



38 CFR Part 3

2900-AS21

Presumptive Service Connection for Bladder, Ureter, and Related Genitourinary Cancers 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 urinary bladder, ureter, and related genitourinary (GU) cancers due to exposure to Particulate Matter 2.5 (PM_{2.5}) and to implement certain provisions of the Sergeant First Class Heath Robinson Honoring our Promise to Address Comprehensive Toxics Act of 2022 (PACT Act). The new presumptions would apply to Veterans who served on active military, naval, air, or space service in 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. This amendment is necessary to provide expeditious health care, services, and benefits to these veterans. This IFR addresses the needs and concerns of Gulf War veterans and Service members who have served and continue to serve in these locations and have been diagnosed with bladder, ureter, and related GU cancers. Neither Congress nor the President has established an end date for the Gulf War. Therefore, to expedite the provision of health care, services, and benefits to current and future Gulf War veterans who may be affected by PM_{2.5} due to their military service, VA is establishing presumptive service connection for urinary bladder, ureter, and related GU cancers. This IFR will ease the evidentiary burden of Gulf War Veterans who file claims with VA for these conditions.

DATES: *Effective date:* This interim final rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

Comment date: Comments must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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-AS21.

FOR FURTHER INFORMATION CONTACT: Sara Cohen, Lead, Part 3 Regulations Staff, Robert Parks, Chief, Part 3 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

On August 10, 2022, Congress enacted Pub. L. 117-168, the PACT Act. The PACT Act provided a process for VA to establish presumptive service connection based on toxic exposures. 38 U.S.C. 1171 *et seq.* 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). The diseases subject to the presumption include kidney cancers and “[r]eproductive cancer of any type.” 38 U.S.C. 1120(b)(2)(E), (G). Kidney and reproductive cancers are part of genitourinary (GU) tract. Although the GU system is composed of kidneys, ureters, urinary bladder, urethra,¹ reproductive and genital organs, including the ureteric orifice, urachus, and over-lapping sites of the bladder (the urinary organs), the PACT Act did not address all these organs.

Following the 38 U.S.C. 1171 *et seq.* process, VA determined it was necessary and clinically appropriate to consider expanding presumptive status consideration to cancers of these additional organs. One of VA’s priorities is to address the long overdue needs of the Gulf War cohort and to address the imminent need for these veterans to receive care, services, and benefits. VA has reviewed both medical and scientific literature, and concludes that (1) urinary bladder cancer is sufficiently linked to PM_{2.5} and that (2) cancers of the ureter, ureteric orifice, urachus, and over-lapping sites of the bladder are closely related to urinary bladder cancer with a common embryologic, anatomical, structural, and functional relationship. Moreover, the cancers of the ureter, ureteric orifice, urachus, and over-lapping sites of the bladder are exposed to toxic waste from the kidneys and the bladder as part of the GU system’s function. Because, as discussed below, there is a medical nexus between the composition and duration of PM_{2.5} and airborne hazard exposures to the development of GU cancers, VA has

¹ VA does not address urethral cancer in this rulemaking, because such cancer is a reproductive cancer, and therefore already subject to presumptive service connection under 38 U.S.C. 1120(b)(2)(E). See 89 FR 79815, 79824 (2024) (proposed rule).

determined that presumptions of service connection for these cancers are warranted.

See 38 U.S.C. 1174(a)(1).

In this IFR, VA adds 38 CFR 3.320a to its adjudicatory regulations to presume service connection for these cancers for certain Gulf War Veterans. VA adds these cancers as presumptive in 38 CFR 3.320a by IFR so that any Veteran with these cancers 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*;² NASEM's 2011 report, *Long-Term Health Consequences of Exposure to Burn Pits in Iraq and Afghanistan*;³ and NASEM's 2010 report, *Review of the Department of Defense (DoD) Enhanced Particulate Matter Surveillance Program*.⁴ See 86 FR at

² 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>.

³ 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").

⁴ 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").

42725-42726. The 2010 report concluded that Service members deployed to the Middle East “are exposed to high concentrations of PM_{2.5}.”⁵ See 86 FR at 42725. Toxic compounds present in burn pit fumes include PM_{2.5}.⁶ 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.⁷ 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.⁸

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

In the present rulemaking, after reviewing the three considerations of burn pit use, PM_{2.5} levels, and desert climates, VA has determined that the qualifying periods of service should include both those listed in 38 CFR 3.320(a)(5) and those listed in 38 U.S.C. 1119(c) to ensure that (1) veterans currently eligible for the presumption of exposure to PM_{2.5} in 38 CFR 3.320 and (2) veterans eligible for the presumption of

⁵ NRC, *supra*.

⁶ 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/>.

⁷ *Id*.

⁸ American Cancer Society. *Military Burn Pits and Cancer Risk*. 2022. <https://www.cancer.org/healthy/cancer-causes/chemicals/burn-pits.html>.

exposure to BPOT in 38 U.S.C. 1119 are both covered in this rulemaking. Thus, VA's new presumptions in 38 CFR 3.320a will not simply cover the locations in current 38 CFR 3.320(a)(5), but also 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 2001.⁹ 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 Asia¹⁰ and is the only combatant command that conducts open burn pit operations.¹¹ Egypt, Jordan, Lebanon, and Yemen were included as locations with open, active burn pits.¹² 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 1993.¹³ Additional deployments occurred in 1992, 1995, 2012, and 2022.¹⁴

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.¹⁵ The study found that Military Exposure Guideline (MEG) values for PM_{2.5} were exceeded at all 15 sites for the entire

⁹ See Letter from Office of Under Secretary of Defense to the U.S. House of Representatives Committee on Appropriations (May 7, 2001), available on the rulemaking docket at www.regulations.gov (hereinafter "Defense Letter").

¹⁰ U.S. Central Command. Area of Responsibility. <https://www.centcom.mil/AREA-OF-RESPONSIBILITY/>.

¹¹ Department of Defense. Open Burn Pit Report to Congress. 2019. <https://www.acq.osd.mil/eie/Downloads/Congress/Open%20Burn%20Pit%20Report-2019.pdf>.

¹² See Defense Letter, *supra*.

¹³ 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>.

¹⁴ 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/>.

¹⁵ Department of Defense. Enhanced Particulate Matter Surveillance Program Final Report. 2008. <https://apps.dtic.mil/sti/pdfs/ADA605600.pdf> (hereinafter "EPMSP Report").

one-year sampling period.¹⁶ 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 PM₁₀ and PM_{2.5} mass exposure guidelines and standards.¹⁷ 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.¹⁸

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.¹⁹ 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.”²⁰ 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.

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ *Id.*

¹⁹ NASEM 2011 Report, *supra*.

²⁰ 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>.

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.²¹ Based on evidence of burn pit use, PM_{2.5} levels 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} beyond the locations listed in 38 CFR 3.320 to Egypt, Jordan, Lebanon, Somalia, and Yemen. Moreover, for consistency with 38 U.S.C. 1119(c)(1)(B), which presumes toxic exposure in certain countries (including Afghanistan, Syria, Djibouti, and Uzbekistan) back to September 11, 2001, new 38 CFR 3.320a will have a presumption of exposure for Veterans who served in those countries on or after September 11, 2001.

VA notes that the PACT Act's definition of a "covered Veteran" in 38 U.S.C. 1119(c) does not include all areas historically included in the Southwest Asia theater of operations, omitting 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, in this IFR, VA shall maintain the locations currently included in the Southwest Asia theater of operations under 38 CFR 3.317(e)(2) and 3.320(a)(6), as that list was based on Executive Order 12744 of January 21, 1991, which designated the combat zone of the Persian Gulf War. Doing so allows individuals with service in those locations to still qualify as covered veterans under 38 CFR 3.320a. VA will carry over the definition of "Southwest Asia Theater of Operations" from 38 CFR 3.317(e)(2) and 3.320(a)(6) into 38 CFR 3.320a.

b. Urinary bladder, ureter, and related cancers

²¹ EPMSR Report, *supra*.

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 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, to render a conclusion on the strength of the evidence, and to provide a recommendation to the Secretary with respect to a presumption. 38 U.S.C. 1173. If the Secretary decides to accept the recommendation, the Rulemaking and Implementation Phase then begins. 38 U.S.C. 1174.

Here, after research and assessment, and at the MEESC's recommendation, on February 26, 2024, the Secretary initiated a formal evaluation of GU cancers and their possible association with exposure to PM_{2.5} pollution in the Southwest Asia Theater of Operations. In April 2024, the formal evaluation concluded and the recommendation was to establish a presumption.²² On June 25, 2024, the recommendation was conveyed to the Secretary. On October 25, 2024, the Secretary accepted the recommendation, paving the way for this rulemaking.

²² The MEESC report (hereinafter MEESC Report) is attached to this rulemaking, available at www.regulations.gov.

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; must be free from suppression or distortion of scientific or technological findings, data, information, conclusions, or technical results; must 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).

The Secretary had 160 days from June 25, 2024 (i.e., until December 2, 2024) to make a decision on the formal evaluation's recommendation. 38 U.S.C. 1174(a). The Secretary accepted the recommendation long before the 160 days, on October 25, 2024, paving the way for this rulemaking.

Throughout this process, the MEESC considered whether VA should expand the PACT Act's existing organ-specific presumptions to organ-system presumptions based on common embryologic development, proximity to each other, and use of common structural pathways. For example, kidney/renal cancers are covered under the PACT Act, as are all reproductive organs. The MEESC considered whether it made sense from a clinical and/or scientific standpoint to cover a significant portion of the GU system

(made up of the urinary and reproductive systems) but exclude other organs within this same system.

As further discussed below, the GU system is composed of kidneys, ureters, urinary bladder, urethra, reproductive, and genital organs. The PACT Act provided a presumption for kidney/renal cancer and all reproductive organ cancers for certain veterans; however, it did not include ureteral, urinary bladder, and several related cancers of the GU system. VA has determined it is necessary and clinically appropriate to consider expanding presumptive status to cancers of these additional organs for specific veteran populations. Clinical and scientific review provides a strong scientific rationale to add the urinary bladder, ureters, and associated structures.

The GU system as a whole encompasses the reproductive and urinary system organs. These organs are usually grouped together because of a common embryological origin, proximity to each other, and use of common structural pathways.²³ The GU system shares common embryologic, anatomic, structural, and functional relationships through the intermediate mesoderm, splanchnopleuric mesoderm, and the endoderm.²⁴

The urinary system's function is to filter blood and create urine as a waste by-product. The organs of the urinary system include the kidneys, renal pelvis, ureters, bladder, and urethra.²⁵ The kidneys and ureters form early in the embryotic period, after which the bladder and urethra are formed.²⁶ Week four of gestation commences with the development of the urinary tract, which includes the kidney, ureter, and urinary bladder. Bladder development is comprised of the intermediate mesenchyme

²³ Genitourinary System, Science Direct. <https://www.sciencedirect.com/topics/medicine-and-dentistry/genitourinary-system>.

²⁴ Rehman S, Ahmed D, (Aug 8, 2023). Embryology, Kidney, Bladder, and Ureter. StatPearls [Internet]. <https://www.ncbi.nlm.nih.gov/books/NBK547747/> (hereinafter "Rehman").

²⁵ Anatomy of the Urinary System. <https://www.hopkinsmedicine.org/health/wellness-and-prevention/anatomy-of-the-urinary-system>.

²⁶ Kucharz, E.J. (1992). Urinary and Reproductive Systems. In: The Collagens: Biochemistry and Pathophysiology. Springer, Berlin, Heidelberg. https://doi.org/10.1007/978-3-642-76197-3_18.

(embryonic connective tissue in the mesoderm) and occurs when the urogenital septum divides.²⁷ Once the bladder is formed, it connects to the other organs. As the kidneys ascend, the ureters elongate and open into the bladder superiorly, while the roots of the mesonephric ducts are carried inferiorly, before fusing to form the trigone region. Endodermal cells from the urogenital sinus soon replace the mesodermal cells epithelium of the trigone region, thus completing development.

Between 32-36 weeks gestation, this development is completed and the organs become distinct. The urachus, an embryonic remnant, connects the bladder to the umbilical cord during fetal development and is the main fetal excretory organ. After birth, this tube closes and becomes a ligament, although it fails to close some cases.²⁸

The kidney consists of various cell types originating from the ureteric bud and the metanephrogenic mesenchyme, which differentiate into more than 26 different cell types in the kidney. The ureteric bud contributes to the development of the ureter and parts of the kidney, which serves a critical role in the formation of the renal collecting system.²⁹ Embryologically, the urothelium of the urinary bladder and urethra is derived from the ventral urogenital sinus, like the epithelium in the renal pelvis and ureters.³⁰ In utero, the intermediate mesoderm forms the kidneys, ureters, and renal vasculature. The splanchnopleuric mesoderm forms the smooth muscle and connective tissue of the bladder. The endoderm forms the inner bladder and urethra.³¹ The development of the ureter and kidney cells are closely linked through the interaction of the ureteric bud and metanephric mesenchyme, leading to the formation of the complex structures of the

²⁷ Rehman, *supra*.

²⁸ See MEESC memorandum, "Additional Clarification and Details on Genitourinary Cancer Formal Evaluation in Support of Rulemaking" dated November 6, 2024 (hereinafter MEESC Memorandum), attached to this rulemaking, available at www.regulations.gov.

²⁹ Qais Al-Awqati; Juan A. Oliver, (February 2002). Stem Cells in the Kidney. *Kidney International*, Volume 61, Issue 2. <https://www.sciencedirect.com/science/article/pii/S0085253815482262?via%3Dihub>.

³⁰ Guo-Xia Tong, Woojin M Yu, Nike T Beaubier, et. al., (September 2009) Expression of PAX8 in Normal and Neoplastic Renal Tissues: An Immunohistochemical Study. *Modern Pathology*, Volume 22, Issue 9, 1218-1227. <https://www.sciencedirect.com/science/article/pii/S0893395222024747?via%3Dihub>.

³¹ Rehman, *supra*.

urinary system.³² The urethra in the neck of the bladder develops into the male urethra prostatic part, and female urethra.³³

The organs of the GU system are necessarily interrelated. The kidneys filter waste and fluid, including toxic exposures that get into the body, to produce urine. Once the kidneys produce the urine, it is transported from the kidneys to the urinary bladder by the ureters, which are bilateral tubular structures that connect the kidneys to the urinary bladder. The openings of the ureters into the urinary bladder are called the ureteric orifices. The urine, which contains the waste that was filtered from the body by the kidneys, is stored in the urinary bladder until it is time to urinate. When it is time to urinate, the urethra, a small tube, allows the urine to pass outside the body.

As discussed, the GU system cancers share common embryologic, anatomic, structural, and functional relationships. Necessarily, each of these organs is exposed to the waste/toxins, starting in the kidneys, which is turned into urine. The urothelium is exposed to toxins in the urine, so that any carcinogenic effect would also be expected in the bladder and ureter. The urine exposes the remaining GU structures to the toxins and any resultant carcinogens, including PM_{2.5}.³⁴ Hence, any carcinogens in the kidneys or bladder necessarily pass through the remainder of the GU system, providing the exposure to carcinogens to each part of the GU system.

1. Association between PM_{2.5} and urinary bladder cancer

In support of this rulemaking, as required by 38 U.S.C. 1173, VA conducted a formal evaluation of whether a sufficient association between PM_{2.5} and bladder cancer existed. The results of the studies reviewed by VA's experts showed an association

³² Shah MM, Tee JB, Meyer T, Meyer-Schwesinger C, Choi Y, Sweeney DE, Gallegos TF, Johkura K, Rosines E, Kouznetsova V, Rose DW, Bush KT, Sakurai H, Nigam SK. The instructive role of metanephric mesenchyme in ureteric bud patterning, sculpting, and maturation and its potential ability to buffer ureteric bud branching defects. *Am J Physiol Renal Physiol*. 2009 Nov;297(5):F1330-41. doi: 10.1152/ajprenal.00125.2009. Epub 2009 Sep 2. Erratum in: *Am J Physiol Renal Physiol*. 2010 May;298(5):F1285. PMID: 19726549; PMCID: PMC2781331, <https://pubmed.ncbi.nlm.nih.gov/19726549/>.

³³ Rehman, *supra*.

³⁴ MEESC Report, *supra*.

between PM_{2.5} and bladder cancer and that 6-19% of bladder cancers are attributable to occupational exposures. Studies from 2003 to 2022 supported the association between PM_{2.5} and bladder cancer.

A 2003 study estimated occupational exposure caused death due to bladder cancer for 534 to 1,451 men and 116 to 740 women annually.³⁵ Nine years later, the International Association for Research on Cancer (IARC) also found evidence that air pollution was associated with developing bladder cancer.³⁶ In 2017, another study positively correlated the concentration of ambient PM_{2.5} with development of, and death from, bladder cancer.³⁷ That same year a study also found airborne pollution and particulate matter posed an elevated risk for bladder cancer.³⁸ Two 2020 studies similarly found an elevated hazard ratio between exposure to air pollution and PM and the development of bladder cancer, concluding such exposures may be a risk factor for bladder cancer.³⁹ According to a 2020 scientific review of bladder and kidney cancer, studies suggested positive, even though mostly non-significant, associations between air pollution exposure, including PM_{2.5}, and bladder cancer mortality and kidney cancer incidence. Bladder cancer showed a positive association: bladder cancer mortality had an adjusted odds-ratio of an average of 13% percent with a slight increase of PM_{2.5}.⁴⁰

³⁵ Steenland K, Burnett C, Lalich, et al., (May, 2003). Dying for work: The magnitude of US mortality from selected causes of death associated with occupation. *Am J Ind Med.* 43(5):461-82. <https://pubmed.ncbi.nlm.nih.gov/12704620/>.

³⁶ IARC (International Association for Research on Cancer). Air Pollution and Cancer, IARC Scientific Publication No. 161, 2013. <https://publications.iarc.fr/Book-And-Report-Series/Iarc-Scientific-Publications/Air-Pollution-And-Cancer-2013>.

³⁷ Yeh, H. L., Hsu, S. W., Chang, Y. C., Chan, T. C., Tsou, H. C., Chang, Y. C., & Chiang, P. H. (2017). Spatial Analysis of Ambient PM_{2.5} Exposure and Bladder Cancer Mortality in Taiwan. *International journal of environmental research and public health*, 14(5), 508; <https://pmc.ncbi.nlm.nih.gov/articles/PMC5451959>.

³⁸ Turner MC, Krewski D, Diver WR, Pope CA 3rd, Burnett RT, Jerrett M, Marshall JD, Gapstur SM. Ambient Air Pollution and Cancer Mortality in the Cancer Prevention Study II. *Environ Health Perspect.* 2017 Aug 21;125(8):087013; <https://ehp.niehs.nih.gov/doi/10.1289/EHP1249>.

³⁹ Coleman NC, Burnett RT, Higbee JD, Lefler JS, Merrill RM, Ezzati M, Marshall JD, Kim SY, Bechle M, Robinson AL, Pope CA 3rd. Cancer mortality risk, fine particulate air pollution, and smoking in a large, representative cohort of US adults. *Cancer Causes Control.* 2020 Aug;31(8):767-776. (hereafter Cancer mortality risk); <https://pubmed.ncbi.nlm.nih.gov/32462559>.

⁴⁰ Zare Sakhvidi MJ, Lequy E, Goldberg M, Jacquemin B. Air pollution exposure and bladder, kidney and urinary tract cancer risk: A systematic review. *Environ Pollut.* 2020 Dec;267:115328; <https://www.sciencedirect.com/science/article/abs/pii/S0269749120360164?via%3Dihub>.

The EPA also concluded that long-term exposure to PM_{2.5}, in the form of diesel exhaust emissions, has a likely causal relationship to the development of bladder cancer.⁴¹ This is supported by a 2022 EPA study.⁴² Supporting the previous studies, a 2022 large pooled study found evidence of an association between long-term PM_{2.5} mass exposure and bladder cancer. A 2024 study performed a meta-analysis which combined the results of from 18 cohort studies, 10 case-control studies, and nine ecological studies, studies published through early 2024. The authors stated that a 5 microgram increase per cubic meter in the atmosphere in PM_{2.5} was significantly associated with an increased relative risk for bladder cancer of 7%.⁴³

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.⁴⁴ 86 FR at 42725-42726. Thus, VA has determined that it will consider bladder cancers for this population to be associated with exposure to PM_{2.5}. Accordingly, VA concludes it is appropriate to add bladder cancer to 38 CFR 3.320a.

2. Association between PM_{2.5} and cancers of the ureter, ureteric orifice, urachus, over-lapping and sites of the bladder

Ureter cancer is a rare type of cancer; however, between 5% and 10% of all urothelial cancers start in the ureter.⁴⁵ As discussed above, all parts of the GU system

⁴¹ EPA Supplement to the 2019 Integrated Science Assessment for Particulate Matter (Final Report, 2022) <https://www.epa.gov/isa/integrated-science-assessment-isa-particulate-matter> (hereafter “EPA supplement”).

⁴² *Id.*

⁴³ Li J, Deng Z, Soerensen SJC, Kachuri L, Cardenas A, Graff RE, Leppert JT, Langston ME, Chung BI. *Ambient air pollution and urological cancer risk: A systematic review and meta-analysis of epidemiological evidence.* Nat Commun. 2024 Jun 15;15(1):5116, <https://pmc.ncbi.nlm.nih.gov/articles/PMC11180144/>.

⁴⁴ NASEM, Gulf War and Health Series: Volume 3: Fuels and Products of Combustion (2005), <https://doi.org/10.17226/11180> and Volume 11: Generational Health Effects of Serving in the Gulf War (2018), <https://doi.org/10.17226/25162>. NASEM, Respiratory Health Effects of Airborne Hazards Exposures in the Southwest Asia Theater of Military Operations (2020), <https://doi.org/10.17226/25837>.

⁴⁵ Saint John’s Cancer Institute. *Ureteral Cancer and Ureteral Urothelial Carcinoma (UTUC)*. <https://www.saintjohnscancer.org/urology/conditions/ureteral-cancer/>.

share the same embryonic origin. The development of ureter and kidney cells is closely linked through the interaction of the ureteric bud and metanephric mesenchyme, leading to the formation of the complex structures of the urinary system.

The PACT Act has associated kidney cancer with PM_{2.5} for certain Veterans. The kidneys transport waste into the ureters.⁴⁶ From the ureters, the ureteric orifices empty the urine into the urinary bladder. Each of these organs is exposed to waste and toxins produced by the kidneys, thus exposing them to any carcinogens.⁴⁷ Accordingly, the same PM_{2.5} that affected the kidneys necessarily affects the entire GU tract. Because individuals with renal pelvis or ureter cancer can develop cancer in the kidneys and/or bladder over time,⁴⁸ there are common risk factors for cancer development throughout the uroepithelium. As such, VA concludes that bladder, ureter, and kidney cancers should all be treated the same for purposes of the presumption.⁴⁹

III. Addition of urinary bladder, ureter, and related cancers to 38 CFR 3.320a

Since August 5, 2021, VA has presumed for certain Veterans that asthma, rhinitis, or sinusitis are associated with PM_{2.5}. 38 CFR 3.320(a)(2); 86 FR at 42732-42733. VA added nine rare cancers to the list of disabilities presumptively associated with PM_{2.5} on April 26, 2022. 38 CFR 3.320(a)(3); 87 FR 24421, 24429 (2022). VA instituted these presumptions based on scientific and medical studies, which focused on the respiratory effects of PM_{2.5} for veterans who served in the Southwest Asia theater of operations, Afghanistan, Syria, Djibouti, and Uzbekistan during the Gulf War. 86 FR at 42729; 87 FR at 24424-24525.

As discussed above, in the PACT Act, Congress enacted a presumption associating kidney cancer and reproductive cancers (which includes male urethra and

⁴⁶ MEESC Memorandum, *supra*.

⁴⁷ *Id.*

⁴⁸ MEESC Report, *supra*.

⁴⁹ *Id.*

prostate cancer) with toxic exposures in covered locations. 38 U.S.C. 1120(b)(2)(E), (G). Although the PACT Act covers almost 73% of existing cancers, it did not include all genitourinary tract cancers.⁵⁰ Yet 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 urinary bladder cancer is related to PM_{2.5} inhalation and BPOT exposure, and cancers of the ureter and related cancers receive toxins in the same manner as the bladder, VA concludes they should be extended a presumption in new 38 CFR 3.320a.

As discussed above, VA is enacting this presumption pursuant to the 38 U.S.C. 1171 *et seq.* process. But VA also notes the alternative authority to add these presumptions 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 in order to establish rights to benefits, such as presumptions of service connection.

IV. New 38 CFR 3.320a

VA will use the heading of “[p]resumptive service connection for bladder, ureter, and related genitourinary cancers” for 38 CFR 3.320a. VA will 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 provide the standard exceptions for presumptions in paragraph (d).

Although this rulemaking is based on current medical and scientific evidence related to the respiratory health effects of PM_{2.5} on veterans who served during the Gulf War and are otherwise covered by the PACT Act, 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.

⁵⁰ MEESC Report, *supra*.

V. 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 of this rule is capable of operating independently. If any 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 rulemaking 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.

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.

VA concludes that the ordinary notice-and-comment procedures here would be impracticable, in that they would cause Veterans serious harm by further delaying and in some cases outright preventing Veterans from receiving the benefits of these presumptions given the nature of the diseases at issue. In particular, bladder and ureter cancers are diseases of significant morbidity and mortality. Bladder cancer alone is fairly common and causes morbidity and mortality. According to the latest national statistics available from the Centers for Disease Control and Prevention (CDC) which were from 2021, bladder cancer is the seventh most common cancer in the U.S. with a rate of 18.1 cases per 100,000 persons.⁵¹ In 2021, 75,450 new cases of urinary bladder

⁵¹ United States Cancer Statistics: Data Visualizations, <https://gis.cdc.gov/Cancer/USCS/#/AtAGlance/>.

cancer were reported in the U.S.⁵² In 2022, which is the latest year for which CDC has available mortality data, 17,334 people died of urinary bladder cancer in the U.S. Most of the deaths were in men, according to the CDC.⁵³ In 2022, the latest year for which mortality data are available, in the United States, 12,460 men died of urinary cancer.⁵⁴ For ureter cancer, the five-year survival rate is 5% or less.⁵⁵

Overall, delaying this rulemaking for notice and comment runs the real risk of harming the very population this rulemaking intends to help. Moreover, the 38 U.S.C. 1119(c) locations are dictated by Congress; they cannot be removed by either VA or public comment.

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 avoid 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

⁵² *Id.*

⁵³ *Id.*

⁵⁴ *Id.*

⁵⁵ Social Security Administration, Program Operations Manual System, <https://secure.ssa.gov/poms.nsf/lnx/0423022345>.

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.

For the foregoing reasons, and as explained in further detail in the IFR, the Secretary of Veterans Affairs is issuing this rule as an IFR with an immediate effective date. 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 IFR will have no such effect on state, local, and tribal governments, or on the private sector.

Paperwork Reduction Act

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 3.320a is currently approved by the Office of Management and Budget (OMB) and has been assigned OMB control numbers 2900-0747, 2900-0886, 2900-0004, and 2900-0002.

Congressional Review Act

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

copy of this Regulation and the Regulatory Impact Analysis (RIA) associated with the Regulation.

List of Subjects in 38 CFR Part 3

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

Signing Authority

Denis McDonough, Secretary of Veterans Affairs, signed and approved this document on December 20, 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.

Michael P. Shores,
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 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 part 3 continues to read as follows:

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

2. Add § 3.320a to read as follows:

§ 3.320a Presumptive service connection for bladder, ureter, and related genitourinary cancers.

(a) *Presumption of exposure.* A covered veteran as defined in paragraph (c) of this section 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 (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) Urinary bladder cancer, including over-lapping sites of the bladder.

(2) Ureter cancer, including the ureteric orifice, and urachus.

(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.

(Authority: 38 U.S.C. 501, 1119, 1120, 1174)

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