2020, 109681, *https://www.sciencedirect.com/science/article/pii/S0013935120305740?via%3Dihub.*

[64] HOME Information Paper, *supra;* Secretary's December 13, 2024 Memorandum, *supra.*

[65] Menssen AJ, Walter MJ. Genetics of progression from MDS to secondary leukemia. Blood. 2020 Jul; *https://pubmed.ncbi.nlm.nih.gov/32430504/* (hereinafter ''Menssen''); Akriti Jain et al. Patterns of lower risk myelodysplastic syndrome progression: factors predicting progression to high-risk myelodysplastic syndrome and acute myeloid leukemia, *https://pmc.ncbi.nlm.nih.gov/articles/PMC11215361/* (hereinafter ''Jain'').

[66] Jennifer L. Dotson et al. Myelodysplastic Syndrome, *https://www.ncbi.nlm.nih.gov/books/NBK534126/* (hereafter ''Dotson'').

patients with both MDS and AML fail to respond to available therapies[67] and often die from complications and/or disease progression.[68] Even among those with MDS who do not progress to AML, the five-year survival rate is only 37%[69], meaning that 2 of 3 individuals with MDS will not survive 5 years. Like MDS, patients diagnosed with myelofibrosis can progress to AML based on their risk.[70] For low-risk patients, the five-year AML transformation rate is 6%, but it is 21% for high-risk patients (and 37% of patients diagnosed with myelofibrosis are high risk).[71] Even for those individuals who do not progress to AML, the five-year mortality is nonetheless relatively high at 51%.[72] Accordingly, VA has determined that expanding the presumptions to include these two conditions is necessary to ensure veterans diagnosed with MDS and myelofibrosis are given the benefit of a presumption before these diseases progress.

MDS are a group of rare cancers that occur when the blood-forming cells in the bone marrow become abnormal.[73] The blood cells produced by the abnormal bone marrow cells are damaged and accumulate in the bone marrow engulfing the normal blood cells.[74] As a result, individuals with MDS do not produce enough normal, healthy blood cells.[75] Most cases arise after age 65.[76] In the U.S. population, annually, 4.9 out of every 100,000 persons will develop MDS (*i.e.,* 20,451 annually).[77] The five-year prevalence (FY18–FY23) among post-9/11 veterans enrolled in VHA for health care is 10.78 out of 100,000. Given that data, it is estimated that approximately 102 to 136 post-9/11 deployed veterans with MDS could eventually have their disease progress to AML.[78]

MDS are categorized into subtypes of those individuals who have a lower or higher risk for progressing to AML.[79] For those with lower risk for AML, median survival is three to 10 years, whereas patients with higher-risk disease have a median survival of less than three years.[80]

Myelofibrosis is also a rare blood cancer that occurs when scar tissue forms in the bone marrow, disrupting the production of heathy blood cells.[81] The prevalence for developing myelofibrosis is one to nine out of every 100,000 in the U.S.[82] The five-year (FY18–FY23) prevalence rate of myelofibrosis among post 9–11 veterans enrolled in VA health care was 4.26/100,000.[83] The overall life expectancy depends on the severity of the disease, with an overall median survival estimated at six years.[84] The overall 10-year survival rate from one study showed that intermediate risk patients had a 30% survival rate and high risk patients had a 0% to 13% survival rate.[85] Based on the five-year veteran prevalence data cited above, it is estimated that approximately 14 to 27 post-9/11 deployed veterans with myelofibrosis could eventually have their disease progress to AML.[86]

As discussed above, $PM_{2.5}$ exposure has been shown to be associated with the development of leukemias and multiple myelomas. Because a significant number of cases of MDS and myelofibrosis progress to leukemia, and because these diseases have a severe outcome and significant mortality rates on their own, VA has determined a presumption of service connection is warranted for MDS and myelofibrosis as precursors to AML.

IV. Addition of Leukemias, Multiple Myelomas, MDS, and Myelofibrosis to 38 CFR 3.320b

In the PACT Act, Congress authorized VA to enact additional presumptions based on a positive association with a substance, chemical, or airborne hazard. 38 U.S.C.1120(b)(15). Because the evidence shows a positive association between exposure to $PM_{2.5}$ and acute leukemias, chronic leukemias, and multiple myelomas, VA concludes that these conditions and MDS and myelofibrosis, as precursors to AML, should be extended a presumption of service connection in new 38 CFR 3.320b. VA includes monoclonal gammopathy of undetermined significance (MGUS)[87] as part of multiple myelomas because the VA Schedule of Rating Disabilities places MGUS as part of the same diagnostic code as multiple myeloma. 38 CFR 4.117, Diagnostic Code 7712.

VA will use the heading of ''[p]resumptive service connection for leukemias, multiple myelomas, myelodysplastic syndromes and myelofibrosis'' for 38 CFR 3.320b. VA will describe the presumption of exposure in paragraph (a), describe the presumptions of service connection in paragraph (b), and provide the standard exceptions for presumptions in paragraph (c).

Although this rulemaking is based on current medical and scientific evidence related to the health effects of $PM_{2.5}$ on veterans who served during the Gulf War, VA will continue to review new scientific evidence as it develops regarding all health effects resulting from exposure to BPOT, including $PM_{2.5}$. This rulemaking does not limit the future establishment of additional presumptions of service connection.

V. Authority

As discussed above, VA is enacting these presumptions pursuant to the 38 U.S.C. 1171 *et seq.* process or alternatively under 38 U.S.C. 501(a)(1), which permits VA to issue necessary or appropriate regulations with respect to the nature and extent of proof and evidence to establish rights to benefits, such as presumptions of service connection.

VI. Severability

The purpose of this section is to clarify the agency's intent with respect to the severability of provisions of this rule. Each provision the agency of this rule can operate independently. If any

[67] Elias Jabbour et al. Acute Myeloid Leukemia Following Myelodysplastic Syndrome and Failure of Therapy with Hypomethylating Agents: An Emerging Entity With a Poor Prognosis, *https://pmc.ncbi.nlm.nih.gov/articles/PMC4098769/* (''hereinafter ''Jabbour'').

[68] Jain, *supra.*

[69] Mikkael Sekeres et al. Diagnosis and Treatment of Myelodysplastic Syndromes, *https://jamanetwork.com/journals/jama/fullarticle/2795886* (hereafter ''Sekeres'').

[70] Barbara Mora et al. Prognostic and Predictive Models in Myelofibrosis, *https://pubmed.ncbi.nlm.nih.gov/39179882/* (hereafter ''Mora'').

[71] Ayalew Tefferi et al., One Thousand Patients With Primary Myelofibrosis: The Mayo Clinic Experience, *https://pmc.ncbi.nlm.nih.gov/articles/PMC3538387/* (hereafter ''Tefferi'').

[72] Srdan Verstovsek et al. Changes in the incidence and overall survival of patients with myeloproliferative neoplasms between 2002 and 2016 in the United States, *https://pubmed.ncbi.nlm.nih.gov/34689695/* (hereafter ''Verstovsek'').

[73] Dotson, *supra.*

[74] *Id.*

[75] *Id.*

[76] *Id.*

[77] *Id.*

[78] HOME Information Paper, *supra.*

[79] Sekeres, *supra.*

[80] *Id.*

[81] National Cancer Institute, ''Myelofibrosis,'' *https://www.cancer.gov/search/results?swKeyword=Myelofibrosis*; Orpha.net, Knowledge on rare diseases and orphan drugs, ''Myelofibrosis,'' *https://www.orpha.net/en/disease/detail/824?name=myelofibrosis&mode=name.*

[82] *Id.*

[83] HOME Information Paper, *supra.*

[84] Domenico Penna et al., 20+ Years and alive with primary myelofibrosis: Phenotypic signature of very long-lived patients, *https://onlinelibrary.wiley.com/doi/full/10.1002/ajh.25351#xd_co_f=ZDY0YjJhMDEtN2RlYS00MWM0LWJkZDUtZjNlNTcyN2IxNmE4~* (hereafter ''Penna'').

[85] Tefferi, *supra.*

[86] HOME Information Paper, *supra.*

[87] The PACT Act added MGUS as a condition presumptive to herbicide exposure. 38 U.S.C. 1116(a)(2)(L).

provision of this rule is determined by judicial review or operation of law to be invalid, that partial invalidation will not render the remainder of this rule invalid. Likewise, if the application of any portion of this rule to a particular circumstance is determined to be invalid, the agency intends that the rule remain applicable to all other circumstances.

Moreover, we clarify here that VA benefits standards are distinct from the applicable standards for civil litigation, such that this final rule should have no effect on civil actions, to include Camp Lejeune Justice Act litigation.

Administrative Procedure Act

Pursuant to 5 U.S.C. 553(b)(B) and (d)(3), VA has concluded that there is good cause to publish the IFR without prior opportunity for comment and to publish the rule with an immediate effective date. There is good cause to immediately address the needs of Service members and veterans who have been exposed to airborne hazards, *i.e.* $PM_{2.5}$, due to their service in the Southwest Asia theater of operations, Afghanistan, Syria, Djibouti, Uzbekistan, Somalia, Egypt, Jordan, Lebanon, and Yemen.

Given the nature of the diseases at issue, VA concludes that the ordinary notice-and-comment procedures here would be impracticable, in that they would cause veterans serious harm by delaying and in certain situations entirely denying veterans the benefits of these presumptions. In particular, good cause exists because this veteran population is aging and leukemias, multiple myelomas, MDS, and myelofibrosis are diseases of significant morbidity and mortality.[88]

For the population who served from August 1990 to present, which are the veterans affected by this rulemaking, there are 551,000 veterans aged 65 and older.[89] Per the most recent data available from the U.S. Centers for Disease Control and Prevention, which was from 2020 to 2021, the life expectancy for the overall United States population has dropped from 77 years to 76.1 years. The life expectancy of men dropped from 74.2 years to 73.2 years and women from 79.9 years to 79.1 years.[90] According to a 2017 VA National Center for Veterans Analysis and Statistics report, life expectancy is 0.8 and 1.2 life years shorter for male and female veterans, respectively, than the general U.S. population.[91]

Leukemias account for 3.1% of all new cancer cases each year and account for 3.9% of all cancer deaths each year.[92] The age adjusted rate of new cases of leukemias is about 14.1 per 100,000 per year, and the age-adjusted death rate is about 5.9 per 100,000 per year.[93] The five-year overall survival rate is about 67%, such that one out of every three veterans with leukemia will not live five more years. The survival rate varies across different types of leukemias because some types of leukemia are more aggressive and fatal than others. The median age at diagnosis of leukemias is 67, and the median age at death is 76, with the highest proportion of deaths among those between the ages of 75 and 84.[94] As highlighted above, there are 551,000 Veterans who served after 1990 in this 65+ age range.

Myelomas are rarer than leukemias, with a lifetime risk of 0.8%.[95] The age-adjusted rate of new cases of myelomas is 7.2 per 100,000 and the age-adjusted death rate is 3.0 per 100,000; myelomas account for 1.8% of all new cancer cases, and 2.0% of all cancer deaths.[96] The five-year survival rate for those with myelomas is 61.1%, such that more than one out of every three veterans with myelomas will not live five more years, though the rate varies by stage at diagnosis.[97] The median age at diagnosis for myelomas is 69 and the median age at death is 76, with the highest proportion of deaths among those between 75 and 84.[98]

MDS are uncommon and are typically diagnosed in individuals after age 65.[99] Approximately 30% to 40% of MDS patients eventually progress to AML.[100] Once the disease has progressed to AML, patients have a very poor prognosis.[101] Those with higher-risk disease have a median survival of less than three years.[102] For those with MDS who do not progress to leukemia, the overall five-year survival rate in the U.S. is approximately 37%.[103]

The median age of diagnosis for myelofibrosis is 65.[104] Approximately 37% of the patients will be high risk.[105] The overall five-year mortality rate for myelofibrosis is 51%, and the overall life expectancy depends on the severity of the disease, with a median survival estimated at six years.[106] The overall 10-year survival rate from one study was 30% for the intermediate risk population and 0% to 13% for high risk population.[107]

Those with myelofibrosis also may develop AML,[108] with the same poor prognosis. For high-risk patients, the five-year transformation rate is 21 [109]

Given this population's life expectancy, it is not served by waiting for a notice and comment period before obtaining the benefits of this presumption. Indeed, delaying this rulemaking for notice and comment runs the real risk of harming the very population this rulemaking intends to help. The new presumptions are entirely pro-claimant in nature. They do not adversely affect any person. And because VA has a sufficient scientific basis to support the new presumptions, withholding the presumptions during the notice and comment process could unnecessarily deprive veterans and beneficiaries of benefits to which they would otherwise be entitled and prolong their inability to timely receive benefits. Additionally, this could create risks to beneficiaries' welfare and health that would be exacerbated by any additional delay in implementation. Due to the complexity and the historical scientific uncertainty surrounding these issues of airborne hazard exposures and disease, many veterans who will be affected by this rule have long borne the burden and expense of their disabilities while awaiting the results of research and investigation. Under these circumstances, there is good cause to

[88] National Cancer Institute, Cancer Stat Facts: Leukemia, *https://seer.cancer.gov/statfacts/html/leuks.html*; National Cancer Institute, Cancer Stat Facts: Myeloma, *https://seer.cancer.gov/statfacts/html/mulmy.html* (hereafter ''NCI, *supra*''); Sekeres, *supra*; Tefferi, *supra*; Penna, *supra.*

[89] Jonathan Vespa, ''Aging Veterans: America's Veteran Population in Later Life,'' American Community Survey Reports, July 2023, *https://www.census.gov/content/dam/Census/library/publications/2023/acs/acs-54.pdf.*

[90] CDC National Center for Health Statistics, ''Life expectancy in the U.S. dropped for the second year in a row in 2021,'' CDC National Center for Health Statistics, August 31, 2022, *https://www.cdc.gov/nchs/pressroom/nchs_press_releases/2022/20220831.htm.*

[91] Department of Veterans Affairs, National Center for Veterans Analysis and Statistics, ''Mortality rates and life expectancy of Veterans from 1980 to 2014, and by education and income'' April 2017, *https://www.va.gov/vetdata/docs/SpecialReports/Mortality_study_USVETS_2015_1980_2014.pdf.*

[92] NCI, *supra.*

[93] *Id.*

[94] *Id.*

[95] *Id.*

[96] *Id.*

[97] *Id.*

[98] *Id.*

[99] American Cancer Society, Key Statistics for Myelodysplastic Syndromes (MDS), *https://www.cancer.org/cancer/types/myelodysplastic-syndrome/about/key-statistics.html*; Dotson, *supra.*

[100] Menssen *supra*; Dotson, *supra,*

[101] Sekeres, *supra,*

[102] *Id.*

[103] *Id.*

[104] National Organization for Rare Diseases, ''Primary Myelofibrosis,'' *https://rarediseases.org/rare-diseases/primary-myelofibrosis/.*

[105] *Id.*

[106] Verstovesek, *supra*; Penna 20+ Years, *supra.*

[107] Primary myelofibrosis, *supra.*

[108] Mora, *supra.*

[109] Primary myelofibrosis, *supra.*

prevent imposing further delay on their receipt of benefits, potentially at the risk of their welfare and health.

Overall, the Secretary's decision to extend new presumptions to veterans who have been exposed to $PM_{2.5}$ due to their service in the Southwest Asia theater of operations, and Somalia, Afghanistan, Djibouti, Egypt, Jordan, Lebanon, Syria, Yemen, and Uzbekistan requires immediate effect to help them access these benefits without undue delay. For veterans that are not otherwise eligible for health care, these presumptions could result in needed health care eligibility based on service connection.

Section 553(d) of 5 U.S.C. also requires a 30-day delayed effective date following publication of a rule, except for ''(1) a substantive rule which grants or recognizes an exemption or relieves a restriction; (2) interpretative rules and statements of policy; or (3) as otherwise provided by the agency for good cause found and published with the rule.'' Pursuant to section 553(d)(3), the Secretary finds that there is good cause to make the rule effective upon publication, for the reasons discussed above. However, VA will consider and address comments that are received within 60 days of the date this IFR is published in the **Federal Register**.

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*.

Unfunded Mandates

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

Paperwork Reduction Act (PRA)

Although this interim final rule contains provisions constituting 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 existing collection of information. The collection of information for 38 CFR 3.320b is currently approved by the Office of Management and Budget (OMB) and has been assigned OMB control numbers 2900–0747, 2900–0886, and 2900–0004.

Congressional Review Act

Pursuant to Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (known as the Congressional Review Act) (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs designated this rule as satisfying the criteria under 5 U.S.C. 804(2).

List of Subjects in 38 CFR Part 3

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

Signing Authority

Denis McDonough, Secretary of Veterans Affairs, approved and signed this document on December 31, 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.

Consuela Benjamin,

Regulation Development Coordinator, Office of Regulation Policy & Management, Office of General Counsel, Department of Veterans Affairs.

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

PART 3—Adjudication

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

■ 1. The authority citation for subpart A continues to read as follows:

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

■ 2. Add § 3.320b to read as follows:

§ 3.320b Presumptive service connection for leukemias, multiple myelomas, myelodysplastic syndromes, and myelofibrosis.

(a) *Presumption of exposure.* A covered veteran as defined in § 3.320a(c) shall be presumed to have been exposed to certain toxic substances, chemicals, and airborne hazards, including fine particulate matter, 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.

(b) *Presumption of service connection.* Except as provided in paragraph (c) of this section, the following diseases becoming manifest in a covered veteran, as defined in § 3.320a(c), 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) Acute leukemias.

(2) Chronic leukemias.

(3) Multiple myelomas, including monoclonal gammopathy of undetermined significance (MGUS).

(4) Myelodysplastic Syndromes (MDS).

(5) Myelofibrosis.

(c) *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.

(Authority: 38 U.S.C. 501, 1119, 1171, 1172, 1173, 1174)

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