



OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
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TRICARE
MANAGEMENT ACTIVITY

OD

CHANGE 145
6010.51-M
SEPTEMBER 11, 2012

**PUBLICATIONS SYSTEM CHANGE TRANSMITTAL
FOR
TRICARE OPERATIONS MANUAL (TOM), AUGUST 2002**

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: 15918

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 Aug 2002 TSM, Change No. 98.


Reta M. Michak
Director, Operations Division

ATTACHMENT(S): 12 PAGES
DISTRIBUTION: 6010.51-M

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