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**VETERANS HEALTH ADMINISTRATION (VHA)**  
**DEPARTMENT OF VETERANS AFFAIRS (VA)**  
**BEFORE THE**  
**COMMITTEE ON VETERANS' AFFAIRS**  
**SUBCOMMITTEE ON HEALTH**  
**U.S. HOUSE OF REPRESENTATIVES**

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Good afternoon, Madam Chair, Ranking Member Brownley, and other Members of the Subcommittee, thank you for inviting us here today to present our views on several bills that would affect VA programs and services. Joining me today is Dr. Michael Brennan, Executive Director, Office of Construction and Facilities Management, Dr. Wendy Tenhula, Deputy Chief Research and Development Officer, Office of Research and Development, VHA, and Mr. David Perry, Chief Officer, Workforce Management and Consulting, VHA.

**H.R. 3225 Build, Utilize, Invest, Learn, and Deliver (BUILD) for Veterans Act of 2023**

The BUILD for Veterans Act of 2023 would support improvements of VA's capital asset programs' management and performance to better serve Veterans, their families, caregivers, and survivors. However, VA cites concerns with this bill.

Section 101(a)(1) of the bill would require VA, not later than 540 days from the date of enactment, to ensure that VA has dedicated offices or entities and sufficient staff, including at each VA medical center (VAMC), to conduct relevant critical responsibilities for the life cycle of capital asset management at the local, regional, and VA central office level. This could include ensuring such mix as VA considers appropriate of personnel with duties in the following categories: facility planning; long-range capital planning; management of certain projects and capital assets; property disposal or transfer, environmental remediation, and historic preservation; engineering, maintenance, and repair; the collection of views of Veterans and VA employees to understand VA's capital asset needs; and other relevant functions. VA would have to ensure, to the greatest extent possible, that these requirements would be assigned to a different individual or group of individuals so as to organize common work in a cohesive manner and not overburden a small number of staff. Within 180 days of enactment, VA would have to: designate and notify appropriate Congressional committees one individual as the lead senior official responsible for the integration and coordination of, and accountability for, the evaluation of VA's capital asset workforce needs; a required staffing model; and the ongoing implementation and monitoring of actions to ensure adequate capital asset staffing across VA, including those at the field, regional, and central offices of VHA, the National Cemetery Administration, the Veterans Benefits Administration, and the Office of Acquisition, Logistics, and Construction (OALC). Within

one year of enactment, VA would have to establish a staffing model for the relevant Administrations, Staff Offices, and other elements to carry out paragraph (1) that ensures a minimum base level of capital asset staffing and is adjusted based on the volume and complexity of capital asset work of a particular facility, catchment area, region, or central office responsibility. VA would have to update this staffing model regularly. In a state or territory where VA does not operate a full-service VAMC, VA would have to ensure, to the greatest extent practicable, that VA has a dedicated office or entity and sufficient staff at the largest VA medical facility in the state or territory. Section 101(a)(6) would state that the purpose of this subsection is to ensure that field, regional, and central offices of VA have an appropriately sized and credentialed capital asset workforce to allow for efficient and effective execution of their relevant segment of capital asset work. It would further clarify that nothing in this section would be intended to mandate a realignment of capital asset workforce roles, responsibilities, and reporting structures.

Under section 101(b), VA would have to ensure that appropriate professional certifications, educational background, and other qualifications were in effect for individuals employed in a position at a required dedicated office or entity to manage the duties under subsection (a)(1).

Section 101(c) would define the duties of the dedicated offices or entities at VAMCs. Duties of offices or entities required at a VAMC could include the following, as VA considers appropriate to achieve efficient and effective capital asset management and performance as it pertains to relevant activities at the field level: developing, monitoring, and implementing capital asset objectives in the area; coordinating capital asset management and planning with others in VA; delivering effectively capital asset projects; maintaining and repairing existing infrastructure; conducting capital asset disposal or transfer, environmental remediation, and historic preservation; monitoring regularly state-of-the-art best practices in health care capital asset delivery and management; monitoring constantly the needs of Veterans and employees for medical space and services including views and expectations expressed by relevant local or national Veterans Service Organizations (VSO); understanding and implementing capital asset policies; providing feedback to improve these policies; and understanding the importance of collaboration and coordination within VA to achieve success in all phases of capital asset management. VA would have to collect views and expectations through multiple channels, allow for anonymous and confidential submission of views, include diverse viewpoints, coordinate with existing VA efforts, and use these views and expectations to inform VA offices and leadership in the development of capital asset improvement.

Section 101(d) would require VA to develop a standardized process to solicit feedback regularly from VA employees on ways to improve VA's capital asset management program. To the degree practicable, VA would have to align this process with the performance of market area assessments under 38 U.S.C. § 7330C(a).

Under section 101(e), VA would have to use the results of the report required under section 202 of the BUILD for Veterans Act in establishing offices, entities, or organizational structures required under subsection (a) and carrying out the requirements of this section.

**Position: VA does not support section 101.** In general, throughout this bill, OALC should be corrected to read the Office of Construction and Facilities Management (CFM). Currently, 38 U.S.C. § 312A gives the Executive Director of CFM authorities and responsibilities pertinent to this bill.

VA does not support section 101. Current organizational structure within VA includes staff who are responsible for the functions set forth in the section. This would require extensive analysis and clarification on the specific goal. VHA is in the early stages of a facilities staffing methodology that will be informed by standard performance metrics, and this may require more than 540 days to develop a firm model. VA does not support subsection (c), which would define specific duties for offices or entities at VAMCs and would locate the management outside of the program office in certain circumstances. Given that subsection (a) already sets forth more general (and less prescriptive) requirements, subsection (c) is unnecessary and would make implementation more difficult. VA also does not support subsection (d), which would require a standardized process for soliciting feedback. VA is improving and standardizing planning processes that should satisfy the intent of this section without detailing specific requirements or parameters in statute. Allowing VA to define these requirements will ensure VA is responsive to and able to adapt to changing circumstances. VA will be transparent on how we are organizing to support improvements of VA's capital asset programs management and performance to better serve Veterans, their families, caregivers, and survivors.

Section 102 would require VA, within 1 year of enactment, to develop goals and metrics to assess and monitor the performance of VA's capital asset management programs, including those carried out by a non-VA entity under 38 U.S.C. § 8103(e)(1), to make sound decisions regarding infrastructure decisions in alignment with VA's mission and budget. VA would have to develop an internal dashboard or other tool to monitor progress toward meeting those goals, establish and implement governance processes to direct necessary changes to improve performance and achievement of those goals, and submit to Congress a report on the development of those goals and metrics, the implementation of the internal dashboard, and the internal governance process.

**Position: VA has no objection to section 102.** VA supports section 102, and VA has developed actionable capital program and asset goals and metrics that will help inform VA capital decisions and enhance long-term improvement of VA's capital efforts. VA will continue to assess whether additional measures would be helpful as the effort continues. There are no costs associated with section 102.

Section 103 would require, within 180 days of enactment, VA and the Department of Defense (DoD) to add representatives from the Indian Health Service (IHS) and the Department of Health and Human Services (HHS) to the Capital Asset Planning Committee (CAPC) to facilitate Federal health infrastructure planning, coordination, and investment.

**Position: VA supports section 103.** VA supports section 103 but defers to IHS and HHS. There are no costs associated with section 103.

Section 201 would require VA to conduct a comprehensive review of the climate resilience of facilities, land, and other relevant capital assets that may be at risk due to changes in the climate. Within 540 days of enactment, VA would have to submit to Congress a report with respect to mission critical VA capital assets and the actions VA will take in response to the findings of such review. Within 1 year of submitting this report, VA would have to submit an additional report to Congress detailing the results of this review for all VA capital assets and the actions VA will take in response to the findings of such review. VA would have to provide an update to this report to Congress at least once every 5 years after the submission of the additional report described above.

**Position: VA has no objection, if section 201 is amended, and subject to the availability of appropriations.** VA supports the overall objectives of this section but would require an initial reporting deadline of 2 years (rather than 540 days) to allow VA sufficient time to develop requirements for the comprehensive assessment, conduct the assessment, and generate the recommendations for action as outlined in the bill. VA appreciates that the initial report in this version of the bill would be limited to assessing mission critical assets, which would still be a significant undertaking. VA would require additional staffing to meet these requirements. VA also recommends amending subsection (c)(2), which would require a report on all VA capital assets. VA recommends limiting this to only assets involving land in excess of 10 acres and buildings greater than 25,000 gross square feet under operation, ownership, and control by VA. The current language is very broad and would create requirements that are not feasible. Leases should be excluded if they are executed contracts that VA does not have unilateral ability to modify without reopening contract negotiations. VA estimates that the study of 152 VAMCs and 155 National Cemeteries will cost \$134,510,000; owned assets only.

Section 202(a) would require VA, within 1 year of enactment, to submit to Congress a strategic plan (a “Strategic Plan to Improve VA’s Delivery and Management of Capital Assets”) to improve the planning, management, budgeting, staffing, capacity, and performance by VA related to capital assets. This plan would have to consist of at least two parts: the first focused on the human capital needs for VA’s capital asset and related areas workforce, and the second covering the methods undertaken by VA to accomplish changes to improve the planning, execution, and delivery of VA’s capital asset projects. Section 202(b) would require VA to submit subsequently two additional reports 3 years apart providing updates on changes, actions taken, and other plans.

**Position: VA would have no objection, if section 202 is amended, and subject to the availability of appropriations.** VA does not support the proposed Part 1 of the plan. VA is focused on the strategic initiatives needed to improve capital asset management, so redirecting that focus to reporting on individual positions would redirect resources allotted to the larger tasks at hand. While not in the detail requested, VA provides staffing figures in the organizational budget chapters within the President's Budget submission. We recommend Part 1 of the plan be removed.

VA does not object to the intent of the proposed Part 2 of the plan. VA is in the process of improving the planning, execution, and delivery of capital asset projects. VA submitted a report to the Subcommittees on Military Construction, Veterans Affairs, and Related Agencies of the Committees on Appropriations of the House of Representatives and the Senate in response to a request associated with the Fiscal Year (FY) 2020 appropriations act; we ask that the proposed Part 2 be revised to request an update to that plan with the same timeframe (1 year from enactment). VA believes these actions would require time to plan, program, and resource to meet this requirement. We also recommend removal of the subsequent reporting requirements under section 202(b). If these changes are made, VA would support this section. VA estimates Part 2 of the plan will cost \$1.5 million.

Section 203(a) would require VA, within 1 year of enactment and to the greatest extent practicable, to centralize and consolidate the management and oversight of all disposal and reuse activities within one office or suboffice of VA which have the sole focus of property disposal, including reuse, transfer, and demolition. The office or suboffice would have to focus on developing and implementing a measurable plan with yearly goals to dispose of, reuse, or transfer relevant capital assets. To the greatest extent practicable, VA would have to consolidate the functions and employees of the office or suboffice within one organization element of VA so as to improve effectiveness, efficiency, and accountability. Within 1 year of enactment, VA would have to submit to Congress a report on its actions to carry out this subsection.

Section 203(b) would require VA to include as part of its annual budget submission a report containing a specific timeline to accomplish the disposal and reuse actions VA included in the disposal and reuse reports in the annual budget request. Among other elements, VA would have to consider the need for a dedicated fund to handle these vacant or unused properties.

Section 203(c) would require VA, on an annual basis as part of its budget justification, to include a report on actions described in subsection (b).

**Position: VA does not support section 203.** VA does not support the overall objectives of this section. As the bill itself acknowledges, VA already identifies properties annually via the Disposal and Reuse Report. Challenges with vacant and underutilized property, such as the historic nature, the location potentially within a campus, and limited funding make additional requirements for vacant property overly

rigorous. This section would create unfunded requirements that would detract from other VA capital asset management efforts. The proposed organizational alignment would not provide any efficiencies or change internally who works together on these projects. The reporting requirements would be contingent on multiple factors, many of which are not in VA's control, and which could jeopardize VA's ability to submit the reports, as required.

Section 204 would require VA to submit to Congress a report, not later than 180 days from the date of enactment, on potential options and alternatives to improve, reform, and provide more flexibility to VA's minor construction activities to increase effectiveness in commencing and delivering minor construction capital asset projects.

**Position: VA has no objection, if section 204 is amended, and subject to the availability of appropriations.** VA supports, if amended. Section 204(c) needs to be updated to reflect the \$30,000,000 threshold for major medical facility projects/minor construction limitation as adjusted in section 5001 of the National Defense Authorization Act for FY 2024 (P.L. 118-31).

Section 205 would require VA, not later than 180 days from the date of enactment, to report on any potential improvements to the alignment of funding for information technology to facilitate more effective and efficient activation of medical and other relevant space.

**Position: VA has no objection, if section 205 is amended, and subject to the availability of appropriations.** VA is working on improvement plans. VA would require an initial reporting deadline of 1 year, however, to allow sufficient time to complete the internal work and prepare a report. VA estimates this provision to include resources to cost \$2 million.

Section 206 would amend 38 U.S.C. § 8120 to require VA to report, not later than 30 days after the end of the fiscal year and every 60 days thereafter through the fiscal year, detailed information on completed and planned key capital asset investments, including major construction, minor construction, non-recurring maintenance, leases, or other categories. VA would also be required to report on the same schedule described above, on the super construction projects carried out by the appropriate non-VA entity described in 38 U.S.C. § 8103(e)(1) during the year.

**Position: VA has no objection to section 206, subject to the availability of appropriations.** VA supports parts of section 206. VA provides information on planned major construction, minor construction, major leases, minor leases, and non-recurring maintenance projects in Volume IV of its annual budget. Data on future awards for major construction and leases is provided in the individual project prospectuses and status summaries. Due to the planning and execution cycles for minor construction, minor leases, and non-recurring maintenance projects, reporting would be limited to projects scheduled to be awarded in the current budget year. VA also does not support the proposed section 8120(a)(2)(A)(ix); the observations of best practices, impediments,

and accomplishments would be addressed in the report VA has suggested in response to section 202. The frequency of the reporting requirements for this section would be onerous and inconsistent with reporting substantial progress on a large construction project; VA suggests a biannual frequency (every 180 days) instead. VA believes these actions would require time to plan, program, and resource to meet these requirements. VA has other clarifying technical assistance it can provide on this section as well. For the part the VA supports, VA estimates a cost of \$1 million.

Section 207 would require VA, within 180 days of enactment and as part of its annual budget submission, to submit to Congress a report summarizing the projected amount of funding for infrastructure and capital assets needed over 10 fiscal years.

**Position: VA does not support section 207.** VA does not support section 207. VA already provides the total 10-year, long range action plan capital requirement and the major construction 5-Year Development Plan (FYDP) requirements annually in the President's Budget request, Volume IV. The FYDP identifies major construction projects on which VA has begun active planning and could require additional funding in the next 5 budget years. The FYDP provides appropriate rigor to the planning process to ensure that proposed major construction projects make the best case possible for why they should receive funding, and the requested funding is a valid estimate of the actual cost to complete the identified projects. The long-range action plan also consists of new (not funded or partially funded) investments and includes individual capital projects and lump sum resource requirements over a 10-year planning horizon focused on reducing gaps, increasing efficiencies, and providing better services to Veterans. VA does not support breaking down the long-range plan into individual annual capital program requirements beyond the budget year request. Project cost estimates include acquisition costs only, which will likely change as projects move through the investment process, and requirements become more refined. Long range action plan projects in years 2 through 10 and lump sum requirements are considered potential future year needs, and most cannot be credibly assigned a specific funding year while they are still being developed and prioritized.

Section 208 would require the Office of Inspector General (OIG), not later than 3 years after enactment and at least twice during the following 6-year period, to submit to Congress a report examining the management and performance of relevant VA capital asset projects.

**Position: VA defers section 208 to OIG.**

Section 209 would require the Comptroller General to report to Congress, not later than 3 years after the date of enactment and triennially thereafter until the date that is 9 years after the date of enactment, on VA's progress toward meeting VA's goals, metrics, and other plans under this Act, particularly under sections 101, 102, and 202.

**Position: VA defers section 209 to the Comptroller General.**

Section 210 would require VA, not later than 1 year after the date of enactment, to submit to Congress a report, disaggregated by VAMC or other relevant health care facility, on the physical infrastructure needed to provide dental services to eligible Veterans and the project-by-project cost and total cost to establish this physical infrastructure and an estimated timeline to complete such projects upon receipt of appropriate funding.

**Position: VA does not support section 210.** VA already provides much of the information required by this section through the Strategic Capital Investment Planning (SCIP) process. An additional report would be redundant.

Sections 210, 211, 213, and 214 would require a focused investment plan aligned to one single program area (dental, long-term care, women's health, and research); however, VA is working toward more comprehensive capital plans and strategies that include these areas. In some markets, VA may need to establish a new hospital, and in that capital strategy, dental, long-term care, women's health, and research would all be components of that larger plan, but costs for each would not be identifiable because they would be tied to a larger investment. Further, through VA's market area assessments and development of high-performing integrated health care networks, VA does not plan or assess individual components or programs like this. These sections aim to carve out distinct program areas and require development of capital investment needs focused on them, but these needs must be coordinated with the total market needs, larger facility master plans, and other development work. It is not feasible to provide the costs for specific components when these would be furnished as part of an integrated, larger, multi-focused capital plan.

Section 211(a) would require VA, not later than 1 year after the date of enactment, to submit to Congress a report, disaggregated by VAMC or other relevant health care facility, on the physical infrastructure needed to support current and future anticipated long-term care needs and models of care for Veterans, including infrastructure needed to support the delivery of long-term care for women Veterans, Veterans with spinal cord injuries and diseases (SCI/D), Veterans with traumatic brain injury (TBI), Veterans with unique behavioral health needs, Veterans with memory loss, and other population groups with unique needs or projected future needs. VA would also need to include information regarding VA's plans to provide such care as VA builds internal capacity, but space is not yet available to meet the demand for such care, and with respect to any projects specified, the estimated individual project cost and total cost to accomplish those projects and the estimated individual project timeline to accomplish each such project upon receipt of appropriate funding.

Section 211(b) would require VA to include in the report required under subsection (a) information on how VA's infrastructure prioritization processes, such as the SCIP process, could be modified to include higher prioritization of projects that support the provision of a health care service that is not widely available, or is not available in compliance with appropriate quality or access standards, from non-VA providers.



Section 211(c) would further require VA, in developing the report under subsection (a), to consult with relevant regional and national program offices in VHA with responsibility to manage the various health care services covered by the report, including long-term care and care relating to SCI/D, to ensure the report contains a holistic, comprehensive, and integrated plan to address the capital asset and other space needs for this population.

Section 211(d) would require VA, in the report under subsection (a), to indicate the projects that can be most efficiently and effectively accomplished through smaller individual infrastructure projects or through a larger medical facility replacement or new site of care.

**Position: VA does not support section 211.** VA does not support section 211 for reasons set forth above in discussion of section 210. VA already provides much of the information required by this section through both the SCIP process and various reports to Congress. An additional report would be redundant.

Section 212 would require VA to provide a report on the feasibility and advisability of requesting that Congress create a dedicated budget account from which VA would request funds based on relevant methodology, formulas, and percentages tied to the existing and future capital asset needs of VA, and if such funds are provided, to draw upon them to pay for maintenance, preventative maintenance, and repair of capital assets.

**Position: VA does not support section 212.** VA does not support section 212. The Medical Facilities account supports the maintenance, preventative maintenance, and repair of VHA real property capital assets and related personal services costs. This account includes 1,717 leases and is used to keep 5,598 owned buildings, parking lots, roads and walkways, and vehicles in good working condition, as well as maintaining a clean environment, linens, and medical equipment at all VHA facilities. Creation of a separate account would jeopardize the flexibility within the existing account to respond to changing workload demand requirements during the fiscal year.

Section 213 would require VA to continue submitting to Congress a report on an annual basis for a 10-year period (or until all projects have been completed) on the Women Veterans Retrofit Initiative, as initially required under section 5102 of the Deborah Sampson Act of 2020 (title V of P.L. 116-315; 38 U.S.C. § 8110 note). The report would require identification of funding provided specifically to support the retrofitting requirements under section 5102 (Women's Health), which segregates these improvements from a facility integrated master plan.

**Position: VA does not support section 213.** VA does not support this section for reasons set forth above in discussion of section 210. As part of the report required by section 5102, VA provides a list of projects to be funded in a given fiscal year, the status of those projects, and provides a 5-year plan that represents the items requested

in subsection C that is being added. This section does not appear to expand beyond what is already provided and is duplicative.

To date, no additional funds have been provided so reporting has been limited to planned projects, but VA anticipates funding from normal appropriations. Expansion of reporting and more focused management on prioritization of these investments would require significant resources to fulfill this recurring requirement.

Section 214 would require VA, not later than 1 year after the date of enactment, to submit to Congress a report on the capital asset and information technology needs of VA's research and development facilities.

**Position: VA does not support section 214.** VA does not support section 214 for reasons set forth above in discussion of section 210. VA already provides much of the information required by section 214 through reports on facility infrastructure needs for research and development through the SCIP process, which is submitted to Congress annually. An additional report would be redundant.

Section 215 would require VA to review all relevant authorities, including those in 38 U.S.C. § 312A to determine whether the provisions of such authority are still meaningful, relevant, and reflect the current operational needs, organizational structure, and all other requirements for the full life-cycle of effective and efficient management of capital assets. VA would have to report to Congress, not later than 270 days after the date of enactment, on whether these authorities should be revised to align more closely with current and future projected operational needs.

**Position: VA has no objection, if section 215 is amended, and subject to the availability of appropriations.** VA supports the overall objectives of this section but recommends the reporting timeframe be adjusted until after the implementation of the efforts currently underway and otherwise proposed in this legislation. If the due date were moved to 18 months from the date of enactment, this would allow VA time to continue enhancing enterprise integration and fully address any gaps in the legislation. VA believes these actions would require time to plan, program, and resource to meet these requirements. VA estimates this provision will cost \$2 million.

Section 216 would require VA to submit to Congress a report, within 1 year of enactment, on actions VA is taking or plans to take to enhance VA's ability to prevent, detect, and report waste, fraud, and abuse occurring in capital asset projects. The report would have to include an assessment of whether new training or enhancements to existing training should be undertaken and recommendations for such legislative and administrative action as VA determines appropriate. In carrying out this section, VA would have to consult with OIG and the Comptroller General on matters relating to best practices and strategies to improve detection and prevention by VA of waste, fraud, and abuse in capital asset projects and management, and VA could consult with such other persons and entities as VA considers appropriate.

**Position: VA does not support section 216.** While VA agrees with the need to eliminate waste, fraud, and abuse in all VA programs and operations, including those involving capital asset projects, this section would provide VA no additional authority to handle such issues; portions of this section are also vague and unclear as to what would be within the scope of this section. VA already incorporates recommendations from OIG, the Comptroller General, and others on how to detect and prevent waste, fraud, and abuse, so it is unlikely that this section would result in any substantive improvements to VA's systems and processes. If Congress chooses to retain this section, VA recommends at least that the report be due not later than 1 year after submission of the OIG report required by section 208.

### **H.R. 3303 Maternal Health for Veterans Act**

Section 2(a) of H.R. 3303 would require VA, not later than 1 year after the date of the enactment of this Act, and annually thereafter until September 30, 2028, to submit to Congress a report that contains a summary of the activities carried out by VA relating to the coordination of maternity health care, data on the maternal health outcomes of Veterans who receive VA care (whether in a VA facility or through the Veterans Community Care Program (VCCP), and recommendations to improve the maternal health outcomes of Veterans, with a particular focus on Veterans from demographic groups with elevated rates of maternal mortality, severe maternal morbidity, maternal health disparities, or other adverse perinatal or childbirth outcomes.

Section 2(b) of the bill would authorize to be appropriated \$15 million for each of FYs 2024-2028 for VA programs relating to the coordination of maternity health care, including the maternity care coordination program described in VHA Directive 1330.03; Maternity Health Care and Coordination. Amounts authorized would be in addition to any other amounts authorized for the coordination of VA maternity health care.

**Position: VA supports, if amended, and subject to the provision of appropriations.** Section 2 is in alignment with many of VA's current efforts to enhance health and health outcomes for pregnant Veterans, where we are gathering and analyzing data and focusing on high-risk groups. VA is disaggregating data on severe maternal morbidity (SMM) by Veterans' race and ethnicity, age, and residence (urban or rural area) on a quarterly basis and will evaluate trends over time; the first quarterly data was available for review in February 2024. This month, VA will finish developing and implementing a systematic process to compile and review data on VA Maternity Care Coordinators' (MCC) required completion of mental health screening and screening results.

VA is tracking severe maternal morbidity and mortality and has improved its data collection efforts to support real-time tracking of conditions and health outcomes. We recognize the critical importance of maternity care and have taken significant steps to improve the delivery of such care to Veterans. Every VHA facility offers maternity care coordination. VA MCCs understand the needs of Veterans and support them through every stage of pregnancy and the postpartum period. Beginning October 1, 2023, VA

expanded the national MCC Program to include follow up of postpartum Veterans for 12 months after delivery, and VA increased the number of contacts with Veterans from 4 to 8 during this period. Through these contacts, MCCs screen pregnant and postpartum Veterans for social determinants of health, mental health risk factors, relationship health and safety, and health risks (such as gestational diabetes and hypertensive disorders of pregnancy). Identifying these maternal risk factors allows VA MCCs to connect pregnant and postpartum Veterans with VA health care providers and resources, ensuring access to care and follow-up screening. This follow-up has proven necessary because of the significant proportion of poor maternal outcomes that can happen in the late postpartum period.

VA has tremendous resources to offer pregnant and postpartum Veterans, including primary care, mental health care, treatment for substance use disorder, intimate partner violence assistance, housing assistance, and resources to address food insecurity. VA also identifies peri-pregnancy Veterans at increased risk to offer clinical intervention, connect them with resources, provide care, and reduce pregnancy-associated morbidity and death.

VA has also created a training module for community health care providers to establish a basic understanding of mental and physical health diagnoses common in Veterans, military culture, trauma-sensitive care principles, and suicide awareness and prevention. This web-based course is available 24 hours a day, 7 days a week, and offers a variety of accreditations to multiple health care disciplines.

Regarding the bill's specific requirements, VA can and does provide data requested by Congress, so an additional reporting requirement in statute is not technically necessary. We note there is some ambiguity in the bill text, as it would require VA to provide “data on the maternal health outcomes of Veterans who receive medical care or services” furnished by VA (whether in VA facilities or through VCCP). This language is not limited to Veterans who receive maternity care furnished by VA (we note for clarity that currently, no VA medical facility furnishes maternity care; all maternity care for eligible Veterans is authorized under VCCP). Instead, VA would be required to report on maternal health outcomes for any Veteran who receives any care from VA. VA would not have this data available unless it had authorized maternity care. In this light, the bill may be improved by amending this to refer to “data on the maternal health outcomes of Veterans who receive maternity care services furnished...” by VA. VA would be able to provide this information.

Regarding section 2(b), VA believes that its FY 2024 President's Budget request is sufficient to implement its current authorities and programs without any additional funding. We would recommend the bill be updated to refer to FY 2025-2029, as FY 2024 is already underway, and VA would face challenges in allocating any additional funds, even if appropriated, within this period of time to implement this bill. If this bill were to be enacted without updating to FY 2025a, this would require a shift in resources from other programs to support these initiatives. This could entail the reallocation of

funds from other high-priority efforts. VA estimates a total 5-year cost of \$1.9 million to carry out this report.

## **H.R. 3584 Veterans Cannabis Analysis, Research, and Effectiveness (CARE) Act**

Section 2(a) of the bill would require VA, in carrying out responsibilities under 38 U.S.C. § 7303, to conduct and support research relating to the efficacy and safety of certain forms of cannabis on the health outcomes of Veterans enrolled in VA care who are diagnosed with chronic pain, PTSD, and other conditions determined appropriate by VA. VA would have to ensure that such research is conducted in accordance with applicable regulations relating to the oversight of research, including regulations prescribed by VA's Office of Research and Development, HHS through the National Institute on Drug Abuse (NIDA), the Food and Drug Administration (FDA), the Drug Enforcement Administration, and the National Institutes of Health.

Section 2(b) would require that this research include a mechanism to ensure the preservation of all data, including all data sets collected or used for this research, in a manner that will facilitate further research.

Section 2(c) would define the forms of cannabis to be evaluated in the research required by subsection (a). Specifically, this would include varying forms of cannabis, including full plants and extracts, at least three different strains of cannabis with significant variants in phenotypic traits and various ratios of tetrahydrocannabinol (THC) and cannabidiol (CBD) in chemical composition, and other chemical analogs of THC. This would also include varying methods of cannabis delivery, including topical application, combustible and non-combustible inhalation, and ingestion.

Section 2(d) would require VA, before conducting and supporting such research, to submit a plan to Congress and to issue any requests for proposals VA determines appropriate for implementation.

Section 2(e) would require VA to submit annual reports to Congress during the 5-year period beginning on the date of the enactment of this Act on the implementation of this section.

Section 2(f) would define the term "covered veteran" to mean Veterans enrolled in VA health care.

**Position: VA supports, if amended, and subject to the availability of appropriations.** We are concerned that, as drafted, the bill is too prescriptive in its design. In particular, section 2(c) raises concerns as full plant products contain high levels of THC as well as other molecules that have undetermined therapeutic benefit or harmful effects.

VA generally supports efforts to study the effects of cannabis products on the health outcomes of users of such products to determine whether the use of such

products can benefit Veterans who have been diagnosed with PTSD and who are experiencing chronic pain or other conditions as deemed appropriate by VA. We recommend extensive amendments to this bill, though, to ensure that its requirements would yield scientifically and clinically valid results. VA recommends convening subject matter experts from within VA and from other Federal entities (e.g., NIDA, FDA) to develop and implement a plan for an observational study on the effects of cannabis products on the health outcomes of users of such products, including but not limited to covered Veterans. Enabling VA to coordinate with other agencies would result in unbiased data collection and the ability to focus on specific methods and dosages of those cannabis compounds that may be more beneficial to health outcomes. Further, the data that result from the collaborative, retrospective analysis would be robust and would likely allow VA to render a determination as to the advisability of proceeding with additional clinical trials.

VA also recommends that it be charged with determining the feasibility and advisability of establishing patient registries to support research to provide insight into how cannabis products are used and associated with medical outcomes. This would be methodologically sound and would build upon existing efforts and research to inform conclusions based on the latest, evidence-based work. It would also support the goal of section 2(b) by ensuring that this work would support future efforts as well.

VA further recommends that, as it determines necessary, it be required to initiate additional scientifically peer-reviewed clinical trials to determine the safety and efficacy of cannabis-derived pharmaceutical products or cannabinoid pharmaceutical products. Section 2(c) of the bill recognizes that variations in dosages of cannabis and their effects on either chronic pain or PTSD could result in different outcomes due to variations in cannabinoids and variations in potencies that arise from different methods of administration (e.g., smoking, edible, transdermal). If VA conducted additional clinical trials, it could control for these variables to determine if specific methods of administration or specific dosages were more effective than others. VA also could carry out additional scientifically peer-reviewed clinical trials, as appropriate, to determine whether the reported benefits of the use of cannabis-derived pharmaceutical products or cannabinoid pharmaceutical products in the general population could be replicated in the population of covered Veterans.

We further recommend that any agency or Department of the Federal Government be exempt from the Paperwork Reduction Act in terms of the voluntary collection of information during the conduct of research engaged in or supported under this section. This would remove a potential barrier to collaborations with other Federal agencies, and this language would mirror the authority recently granted to VA through 38 U.S.C. § 7330D (as added by section 181 of the Joseph Maxwell Cleland and Robert Joseph Dole Memorial Veterans Benefits and Health Care Improvement Act of 2022 (Division U of P.L. 117-328)).

VA is already conducting clinical trials related to cannabis and would use existing criteria applicable to those studies for the purpose of assessing the feasibility of future

clinical trials. VA has utilized the scientific peer review system and is currently supporting a clinical trial of CBD prescribed at a fixed dosage, not the entire plant, titled “Cannabidiol as an Adjunctive to Prolonged Exposure for the Treatment of PTSD” to treat PTSD where CBD is used as an add-on treatment to standard of care psychotherapy. This study was recently extended, until December 2024, and results will be available after the study’s completion.

VA proposes clarifying that the eligibility or entitlement of a covered Veteran to any other benefit under law would not be affected by the Veteran’s participation in any research or trial under this section. VA also recommends including a provision stating that nothing in this section would affect or modify other specific laws or authorities affecting other Federal agencies.

VA also proposes a new section 3 that would authorize to be appropriated additional funds to the Medical and Prosthetic Research account and the Information Technology Systems account for purposes of carrying out these provisions. Appropriated funds would remain available until expended. This would ensure that sufficient resources could be made available to support both research and necessary information technology projects to implement these requirements.

Finally, we note that Congress recently enacted the Medical Marijuana and Cannabidiol Research Expansion Act (P.L. 117-215), which established new provisions of law and amended various provisions in titles 21 and 42 of the United States Code regarding research on CBD and marijuana. While this law does not provide a needed authority to VA, given that VA already funds clinical trials that include medical uses of marijuana for conditions that impact Veterans, we do note that it may enable VA and other parties to conduct research on medical marijuana more easily. However, the Department of Justice and HHS have primary responsibility for implementing the provisions of this new Act, and until those Departments have issued guidance or regulations to implement these new authorities, it may be premature to begin new research under processes that may be outdated. The proposed amendments described above would provide these agencies time to issue guidance or regulations, and the coordination requirements in the proposed amendments would ensure VA’s efforts are aligned with other Federal agencies. We also suggest that the Subcommittee solicit HHS for its views on this bill.

VA would be happy to provide specific amendments to the bill text and to discuss our recommendations further with the Committee.

#### **H.R. 3644    Addressing Care Timelines (ACT) for Veterans Act**

Section 2(a) of the bill would amend 38 U.S.C. § 1703(a)(3), which generally limits VA to furnishing care or services under VCCP to care or services authorized by the Secretary. The bill would amend this authority to provide that, in the case of emergency treatment furnished to a covered Veteran by an eligible entity or provider in the course of authorized care or services, VA could deem such emergency treatment to

be authorized if the covered Veteran (or someone acting on the Veteran's behalf) or the eligible entity or provider submitted notice to VA in such form and containing such information as VA may determine appropriate. VA could not require such notification to be submitted earlier than 96 hours after the date on which such eligible entity or provider furnishes such emergency treatment to a covered Veteran. The term "emergency treatment" would have the same meaning given that term in 38 U.S.C. § 1725.

Section 2(b) of the bill would provide that these amendments would take effect on the date that is 1 year after the date of the enactment of this Act.

**Position: VA does not support.** VA currently authorizes emergency care furnished by an authorized entity or provider if VA is notified within 72 hours of the start of such care for covered veterans. VA has been reviewing the existing "72-hour rule" under 38 C.F.R. 17.4020(c) to determine whether changes are appropriate, including whether reliance on other statutory authorities (such as 38 U.S.C. §§ 1725 and 1728) might be more appropriate. VA would welcome the opportunity to discuss potentially broader reforms regarding eligibility for and administration of emergency care benefits to simplify the process for Veterans and VA.

The bill would generally expand VA's current 72-hour rule, which allows VA to authorize under the VCCP emergency care or services when VA is notified of such care within 72 hours of that care beginning. The bill, however, would extend this period to 96 hours, and it would potentially extend this even further. Current regulations provide that notice must be provided "within 72 hours of the beginning of such treatment," while the bill would refer to "after the date on which such health care provider furnishes such emergency treatment." In this context, the bill's language could mean that the 96-hour notice period would not begin until 12:01 a.m. of the date after care begins. VA is unclear whether this is the intent, but we recommend clarifying this language. If this is the intent and result, this would require systems and process changes to ensure accurate adjudication.

Additionally, we note that the phrase "in the course of care or services authorized under subparagraph (A)" could unintentionally narrow the scope of this text. As written, it would seem the authority to deem emergency treatment as authorized would only apply in situations where that emergency treatment was furnished during the delivery of other care or services. In other words, if a Veteran had been authorized by VA to see an orthopedist for a hip injury, and if during an appointment with the orthopedist, the Veteran had a heart attack that required emergency treatment, VA could deem that emergency treatment as covered. Currently, under VA's 72-hour rule, any emergency treatment, whether furnished "in the course of care or services authorized" by VA or not, that is furnished by an eligible entity or provider to a covered Veteran can be authorized within 72 hours of the emergency care or services being furnished. See 38 C.F.R. 17.4020(c)(2). In this context, if the bill is interpreted to override VA's discretionary authority under the 72-hour rule, the resulting benefit may be significantly narrower than VA's current authority.



Although section 2(b) of the bill would make the amendments effective 1 year from the date of the enactment of this Act, this could still present complications and could be a difficult timeline to meet. VA would need to update its regulations to reflect this change (which would normally take more than 1 year to complete), making this timeline unrealistic. Separately, but related, VA would need different contractual terms than are currently in place to give effect to this change; that would either require a modification of current contracts or inclusion of these terms in future contracts. VA's efforts to develop the next generation of Community Care Network (CCN) contracts are already underway, so attempting to modify current contracts would likely not be feasible or advisable. If VA attempted to include this in the next generation contracts, this could delay the award of such contracts, and if these delays resulted in a gap between the expiration of the existing contracts and the award of the next contract, this gap could have significant consequences in terms of Veterans' access to community care.

We appreciate that this bill reflects and incorporated most of the technical assistance VA provided on an earlier draft of this bill. These changes improved the clarity of the bill in several ways from the prior draft.

#### **H.R. 3649 Veterans National Traumatic Brain Injury Treatment Act**

Section 2(a) of the bill would require VA to implement a pilot program to furnish hyperbaric oxygen therapy (HBOT) to Veterans with TBI or PTSD through health care providers who are not VA employees, Medicare providers, DoD, IHS, or federally-qualified health centers.

Section 2(b) would require VA to select three Veterans Integrated Service Networks (VISN) in which to operate the pilot program.

Section 2(c) would establish in the general fund of the Treasury the VA HBOT Fund; the sole source of monies for the Fund would be from donations received by VA for the express purposes of the Fund. Amounts in the Fund would be available without fiscal year limitation to pay for HBOT, and the Fund would terminate on the day that is 5 years after the date of the enactment of this Act (as established by section 2(d)).

Section 2(e) would define HBOT to mean hyperbaric oxygen therapy with a medical device either approved by the FDA or issued an investigational device exemption by the FDA.

**Position: VA strongly opposes.** VA, DoD, and others have conducted extensive research on the efficacy of HBOT on TBI, and the research has found no support for this as an effective treatment (particularly for mild TBI). In fact, there is a strong clinical basis that HBOT is not recommended for treating TBI. There is no evidence to support a sufficient basis for HBOT as a treatment for PTSD either. In this context, we are concerned that this bill could result in adverse health outcomes for participating Veterans; there is also little ability to monitor performance with definitive,

evidence-based metrics. The bill also would result in significant burdens on Veterans in terms of the time commitment involved in treatment and potential personal liability for portions of treatment that are not covered by VA (such as travel or room and board, if applicable). Further, the resources associated with providing this treatment in terms of clinical and administrative time would mean fewer resources for evidence-based therapies for Veterans.

In 2017, VA initiated a clinical (non-research) program to evaluate the feasibility of referring Veterans diagnosed with PTSD (with or without a history of mild TBI) for HBOT treatment provided by DoD or community providers. This clinical program evaluation was designed to better understand the treatment protocol requirements and burdens on Veterans and VA in the context of PTSD treatment. The evaluation was not designed to examine or measure the efficacy of HBOT as a treatment for PTSD, TBI, or any other indication. VA proactively began the clinical program evaluation to understand the logistical and administrative requirements and barriers for providing this treatment for these indications, which are considered “off-label” because they have not been approved by FDA. VA’s clinical program evaluation found that fewer than half of the Veterans referred completed the full course of HBOT treatment. Some Veterans were not interested in engaging or continuing treatment due to the treatment schedule (appointments are scheduled for 1-2 hours per day, 5 days a week, for 4-8 weeks) and the need to travel or because of the availability of evidence-based treatment alternatives. We anticipate that similar results could occur if this bill were enacted, in which case Veterans would be delayed in receiving evidence-based care to treat their conditions.

VA and DoD have developed evidence-based clinical practice guidelines (CPG) for both TBI and PTSD; the most recent update for the TBI CPGs was completed in June 2021, while the most recent update for the PTSD CPGs was completed in June 2023. The CPGs for PTSD found there is insufficient evidence to recommend for or against HBOT as a treatment for PTSD. The CPGs for TBI strongly recommend against the use of HBOT for the treatment of patients with symptoms attributed to mild TBI. Reviews of available research found no evidence of improved symptom severity and only a mixed effect on quality of life. When HBOT was compared to a sham intervention (effectively, a placebo treatment), HBOT actually was associated with decreased quality of life at long-term follow up at 2 and 3 years. In addition to the lack of patient improvement, the use of HBOT after mild TBI may have harmful impacts, including seizures. Emerging treatments are often marketed to patients struggling with chronic symptoms, and providers need to understand the potential negative impacts that referrals for unfounded treatments can have on the provider-patient relationship. The CPGs explain that when treatments do not work, it may lead to disappointment, damage to a patient’s trust, an increase in the likelihood of the patient taking on a “sick role,” and even harm to the patient. Given the evidence of harm in the literature and FDA’s findings, the CPGs conclude that HBOT is not currently identified as a safe or effective treatment after mild TBI.

VA also has procedural concerns with this bill. Initially, the bill seems to establish a parallel program to VCCP for HBOT. Congress enacted VCCP to consolidate the various community care programs and to simplify eligibility by establishing a common set of criteria to determine when Veterans would qualify for community care. This bill appears to require VA to furnish this care exclusively through non-VA providers regardless of whether VA could furnish treatment for PTSD or TBI. The bill expressly excludes VA, Medicare, DoD, and IHS providers, as well as federally-qualified health centers. Given this narrow range of potentially eligible entities, it is not clear that VA would have any means to verify the quality of those providers or the quality of services they would furnish under this bill. Additionally, this narrow scope of eligible providers could both limit Veterans' access to timely care and would very likely increase costs to VA as there would likely need to be a separate referral, scheduling, and follow-up process created for this authority. We recognize that there is a limited number of providers and HBOT treatment centers, but imposing additional restrictions would seem to make implementation more difficult and costly. Further, given that multiple treatments are often required and the limited number of providers, the likelihood that Veterans would need to travel to receive this care is high. This may be inconvenient and place a significant financial burden on patients.

The bill does not define which Veterans could receive care under this authority; it is unclear whether this is limited to enrolled Veterans or if another population would apply. Additionally, there are no criteria set forth in the bill to determine when HBOT would be offered to Veterans—whether this would be required to be a treatment of first resort or last resort, purely at the Veteran's election, or as otherwise clinically indicated. We emphasize that providers must determine that care is medically necessary and in the best interest of the patient to furnish it in accordance with current legal and ethical standards. We would infer these requirements would continue to apply if this legislation were to become law in the absence of specific language to this effect, but we recommend the bill include such requirements to reduce the potential for confusion. Given the CPGs described above strongly recommend against the use of HBOT for the treatment of patients with symptoms attributed to mild TBI, it is not clear that VA actually could refer such patients for treatment.

The funding mechanism proposed in this bill also raises significant questions and concerns. No other VA program operates under such parameters as proposed by this bill, so VA would need to develop new procedures and requirements to govern the use of an account like this. It is unclear whether there would be sufficient funds donated to VA to cover the costs of treatment. VA would need to wait until there were sufficient resources in the new HBOT Fund to support the delivery of care, which could delay VA's implementation of this (potentially by months or years). VA would need to develop new processes and procedures to determine who would manage these funds in VA and how the funding would be distributed. It is also unclear whether a new administrative office would be needed to handle the financial aspects that are unique to this arrangement. This could result in additional oversight costs that would divert funds from Veterans care.

In general, if Congress proposes to require VA to operate a new program, conventional appropriations measures would make it more feasible to carry out. This both ensures accountability for Congress (by ensuring Congress is responsible for funding these programs appropriately) and reliability for VA (by ensuring that there is a clear and dedicated resource pool for different programs).

The bill also lacks critical elements, such as a clear termination date—the bill only refers to the termination of the HBOT Fund, not the program authority in the first place, which would seemingly require VA to continue the program after the termination of the HBOT Fund (meaning within current appropriations accounts). In the absence of further clarity, VA would likely have challenges with implementing this bill, and this could further increase administrative expenses that would divert funds from other evidence-based care.

#### **H.R. 4424 Vietnam Veterans Liver Fluke Cancer Study Act**

Section 2(a) of the bill would require VA, not later than 120 days after the date of the enactment of this Act, in consultation with the Director of the Centers for Disease Control and Prevention (CDC), to commence an epidemiological study on the prevalence of cholangiocarcinoma in covered Veterans of the Vietnam era. This study would need to use data from the VA Central Cancer Registry and the National Program of Cancer Registries. The study would have to identify the rate of incidence of cholangiocarcinoma in covered Veterans in the Vietnam era and in residents of the United States (U.S.) from the beginning of the Vietnam era to the date of the enactment of this Act. For each of these two groups, the study would have to identify the percentage of individuals with cholangiocarcinoma by various demographic characteristics, including age, gender, race, ethnicity, and the geographic location of the patient at the time of diagnosis.

Section 2(b) would require VA, within 1 year of completing this study, to submit to Congress a report that contains the results of the study and recommendations for administrative or legislative actions required to address issues identified in the study.

Section 2(c) would require VA to track the prevalence of cholangiocarcinoma in covered Veterans of the Vietnam era using the VA Central Cancer Registry and provide such information to Congress in periodic follow-up reports (as required by section 2(d)).

Section 2(e) would define the term “covered veterans of the Vietnam era” to mean Veterans who served in the Vietnam theater of operations during the Vietnam era.

**Position: VA does not support.** VA fully supports the need to conduct research to understand the health risks and conditions of Veterans who served in combat areas or were otherwise placed at higher risk due to their military service; however, the bill’s requirements would not be as useful to VA as VA’s current efforts. For nearly a century, VA research and development has been improving the lives of Veterans and all

Americans through health care discovery and innovation. Congress' generous support of more than \$900 million for VA research supports more than 7,000 active research projects designed to enhance the delivery of care for Veterans and others.

Cholangiocarcinoma is a rare cancer of the biliary tract, which is comprised of the gallbladder and bile ducts. Liver fluke infection is a type of parasitic infection that is prevalent in Southeast Asia and is acquired from the ingestion of raw or poorly cooked freshwater fish infected by this parasite. Liver fluke infection is a well-recognized risk factor for the development of cholangiocarcinoma. Liver flukes can survive in human bile ducts for decades and can cause a state of inflammation that can lead to cholangiocarcinoma, a cancer that is diagnosed far more commonly in countries like Thailand and Vietnam than in the U.S. Vietnam War Veterans have been concerned about exposure to liver flukes during deployment and subsequent development of cholangiocarcinoma.

Other risk factors for cholangiocarcinoma are biliary tract diseases such as primary sclerosing cholangitis (an autoimmune disease), chronic cholelithiasis (bile duct stones), cirrhosis (liver scarring from several causes), and infections such as Hepatitis B or C. An evaluation of VA health records in 2018 indicated that Vietnam Veterans who receive VA health care have similar or lower age-adjusted incidence rates of cholangiocarcinoma when compared with the U.S. population in most age categories (fewer than the U.S. rate of 1.6 cases/100,000 persons/year). VA does recommend that all Veterans who have not been tested for Hepatitis B or C in the past obtain those tests, as there is definitive treatment available to clear most Hepatitis B and C viral infections.

VA also has a current research study on rates and causes of mortality in Vietnam era Veterans. An analysis of deaths from 1979-2019 from cholangiocarcinoma is in final stages of preparation for submission to a peer-reviewed scientific journal. This analysis compares deaths from cholangiocarcinoma between all Veterans who served in the Southeast Asia theater of operations and all of those Veterans who served elsewhere in the world during the Vietnam War era. Because cholangiocarcinoma has a very high mortality rate, comparing death rates is an accurate way of counting cases and comparing incidence of this unfortunate cancer. VA's mortality study is very likely the most definitive way that the real incidence of cholangiocarcinoma can be measured because counting cases of Veterans who receive health care in VA does not include all Vietnam-era Veterans nor all diagnoses of cholangiocarcinoma as Veterans receive care outside VA. VA designed this study in collaboration with scientists from the Uniformed Services University of the Health Sciences. The VA mortality study shows that there is no difference in mortality rates from cholangiocarcinoma among all Vietnam-War deployed Veterans compared to all Veterans who served elsewhere in the world during the era, except for Marines. Vietnam War-deployed Marines appear to have a higher rate of death from cholangiocarcinoma compared to non-deployed Marine Vietnam Veterans. The reasons for this cannot be definitively determined; data to compare risk factors (including exposure to undercooked fish and diagnoses of liver fluke infections) are not available. It is possible that Marine deployment locations or

experiences resulted in greater exposure to liver fluke infections, but other risk factors could explain this outcome as well. These research results, once peer reviewed, will be communicated to Veterans and clinicians to be watchful for signs and symptoms of cholangiocarcinoma.

Given VA's observations with existing studies, the bill's requirements would not be as useful to the agency as VA's current efforts at this time. Any additional epidemiological study would face significant hurdles in counting cases because of the lack of available and comprehensive health care data (such as cancer diagnoses and risk factors) on the entire population of Vietnam-era Veterans over the years since the war, whereas VA has conducted this mortality study by compiling a roster of all Vietnam Veterans along with a database of their death dates and causes. For example, reliable health care encounter data are available only from 2000 forward for both DoD and VA. Thus, there is at minimum a 25-year gap (1975 to 2000) where we would be unable to ascertain cholangiocarcinoma incidence. As noted earlier, given the high mortality of cholangiocarcinoma, using cholangiocarcinoma mortality as the primary outcome in the Vietnam-era Mortality Study provides the most robust epidemiologic assessment of this condition in Vietnam-era Veterans. We do not believe the bill would provide additional information that would justify the resources needed for implementation.

Further, section 505 of the Sergeant First Class Heath Robinson Honoring our Promise to Address Comprehensive Toxics (PACT) Act of 2022 (P.L. 117-168) requires a review of cancer rates among Veterans. In implementing this requirement, VA has developed a bilateral agreement with state tumor cancer registries, which have accurate current data on cancer diagnoses and which could be leveraged to further the work this bill proposes to undertake. In this regard, VA is effectively already meeting the requirements of this bill. VA also suggest that the Subcommittee solicit HHS for its views on this bill.

## **H.R. 5247 Expedited Hiring for VA Trained Psychiatrists Act of 2023**

H.R. 5247 would add a new section 7406A to title 38, United States Code, to allow VA to begin the process of appointing a psychiatrist *before* the psychiatrist completes a residency sponsored by or affiliated with VA, provided the individual meets the requirements in the VA qualification standards for psychiatrists. VA could appoint a psychiatrist under the proposed section 7406A(a) if the position remained unfilled for at least 35 days or more.

**Position: VA does not support.** VA does not support this bill because it is redundant given existing policy and authorities. VA currently has authority to begin the appointment process for psychiatrists prior to their completion of a residency contingent upon them meeting the qualification requirements by the time of appointment. VA focuses on expediting the hiring of both current and former trainees based on their qualifications.

## H.R. 5530 VA Emergency Transportation Access Act

Section 2(a) of the bill would provide that VA may not change the rate of payment or reimbursement provided for the transportation of a Veteran or other eligible individual on a special mode of transportation, as in effect on January 1, 2023, unless such change would increase the rate of such payment or reimbursement or, before the effective date of such change, VA: (1) conducted a thorough review and analysis of the effects of the change on VA, industry, and Veterans; (2) developed a formal process to ensure any changes made to such rate would not reduce Veterans' access to care; and (3) ensured the new rate reflects, at a minimum, the actual cost of such transportation.

Section 2(b) would require VA, in carrying out any such review and developing any process, to consult with a committee made up of relevant industry experts, representatives from the Centers for Medicare and Medicaid Services (CMS), VA employees with subject matter expertise in various areas (transportation, access to care, integrated Veteran care, rural Veterans, Native American Veterans, and other matters determined appropriate), and representatives of VSOs.

Section 2(c) would require that, not later than 2 years before the effective date of any change made to the rate of payment or reimbursement for special mode transportation that affects the payable rate under any contract, VA would have to establish a template and a standardized process for entering into and making changes to rates in effect under such contract, issue guidance about the use of such template and process within VA and across the industry associated with special mode transportation, and submit a report to Congress that includes a description of the template and process.

Section 2(d) would define the term "special mode of transportation" to mean an ambulance, ambulette, air ambulance, wheelchair van, or other mode of transportation specially designed to transport disabled persons. The term would not include a mode of transportation not specifically designed to transport disabled persons (such as buses, subways, taxis, trains, or airplanes) or a modified, privately owned vehicle with special adaptive equipment or that is capable of transporting disabled persons.

**Position: VA does not support.** In 2011, Congress authorized VA to pay to providers of transportation the lesser of the actual charges for transportation or the amount determined by CMS, unless VA has entered into a contract for that transportation with the provider.

In 2020, VA proposed to put in place the very change Congress had authorized. VA's publication of a proposed rule triggered a comment period, during which VA received five substantive comments. VA responded to these comments in a final rule, known as the Change in Rates Rule, which was published in the Federal Register on February 16, 2023. VA stated in the final rule that we would delay the effective date of the final rule by 1 year (to be February 16, 2024) to ensure that ambulance providers had adequate time to adjust to VA's new methodology for calculating ambulance rates

(88 FR 10035). We further stated in the final rule that such adjustment could include ambulance providers entering negotiations with VA to contract for payment rates different than those under the CMS ambulance fee schedule, as contemplated in the final rule. Congress granted VA the discretion in 38 U.S.C. § 111(b)(3)(C) to use the CMS ambulance fee schedule as part of VA's methodology to calculate ambulance payments, ostensibly finding such schedule to be sufficient. VA cannot modify or increase the CMS ambulance fee schedule rates.

After publication of the final rule, however, VA received feedback from both internal and external stakeholders, including VA employees, ambulance providers, and industry experts, that more time was necessary for successful implementation of the rule. Specifically, the delay of the effective date was necessary to accommodate unforeseen difficulties in air ambulance broker contracting. These difficulties relate to air ambulance brokers requiring a contract or subcontract in place with all potential air ambulance providers that covers emergency, non-VA initiated trips. Based on this feedback and evaluation of the continued effort that would be required by air ambulance brokers to negotiate and enter into contracts before February 16, 2024, we delayed the effective date of the regulation by 1 year (to be February 16, 2025). VA understands the Committee is specifically concerned about the effect these proposed rules would have on unauthorized emergency transportation, and VA is exploring options to try to address this concern. We would welcome the opportunity to discuss this further with the Committee.

VA's regulations, as proposed for 38 C.F.R. § 70.30(a)(4), would allow VA to enter into a contract with a vendor of special mode transportation (including air ambulance transport), and the terms of that contract would govern the payment rates for such transport. Such contracts could provide for a different rate as agreed, in the event that VA determined it may be justified based on local considerations, such as for rural areas.

VA has other concerns with the bill beyond its apparent retreat from prior Congressional intent. The bill is unclear in several critical respects. For example, the bill refers to a "rate" of payment throughout the text, but there is not a singular rate for transportation given the variability in geography, type of vehicle or conveyance (ambulance versus helicopter, for example), and type of service furnished. Other Federal agencies, particularly CMS, have established rates for ambulance services that reflect appropriate charges for such transportation, which do not reflect billed charges. VA's pending regulatory changes would give effect to the discretion Congress provided to VA to align its payment structures with these other Federal agencies (including CMS). By referring to special mode transportation of Veterans or other eligible individuals, this would also apply to health care programs for family members (such as the Civilian Health and Medical Program of VA (CHAMPVA) or the Children of Women Vietnam Veterans). VA currently pays for special mode transportation for eligible individuals under these programs consistent with the CMS ambulance fee schedule. It is unclear whether this was the intent of the bill.



Subsection (a)(2) would require VA to conduct thorough analyses of the proposed changes to rates for special mode transportation, but these would largely duplicate the requirements associated with a regulatory impact analysis, which VA already provided. In this context, these requirements would be duplicative and unnecessary.

Further, under subsection (a)(2)(B), VA would have to develop a formal process to ensure that any change made to such rate does not reduce the access to care for Veterans. It is unclear how VA would be able to determine whether any changes would affect access to care; access is influenced by many different variables, some of which are completely outside of VA's control (principally, the decision of private providers to offer services in the marketplace in the first instance). In this context, VA could likely never develop a process, formal or otherwise, that would ensure that rate changes do not reduce access to care.

We are also concerned about the language in subsection (a)(2)(C), which would direct VA to ensure that "the new rate reflects, at a minimum, the actual cost of such transportation." It is unclear what "the actual cost" is intended to mean, but we infer that the intent is to ensure that VA always pays, at a minimum, the billed charges for transportation. However, the billed charges do not reflect the "actual cost of such transportation," as billed charges also include profit margins and administrative expenses beyond the cost of the transportation. To the extent the bill is intended to require VA to pay billed charges, this would effectively allow private entities without a contract with VA to charge any amount, and VA would be obligated to pay this amount. This would seriously undermine VA's efforts to establish a contracted network of providers, which could increase both the predictability and accessibility of services while also providing cost assurances for the Government and taxpayers. Requiring VA, by statute, to pay no less than the billed charges would make budgeting and accountability impossible. It also raises questions about whether this would effectively allow private entities to determine Federal obligations of appropriated funds.

Subsection (b) of the bill would require VA to consult with various entities, including non-Governmental entities. The bill text appears to direct VA to establish a committee composed of relevant industry experts and representatives of VSOs, but this would seemingly require this to be a Federal Advisory Committee subject to the Federal Advisory Committee Act (FACA). There is no further discussion of this requirement or explicit authorization pursuant to FACA, and there is no express waiver of the need to comply with FACA. We recommend the drafters clarify the intent of this provision and whether this committee would be subject to FACA. We do not believe this provision is necessary as the consultation requirements would largely duplicate the public comment period that was previously available for VA's proposed regulations.

Subsection (c) of the bill would prohibit rate changes until a 2-year period elapsed from the time that a template and standardized process for entering into and making changes to rates and guidance about the template and process was issued with VA and across the industry. This would ultimately make entering into contracts at set

rates more difficult, which appears antithetical to Congress' goal of ensuring accountability and predictability for the costs of these services. We are also concerned that the 2-year delay for the effective date of any change would result in VA paying greater costs for that entire period of time.

We understand the Committee's concerns regarding transportation access, and we would welcome the opportunity to discuss these in more detail.

## **H.R. 5794 VA Peer Review Neutrality Act**

H.R. 5794 would add a new 38 U.S.C. § 7311B; the proposed subsection (a)(1) would require peer review committee members to withdraw from participation if the individual has direct involvement with the care under review, or the individual is unable to conduct an objective, impartial, accurate, and informed review. In addition, under the proposed subsection (a)(2), VA would have to conduct an additional review by a neutral peer review committee at another VA facility for quality management reviews conducted with respect to care provided by a peer review committee member. Under the proposed subsection (b)(1), individuals with knowledge of confidential quality assurance information regarding a matter under investigation could not serve as a factfinder or member of an administrative investigation board (AIB) examining such matter, nor disclose confidential quality assurance information to an AIB or factfinder. Under the proposed subsection (b)(2), VA would be required to ensure a member of an AIB or a factfinder does not: (1) have any personal interest or other bias concerning the investigation being conducted, (2) have direct involvement in matters being investigated, and (3) have a supervisory or personal relationship with the subject of the investigation. Any individuals with any of the three identified relationships or personal interest or bias would have to inform the authority responsible for the investigation and recuse themselves.

**Position: VA supports, if amended.** VA supports the underlying premises in the bill, such as maintaining the integrity of peer reviews, protecting confidential quality assurance information, and ensuring investigations are free of bias and potential investigatory conflicts of interest that would compromise the integrity of the investigation. However, significant amendments to the bill's language would be needed to align these common interests for VA's support. The bill appears to overlook major components of existing statute and VA's existing processes for peer review, investigating patient care matters, protecting quality assurance information, and conducting impartial investigations.

VA has no concerns with the proposed section 7311B(a)(1), which is in line with current VA guidelines. Similarly, VA has no concerns with the proposed section 7311B(a)(2), which is also in line with current VA guidelines.

However, VA recommends that the proposed section 7311B(b)(1) be removed. VA has existing investigation formats for patient care concerns that comply with 38 U.S.C. § 5705, which deals with confidentiality of medical quality assurance records.

Some investigations are confidential quality assurance reviews, but some are purposefully not covered by 38 U.S.C. § 5705, namely Focused Professional Practice Evaluations for Cause and Focused Clinical Care Reviews, fact findings, and AIBs. These reviews are critical for addressing concerns regarding substandard care that may be detrimental to Veterans because they are administrative investigations that provide a mechanism for information to be discovered, and in turn, utilized for administrative action if necessary. The non-disclosure element of the proposed provision extends provisions of 38 U.S.C. § 5705(b)(1), which already defines rules for release of information. VA agrees that employees who have knowledge of events being investigated because of their role in the quality review process cannot be a factfinder or member of an AIB. However, the vague language of the bill may preclude an employee from testifying or providing information obtained through the individual's role in an event or their appropriate peripheral involvement in an event. To ensure appropriate administrative action can be taken in response to misconduct, the discoverable investigatory processes must be able to collect information from all sources related to an event and not protected under 38 U.S.C. § 5705. VA can provide narrative examples of how these concerns could arise to the Committee upon request. If the proposed paragraph (b)(1) is not struck in its entirety, VA at least recommends removing the prohibition on disclosing information in at least some situations. Further, any clarifications should be included as an amendment to 38 U.S.C. § 5705, rather than as part of the proposed section 7311B, to avoid confusion and creating multiple statutes covering the same matter. VA can provide further technical assistance on this issue if needed.

VA also recommends amending the proposed section 7311B(b)(2). VA takes seriously the administrative investigation process and the impartiality of those conducting investigations. VA Directive 0700, Administrative Investigation Boards and Factfindings, and VA Handbook 0700, Administrative Investigation Boards and Factfindings, provide the framework for VA's general administrative investigations and include a specific requirement for those participating in fact findings and AIBs to undergo training. In 2021, VA updated these policies and training to emphasize the avoidance of potential investigatory conflicts of interest. VA policy requires that authorities responsible for investigations ensure that members of AIBs and factfinders are free from such conflicts. VA AIB members and factfinders are already required to be objective, impartial, and free from personal interests, bias, or involvement in the matter. AIB Members and factfinders also are already required to recuse themselves if they do not meet these standards.

VA supports the assurances that investigators do not have potential investigatory conflicts of interest or personal relationships impacting their objectivity regarding the incidents they are investigating. VA is concerned that moving these requirements from policy to statute will increase the likelihood and weight of employees challenging disciplinary actions by arguing that the underlying investigation violated the statute and constituted harmful procedural error. To mitigate this risk, VA recommends that the bill simply state that VA will ensure that its investigators are impartial and that VA must include appropriate measures in policy. This would allow VA to tailor and monitor the

issue in light of the complexities and unique requirements of its administrative investigation structure.

Investigations within VA vary in severity and response, from every day information gathering where a supervisor asks an employee about minor infractions (e.g., being late to work) all the way to an AIB, which may investigate much more severe misconduct such as inappropriate conduct of a sexual nature or inappropriately striking a patient. Per VA policy, AIB members are not permitted to have a supervisory relationship with the subject of the investigation. The same rule was intentionally not applied to factfindings, as they are intended to provide an investigative process for, among other things, first-line supervisors to address issues within their office of business unit. It is imperative that supervisors maintain their authority to conduct investigations, when appropriate. A first-line supervisor is the appropriate individual to inquire into the routine misconduct issues that surface every day within VA (e.g., tardiness, customer service complaints, observing suspected impairment, etc.). To ensure optimal operations, proposed subsection (b)(2)(B) would need to be amended to remove the provision disallowing this practice to allow routine exercises of supervisory authority. The bill could include further language clarifying that subordinates should not investigate an issue in which their supervisor has a significant interest (e.g., the supervisor is the subject of a related investigation). VA also supports adding explicit safeguards that preclude supervisors from completing an investigation when they are implicated in the misconduct under review. There would be no costs associated with this bill.

#### **H.R. 6324 Fiscal Year 2024 Veterans Affairs Major Medical Facility Authorization Act**

This bill would authorize major medical facility projects in American Lake, WA; Dallas, TX; El Paso, TX; Perry Point, MD; Portland, OR; Reno, NV; San Diego, CA; San Francisco, CA; San Juan, PR; St. Louis, MO; and West Haven, CT. It would authorize to be appropriated in FY 2024, or the year in which funds are appropriated for VA's major construction account, \$4,603,129,000 for these projects.

**Position: VA supports, if amended.** VA supports the authorization of the projects identified in this bill. VA has previously provided and is requesting an amendment regarding the authorization for the San Diego, CA project. VA recommends the bill also authorize "central utility plant upgrades" and the seismic retrofit of the existing spinal cord injury building 11 at the VA San Diego Healthcare System. VA can provide technical assistance on this language if needed.

#### **H.R. 6373 Veterans Spinal Trauma Access to New Devices (STAND) Act**

Section 2 of the bill would amend 38 U.S.C. § 1706 by adding a new subsection (d). The proposed subsection (d)(1) would require VA, in managing the

provision of hospital care and medical services, to furnish (through direct provision of service, referral, or a VA telehealth program) a preventative health evaluation annually to any Veteran with an SCI/D who elects to undergo the evaluation. The proposed paragraph (2) would require that the evaluation include an assessment of any circumstance or condition the Veteran is experiencing that indicates a risk for any health complication related to the SCI/D, chronic pain and its management, dietary management and weight management, prosthetic equipment, and the provision of any assistive technology that could help maximize the independence and mobility of the Veteran.

Proposed paragraph (3) would require VA, in maintaining, prescribing, or amending any guidance, rules, or regulations issued by VA regarding the requirements in the new subsection (d), to consult with VA's SCI/D program managers, VA clinicians employed as specialists in SCI/D, and organizations named in or approved under 38 U.S.C. § 5902 (generally, organizations that prepare, present, and prosecute claims for VA benefits). Before issuing any guidance, rules, or regulations regarding the requirements set forth in this new subsection, VA would have to consult with manufacturers of assistive technologies and other entities relevant to the provision of assistive technologies if the guidance, rules, or regulations would directly affect such manufacturers or entities. VA would have to ensure, to the extent possible, that any Veteran known by VA to have an SCI/D receive information annually about the annual evaluation and the benefits to undergoing this evaluation.

Proposed paragraph (4) would require VA, within 1 year of the enactment of this Act and every 2 years thereafter, to submit to Congress a report on the number of Veterans who received medical care or hospital services from VA and used an assistive technology, received VA care or services and were assessed for the provision of an assistive technology, and received VA care or services and were prescribed an assistive technology. VA would also need to report the year-to-year change in the percent of Veterans with an SCI/D who received an evaluation described above.

Proposed paragraph (5) would require VA, in evaluating the performance metrics of a VISN for any year beginning after the date that is 1 year after the date of the enactment of this Act, to consider the provision of the preventative health evaluations described above.

Proposed paragraph (6) would define the term "assistive technology" to mean a powered medical device or electronic tool used to treat or alleviate symptoms or conditions caused by an SCI/D, including a personal mobility device (including a powered exoskeleton device) and a speech-generating device.

**Position: VA opposes.** VA is committed to providing comprehensive, lifelong, innovative, and specialized care that is safe and evidence-based for Veterans with SCI/D. VA opposes this bill because it would reduce VA's ability to ensure the safety of Veterans and would compromise the integrity of the clinical decision-making process. It

would also increase administrative costs to VA, burden clinicians' time, and ultimately result in reduced access to clinically appropriate care.

In particular, VA is opposed to proposed subsection (d)(3), which would require VA to consult with the manufacturers of assistive technologies "and other entities relevant to the provision of assistive technologies" if VA's guidance, rules, or regulations "would directly affect such manufacturers or entities." Mandatory consultation with such entities in the development of clinical guidance would introduce a conflict of interest that could easily compromise patient safety. This would not only set a concerning precedent, but it would contradict best practice for the development of clinical protocols in health care settings. Research indicates that increased stakeholder involvement in the development of clinical protocols or clinical practice guidelines can result in poor quality protocols that fail to ensure safety and do not meet the needs of clinicians in guiding best care for patients. The recommended course of action for the development of high-quality clinical protocols is to utilize research and subject matter experts from a range of settings and expertise. VA's assessment and procurement of assistive technologies is consistent with the standard practice of care for Veterans with SCI/D.

Additionally, the provisions in proposed subsection (d)(4), which would require detailed reports from VA, would consume clinicians' and administrators' time without apparent value; this additional burden would reduce the ability to see more Veterans in clinical appointments and to process requests for assistive technology and other devices, ultimately reducing Veterans' access to timely and appropriate care. VA's current data systems capture when assistive technology is procured, but the other data elements in the bill are not available. VA's systems are not able to capture instances where Veterans are evaluated, but not found suitable, for assistive technology, or Veterans who decline assistive technology.

VA is also concerned about the breadth of the definition of the term "assistive technology" in the bill. The term would mean a powered medical device or electrical tool used to treat or alleviate symptoms or conditions caused by an SCI/D, including a personal mobility device (including a powered exoskeleton device) and a speech generating device. Given the breadth of this term, the associated procedural requirements would apply in multiple instances; this would make practical implementation very difficult, if not impossible.

The provisions of this bill that would not result in these outcomes are unnecessary because VA is already meeting those requirements. For example, VA already provides annual evaluation for Veterans with SCI/D, and these requirements meet or exceed all elements of the bill in this regard. Furthermore, explicitly prioritizing powered assistive technology during annual evaluations diminishes the value all other aspects of the comprehensive medical and functional evaluation that is performed. While assistive technology is seen as a critical component of the evaluation, it is not weighted above other interventions or considerations in providing Veteran-centered care.

To the extent the bill is concerned that Veterans do not have an opportunity to determine which assistive technologies would be best for them, VA providers work closely with Veterans to identify their needs and recommend the best solutions for them. When devices like exoskeletons are identified, VA allows Veterans to try these devices for up to 90 days to determine whether these are appropriate for them. Recent data indicate that nearly 40% of Veterans who use an exoskeleton during this trial period decide against using it beyond the trial period. This approach ensures Veterans receive the device or technology that best meets their functional needs while avoiding waste that could otherwise result if these technologies were furnished without personal experience. This reflects VA's commitment to both clinically appropriate care as well as accountable fiscal stewardship.

Additionally, it is critical to ensure that Veterans can safely use any devices they are prescribed. VA was an early adopter of exoskeleton technology, and powered exoskeletons have been provided to Veterans with SCI/D since 2015, shortly after the FDA first approved powered exoskeletons for home use. To provide guidance and ensure consistency in screening, evaluation, and training, VA developed a rigorous clinical protocol, which was shared with VA facilities in December 2015. This clinical protocol was updated in 2018, reflecting additional exoskeleton products that received FDA clearance for personal use in the community.

Further demonstrating VA's commitment to supporting exoskeletons and innovative technology, VA performed one of the largest national randomized, controlled multi-center exoskeleton research studies, investigating home/community use, efficacy, and safety of powered exoskeletons in Veterans with SCI/D. Powered exoskeletons can lead to assisted ambulation in individuals with SCI/D, yet they require careful evaluation of potential users, extensive training, inclusion of a companion for safe use, extensive clinician experience, and specific manufacturer training and expertise by staff for safe and effective use by individuals with SCI/D. Notably, the criteria for each device are largely based on FDA specifications. VA has taken an individualized approach to Veterans' exoskeleton training to minimize the burden on Veterans who are interested in and are evaluated for clinical appropriateness to utilize this technology.

After a Veteran is determined to be clinically appropriate for an exoskeleton device, training with the device can occur at a VA SCI/D Center or at a facility that provides equivalent certified exoskeleton training. Training typically requires 20-30 visits over a series of months to achieve proficiency with the device. Device issuance is considered when all critical skills are safely demonstrated by the Veteran and their companion(s). Clinical training and home trials must occur before a device can be purchased to ensure that the device meets the needs of the Veteran and is safe in the home environment.

Exoskeletons are complicated medical devices, and exoskeleton-trained clinicians must consider a number of factors when issuing this equipment. Factors include but are not limited to: level of spinal cord injury, height, weight, hip and leg length measures, joint range of motion (flexibility), skin integrity, spasticity, arm/hand

strength, bone density, history of fractures, blood pressure, autonomic dysreflexia, cardiovascular health, cognition, environments of intended use, Veteran's goals for use of the device, vision, and the ability to develop the skill needed to operate this equipment. Due to the complexity of the devices, a large number of Veterans who are interested in exoskeletons are not appropriate for the use of these devices. Additionally, for safety reasons, the devices currently available in the U.S. require a companion to be present when an individual is utilizing this technology. Many individuals lack access to an appropriate companion to help with management of the device, which can weigh up to 51 lbs. Requiring the presence of a companion while utilizing the device can result in the perception of decreased independence to users who are fully independent when using a wheelchair. The involvement of a companion also prolongs the training period and requires a significant commitment from both the Veteran and companion.

Exoskeletons have been studied in a number of settings, and there are many potential benefits, such as standing, walking, cardiovascular response, spasticity management, weight loss, bowel function, and bone density. Evidence of adverse events, including fractures, falls, skin breakdown, autonomic dysreflexia, and soft tissue injuries have been reported across subjects, studies, and devices. Currently, there are no established CPGs regarding the use of exoskeletons. For each individual, it is still largely unknown if the benefits outweigh the risks and how to identify candidates who will most likely benefit from the technology. Therefore, VA has developed a clinical protocol that emphasizes patient preference and safety. Importantly, through safe, evidence-based services and devices, VA will continue its ongoing efforts to support Veterans with SCI/D in their goals of optimizing their health, functional mobility, and independence. Those efforts include the careful evaluation and when appropriate, provision of assistive technology devices including powered exoskeletons.

VA is focused on ensuring Veterans have access to and can use specialized technology to address their needs. A new Office of Advanced Manufacturing is focused on these efforts specifically in the context of assistive technology. VA is continually reviewing current clinical protocols to ensure Veterans can receive timely, high-quality, and evidence-based care and technology.

#### **H.R. 7347 Reporting on Determination to Include Newly Approved or Licensed Psychedelic Drugs in the VA Formulary**

This bill would add a new section 8125A to title 38, United States Code, that would require VA, not later than 180 days after a psychedelic drug is approved under 21 U.S.C. § 355 or licensed under 42 U.S.C. § 262, to submit to Congress a report regarding such drug that includes VA's determination whether to include the drug in VA's formulary and VA's justification for that determination.

**Position: VA does not support.** VA does not support this bill because it is unnecessary. VA already has processes in place where formulary decisions regarding inclusion or exclusion of a drug are released publicly. In this context, the bill would include additional administrative burden without any increase in transparency or



accountability. VA publicly lists changes to the formulary (see <https://www.va.gov/formularyadvisor/>), and any of the documents that VA reviewed and influenced VA's decision are publicly available (see <https://www.pbm.va.gov/PBM/NationalFormulary.asp>). We are also concerned about the precedent this could set; further reporting would only delay actions that would improve Veterans' access to new drugs and treatments. VA makes decisions regarding which drugs to include in the formulary in consideration of the best clinical outcomes of Veterans; if the FDA approves any psychedelic drugs, VA will review these drugs using the same process as any other drug or medication. If or when FDA approves any psychedelic medications, we anticipate such drugs would be prescribed in combination with evidence-based psychotherapy or other psychosocial support as directed in the FDA approval. In this context, the existence of a drug on VA's formulary would not necessarily guarantee Veterans access to these drugs, in VA or in non-VA facilities, if the related therapy or psychosocial support is not available at a given facility.

These concerns are hypothetical at this point, though, as no psychedelic drugs have been approved by FDA yet. VA is developing plans to respond in the event such drugs are approved. All drugs that are approved by the FDA are available to Veterans with clinical need, regardless of whether the drug is available on the formulary.

VA has supported and is supporting three main efforts to ensure that Veterans will have access to safe and effective treatments, including psychedelics, when approved. VA co-hosted a State-of-the-Art Conference in September 2023 to address two major objectives: first, to better understand the current state of scientific evidence and to identify a strategic framework to consider future psychedelic treatment research for select mental health conditions; and second, to determine the necessary next steps for potential VA system-wide clinical implementation for psychedelic compounds for potential future use. Additionally, VA issued a request for applications for proposals from its network of VA researchers (in collaboration with academic institutions) to study the use of certain psychedelic compounds in treating PTSD and depression. Finally, VA is establishing a workgroup to develop plans for potential future clinical deployment, provider training, evaluation, and further research. We would be pleased to brief the Committee in more detail on these efforts. Additionally, we request that the Subcommittee solicit HHS for its views on this bill.

## **Conclusion**

This concludes my statement. We appreciate the Subcommittee's continued support of programs that serve the Nation's Veterans and look forward to working together to further enhance the delivery of benefits and services to Veterans and their families.