OFFICE OF THE UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, D.C. 20301-4000

PERSONNEL AND READINESS

The Honorable Adam Smith
Chairman
Committee on Armed Services
U.S. House of Representatives
Washington, DC 20515

MAY 24 2019

Dear Mr. Chairman:

This report is in response to House Report 115–676, pages 132–133, accompanying H.R. 5515, the National Defense Authorization Act for Fiscal Year 2019, that requests that the Department of Defense submit a report describing a plan for the Military Health System (MHS) to provide mental health care services as part of the transition of military treatment facilities.

The enclosed report includes the following: (1) mental health care provider structure; (2) policy and process management to deliver services; (3) ability to maintain readiness of the military health workforce; (4) innovation and delivery of treatments for Traumatic Brain Injury (TBI), Chronic Traumatic Encephalopathy (CTE), and Post-Traumatic Stress Disorder (PTSD), including public-private investment partnerships to pursue treatments; (5) inclusion of evidence-based suicide prevention programs; (6) acquisition strategies for delivery of TBI, CTE, and PTSD therapies; and (7) plans to field Food and Drug Administration-cleared pharmaceuticals and medical devices.

The Defense Health Agency's (DHA) integrated mental health care model, portfolio of collaborative research initiatives, and streamlined approach to acquisition management will enable a standardized system of continuous improvement, innovation, and high-quality mental health care for members of the Armed Forces and covered beneficiaries. The MHS organizational transformation to manage the delivery of mental health care within the DHA will provide enterprise-wide reliability at the point of care, and improve patient outcomes to members of the Armed Forces and other covered beneficiaries.

Thank you for your interest in the health and well-being of our Service members, veterans, and their families. A similar letter is being sent to the Senate Committee on Armed Services.

Sincerely,

James N. Stewart
Assistant Secretary of Defense for Manpower and Reserve Affairs, Performing the Duties of the Under Secretary of Defense for Personnel and Readiness

Enclosure:
As stated

cc:
The Honorable William M. "Mac" Thornberry
Ranking Member

OFFICE OF THE UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, D.C. 20301-4000

PERSONNEL AND READINESS

MAY 24 2019

The Honorable James M. Inhofe
Chairman
Committee on Armed Services
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

This report is in response to House Report 115–676, pages 132–133, accompanying H.R. 5515, the National Defense Authorization Act for Fiscal Year 2019, that requests the Department of Defense submit a report describing a plan for the Military Health System (MHS) to provide mental health care services as part of the transition of military treatment facilities.

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Thank you for your interest in the health and well-being of our Service members, veterans, and their families. A similar letter is being sent to the House Committee on Armed Services.

Sincerely,

James N. Stewart
Assistant Secretary of Defense for Manpower and Reserve Affairs, Performing the Duties of the Under Secretary of Defense for Personnel and Readiness

Enclosure:
As stated

cc:
The Honorable Jack Reed
Ranking Member

REPORT TO CONGRESSIONAL ARMED SERVICES COMMITTEES

House Report 115-676, Pages 132-133 to Accompany H.R. 5515, the National Defense Authorization Act for Fiscal Year 2019

Mental Health Care in the Military Health System

May 2019

The estimated cost of report or study for the Department of Defense (DoD) is approximately $6,100 for the 2019 Fiscal Year. This includes $6,100 in expenses and is DoD labor. Generated on January 30 RefID: A-64066AE

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EXECUTIVE SUMMARY

This report is in response to House Report 115–676, pages 132–133, accompanying H.R. 5515, the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2019, that requests the Secretary of Defense to submit a report on "Mental Health Care in the Military Health System" to the Armed Services Committees of the Senate and House of Representatives. Specifically, the report describes a plan for the Military Health System (MHS) to provide mental health care services as part of the transition of the military treatment facilities (MTFs).

The Department of Defense (DoD) MHS is engaging in an organizational transformation to manage health care within the Defense Health Agency (DHA), including the delivery of mental health care and traumatic brain injury (TBI) services to members of the Armed Forces and covered beneficiaries. Importantly, the MHS primarily manages TBI in standalone clinics, not within Behavioral Health (BH) programs. Per recommendations in section 702 of the NDAA for FY 2017 (Public Law 114–328), the DHA is currently collecting data from initial implementation sites to establish a resourcing baseline for operational readiness and healthcare delivery. Data collected will inform DHA's approach to an integrated system of care, which will be modeled after the Army's Behavioral Health System of Care (BHSOC) and the Army and Navy's concussion care clinics. Detailed recommendations for health care staffing, structure, and processes will be provided at the conclusion of Phase I (October 1, 2018 – September 30, 2019) of the transition plan to implement section 702.

In the new integrated system of care, the DHA will organize and execute health care delivery policies and issuances, while the Military Departments (MILDEPs) will continue to develop operational medicine Instructions, Directives, and Memoranda for the deployment environment. Standardized procedures for implementation of policies throughout the MHS will follow DHA publications, which will identify metrics of effectiveness, implementation, and outcomes to determine compliance and success of the document and processes identified.

The MHS leads and supports a robust portfolio of cross-sector research initiatives to accelerate the innovation and delivery of treatments for TBI, Chronic Traumatic Encephalopathy (CTE), and Post-Traumatic Stress Disorder (PTSD). Currently, the Behavioral Health Clinical Community (BHCC) maintains a focus on PTSD, the Neuro-Musculoskeletal Clinical Community addresses TBI, and there is ongoing work to better define the etiology, risk factors, and treatment considerations for CTE. In 2018-19, the DoD modernized acute concussion care by translating emerging science into real benefit for the service member. This effort includes the recent release of the Military Acute Concussion Evaluation (MACE), version 2, and other new clinical tools. This is part of an effort to improve assessment and treatment by identifying signs and symptoms that may be misattributed to mental health conditions.

The MHS facilitates public-private partnerships by convening clinician-scientists and biotechnology industry leaders in multi-year studies to pursue treatments. In partnership with the Department of Veterans Affairs (VA), MHS embeds evidence-based suicide prevention interventions in the delivery of mental health care services. Execution is buttressed by policy, guidelines, and dissemination of effective interventions that focus on a single outcome—preventing suicide deaths in patients receiving treatment. Population-based suicide prevention initiatives are under the cognizance of respective suicide prevention offices.

Facilitating development and delivery of TBI, CTE, or PTSD therapies requires management and execution of research, development, acquisitions, and medical logistics, which is managed by the DHA and executed by the U.S. Army Medical Research and Materiel Command (USAMRMC). USAMRMC promotes acquisition strategies that utilize Other Transaction Authorities (OTAs) and tailors its acquisition lifecycle to field Food and Drug Administration (FDA)-cleared pharmaceuticals and medical devices, which provide clinicians with therapeutics and tools for rapid, accurate assessments of TBI and PTSD.

Overall, the DHA's integrated mental health care model enables MHS-wide improvements, provides reliability at the point of care, and improves patient outcomes. Service-specific intermediate commands will be in place during the transition of all MTF-associated health care delivery functions to the DHA. Joint VA/DoD Clinical Practice Guidelines (CPGs) for mental health care facilitate delivery of evidence-based mental health care practices strengthening the ability to maintain mental health readiness. Furthermore, the DoD portfolio of collaborative research initiatives, and streamlined approach to acquisition management, enable a standardized system of continuous improvement, innovation, and quality care for members of the Armed Forces and covered beneficiaries.

INTRODUCTION

This report describes the plan for the MHS to provide mental health care services as part of the transition of the MTFs. Importantly, the MHS manages mental health and TBI through distinct processes and clinics. Therefore this report spans efforts in both of those areas. Specific topics include the following: mental health care provider structure; management of policy and processes to deliver services; ability to maintain readiness of the military health workforce; innovation and delivery of treatments for TBI, CTE, and PTSD, including public-private investment partnerships to pursue treatments; inclusion of evidence-based suicide prevention treatments; acquisition strategies for delivery of TBI, CTE, and PTSD therapies; and plans to field FDA-cleared pharmaceuticals and medical devices.

MENTAL HEALTH CARE PROVIDER STRUCTURE, POLICY AND PROCESSES TO DELIVER SERVICES, AND MAINTAIN READINESS

The DoD MHS, which comprises the Office of the Assistant Secretary of Defense for Health Affairs (OASD(HA)), DHA, and MILDEPs, is engaging in an organizational transformation to manage health care within the DHA, which includes the delivery of mental health care services to members of the Armed Forces and covered beneficiaries. This report aligns with the Report to Armed Services Committees, Section 712 of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (Public Law 114-232), "Organizational Framework of the Military Health System to Support the Medical Requirements of the Combatant Commands," April 2019. During this transition, the DHA, in coordination with the MILDEPs, will manage the arrangement of mental health assets while maintaining readiness of the military health workforce to deliver mental health care services operationally in support of deployed forces. Additionally,

during the transition, DHA will continue to monitor access to care, delivery of evidence based care, and patient outcomes throughout the mental health clinics in the MTFs. DHA will make staffing and administrative adjustments to address any areas of concern identified during the Phase I transition period.

Detailed recommendations for health care staffing, structure, and processes will be provided at the conclusion of Phase I (October 1, 2018 – September 30, 2019) of transition plan for section 702 of the NDAA for FY 2017 (Public Law 114–328). Recommendations concerning, "Reform of Administration of the Defense Health Agency and Military Medical Treatment Facilities," require establishing a clear resource baseline for operational readiness and healthcare delivery.

Data collected will inform DHA's approach to an integrated system of care, which will be modeled after the Army's BHSOC. Similar to the Army, DHA faces challenges in consolidating and standardizing programs around the supported population. From 2007 to 2012, Army outpatient BH services more than doubled to meet the surging care needs from the wars in Iraq and Afghanistan. This rapid growth introduced variance in the delivery, effectiveness, cost, and quality of behavioral healthcare. In 2012, the Army redesigned the system to address variation, reduce redundancies, and address key cost and performance drivers. Consequently, the Army distilled over 200 BH programs to the current 11 standardized Army BH programs. The realized gain of efficiencies by the Army BHSOC was recognized by Harvard Business Review in October 2017.

DHA's utilization of the BHSOC value-based systemic model of care throughout the transition, provides an ability to improve healthcare delivery through patient-reported and provider-productivity data. This enables leaders to better plan capacity, review progress toward system goals, and align day-to-day care with strategy. The following BHSOC principles may have broad application during the MTF transition to the DHA:

- Standardized care: Consolidated and standardized programs organized around the supported population
- Performance standards: Established provider-performance standards that reflect both clinical and nonclinical work
- Accounting codes: Decreased the number of Military Expense Performance Reporting System codes, better standardizing outpatient coding across the enterprise

An equitable value-based approach in the transition process, will enable DHA to provide recommendations for mental health care provider staffing. For example, standardizing coding systems around clinic composition, as opposed to provider types, will more accurately inform staffing needs for given patient throughputs, providing insight on patient care through patient-reported outcome data. The delivery of mental health care services and optimization of staffing ratios will be further augmented by the ability to track treatment dosage in accordance with Defense Health Agency-Procedural Instruction (DHA-PI) 6490.01, ensuring all patients with depression or PTSD receive a minimum number of sessions consistent with evidence-based treatment (EBT) strategies for these disorders.

In addition to standardizing clinic structure, DHA implemented the BHCC model 1 year ago. BHCC includes a network of BH clinicians that collaborate on clinical process improvement

projects, as well as standardization efforts to improve patient outcomes. This network enables MHS-wide improvements, provides reliability at the point of care, and promotes accountability to standardization and patient outcome improvement. Table 1 provides a summary of 2018 BHCC initiatives.

Table 1. 2018 BHCC Initiatives.

	2018 BHCC Initiatives
1	Creating and disseminating the Behavioral Health Treatment and Outcomes Monitoring DHA-PI, which sets standards for data collection and analysis in specialty and primary direct care clinics • Requires that DHA analyze: o Behavioral Health Data Portal (BHDP) implementation and utilization across clinics o Use of EBTs across clinics o Patient outcomes and their relationship to EBTs o Other patient/provider/clinic factors
2	Increasing BHDP utilization and implementation • Allows monitoring of patient outcomes and delivery of standard of care (i.e., EBTs) as outlined in DHA-PI 6490.01
3	Leveraging the Post-Traumatic Stress (PTS) Provider Prescribing Profile • Enables the review and monitoring of prescribing practices at MTFs of pharmaceutical agents for treatment of PTS, allowing assessment for prescribers deviating from the DoD/VA CPGs on PTSD, providing an opportunity to address deviations from the CPG in prescribing practices of pharmaceutical agents in the management of PTS

The DHA's newly integrated systems of care will rely on the existing BH clinical infrastructure for the organization and execution of mental health care policies and processes. The DHA will develop and execute health care delivery instructions, while the MILDEPs will continue to develop operational medicine Instructions, Directives, and Memoranda for the deployed environment. Standardized procedures for implementation of policies throughout the MHS will follow DHA publications (e.g., Procedural Instructions, Procedural Manuals, Technical Manuals, Interim Procedures Memoranda (IPM), and Multi-Service Regulations). DHA publications will identify metrics of effectiveness, implementation, and outcomes to determine compliance and success of the policies, procedures and processes implemented. Table 2 provides an overview of each governing body's role and scope in policy development and management.

Table 2. Policy and Process Overview.

Governing Body	Role in Policy	Scope of Policy
OASD(HA)	Develop Department of Defense Instructions (DoDIs) that align to DoD objectives	Matters related to both MILDEP and DHA equities
DHA	Create DHA-PIs and DHA-PMs to execute DoDI objectives and goals	Management and policy implementation matters related to health care delivery within MTFs
MILDEPs	Develop Service-specific instructions to execute and operationalize policies and procedures	Unique to Service-specific operational readiness matters
Military Medical Departments		Matters related to operational medicine in the deployed environment and Service-managed installation functions separate from health delivery and MTF operations

IPM 18-001, "Standard Appointing Processes, Procedures, Hours of Operation, Productivity, Performance Measures and Appointment Types in Primary, Specialty, and Behavioral Health Care in Medical Treatment Facilities (MTFs)," outlines standard of care and access, establishing DHA procedures to describe standard appointing processes, procedures, and appointment types in primary, specialty, and behavioral healthcare in MTFs. In short, the revision of the IPM will be incorporated into a DHA-PI that intends to standardize targets consistent with the BHSOC, as the described model for DHA, delivers care. The standardization of processes and procedures in all MTFs via the IPM aims to improve medical readiness, reduce unwarranted variation, enhance the patient experience, increase access to care, minimize fragmentation, and support the principles of a highly reliable organization.

DHA-PI 6490.01, "Behavioral Health Treatment and Outcome Monitoring," released in July 2018, provides an example of DHA procedures to implement policy regarding BHDP operations and data collection. Specifically, the PI provides guidance for:

- Addressing the standardization of BH outcome data
- Designating the Army as the DoD lead Service for maintenance and sustainment of the BHDP
- Designating DHA Information Operations (J-6) as lead on transitioning BHDP functional requirements related to outcomes monitoring to future electronic health records data collection platforms and processes
- Addressing standardization of collection data and relationship of treatment protocols and outcomes
- Identifying barriers to provider implementation of evidence-based clinical guidance approved by DoD

Service-specific intermediate commands will be in place during the transition of all MTF-associated health care delivery functions to the DHA. Each Military Medical Department infrastructure that is currently in place during the transition enables the respective Surgeons General (SGs) to maximize readiness:

- The proposed Army Medical Readiness Command HQ Organizational Structure will enable the Army to project and communicate readiness requirements derived from training and operational plans directly to DHA. The Army SG and staff will coordinate operational requirements with DHA and advise the Director, DHA on matters pertaining to military health readiness requirements and safety of members of the Army.
- The Air Force (AF) SG will oversee the AF Medical Operations and Research Directorate, which will be the primary staff office for defining and executing operational medicine and readiness. This Directorate will communicate operational capability, requirements, and the utilization of AF Medical Service personnel to the Office of the Surgeon General to outline readiness requirements and facilitate readiness decisions.
- In conjunction with the transfer of administration and management of MTFs to the DHA, Navy Medicine (NAVMED) developed the Navy Medicine Readiness and Training Command (NMRTC) structure. The NMRTC is an integrated system of health that supports the fleet and Fleet Marine Force. The specific responsibilities of NMRTC include maintaining the readiness of assigned medical forces, supporting instillation and

operational commanders' requirements, and providing a Navy command structure essential for proper execution of Service-specific requirements. The commands will be established across the NAVMED enterprise, and initially be co-located with MTFs, as the structure to preserve Navy equities and focus on readiness and operational support.

The joint VA/DoD CPGs for mental health care strengthens DoD's ability to assess and maintain the readiness of the military health workforce in the delivery of mental health care services. Furthermore, several mental health activities and programs are in place to improve mental health care for Service members and beneficiaries. Objectives in CPGs for Patients at Risk for Suicide, Major Depressive Disorder (MDD), PTSD, and Substance Use Disorder (SUD) are detailed in Table 3 Examples of mental health programs and activities available at MTFs (Contiguous United States (CONUS)/Outside Contiguous United States (OCONUS)), inpatient and outpatient services available for direct care (CONUS/OCONUS) and purchased care (CONUS/OCONUS) are shown in Table 4.

Table 3. VA/DoD CPGs.

CPG	Description
Patients at Risk for Suicide	• Aims to reduce current unwarranted practice variation and provide facilities with a structured framework to help improve patient outcomes (prevent suicide and other forms of suicidal self-directed violent behavior) • Provides evidence-based recommendations to assist providers and their patients in the decision-making process • Identifies outcome measures to support the development of practice-based evidence that can ultimately be used to improve clinical guidelines
MDD	• Assess the patient's condition and determine the best treatment method • Optimize the use of therapy to improve symptoms and functioning, treatment of the condition's acute phase, prevent relapse, and improve both health and quality of life outcomes • Minimize preventable complications and morbidity • Emphasize the use of patient-centered care
PTSD	• Enhance assessment of the patient's condition and determine the best treatment method in collaboration with the patient and, when possible and desired, the patient's family and caregivers • Optimize the patient's health outcomes and improve quality of life • Minimize preventable complications and morbidity • Emphasize the use of patient-centered care
SUD	• Assess the patient's condition and determine in collaboration with the patient the best treatment method • Optimize each individual's recovery to decrease or eliminate consumption, improve health and wellness, live a self-directed life, and strive to reach his or her full potential • Minimize preventable complications and morbidity • Emphasize the use of patient-centered care

Table 4. Select Mental Health Care Programs and Activities.

Program/Activity	Description
TRICARE	• Provides civilian health benefits for U.S Armed Forces military personnel, military retirees, and their dependents, including some members of the Reserve Component • Provides psychological health care coverage for the spectrum of mental health issues, from those that are mild and transient to those that constitute severe mental illness • Includes both inpatient and outpatient care, providing access to full array of high-quality health care services while maintaining the capability to support military operations through Direct Care facilities and Purchased Care networks
Direct Care System Mental Health Services	In response to limitation in coverage for EBTs for mental health and SUDs, a Final Rule, "TRICARE: Mental Health and Substance Use Disorder Treatment," was published in the Federal Register on September 2, 2016: • Expands the SUD benefit to various treatments covered by civilian-sector health care programs • Expands TRICARE coverage for SUD treatment to include intensive outpatient programs, partial hospitalization programs, and opioid treatment programs, including office-based opioid treatment, in addition to SUD rehabilitation facilities, without imposing copayments, benefit limitations, and other restrictions that are more stringent than those imposed on medical and surgical benefits • Expands coverage for inpatient mental health services, psychiatric residential treatment centers, and case management services for child and adolescent beneficiaries who have mental disorders that meet both diagnostic criteria of the current edition of the Diagnostic and Statistical Manual of Mental Disorders and TRICARE
Telehealth	• Incorporated throughout the direct care and purchased care components of the MHS, including mobile health applications • Used for pre- and post-deployment health and mental health assessments (MHAs), Temporary Disability Retirement List exams, Medical Evaluation Board Narrative Summaries, and Administrative Separation packets • Includes monitoring health outcomes for chronic disease, particularly comorbidities of mental health conditions like depression, anxiety, and addiction with chronic physical health conditions
inTransition	• Provides a voluntary and confidential telephonic coaching program that provides continuity of care (i.e., "warm hand-off") within and between DoD and VA health care systems as Service members and Veterans with psychological health needs transition between duty stations and from active duty service to civilian life • Offers specialized coaching and assistance to support Service members in behavioral healthcare who are relocating to another assignment, returning from deployment, transitioning from active duty to reserve, reserve to active duty, or preparing to leave military service and directs the Military Services to utilize the program unless a program is already in place to address gaps in transitional behavioral health care • Enrolls separating Service members automatically into the program if they received care for mental health within 1 year prior to their separation (Service members may decline participation at any time).
Service Member Justice Outreach Programs	• Provides specialized mental health support and services to Service members facing possible adverse discharges due to disciplinary action • Works closely with commands, medical and mental health, legal, chaplains, and other stakeholders to identify and assist a segment of the separating population who may be at higher risk for suicide and other mental health issues that are often corollaries of legal and disciplinary action • Enrolled 378 Service members across three participating pilot sites, from 2014 – 2016, receiving highly positive feedback

SUD Programs	• Includes programs that are non-clinical, readiness components operated by the line • Includes clinical treatment and recovery programs overseen by the Services' medical commands • Includes Service-specific manifestations such as Army Substance Abuse Program, Navy's Substance Abuse and Rehabilitation Program, AF's Alcohol and Drug Abuse Prevention and Treatment Program, and Marine Corps' Substance Abuse Prevention Program, in addition to various residential treatment facilities and intensive outpatient programs for addiction treatment
Combat Operations Stress Control Programs	• Includes requirements for activities that support psychological health in military operations and the early detection and management of combat and operational stress reactions to preserve mission effectiveness and warfighting capabilities and mitigate the adverse physical and psychological consequences of exposure to severe stress
Suicide Prevention Programs	• Administered by each MILDEP • Includes aspects of prevention within basic unit training • Includes a dedicated program office responsible for the application of a comprehensive public health approach to suicide prevention across DoD • Utilizes clinical measures that monitor suicide risk for Service members accessing mental health care in the direct care system
MHS Patient-Centered Medical Homes	• Involves team-based model, led by a physician, which provides continuous, accessible, family-centered, comprehensive, compassionate and culturally-sensitive health care to achieve best outcomes
Comprehensive Pain Management Programs	• Administered by each MILDEP • Includes Interdisciplinary Pain Management Centers to facilitate improved pain care throughout the continuum of care • Provide therapies such as BH treatments, relaxation training, physical and occupational therapies, and pharmacological management by clinical pharmacists • Includes specialists to provide services to Active Duty Service Members, such as acupuncturists, addiction specialists, clinical pharmacists, physical therapists, clinical psychologists

PARTNERSHIPS TO ACCELERATE INNOVATION AND DELIVERY OF TREATMENTS FOR TBI, CTE, PTSD, AND OTHER PSYCHIATRIC DISORDERS

To accelerate the innovation and delivery of treatments for TBI, CTE, or PTSD to members of the Armed Forces and covered beneficiaries, the MHS leads and supports a robust portfolio of cross-sector research initiatives and data-sharing consortiums. The DoD MHS manages TBI and mental health through separate mechanisms and facilitates public-private partnerships by convening clinician-scientists, industry leaders in biotechnology and imaging technology, and patient advocacy organizations in multi-year studies to pursue psychiatric and brain disease treatments.

The MHS collaborates with the VA, Department of Health and Human Services, and Department of Education in an interagency activity to accelerate the delivery of preventive interventions and treatments for TBI, PTSD, and other co-occurring mental health conditions called the National Research Action Plan (NRAP). For example, from 2013-2017, NRAP agencies collectively invested over $600M in research related to TBI treatments; including, pharmacological and

nonpharmacological interventions, methods for guiding personalized treatments, neuromodulation and neural plasticity approaches, biomarkers to detect the effectiveness of specific interventions, and therapies to improve outcomes and quality of life following TBI.

Investments and collaborations related to TBI treatments span the research continuum: MHS is the primary funder for prevention and screening and epidemiology; both the National Institutes of Health (NIH) and MHS for foundational science and treatment; the National Institute on Disability, Independent Living, and Rehabilitation Research for follow-up care; and the VA for chronic TBI. The MHS funds research and development (R&D) efforts that span all technology readiness levels (TRLs), from basic research through fielding and operations. Notably, the focus of R&D investments is associated with TRL 3, "Proof-of-Concept Demonstrated, Analytically and/or Experimentally" and TRL 6, "System Adequacy Validated in Simulated Environment."

In support of NRAP objectives, the MHS jointly funds large-scale studies and public-private research consortia to accelerate the innovation and delivery of treatments for TBI, PTSD, CTE, suicide prevention, and other conditions. Studies include the assessment of Service members risk, resilience, recovery, and long-term health outcomes through longitudinal follow-up research. Furthermore, the Joint Program Committee-5/Military Operational Medicine Research Program (JPC-5/MOMRP) is a DoD-funded program, which supports BH research in all areas of the continuum, and collaborates with DoD and MHS leadership to identify and address gaps in capabilities identified by each Military Department. Table 5 provides examples of MHS collaborations to accelerate the innovation and delivery of treatments across government, academia, and private industry.

Table 5. MHS Partnerships and Initiatives to Accelerate Innovation and Delivery of Treatments for TBI, PTSD, CTE, and Other Psychiatric Disorders.

MHS-Led	Condition	Initiative	Description
✓	TBI	Federal Interagency Traumatic Brain Injury Informatics System	A centralized informatics system, funded by MHS and NIH, developed to accelerate comparative effectiveness research in support of improved diagnosis and treatment for TBI. Experimental data is available for post-hoc on 103 studies and includes over 3.77 million records from 70,926 subjects (as of February 2019).
✓	TBI	TBI Endpoints Development (TED)	An initiative with over 20 universities and hospitals to: • Advance the identification and validation of clinical outcome assessments (COAs) and biomarkers for use as potential FDA-qualified drug development tools, • Initiate development of Clinical Data Interchange Standards Consortium data standards for clinical trials involving diagnosis and treatment of mild to moderate TBI and, • Validate candidate COAs and biomarkers.
✓	TBI	TBI Disease Progression and Risk Factors Studies	A collaboration among the MHS and VA to fund sub-studies related to TBI, which includes studies such as a tau modification study to develop an animal model of repetitive mild Traumatic Brain Injury (mTBI) for tracking disease progression, and an epidemiological study of the chronic effects of mTBI that may include risk factors for neurodegenerative diseases.

	TBI	Targeted Evaluation, Action, and Monitoring of TBI	A collaboration among the MHS, National Intrepid Center of Excellence, Naval Medical Center San Diego, and the University of Pittsburgh to conduct a monitored, multiple interventional trial designed to address the heterogeneity of TBI and identify EBT protocols.
	TBI	Transforming Research and Clinical Knowledge in TBI (TRACK-TBI)	Funded by the MHS and NIH to: • Determine and validate new diagnostic brain imaging modalities • Establish clinically-relevant TBI biomarkers • Refine TBI outcome assessments to improve clinical trial design. To date, over 3,000 patients have been enrolled in this study. TED and TRACK-TBI share data and findings.
✓	PTSD	CPG for the Management of PTSD and Acute Stress Disorder	The MHS and VA published a joint CPG for the Management of PTSD and Acute Stress Disorder (3rd Edition) in June 2017.
✓	PTSD	Cognitive Processing Therapy (CPT) Pilot	A collaboration between the MHS and VA to pilot a new model of CPT care delivery, one of six EBTs recommended in the CPG for the Management of PTSD and Acute Stress Disorder. Pilot outcomes will inform next steps for enterprise-wide adoption.
	PTSD	PTSD Brain Bank	The MHS and VA developed a PTSD Brain Bank, which includes brains from PTSD and MDD patients and healthy control subjects and currently includes specimens from over 200 individuals. Researchers can access the bank through a publicly available research application and review process. Recent discussions include the possibility of recruitment from well-defined longitudinal data sets (e.g., Army Study to Assess Risk and Resiliency in Servicemembers (STARRS), Brain Health Registry, Vietnam-Era Twin Registry).
	PTSD	Consortium to Alleviate PTSD	Funded by the MHS and VA (closing in 2020) as a research collaboration on the efficacy of novel pharmacological, mechanical, and psychotherapy treatments; treatment responsiveness for individualized treatment matching/personalized medicine approaches; effective treatment of comorbid disorders; and potential PTSD biomarkers for diagnostics, theranostics (i.e., combining specific targeted therapy based on specific targeted diagnostic test), and prognostics.
	PTSD	Psychiatric Genomics Consortium (PGC)	The MHS participates in the National Institute of Mental Health-sponsored PGC for PTSD.
	PTSD	PTSD Drug Testing	Supported through USAMRMC Neurotrauma and Psychological Health Project Management Office (NPH PMO) PTSD Drug Treatment research award to non-profit Cohen Veterans Bioscience • Uses an innovative Phase 2 Master Protocol with adaptive elements that accelerate the delivery of treatments by utilizing common infrastructure to gather harmonized datasets across multiple treatment arms, decreasing trial start up timelines.
✓	CTE	CTE Neuroimaging Study	Funded in collaboration with the VA to enable neuroimaging for CTE in living patients (sub-study).

✓	Suicide Prevention	DoD Military Suicide Research Consortium (MSRC)	Co-led by investigators at the VA Rocky Mountain Mental Illness Research Education Clinical Center for Suicide Prevention (Veterans Integrated Service Network 19), focusing on conducting research to deliver evidence-based tools and interventions for suicide prevention that are effective for the military population.
✓	Long-Term Health Outcomes	Naval Health Research Center Millennium Cohort Study	A collaboration between the MHS and VA for a prospective epidemiological research study focused on evaluating the impact of military exposures, including deployment, on the long-term health outcomes of 202,000 Active Duty participants.

Furthermore, in 2018-19, the DoD modernized acute concussion care by translating emerging science into real benefit for the service member. This effort includes the recent release of the MACE, version 2, and other new clinical tools. The MACE 2 represents the current state-of-the-science by outlining a multi modal assessment for those suspected of sustaining a concussion. The Department now employs multimodal evaluation of all domains potentially impacted by concussion, to include vestibular (balance) and oculomotor (eye movements) to increase diagnostic certainty. Multimodal assessments generate "symptom clusters" also termed "concussion profiles," in an effort to predict and accelerate outcomes. This effort is combined with the development of the Pathway of Care to shift TBI evaluation from specialist-centric care models to an enhanced evaluation by first line providers (unit, primary care clinics, and emergency departments). Additionally, the DoD is incorporating new technologies and translating knowledge from the DoD research portfolio into the hands of Soldiers in rapid fashion (including the first ever FDA cleared blood biomarkers for TBI). Table 6 illustrates other key TBI advances that occurred in the DoD.

Table 6. Key TBI advances.

Effort	Description
Blood Biomarkers	• In 2018, the FDA approved the first ever blood-based biomarker for TBI developed by the DoD in partnership with Bayan.
BrainScope	• Devices were deployed in combat with 1st Security Force Assistance Brigade (1SFAB) in 2018; 2 Purple Hearts awarded for concussions within 1SFAB resulting from exposure to "pure blast" as assessed on the BrainScope One.
Closed Head Injury	• Two FDA cleared devices (BrainScope and Infrascanner) are available to aid in triaging closed head injury. The devices are part of an ongoing rapid equipping of the force in Central Command (50 devices at all roles of care). Army Medicine purchased 132 devices for use throughout the Army (February 2018).
Tranexamic Acid (TXA)	• Army researchers demonstrated that TXA, a medication used to control hemorrhage in combat, is the first therapeutic intervention with evidence to benefit morbidity and mortality in acute TBI in the polytrauma patient.
Multimodal Assessment	• Army deployment of multimodal evaluation tools capable of assessing five new domains impacted by concussion to increase diagnostic sensitivity and specificity. • Multimodal assessment generates "symptom clusters," in an effort to predict and accelerate recovery trajectories.
NCAA-DoD Grand Alliance	• Demonstrated 4 factors that contribute to sustaining a concussion: 1) significant hit, 2) history of three or more concussions, 3&4) cumulative sub-clinical hits in the 3-4 hours and 4-5 days prior to a concussion.
Neuromusculoskeletal	• Research demonstrated a 45 percent increase in in lower extremity musculoskeletal injury for up to 18 months after concussion

Prevention	• Service members wearing hearing protection with non-impact blast-induced concussion had significantly lower odds of concussion compared with those not wearing hearing protection
Imaging Biomarker	• TBI Endpoints, a DoD funded TBI study, achieved a scientific milestone March 2019 when the FDA cleared an imaging biomarker software that delivers a standardized way to classify brain contusions. This software provides an imaging biomarker that enables rapid classification to more rapidly identify eligible patients for enrollment in clinical trials.

CTE is a unique distribution of tau protein aggregation in the brains of patients that have sustained repeated head trauma, including sub-concussive events, and corresponds with a wide range and neurological and behavioral symptomatology. There is ongoing work to better define the etiology, risk factors, and treatment considerations for CTE; however, there are no current therapies for CTE. A definitive CTE diagnosis is presently limited to post-mortem analysis, making it difficult to directly link this disease to a specific injury, underlying cause, or symptomatology. Consequently, multidisciplinary partnerships and collaborations are required to identify relationships between TBI to CTE, PTSD or suicide, as these breakthroughs cannot be completed with brain tissue alone.

INCLUSION OF EVIDENCE-BASED SUICIDE PREVENTION PROGRAMS

The MHS embeds evidence-based suicide prevention programs, which are supported by an interagency collaboration with the VA, in the delivery of mental health care services through a combination of policy, guidelines, and initiative implementation. Suicide prevention policies and programs within the MHS focus on preventing suicide deaths through the dissemination of effective interventions.

The MHS is engaged in several initiatives with the VA to advance suicide prevention infrastructure and training in support of Service members, veterans, and their families, particularly during the critical one-year period following separation from service. In November 2017, the DoD and VA signed a suicide prevention Memorandum of Agreement (MOA), which details actions to provide suicide prevention resources for transitioning Service members. The MOA addresses periods of transition, including: discharge, separation, or retirement; and outlines strategies for education, outreach, and strategic communications; lethal means reduction; engagement and capability building; call center efforts; research and program evaluation; data and surveillance.

Currently, the DoD and VA are collaborating to update the CPG for the Assessment and Management of Patients at Risk for Suicide, which will describe the decision points in the management of Suicidal Risk Behavior and provide evidence-based recommendations for practitioners throughout the MHS and VA health care systems. Currently, inTransition, a DoD BH coaching program for transitioning Service members, accommodates self-referral among veterans with any category of discharge. Additionally, MilitaryOneSource, a 24/7 counseling and coaching service, is available to veterans up to 365 days post-transition. Finally, available

24/7 365 days per year, the Veterans Crisis Line will connect Service members and veterans in crisis with qualified VA responders.

The DoD and VA are investing in efforts to create an integrated data environment and interagency platform to support a joint approach to predictive analytics by April 2019. In response to Executive Order (EO) 13822, the DoD, VA, and Department of Homeland Security (DHS) developed a Joint Action Plan (JAP) to ensure seamless access to a continuum of mental health care and suicide prevention resources for transitioning Service members. The MHS continues implementation of the JAP, as well as the Defense Strategy for Suicide Prevention (DSSP), and regularly evaluates progress against baseline metrics.

To standardize evidence-based interventions across the MHS, the DoD Military Suicide Intervention and Reporting Work Group conducted a systematic review of over 45 DoD-wide and Service-specific suicide-related policies and documents. The review serves as the preliminary step for drafting a DHA-PI for suicide intervention. The DHA-PI will align with recommendations provided in the DoD/VA Suicide CPG and codify evidence-based suicide interventions for implementation in all MTFs under DHA administration. In accordance with section 706 of the NDAA for FY 2018, the DHA also implemented MHAs for all separating Service members. Table 6 provides examples of DoD programs and activities targeting suicide prevention.

Table 7. MHS Suicide Prevention Programs and Activities.

Program/Activity	Description
DSSP	• Initiated implementation in 2015, with 13 goals and 60 objectives. DSSP is still in early phases of implementation as a medium- to long-term (7-9 year) strategy • Includes clinical aspects of the JAP for EO 13822, "Supporting our Veterans During their Transition from Uniformed Service to Civilian Life," released in January 2018
inTransition Program	• Enrolls Separating Service members automatically into the program if they present with a mental health diagnosis in the previous twelve months • Collaboration between the VA and DoD to promote self-referral to *inTransition* among Veterans with any category of discharge (an estimated 505,000 individuals with other-than-honorable, or "bad paper," discharges are now eligible for VA healthcare)
Building Healthy Military Communities Pilot	• Initiated in 2017 as a multi-year program to improve health and resiliency among geographically dispersed Service • members through collaboration with states
Separation MHA	• Standardizing practices in support of separation MHAs for all separating Service members in accordance with section 706 of the NDAA for FY 2018
VA/DoD CPG for Assessment and Management of Patients at Risk for Suicide	• Currently being updated; provides clinical practice guidlines based on the best available evidence of effectiveness of clinical and non-clinical prevention and intervention practices
DHA-PI for Suicide Intervention	• Drafting based on a systematic review of 45+ DoD-wide and Service-specific suicide-related policies and documents • Aligning to recommendations in the VA/DoD CPG for Assessment and Management of Patients at Risk for Suicide (Suicide CPG)
DoD Suicide Event Surveillance	• Issued annual report providing empirical in-depth analysis of demographics and risk factors associated with deaths by suicide • Enables monitoring rates of suicide across the Active and Reserve Components of the military

Service-Specific Suicide Prevention Initiatives	• Includes Suicide Review Boards (e.g., AF Suicide Analysis Board), Resilience and Readiness programs (e.g., Navy Reserve Psychological Health Program), Outreach and Care Coordination programs (e.g., Marine Intercept Program and Sailor Assistance and Intercept for Life), and Embedded/Operational Behavioral Health Providers (e.g., Embedded Behavioral Health with Army operational units and Army Medical Homes)
Interagency Research Efforts Targeting Suicide	• Comprises NRAP, Army STARSS – Longitudinal Study, MSRC, and Military Operational Medicine Research Program (MOMRP)

ACQUISITION STRATEGIES FOR DEVELOPMENT AND DELIVERY OF TBI, CTE, AND PTSD THERAPIES

The DHA accelerates the development and delivery of promising breakthrough therapies through the promotion of acquisition strategies that utilize OTAs. Facilitating development and delivery of TBI, CTE, or PTSD therapies requires management and execution of research, development, acquisitions, and medical logistics, which is managed by the DHA and executed by USAMRMC.

To advance the development of treatments for TBI, CTE, PTSD, or other mental health disorders, USAMRMC established a prototype Other Transaction Agreement (pOTA) with the Medical Technology Enterprise Consortium, a 501(c)(3) with members from industry, academia, and the non-profit sector. USAMRMC's NPH PMO, as well as JPC-5/MOMRP and Joint Program Committee-6/Combat Casualty Care Research Program, regularly review TBI and PTSD diagnosis and treatment proposals submitted via the pOTA for programmatic alignment.

The pOTA mitigates challenges associated with time to initiate Phase 2 testing, enabling the NPH PMO's PTSD and TBI Drug Treatment Programs to accelerate the timeline by approximately seven months. Furthermore, assuming optimal performance and available funding, leveraging OTA mechanisms for adaptive platform trial infrastructure will allow each program to: (1) test a minimum of two drugs simultaneously in Phase 2; (2) test up to 24 drugs over the award timeframe; and (3) result in well-characterized drugs for Phase 3 testing. Overall, estimates suggest the advancement of viable candidate drugs for Phase 3 will reduce traditional testing time by approximately 18 years.

PLAN TO FIELD FDA-CLEARED PHARMACEUTICALS AND MEDICAL DEVICES

The acquisition lifecycle is tailored to field FDA-cleared pharmaceuticals and medical devices that meet regulatory requirements for safety and efficacy, providing clinicians with therapeutics and tools for rapid, accurate assessments of TBI and PTSD. Furthermore, USAMRMC medical logistics professionals support the development of acquisition programs to confirm prospective pharmaceuticals and devices meet training and sustainability requirements and achieve interoperability within the MHS network. When necessary, USAMRMC supports the Army's

Rapid Equipping Force, which enables deployed units to be equipped with FDA-approved devices while fielding requirements are under final review.

To accelerate innovations in emerging technologies for medical devices, USAMRMC hosts industry days to showcase the latest industry advances, releases Requests for Information on new capability development, and manages a new product idea submission page. In addition, OASD(HA), DHA, and Service representatives attend medical conferences to collaborate with scientists developing promising technology. The activities outlined above promote active identification of requirement solutions from military science and technology, R&D, academia, and industry for transition into acquisition programs.

CONCLUSION

The MHS is engaged in an organizational transformation to administer and manage health care through the DHA to deliver mental health care services to members of the Armed Forces and covered beneficiaries. The DHA approach to an integrated system of care throughout the transition and beyond, will be modeled after the Army's BHSOC. This will improve the healthcare delivery system through patient-reported and provider-productivity data. This approach will enable leadership to better plan capacity, review progress toward system goals, and align day-to-day care with overarching strategic goals.

To accelerate the innovation and delivery of treatments for TBI, CTE, or PTSD, the MHS leads and supports a robust portfolio of cross-sector research initiatives and data-sharing consortiums. In 2018-2019, the DoD modernized acute concussion care by translating emerging science into real benefit for the service member, which is part of an effort to improve assessment and treatment by identifying signs and symptoms that may be misattributed to mental health conditions. The MHS also embeds evidence-based suicide prevention programs in the delivery of mental health care services through a combination of policy, guidelines, and initiative implementation, supported by interagency collaboration with the VA.

The development and delivery of TBI, CTE, or PTSD therapies is accelerated through research, development, acquisition, and logistics managed by the DHA and executed by USAMRMC. Acquisition and fielding strategies continue to evolve and include the use of OTAs and investments in fielding FDA-cleared pharmaceuticals and medical devices, which provide clinicians with therapeutics and tools for rapid, accurate assessments of TBI and PTSD.

The DHA's integrated mental health care model, portfolio of collaborative research initiatives, and streamlined approach to acquisition management will enable a standardized system of continuous improvement, innovation, and high-quality mental health care for members of the Armed Forces and covered beneficiaries. The MHS organizational transformation to manage the delivery of mental health care within DHA, will provide enterprise- wide reliability at the point of care, and improve patient outcomes to members of the Armed Forces and other covered beneficiaries.

ACRONYMS

Acronym	Term
AF	Air Force
BH	Behavioral Health
BHCC	Behavioral Health Clinical Community
BHDP	Behavioral Health Data Portal
BHSOC	Behavioral Health System of Care
COA	Clinical Outcome Assessment
CONUS	Contiguous United States
CPG	Clinical Practice Guideline
CPT	Cognitive Processing Therapy
CTE	Chronic Traumatic Encephalopathy
DHA	Defense Health Agency
DHA-PI	Defense Health Agency-Procedural Instruction
DoD	Department of Defense
DoDI	Department of Defense Instruction
DSSP	Defense Strategy for Suicide Prevention
EBT	Evidence-Based Treatment
EO	Executive Order
FDA	Food and Drug Administration
FY	Fiscal Year
IPM	Interim Procedures Memorandum
JAP	Joint Action Plan

JPC-5/MOMRP	Joint Program Committee-5/Military Operational Medicine Research Program
MACE	Military Acute Concussion Evaluation
MDD	Major Depressive Disorder
MHA	Mental Health Assessment
MHS	Military Health System
MILDEP	Military Department
MOA	Memorandum of Agreement
MOMRP	Military Operational Medicine Research Program
MSRC	Military Suicide Research Consortium
mTBI	Mild Traumatic Brain Injury
MTF	Military Treatment Facility
NAVMED	Navy Medicine
NDAA	National Defense Authorization Act
NIH	National Institutes of Health
NMRTC	Navy Medicine Readiness and Training Command
NPH PMO	Neurotrauma and Psychological Health Project Management Office
NRAP	National Research Action Plan
OASD(HA)	Office of the Assistant Secretary of Defense for Health Affairs
OCONUS	Outside Contiguous United States
OTA	Other Transaction Authority
PGC	Psychiatric Genomics Consortium
pOTA	Prototype Other Transaction Agreement
PTS	Post-Traumatic Stress
PTSD	Post-Traumatic Stress Disorder

R&D	Research and Development
SG	Surgeon General
STARRS	Study to Assess Risk and Resiliency in Servicemembers
SUD	Substance Use Disorder
TBI	Traumatic Brain Injury
TED	TBI Endpoints Development
TRACK-TBI	Transforming Research and Clinical Knowledge in TBI
TRL	Technology Readiness Level
USAMRMC	U.S. Army Medical Research and Materiel Command
VA	Department of Veterans Affairs