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**DEPARTMENT OF DEFENSE**

**Office of the Secretary**

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

**AGENCY:** Department of Defense.

**ACTION:** Notice of three-year extension of Defense Health Agency Evaluation of Non-United States Food and Drug Administration Approved Laboratory Developed Tests Demonstration Project.

**SUMMARY:** This notice is to advise interested parties of a three-year extension of a demonstration project entitled Defense Health Agency (DHA) Evaluation of Non-United States Food and Drug Administration (FDA) Approved Laboratory Developed Tests (LDTs) Demonstration Project. The original notice was published on June 18, 2014 (79 FR 34726-34729).

**DATES:** Effective July 19, 2017.

**ADDRESSES:** Defense Health Agency (DHA), Attn: Clinical Support Division, 16401 East Centretch Parkway, Aurora, CO 80011-9066.

**FOR FURTHER INFORMATION CONTACT:** Jim Black, Clinical Support Division, Defense Health Agency, Telephone (303) 676-3487.

**SUPPLEMENTARY INFORMATION:** For additional information on the DHA Evaluation of Non-United States FDA Approved LDTs Demonstration Project, please see 79 FR 34726-34729. According to 32 CFR 199.4(g)(15)(i)(A), TRICARE may not cost-share medical devices,

including LDTs, that have not received FDA medical device 510(k) clearance or premarket approval.

The purpose of this demonstration is to improve the quality of health care services for TRICARE beneficiaries. Under this demonstration, the Department of Defense reviews non-FDA approved LDTs to determine if they meet TRICARE's requirements for safety and effectiveness, and allows those that do to be covered as a benefit under the demonstration. This demonstration also extends coverage for prenatal and preconception cystic fibrosis (CF) carrier screening, when provided in accordance with the American College of Obstetricians and Gynecologists guidelines.

The Department has determined that continuation of the demonstration project for an additional three years is necessary to provide the Secretary with sufficient information to fully evaluate the project while continuing to provide TRICARE beneficiaries and their health care providers with seamless access to safe and effective, medically necessary tests to support health care decisions and treatment. During the next three 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 these safe and effective tests and to support future regulatory revisions which will enhance the flexibility of the Military Health

System in responding to emerging technologies. The demonstration project continues to be authorized by 10 U.S.C. 1092.

Dated: June 15, 2017.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer,

Department of Defense.

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