



OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
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TRICARE
MANAGEMENT ACTIVITY

PCSIB

CHANGE 42
7950.2-M
SEPTEMBER 11, 2012

**PUBLICATIONS SYSTEM CHANGE TRANSMITTAL
FOR
TRICARE SYSTEMS MANUAL (TSM), FEBRUARY 2008**

The TRICARE Management Activity has authorized the following addition(s)/revision(s).

CHANGE TITLE: TRICARE EVALUATION OF CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS) APPROVED LABORATORY DEVELOPED TESTS (LDTs) DEMONSTRATION PROJECT

CONREQ: 15919

PAGE CHANGE(S): See page 2.

SUMMARY OF CHANGE(S): LDTs which are identified by U.S. Food and Drug Administration (FDA) regulation as medical devices require FDA premarket clearance or premarket approval to be eligible for cost-sharing by TRICARE. Therefore, requests for these LDTs (ordered or prescribed by TRICARE authorized and contracted network providers) are factually denied by the TRICARE Managed Care Support Contractors (MCSCs), and other TRICARE health care contractors. During the demonstration period TRICARE Management Activity (TMA) may determine that some LDTs, which have not received FDA premarket clearance or premarket approval, will be eligible for cost-sharing by TRICARE. If an LDT is determined by the Director, TMA to be cost-shared, the LDT will be processed by TMA in the same method as any other approved benefit.

EFFECTIVE DATE: January 26, 2012.

IMPLEMENTATION DATE: Upon direction of the Contracting Officer.

This change is made in conjunction with Feb 2008 TOM, Change No. 83.

**Jack Arendale
Chief, Purchased Care Systems
Integration Branch**

**ATTACHMENT(S): 36 PAGES
DISTRIBUTION: 7950.2-M**

WHEN PRESCRIBED ACTION HAS BEEN TAKEN, FILE THIS TRANSMITTAL WITH BASIC DOCUMENT.

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APPENDIX A

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