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

PERSONNEL AND
READINESS

DEC 13 2021

The Honorable Jack Reed
Chairman
Committee on Armed Services
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

The Department's response to section 734 of the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021 (Public Law 116-283), "Registry of Certain TRICARE Beneficiaries Diagnosed with COVID-19," is enclosed.

On July 13, 2020, the Assistant Secretary of Defense for Health Affairs provided guidance for the Defense Health Agency (DHA) to establish the COVID-19 Registry. The Director, DHA, established the COVID-19 Registry at initial operating capability by expanding the Department of Defense Trauma Registry (DoDTR). As of May 2021, DHA has incorporated over 227,000 cases in the COVID-19 repository. Efforts are underway to migrate the COVID-19 Registry as a module within the DoDTR to a functional registry within the DHA Enterprise Intelligence and Data Solutions Military Health System Information Platform.

Thank you for your continued strong support for the health and well-being of our Service members, veterans, and families. I am sending a similar letter to the House Armed Services Committee.

Sincerely,

Gilbert R. Cisneros, Jr.

Enclosure:
As stated

cc:
The Honorable James M. Inhofe
Ranking Member

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

PERSONNEL AND
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DEC 13 2021

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

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Thank you for your continued strong support for the health and well-being of our Service members, veterans, and families. I am sending a similar letter to the Senate Armed Services Committee.

Sincerely,

Gilbert R. Cisneros, Jr.

Enclosure:
As stated

cc:
The Honorable Mike D. Rogers
Ranking Member

Report to the Congressional Armed Services Committees

Section 734 of the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021 (Public Law 116-283) Final Report on "Registry of Certain TRICARE Beneficiaries Diagnosed with COVID-19"

The estimated cost of this report or study for the Department of Defense is approximately $4,730.00 for Fiscal Year 2021. This includes $3,650.00 in expenses and $1,080.00 in DoD labor.

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Introduction

The Defense Health Agency's (DHA) Joint Trauma System (JTS) is the Department of Defense's (DoD) premier performance improvement organization credited with reducing mortality and morbidity in support of the global war on terrorism. As a performance improvement organization, the JTS utilizes a systematic approach in determining the acute and long-term outcomes of all casualties, the quality of care, improvements in prevention and treatment, and the logistical implications. The cornerstone by which the JTS does this is the Department of Defense Trauma Registry (DoDTR), the first and only DoD trauma patient registry to collect combat casualty care epidemiology, treatments, and outcomes from point of injury to recovery. The JTS transitioned from the Army's Medical Department to DHA as part of the establishment of a JTS within DHA mandated by section 707 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2017. As part of the transition, the DHA led the 2018 Organizational Assessment outlining a phased approach to transition both the JTS and the DoDTR to DHA. The coronavirus disease 2019 (COVID-19) pandemic in 2020 delayed the beginning of the DoDTR migration from an Army sponsored system to DHA.

In the midst of the COVID-19 pandemic in March 2020, the Uniformed Services University (USU) approached JTS for advice on how to develop a COVID-19 Registry. The JTS advised that the DoDTR already had a fully approved module for Infectious Disease (ID) that could be used as the foundation for the COVID-19 Registry. Although the DoDTR ID module was geared to treatment of combat casualties, the JTS, in coordination with subject matter experts from the USU, expanded the DoDTR ID module to meet the requirements outlined by the USU ID experts. By June 2020, the COVID-19 Registry began operating at initial operating capability, importing COVID-19 data.

Additionally, performance improvement measures and practice guidelines were disseminated across all Combatant Commands. As knowledge of the COVID-19 disease increased, more treatments for COVID-19 were included for capture in the COVID-19 Registry. These include convalescent plasma and use of remdesivir and monoclonal antibodies, as well as capturing asymptomatic patients who were COVID-19 positive or discharged with a vaccination and returned with a new positive COVID-19 test.

On January 1, 2021, the William M. (Mac) Thornberry NDAA for FY 2021 (Public Law 116-283) was enacted. Section 734 requires the Secretary of Defense to establish a COVID-19 Registry within the DoD. This law established reporting requirements that are currently captured in the DoDTR ID module and will transition to the COVID-19 Registry from the ID module within the DoDTR to a functional registry within the DHA Enterprise Intelligence and Data Solutions (EIDS) Military Health System Information Platform (MIP). The JTS DoDTR was scheduled to transition from an Army sponsored information technology platform to the DHA's MIP, although the emergence of the COVID-19 pandemic caused a reprioritization resulting in prioritizing the expansion of the DoDTR ID module. The Assistant Secretary of Defense for Health Affairs (ASD(HA)) has sponsored the transition of the COVID-19 Registry to the DHA's MIP. The transition will be led by the DHA, J-6, EIDS program manager. DHA, J-6, has drafted a charter that outlines a phased approach to transitioning both the COVID-19 Registry and the DoDTR from the current legacy system to the DHA's MIP.

Executive Summary

This report is in response to section 734 of the NDAA for FY 2021 (Public Law 116-283) that requires DoD to establish a registry of certain TRICARE beneficiaries diagnosed with COVID-19 that captures specific data points on those beneficiaries that do not "opt out" of inclusion in the registry.

DHA, under the leadership of the ASD(HA) and in coordination with the Military Departments, the Office of the Joint Staff Surgeon and USU, identified the COVID-19 Registry as an essential capability gap immediately after COVID-19 was declared a pandemic. Understanding the urgency, subject matter experts from the Military Health System (MHS) components advised the ASD(HA) on the best courses of action to develop the DoD's COVID-19 Registry to provide immediate capability while designing a long term plan to capture eligible beneficiary COVID-19 data.

The ASD(HA) provided guidance and funding for DHA to establish the COVID-19 Registry in coordination with the internal and external stakeholders. The Director, DHA oversaw the coordination between the JTS and the J-6 to establish the COVID-19 Registry at initial operating capability by expanding DoDTR. The DoDTR is a web-based data collection tool, which supports U.S. military performance improvement initiatives with global collection and aggregation of combat casualty care epidemiology, treatments and outcomes. Housed within the DoDTR is the ID module designed to collect trauma-related ID epidemiology; the ID module was expanded to serve as the initial COVID-19 Registry.

On June 1, 2020, the JTS began data collection in the COVID-19 Registry as a pandemic response capability for clinical performance improvement in the DoD. The COVID-19 Registry captures all data points outlined in section 734 of the NDAA for FY 2021 to include demographics, epidemiology, assessment, diagnostic testing, intervention, and outcome data. As of May 2021, DHA has analyzed over 227,000 COVID-19 cases and included these cases in the COVID-19 registry. Out of these 227,000 cases, chart reviews have occurred for approximately 8,000 patients for performance improvement purposes and uploaded into the JTS COVID-19 Registry. In addition to the detailed chart reviews of this subset of COVID-19 patients, the COVID-19 registry currently incorporates a database of all 227,000 beneficiaries diagnosed with COVID-19, allowing the ability to establish database mapping to electronic health record data contained within the MIP and epidemiologic tracking of all beneficiaries diagnosed with COVID-19 within the MHS direct care system. DHA manages TRICARE billing information for all private sector care, allowing the DoD to identify and track those patients diagnosed and treated for COVID-19 in private sector care. All data contributes to the body of science, and rapid analysis and feedback supports critical information dissemination to senior decision makers and updates to the COVID-19 Clinical Practice guidelines.

Part I – Plan to Implement the Registry

The ASD(HA) met with component heads within the MHS, beginning in March 2020, gathering data and advice to develop a COVID-19 Registry within the DoD. DHA thereafter began coordination efforts with internal and external stakeholders to expand the DoDTR ID module in an effort to establish the DoD's COVID-19 Registry capability within 90 days.

On July 13, 2020, the ASD(HA) published a policy memorandum which outlined the strategic plan of action. That policy directed DHA to establish a pandemic/epidemic database and registry within the MIP as the designated permanent data repository for DoD disease reporting and performance improvement activity. The policy further directed the DHA to use protocols and methods for access to authoritative data sources approved by the MHS Chief Information Officer (CIO). The policy directed the MHS CIO and Defense Health Management Systems Program Executive Office (DHMS PEO) to provide access to the DoD electronic health record systems, laboratory reporting systems, Armed Forces Health Surveillance Division Disease Reporting System-internet, health survey information, and TRICARE records for the purpose of accurate disease reporting into the registry, including review by authorized registrars (registrars are registry experts who accredit and verify data for performance improvement). The policy directed that the database and registry adhere to approved national data standards for protected health information, use data sources approved by the MHS governance, and directed actions for the Director, DHA, as listed below.

Specifically, the Director, DHA was directed to:

- Establish a pandemic/epidemic database and registry within the MIP.
- Modify the DoDTR ID module to collect information on pandemic/epidemic patients.
- In conjunction with the Military Departments, establish reporting processes on all COVID-19 positive cases in Disease Reporting System-internet (symptomatic and asymptomatic cases).
- Execute funds approved for pandemic/epidemic activities to support registry management, data abstraction and analysis.
- Assign a functional lead for the registry who will be responsible to ensure development of a concept of operations, requirements development, business case analysis, management of database evolution, availability of clinical subject matter expertise, and appropriate data analysis for performance improvement, population health impact, disease prevention and surveillance.
- Incorporate data reporting, registry and performance improvement requirements into future plans for pandemic/epidemic, disaster response, and wartime readiness.

The JTS, in coordination with the ASD(HA) and the DHMS PEO, published a charter to migrate the COVID-19 Registry (ID module) from the Army sponsored system to the DHA's MIP. The charter defines the scope, objectives, deliverables, high-level risks and major stakeholder roles and responsibilities for the DoDTR project. It also defines the project constraints, strategy, program organization, governance, procedures and overall approach for the work to be completed, and serves as a critical element for planning, executing, controlling and assessing the project. Additionally, the charter serves as an agreement between the project team and the

functional lead, stating what will be delivered according to budget, time constraints, risks, resources and standards agreed upon for the functional lead.

Part II – Cost of Implementing the Registry

In order to establish the COVID-19 Registry at initial operating capability, the DHA invested $35,000.00 in the ID Module (with an additional $5,000.00 for annual updates) and $2,350,000.00 annually for contracted COVID-19 Registry personnel (registrars and data analyst). Final costs of implementing the COVID-19 Registry are unknown although ongoing planning and forecasting is underway in order to provide a clear picture of costs for the new COVID-19 registry, training personnel on the new system, performance improvement personnel (registrars and data analysts), and sustainment funding to maintain the system. Funding will be made available by both the JTS and DHA through DoDTR sustainment funds and additional funds made available through COVID-19 funding sources. Costs will be separated and projected based on initial operating capability, full operating capability, training personnel on the new system, performance improvement personnel (registrars and data analysts), and sustainment funding for future years. The JTS is the current functional owner charged with securing funding for future development and sustainment.

Part III – Location of the Registry

The COVID-19 Registry (expanded ID module) is currently housed within DHA, JTS, as the JTS is the functional owner of the ID module within the DoDTR. As outlined by the ASD(HA), this capability will be prioritized to transition to the DHA and serve as the model for the transition of the DoDTR. The initial scope of the migration is the delivery of the COVID-19 Registry (Pandemic Response Registry) base capability in a form compatible with JTS processes and workflows as agreed upon by JTS and EIDS subject matter experts. It will then be followed by the development of the entire DoDTR using the same model. The initial phase of the project will capture all COVID-19 specific information, including positive lab confirmed cases, and, when testing is not available, the suspected symptomatic case information that has been evaluated by the medical provider. Additional functionality will be deployed in follow-on development processes to expand on this base capability. Finally, a service management plan will be created to outline development and operations agreements post deployment.

Part IV – Recommended Legislative Changes with Respect to Establishing the Registry

The Department will consider future legislative changes and requests as part of the official Department process for legislative proposals.

Conclusion

Section 734 of the NDAA for FY 2021 supports and leverages existing registry work and expertise across several components within the MHS. Continued development and expansion of the COVID-19 Registry supports the Secretary's vision of expanding the DoD's data ecosystem and accelerating data-driven decision making. DHA will continue to lead the registry efforts across the MHS in development and performance improvement in order to build advanced analytic platforms for cross-functional and cross-organizational executive analytics. DHA has prioritized the COVID-19 Registry development as a base capability and will deploy additional functionality in follow on development processes. The COVID-19 Registry captures all data points outlined in section 734 of the NDAA for FY 2021 to include demographics, epidemiology, assessment, diagnostic testing, intervention, and outcome data.

References

1. Section 734 of the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2017, (Public Law 116-283), "Registry of Certain TRICARE Beneficiaries Diagnosed with COVID-19," January 1, 2021
2. Assistant Secretary of Defense for Health Affairs Memorandum, "Guidance for Reporting and Participation in the Department of Defense Pandemic/Epidemic Registry," July 13, 2020
3. Project Charter Defense Health Agency (DHA) Joint Trauma System (JTS) and Program Executive Office, Defense Healthcare Management System (PEO DHMS) Department of Defense Trauma Registry (DoDTR) Migration Project, February 2021
4. Joint Trauma System, Organizational Assessment, Final Report, October 15, 2018
5. Section 708 of the National Defense Authorization Act for Fiscal Year 2017, (Public Law 114-328), "Establishment of the Joint Trauma Education and Training Directorate," Interim Report and Implementation Plan, February 14, 2018