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

PERSONNEL AND READINESS

AUG 2 6 2022

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

Dear Mr. Chairman:

The Department's response to House Report 117–118, page 184, accompanying H.R. 4350, the National Defense Authorization Act for Fiscal Year 2022, "Telehealth Licensure Flexibility Review," which requests a report discussing the temporary policy changes that were enacted because of the coronavirus disease 2019 (COVID-19) pandemic, is enclosed.

The Defense Health Agency (DHA) published three interim final rules in 2020 modifying TRICARE regulations, and implemented several policy changes in order to better respond to the COVID-19 pandemic, falling generally under the areas of beneficiary liability, benefit flexibilities, reimbursement flexibilities, and ancillary changes undertaken to reduce stress on the health care system. Many, but not all, of these changes were temporary. The report details much of DHA's response to the COVID-19 pandemic, why these changes were necessary, and the cost and feasibility of making certain temporary provisions permanent.

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

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Sincerely,

Gilbert R. Cisneros, Jr.

Enclosure:
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cc:
The Honorable Mike D. Rogers
Ranking Member

Report to Congressional Armed Service Committees

In Response to: House Report 117–118, Page 184, Accompanying H.R. 4350, the National Defense Authorization Act for Fiscal Year 2022, "Telehealth Licensure Flexibility Review"

August 2022

The estimated cost of this report or study for the Department of Defense is approximately $4,110 for the 2022 Fiscal Year. This includes $0 in expenses and $4,110 in DoD labor.

RefID: D-6DCA116

1) Introduction

This report is in response to the House Report 117–118, page 184, accompanying H.R. 4350, the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2022, which requests a review on retaining policy changes that were enacted as part of the Defense Health Agency's (DHA) response to the coronavirus disease 2019 (COVID-19) pandemic. This report will address regulatory flexibilities promulgated in interim final rules (IFRs) titled, "TRICARE Coverage and Payment for Certain Services in Response to the COVID-19 Pandemic" (85 FR 27921), "TRICARE Coverage of Certain Medical Benefits in Response to the COVID-19 Pandemic" (85 FR 54914), and "TRICARE Coverage of National Institute of Allergy and Infectious Disease Coronavirus Disease 2019 Clinical Trials" (85 FR 68753). The report will also look at other flexibilities implemented by DHA in policy using existing regulatory authority. The House Armed Services Committee (HASC) requested DHA determine the feasibility and estimated cost of permanently extending flexibilities originally created in response to COVID-19, such as the provider licensure provision.

2) Summary of Flexibilities Promulgated in Response to the COVID-19 Pandemic

DHA implemented numerous changes that collectively improved flexibility, efficiency, and access to care for TRICARE's 9.6 million (M) beneficiaries, providers, the Military Health System, and the country as a whole during the COVID-19 pandemic. Without emergency waiver authority (such as that which the Centers for Medicare and Medicaid Services (CMS) possesses) during national or public health emergencies, DHA promulgated temporary regulatory changes as quickly as possible through the rulemaking process. There were increased costs associated with many of the temporary provisions while others incurred no measurable or significant cost increase. The changes discussed herein fall under three categories: beneficiary liability, benefits, and reimbursement.

A. Beneficiary Liability

DHA implemented two temporary flexibilities for beneficiary liability during the COVID-19 pandemic. The first was a waiver of cost-shares and copayments for COVID-19 testing, implemented at the direction of Congress through the Families First Coronavirus Response Act (Public Law 116–127) as modified by the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) (Public Law 116–136). This change ensured that beneficiaries who needed to be tested for COVID-19 did not avoid doing so for fear of cost, allowing for more effective quarantines, isolation, and contact tracing. This provision terminates when the Department of Health and Human Services' (HHS) Public Health Emergency (PHE) is terminated. This change has cost DHA $63.5M from March of 2020 through the end of FY 2021. Permanently waiving such cost-shares and copayments would cost DHA approximately $50M per year before inflation, depending on the demand for such testing, and would require legislation to continue beyond the pandemic as cost-shares are established by statute.

DHA also used authority granted by Congress in section 718(d) of the NDAA for FY 2017 to waive cost-shares and copayments for telehealth services during the COVID-19

pandemic.[1] The waiver was implemented in response to efforts by Federal, State, and local governments to encourage individuals to stay at home, avoid exposure, and to reduce possible transmission of the virus. Predictably, this is the most costly flexibility implemented by DHA during the pandemic ($92M from May 12, 2020, through September 30, 2021). DHA continues to evaluate the viability and cost of continuing this cost-share waiver. It would cost approximately $58M per year before inflation to continue this waiver in perpetuity.

B. Benefit Flexibilities

The majority of flexibilities implemented by DHA during the COVID-19 pandemic impacted the scope of benefits available to beneficiaries, including expanding the types of providers from which beneficiaries could receive care. Several of the flexibilities were necessary to continue to meet the intent of statutory and regulatory requirements to treat certain providers similarly to Medicare, as CMS waived several provider requirements for the duration of the HHS PHE using their statutory waiver authority.

Telehealth Waivers and Clarifications

One of the biggest concerns early in the pandemic was having individuals stay home in order to reduce infection rates while the health care system prepared to respond. DHA took several actions to improve access to telehealth services during those early months, including the previously discussed waiver of cost-shares and copayments. The second telehealth-related flexibility that DHA enacted was waiving a regulation exclusion that prevented TRICARE from reimbursing for telehealth services provided via audio without a video component (referred to as audio-only telehealth services or telephonic office visits).[2] When first implemented, this coverage provided beneficiaries with the option to obtain some medical services safely from home, thereby reducing their exposure to COVID-19 and minimizing the potential spread of the disease. DHA is in the process of evaluating the appropriateness of continuing this flexibility beyond the COVID-19 pandemic and is reviewing data on telehealth utilization as well as public comments received on the original IFR. It is difficult to estimate the additional costs added by coverage of telephonic office visits alone in the time since implementation of the first COVID-19 IFR, due to the increase in utilization because of pandemic conditions and the cost-share/copayment waiver, in addition to the coverage of telephonic office visits. Claims for identifiable telephonic office visits amounted to approximately $25.9M through the end of FY 2021. We anticipate that permanently implementing this benefit expansion would cost approximately $10M per year before inflation. The vast majority of telephonic office visit costs likely would have been incurred through other modalities (in-person visits or telehealth delivered with a video component).

In addition to adding coverage of telephonic office visits and waiving cost-shares for telehealth services, DHA implemented other flexibilities to improve access to telehealth services. Early in the pandemic, the HHS Office of Civil Rights (OCR) announced it would use enforcement discretion and not enforce some Health Insurance Portability and Accountability

[1] 85 FR 27921.
[2] Ibid.

Act (HIPAA) violations,[3] thereby permitting some non-HIPAA compliant video conferencing applications to be used for the provision of telehealth services for the duration of the PHE (Apple FaceTime, Facebook Messenger video chat, Google Hangouts video, Skype, etc.). In response to HHS OCR's actions, DHA clarified that although the TRICARE telehealth benefit requires platforms to be HIPAA compliant, consistent with the HHS OCR position. This meant providers administering telehealth services to TRICARE beneficiaries could continue to provide such services so long as they complied with HHS OCR's guidance. This clarification has no cost and will not expire; however, DHA expects HHS OCR enforcement actions to resume following the termination of the HHS PHE.

DHA also provided clarification to its overseas contractor and providers such that rather than HIPAA being in place in overseas locations, host-nation and other local laws would apply. This clarification ensured beneficiaries overseas would have access to telehealth without providers being required to follow U.S. laws and regulations in countries where such laws and regulations did not apply. This clarification reduced potential confusion surrounding the provision of telehealth services overseas, and will appropriately continue beyond the pandemic. There is no cost associated with this flexibility.

TRICARE-Authorized Providers

A final flexibility that affected the provision of telehealth services, though one that was not limited to telehealth nor focused solely on telehealth, was a temporary waiver of the regulation requirement that the provider be licensed in the State where they practiced (contingent on the provider having an equivalent license in another State). During the pandemic, particularly in the early weeks and months, there was a great need for providers in areas hit hard by COVID-19 such as New York City, with impacted States requesting assistance from doctors, nurses, and other practitioners located elsewhere in the United States. In some cases, States suspended or otherwise waived licensure requirements. During this time, HHS used authority under the Public Readiness and Emergency Preparedness (PREP) Act to effectively suspend interstate license requirements and allow providers to treat patients with COVID-19 beyond the State where the provider held a license; several State governments adopted similar measures. CMS likewise used waiver authority to modify a regulatory requirement that required all Medicare and Medicaid providers be licensed in the State where they provide services, provided they met specific requirements.

TRICARE's regulations require providers to be licensed at the full clinical practice level in the State where practicing, even if such a licensure is optional. As a result, such waivers did not automatically apply to care reimbursed under TRICARE. Additionally, the reliance on telehealth meant that beneficiaries in some States could only access care if furnished by providers in other States. Because providers had not anticipated the need to administer care to patients in other States, providers were not necessarily licensed in States where telehealth patients happened to reside. In some cases, TRICARE beneficiaries who resided near a State border could not receive care from their regular doctors via telehealth because their providers practiced and were licensed in the adjacent State. Unlike CMS, DHA does not possess legal

[3] https://www.hhs.gov/hipaa/for-professionals/special-topics/emergency-preparedness/notification-enforcement-discretion-telehealth/index.html.

authority to waive regulatory requirements during a national emergency, nor does the authority under the PREP Act apply to TRICARE licensure requirements for providers; therefore, rulemaking was necessary to temporarily permit TRICARE coverage of services provided to beneficiaries by out-of-state licensed providers during the COVID-19 national emergency.[4]

The provider licensure waiver addressed both in-person and telehealth licensure concerns. Under this waiver, the DHA permitted reimbursement of an otherwise-authorized TRICARE provider if, under applicable Federal or State law, such provider: 1) held an equivalent license from any State in the United States; 2) complied with any provisions for interstate practice in that State; and 3) was not affirmatively barred or restricted from practicing in any State in the United States. This temporary change to the TRICARE regulation did not supersede the authority of the States to regulate their individual provider licensure requirement; it only applies in those States that modified interstate licensing requirements or where the Federal Government has pre-empted State licensing requirements such as under the PREP Act declaration.

DHA has long depended on States to manage providers practicing in their jurisdiction. This change did not preempt State authority to regulate provider licensure requirements; rather, it ensured that any providers following licensure requirements modified by any State government or by the Federal Government during the COVID-19 national emergency would be eligible for reimbursement under the TRICARE program for treating TRICARE beneficiaries. This change incurred no new costs as it assumed beneficiaries who were seeing providers under relaxed licensing requirements would have either been seen a different provider or the same provider in a different setting.

DHA is analyzing this provision to determine the appropriateness of continuing this flexibility beyond the pandemic with an eye to the licensure landscape and how it might change beyond the pandemic. Since this provision does not have a cost, any permanent coverage decision would largely depend on the appropriateness of continuing this provision given underlying statutory and regulatory authority, and in deference to States, which hold final authority in regulating providers practicing on patients who are within their boundaries. DHA notes that in cases where an interstate compact exists, whereby one member State recognizes providers licensed in other member States to be licensed the same as if they were licensed in that State, then DHA recognizes that the provider meets the State's licensure requirement.

Additional flexibilities were implemented for providers under the TRICARE program. Given the strain placed on the health care system by patients with severe or life-threatening COVID-19 infections, DHA sought to expand the facilities under which beneficiaries could receive acute care. DHA implemented a waiver of acute care hospital regulations for temporary hospital facilities and freestanding ambulatory surgery centers if the location was enrolled with Medicare's "Hospitals Without Walls" initiative.[5] This change did not increase TRICARE costs as it assumed beneficiaries would have sought care from another provider in the absence of the change. As the "Hospitals Without Walls" initiative is directly tied to the PHE and the waiver relies on provider participation in the initiative, this provision cannot persist after the pandemic.

[4] 85 FR 27921.
[5] 85 FR 54914.

Matching TRICARE's qualifications of certain acute care facilities to Medicare's requirements during the pandemic ensured that TRICARE beneficiaries had access to medically necessary care, at a time when many acute care facilities were at capacity.

Finally, DHA implemented numerous waivers related to providers for which either statute or regulation required that they meet Medicare's requirements. CMS, under the HHS emergency waiver authority, waived some requirements and DHA matched some of those waivers, where appropriate. By law, the TRICARE skilled nursing facility (SNF) benefit is provided in the manner and under the conditions provided by the Medicare SNF benefit. Consistent with Medicare, then, TRICARE's regulation adopted Medicare's requirement that an individual was an inpatient of a hospital for not less than 3 consecutive calendar days before discharge from the hospital (referred to as the "3-day prior hospital stay"). CMS waived this requirement during the COVID-19 pandemic. As required by the TRICARE statute for the SNF benefit to mirror that of Medicare, DHA waived its regulatory requirement for a 3-day prior hospital stay for TRICARE beneficiaries, providing temporary emergency coverage for those beneficiaries who need to be transferred during the period of the COVID-19 pandemic.[6] The provision waiving the 3-day prior hospital qualifying stay requirement for SNF care cost $0.72M through the end of FY 2021, with an expected annual cost of $0.5M per year until the waiver is terminated concurrent with the end of the HHS PHE.

Similarly, the coverage of Critical Access Hospitals (CAH) under TRICARE requires the CAH be designated and certified the same as Medicare, as contained in 42 CFR § 485.606. Medicare waived certain CAH requirements, such as the limitation on the number of beds to 25 and the annual average length of stay requirement of 96 hours, and DHA followed suit by waiving those same requirements. Further, TRICARE is required by law to cover hospice programs consistent with Medicare's requirements. When CMS waived several hospice requirements, such as the time requirement for comprehensive assessments, the requirement for non-core services, and a requirement for onsite visits for hospice aide supervision, DHA waived these requirements so that TRICARE could have a benefit matching Medicare's, as required by law. In each case, a change was made to continue to match Medicare's requirements and, as Medicare's waivers expire at the conclusion of the HHS PHE, it is appropriate for DHA's waivers to similarly expire.

Emerging Treatments, Therapies, and Vaccines

The first flexibility pertaining to COVID-19 therapies that DHA considered was how to treat drugs and devices given an emergency use authorization (EUA) by the FDA. This is the authority the FDA used to authorize the first COVID-19 tests, so it was essential that DHA consider how these tests would be treated under the TRICARE program. The TRICARE program has long required all drugs and devices to be approved or cleared for marketing in the United States by the FDA, with a few exceptions (devices with a category "B" investigational device exemption or a humanitarian device exemption, for example). DHA determined that EUA met this requirement and DHA clarified that a drug or device with an EUA could be cost-shared under TRICARE, paving the way for coverage of not just EUA COVID-19 tests, but for COVID-19 vaccines and treatments, such as monoclonal antibodies. Because this flexibility was

[6] 85 FR 54914.

a clarification of existing regulation, rather than a waiver of the current TRICARE benefit, it is permanently adopted by the TRICARE program and will remain available to DHA for future public health emergencies. There is no additional incremental cost to DHA for implementing this flexibility.

In addition to EUA coverage, DHA considered how it treats other investigational drugs and therapies under TRICARE. Under existing regulatory authority, TRICARE may cover costs associated with administration of an emergency individual investigational new drug[7] (IND), but not the IND itself. During the beginning months of the pandemic, convalescent plasma was one of the only therapies available to patients diagnosed with COVID-19, and was only available as an investigational therapy under an approved FDA expanded access setting. DHA implemented a regulatory flexibility that permitted the coverage of the treatment use of investigational drugs under FDA-approved expanded access settings (individual, intermediate, and widespread) while we considered coverage of this type of investigational therapy and how such coverage aligned with the Congressional mandate to only cover medically necessary care.[8] Because convalescent plasma was largely provided free-of-charge and eventually received an EUA, and because few other investigational therapies were provided under expanded access settings to TRICARE beneficiaries, the cost impact of this provision was minimal. DHA continues to evaluate its coverage of investigational therapies when provided under an FDA expanded access setting. A decision on coverage will largely depend not on cost, but on how these therapies align with the statutory mandate that all care provided under TRICARE be medically necessary and appropriate. DHA lacks the statutory authority to implement permanent TRICARE coverage of any therapies that are not medically necessary and appropriate.

DHA's final benefit flexibility designed to increase beneficiary access to emerging therapies came in the form of an expansion of the clinical trial benefit.[9] By law, DHA may waive the statutory requirement that care be medically necessary and appropriate when performed in an National Institutes of Health (NIH) sponsored or approved clinical trial when an agreement for such care exists between DHA and HHS, once DHA issues regulatory provisions detailing requirements for coverage. DHA has covered cancer clinical trials sponsored or approved by the National Cancer Institute since the late 1990s. During the pandemic, DHA expanded this coverage to temporarily include COVID-19 trials sponsored or approved by the National Institute of Allergy and Infectious Diseases. This flexibility has resulted in insignificant costs to DHA due to low participation, although we expect those costs would be greater if DHA were to permanently implement coverage of some or all NIH-sponsored or approved clinical trials. The cost of doing so would depend on whether such coverage was limited to treatments for COVID-19 (estimated cost of $1.05M over 5 years), expanded to include all NIH clinical trials (estimated cost of $40.03M), or some more limited benefit between the two. Such an expansion is feasible under existing statutory authority and DHA is finalizing analysis to determine the best way forward for the program and its beneficiaries via the

[7] An emergency IND is an investigational drug for which marketing approval has not yet been approved and for which safety and efficacy are not yet established, but which the FDA may authorize on an emergency basis for an individual with a serious or life-threatening illness, when the patient is unable to wait for a more thorough review by the FDA.
[8] 85 FR 54914.
[9] 85 FR 68753.

rulemaking process. However, if DHA desired to expand coverage of clinical trials more commensurate with requirements found in the Affordable Care Act so that clinical trials sponsored or approved by other Federal entities were covered, legislative authority would be required.

C. Reimbursement Flexibilities

TRICARE is required by law to reimburse like Medicare to the extent practicable. In some cases, TRICARE may reimburse differently than Medicare when its statutory authority or population needs make it necessary to do so. However, in most cases, TRICARE reimburses using similar methodologies as Medicare. During the pandemic, DHA made temporary changes to reimbursement of providers to match similar efforts enacted by Medicare. These provisions will expire at the conclusion of the HHS PHE and none is appropriate for permanent implementation, given the requirement to reimburse like Medicare.

The first temporary reimbursement modification was a result of section 3710 of the CARES Act, which directed Medicare to increase the reimbursement amount for COVID-19-positive patients admitted to an inpatient facility. The CARES Act required that the weighting factor of the assigned diagnosis related group (DRG) be increased by 20 percent for an individual diagnosed with COVID-19, confirmed through documentation of a positive COVID-19 laboratory test in the patient's medical record, and discharged during the COVID-19 PHE period. DHA determined that it was practicable to adopt this Medicare DRG adjustment concurrent with Medicare's reimbursement.[10] The cost of this provision was approximately $41.5M through the end of FY 2021.

The second temporary reimbursement modification addressed long-term care hospitals (LTCHs).[11] There are two types of LTCH prospective payment system (PPS) rates under Medicare: (1) standard LTCH PPS payments; and (2) lower site-neutral LTCH PPS payment rates that are paid at the lower of the inpatient PPS comparable per diem amount or the estimated cost of the case. Site-neutral patients include LTCH patients who do not use prolonged mechanical ventilation during their LTCH stay or who did not spend 3 or more days in the intensive care unit during their prior acute care hospital stay. Site neutral LTCH claims are typically paid the regular DRG rate rather than the higher LTCH PPS payment rate. Medicare revised its reimbursement rules for LTCHs under the CARES Act to reimburse all long-term care cases with a discharge date on or after January 27, 2020, and for the duration of the PHE, at the standard rate for claims (i.e., the higher LTCH PPS rate). DHA likewise adopted this reimbursement modification and reimbursed all LTCHs at the standard Federal rate for the duration of the COVID-19 PHE. The cost to DHA of this flexibility was approximately $10.7M from January 27, 2020 through September 30, 2021.

D. Ancillary Changes

In addition to the flexibilities discussed above, TRICARE made two permanent changes to the TRICARE benefit and reimbursement systems. While neither of these permanent changes

[10] 85 FR 54914.
[11] Ibid.

was intended to directly address patients with COVID-19 or their providers, each change was adopted with the intent to reduce overall stress on the health care system. These changes were the permanent adoption of two Medicare reimbursement systems: New Technology Add-on Payments (NTAPs) and the Hospital Value Based Purchasing (HVBP) Program.[12] NTAPs ensure appropriate reimbursement for new, high-cost therapies provided in an inpatient setting in order to ensure TRICARE beneficiaries have access to such therapies and that hospitals are appropriately reimbursed for providing such treatments. The HVBP Program provides incentives to hospitals that show improvement in areas of health care delivery, process improvement, and increased patient satisfaction.

3) Conclusion

Most of the flexibilities discussed above were originally implemented because the COVID-19 pandemic necessitated such actions. These changes improved access to health care services and COVID-19 treatments for TRICARE beneficiaries and ensured that TRICARE-authorized providers were able to treat TRICARE beneficiaries in areas of critical need without worrying about not receiving reimbursement from TRICARE.

Looking forward to a post-COVID health care environment, there may be temporary flexibilities that would be appropriate for DHA to make permanent; many such changes have been or would need to be modified through the rulemaking process. Some adaptations made specifically for the COVID-19 national emergency are likely not appropriate to continue without knowing how future emergencies will need to be handled. While these flexibilities may have been relevant when COVID-19 was at peak and access to care for beneficiaries was crucial, it would be unnecessary and costly for all the DHA COVID-19 flexibilities to remain permanently in place.

The HASC has expressed particular interest in the feasibility of making the provider licensure flexibility provision permanent. DHA intends to continue to monitor State regulation of licensing, particularly any evolution in the treatment of State licensure for the provision of telehealth services, and will pursue proposed and final rulemaking if it determines that such actions are necessary.

Other temporary flexibilities were designed for the particular circumstances of COVID-19. In the ongoing absence of statutory waiver authority similar to Medicare, rulemaking is required to enact temporary changes to the TRICARE regulation that may be required to respond to future emergencies.

In determining which provisions to implement permanently, DHA continues to evaluate how making certain temporary COVID-19 provisions permanent would interact with State requirements, benefit the TRICARE population, impact DHA's costs, and impact providers. DHA possesses authority to permanently implement the temporary changes made except those made with a specific statutory authority, which will also terminate upon conclusion of the pandemic (e.g., those resulting from the CARES Act). Because DoD does not have PHE waiver authority for TRICARE statutory specifications, DoD will continue to evaluate potential flexibilities on a case-by-case basis under existing statutory authority.

[12] 85 FR 54914.