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DEPARTMENT OF DEFENSE

Office of the Secretary

Notice of Five-Year Extension of Defense Health Agency Evaluation of Non-United States Food and Drug Administration Approved Laboratory Developed Tests Demonstration Project

AGENCY: Office of the Secretary, Department of Defense (DoD).

ACTION: Notice.

SUMMARY: This notice is to advise interested parties of an additional five-year extension of the Defense Health Agency's (DHA) Evaluation of Non-United States Food and Drug Administration (FDA) Approved Laboratory Developed Tests (LDTs) Demonstration Project (hereinafter referred to as the "LDT demonstration"). The original notice was published on June 18, 2014. The LDT demonstration was effective July 18, 2014. It remained in effect for three years (July 18, 2017). A notice was published on June 20, 2017 extending the LDT demonstration for three years. The three-year extension was effective July 19, 2017, through July 18, 2020. A second notice extending the LDT demonstration for an additional three years was published on July 10, 2020. The three-year extension was effective July 19, 2020. It is scheduled to end July 18, 2023. As uncertainty remains regarding future regulatory oversight of LDTs, the LDT demonstration will now be extended for five additional years (July 18, 2028). Additionally, this notice announces the removal of preconception and prenatal carrier screening for Cystic Fibrosis (CF) from the LDT demonstration as these carrier screening tests have been added to the TRICARE Basic (*i.e.*, medical) benefit as directed by the National Defense Authorization Act (NDAA) of 2022.

DATES: The extension of this demonstration will be effective July 19, 2023. It will continue through July 18, 2028.

FOR FURTHER INFORMATION CONTACT: LaChanda Black, Defense Health Agency, (303) 676-3575, lachanda.m.black.civ@health.mil.

SUPPLEMENTARY INFORMATION:

For additional information on the DHA LDT demonstration, please see 79 FR 34726-34729, 82 FR 28052, and 85 FR 41574-41575. According to title 32, Code of Federal Regulations (CFR), section 199.4(g)(15)(i)(A), TRICARE may not cost-share devices, including LDTs, that have not received FDA required device 510(k) clearance or premarket approval (referred to as "non-FDA-approved" hereafter). LDTs with FDA clearance or approval are available for cost-sharing under the TRICARE Basic (*i.e.*, medical) benefit as long as they otherwise meet TRICARE criteria for coverage.

On June 18, 2014, a notice was published in the *Federal Register* (79 FR 34726) announcing the start of the LDT demonstration initiated by the DHA to review non-FDA-approved LDTs to determine if they meet TRICARE's requirements for safety and effectiveness, and otherwise meet TRICARE criteria for coverage. Under the LDT demonstration, DHA would allow those LDTs that met such criteria to be covered as a benefit. This demonstration also extended coverage for preconception and prenatal CF carrier screening, when provided in accordance with the most current American College of Obstetricians and Gynecologists (ACOG) guidelines. The purpose of this demonstration is to improve the quality of health care services for TRICARE beneficiaries.

Effective December 27, 2021, Section 702 of the National Defense Authorization Act for Fiscal Year 2022 (NDAA FY 2022), codified at 10 USC 1079(a)(19), extended TRICARE Basic (*i.e.*, medical) benefit coverage for preconception and prenatal carrier screening tests for Cystic Fibrosis, Spinal Muscular Atrophy, Fragile X Syndrome, Tay-Sachs Disease, Hemoglobinopathies, and conditions linked with Ashkenazi Jewish descent. As a result, preconception and prenatal carrier screening for CF will be removed from the LDT demonstration as it is now incorporated into the TRICARE Basic (*i.e.*, medical) benefit.

Non-FDA-approved LDTs covered under the LDT demonstration are available for cost-sharing for eligible TRICARE beneficiaries only when performed by laboratories that are assessed and certified or accredited under minimum quality standards set by the Centers for Medicare and Medicaid Services (CMS) under the Clinical Laboratory Improvement Amendments (CLIA) of 1988, *i.e.*, CLIA certified. CMS regulates laboratories that perform non-FDA-approved LDTs as well as FDA-approved/cleared tests. Laboratories performing moderate or high complexity tests are subject to specific regulatory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections. CLIA certification and biennial surveys evaluate whether the laboratory has verified or established the analytical validity of the tests they offer, including LDTs. Analytical validity refers to how well a test performs in the laboratory; that is, how well the test measures the properties or characteristics it is intended to measure. However, CLIA certification does not assure a device is safe and effective for its intended use or impose any type of post-market surveillance or adverse event reporting requirements.

For the TRICARE Overseas Program (TOP), an exception to the requirement for CLIA certification for overseas laboratories continues. This is due to the majority of overseas laboratories not having CLIA certification. As with the notice published at 85 FR 41574, this notice restates that non-FDA-approved LDTs covered under the LDT demonstration shall be available for cost-sharing for qualified TOP beneficiaries when performed by either CLIA-certified laboratories or laboratories that are assessed by the TOP contractor to be in accordance with the host nation's credentialing/accreditation standards when those standards for credentialing/accreditation are comparable to CLIA standards.

LDTs provide an important health care capability for the TRICARE Program. Nonetheless, LDTs are complex and do have some risks associated with their use. For example, inaccurate tests may place patients at otherwise avoidable risk. While laboratories that offer LDTs are subject to the Federal Food, Drug, and Cosmetic Act (FFDCA), the FDA has generally

exercised enforcement discretion towards LDTs, such that it has generally not enforced applicable provisions under the FFDCA and FDA regulations with respect to LDTs. TRICARE's regulatory requirement at 32 CFR 199.4(g)(15)(i)(A) requires LDTs covered in the TRICARE Program to be FDA-approved or cleared, if required under FFDCA. Further, as mentioned above, the FDA generally exercises enforcement discretion for most LDTs, and most laboratories offering LDTs do not submit their devices to the FDA for review. Therefore, most LDTs do not satisfy the requirements at 32 CFR 199.4(g)(15), that the safety and efficacy of these devices be established in order to permit cost-sharing. As a result, TRICARE is unable to cost share for such LDTs.

However, in some instances, LDTs are important and necessary tests and in many instances, there are no FDA-approved/cleared alternatives. Therefore, the TRICARE Program has endeavored to evaluate LDTs through its demonstration project initiated in 2014. Although ongoing for more than eight years, additional work is necessary to ensure that the TRICARE program conducts the appropriate evaluation of these tests based on reliable evidence, and permit TRICARE cost-sharing of medically necessary and appropriate LDTs that are found to otherwise meet TRICARE criteria for coverage, including requirements for safety and effectiveness.

While the DoD had hoped that another LDT demonstration extension would not be required, uncertainty remains regarding future regulatory oversight of LDTs. In the absence of any change in the oversight of LDTs at this time, the DoD has determined that continuation of the LDT demonstration for an additional five years is necessary to provide TRICARE beneficiaries and their health care providers with seamless access to safe and effective, medically necessary tests, as determined by TRICARE, to support health care decisions and treatment.

Health care costs projected for the LDT demonstration over the five-year extension (Fiscal Year (FY) 2023-FY 2028) are $198.8 million (M) and $2.1M in administrative costs for all contracts combined. Because all managed care support contractors currently have systems in

place for the LDT demonstration, no additional start-up costs are anticipated for this five-year extension.

During the next five years, the DHA will continue to evaluate the LDT examination and recommendation process to assess feasibility, resource requirements, and the cost-effectiveness of establishing an internal safety and efficacy review process to permit TRICARE cost-sharing for an ever-expanding pool of non-FDA-approved LDTs, including tests for cancer risk, diagnosis, and treatment; blood and clotting disorders; a variety of genetic diseases and syndromes; and neurological conditions. The results of the evaluation will provide an assessment of the potential improvement of the quality of health care services for beneficiaries who would not otherwise have access to tests that meet TRICARE requirements for safety and effectiveness. Based on the results of the demonstration evaluation, and status of the regulatory oversight of LDTs, a recommendation will be made on whether to modify 32 CFR 199.4(g)(15) to permit TRICARE cost-sharing of non-FDA approved LDTs that are found to meet TRICARE requirements for safety and effectiveness. Our intent is for the LDT demonstration to conclude at the end of this five-year extension. Should the FDA issue final guidance on LDTs and/or enforce the requirement for clearance or premarket approval for LDTs, the Director, DHA will modify or terminate the LDT demonstration, as appropriate, and the DoD will ensure compliance with applicable federal law and regulations.

The LDT demonstration continues to be authorized by 10 U.S.C. 1092.

Dated: July 7, 2023.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer,

Department of Defense.

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