

- (3) *Department of the Navy*.  
 (i) Department of the Navy, Chief of Naval Operations, CNO N09N2, 2000 Navy Pentagon, Washington, DC 20350-2000. (Collateral MDR).  
 (ii) Department of Navy, Chief of Naval Operations, CNO N2/N6, 2000, Navy Pentagon, Washington, DC 20350-2000. (Sensitive Compartmented Information MDR).  
 (4) *Department of the Air Force*.  
 Department of the Air Force, HAF/IMIO (MDR), 1000 Air Force Pentagon, Washington, DC 20330-1000.  
 (5) *United States Marine Corps*.  
 Commandant of the Marine Corps, HQMC Code PP&O, Security Division (PS), 3000 Marine Corps Pentagon, Room 4A324, Washington, DC 20350-3000.  
 (6) *Defense Advanced Research Projects Agency*.  
 Defense Advanced Research Projects Agency, 3701 N. Fairfax Drive, Arlington, VA 22203-1714.  
 (7) *Defense Contract Audit Agency*.  
 Director, Defense Contract Audit Agency, Attention: CPS, 8725 John J. Kingman Road, Suite 2135, Fort Belvoir, VA 22060-6219.  
 (8) *Defense Information Systems Agency*.  
 Defense Information Systems Agency, Attention: Security Division, MPS 6, 5111 Leesburg Pike, Suite 100, Falls Church, VA 22041.  
 (9) *Defense Intelligence Agency*.  
 Defense Intelligence Agency, Attention: DAN-1A (FOIA), Washington, DC 20340-5100.  
 (10) *Defense Logistics Agency*.  
 Defense Logistics Agency, Attention: DLA/DSS-S, 8725 John J. Kingman Road, Suite 2533, Fort Belvoir, VA 22060-6221.  
 (11) *Defense Security Service*.  
 Defense Security Service, Office of FOIA & Privacy, 1340 Braddock Place, Alexandria, VA 22314-1651.  
 (12) *Defense Threat Reduction Agency*.  
 Defense Threat Reduction Agency, Attention: SCR, 8725 John J. Kingman Road, Fort Belvoir, VA 22060-6201.  
 (13) *Missile Defense Agency*.  
 Missile Defense Agency, Attention: MDA/DS, 7100 Defense Pentagon, Washington, DC 20301-7100.  
 (14) *National Geospatial-Intelligence Agency*.  
 National Geospatial-Intelligence Agency, Mail Stop D-10, 4600 Sangamore Road, Bethesda, MD 20816-5003.  
 (15) *National Reconnaissance Office*.  
 National Reconnaissance Office, NRO-MSO-ASG-IMSC-IART, 14675 Lee Road, Chantilly, VA 20151-1715.  
 (16) *National Security Agency/Central Security Service*.  
 National Security Agency, Declassification Office, DJP5,

- 9800 Savage Road, Suite 6884, Fort George G. Meade, MD 20755-6884.  
 (17) *North American Aerospace Defense Command*.  
 HQ NORAD/CSO, 250 Vandenberg St. Ste B016, Peterson AFB, CO 80914.  
 (18) *U.S. Africa Command*.  
 US Africa Command, Unit 29951, ATTN: COS-FOIA, APO AE 09751.  
 (19) *U.S. Central Command*.  
 U.S. Central Command, Attention: CCJ6-RDD, 7115 South Boundary Blvd., MacDill AFB, FL 33621-5101.  
 (20) *U.S. European Command*.  
 U.S. European Command, Attention: ECJ1-AX, Unit 30400, APO AE 09131.  
 (21) *U.S. Joint Forces Command*.  
 U.S. Joint Forces Command, Code J02SM, 1562 Mitscher Ave., Suite 200, Norfolk, VA 23511-2488.  
 (22) *U.S. Northern Command*.  
 U.S. Northern Command, HQ USNORTHCOM/CSO, 250 Vandenberg Street, Suite B016, Peterson AFB, CO 80914-3804.  
 (23) *U.S. Pacific Command*.  
 U.S. Pacific Command, Attention: J151 FOIA, Box 64017, Camp Smith, HI 96861-4017.  
 (24) *U.S. Southern Command*.  
 U.S. Southern Command, Attention: SCJ2-SM-CFO (FOIA), 3511 NW. 91st Avenue, Miami, FL 33172-1217.  
 (25) *U.S. Special Operations Command*.  
 U.S. Special Operations Command, Attention: SOCS-SJS-SI (FOIA), 7701 Tampa Point Blvd., MacDill AFB, FL 33621-5323.  
 (26) *U.S. Strategic Command*.  
 U.S. Strategic Command, Attention: CS50, 901 SAC Blvd., STE 1C17, Offutt AFB, NE 68113-6000.  
 (27) *U.S. Transportation Command*.  
 US Transportation Command, Chief, Command Information Management, ATTN: TCCSIM, 508 Scott Drive, Scott AFB IL, 62225-5357.

Dated: December 21, 2011.

**Aaron Siegel,**

*Alternate OSD Federal Register Liaison Officer, Department of Defense.*

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**BILLING CODE 5001-06-P**

## DEPARTMENT OF DEFENSE

### Office of the Secretary

#### Reserve Forces Policy Board (RFPB); Member Solicitation

**AGENCY:** Office of the Secretary of Defense Reserve Forces Policy Board, Department of Defense.

**ACTION:** Notice of Advisory Committee Member Solicitation.

**SUMMARY:** Pursuant to the Federal Advisory Committee Act of 1972 (5

U.S.C., Appendix, as amended), the Sunshine in the Government Act of 1976 (5 U.S.C. 552b, as amended), and 41 CFR 102-3.150, the Department of Defense announces the following Federal advisory committee member solicitation of the Reserve Forces Policy Board (RFPB).

**FOR FURTHER INFORMATION CONTACT:**  
 LtCol Ken Olivo, Designated Federal Officer, (703) 697-4486 (Voice), (703) 693-5371 (Facsimile), [RFPB@osd.mil](mailto:RFPB@osd.mil). Mailing address is Reserve Forces Policy Board, 7300 Defense Pentagon, Washington, DC 20301-7300. Web site: <http://ra.defense.gov/rfpb/>.

**SUPPLEMENTARY INFORMATION:** As specified in Section 10301, Title 10, U.S. Code, the Reserve Forces Policy Board serves "as an independent adviser to the Secretary of Defense to provide advice and recommendations to the Secretary of Defense on strategies, policies, and practices designed to improve and enhance the capabilities, efficiency, and effectiveness of the reserve components." The Board consists of 20 members. This includes ten persons appointed or designated by the Secretary of Defense, each of whom must be a United States citizen having significant knowledge of and experience in policy matters relevant to national security and reserve component matters and must be one of the following pursuant to 10 U.S.C. 10301(c)(6):

"(A) An individual not employed in any Federal or State department or agency.

(B) An individual employed by a Federal or State department or agency.

(C) An officer of a regular component of the armed forces on active duty, or an officer of a reserve component of the armed forces in an active status, who—

(i) Is serving or has served in a senior position on the Joint Staff, the headquarters staff of a combatant command, or the headquarters staff of an armed force; and

(ii) has experience in joint professional military education, joint qualification, and joint operations matters."

The vacancy to be filled on the Board is one of those ten positions.

The Federal Advisory Committee Act (FACA) of 1972 (5 U.S.C. Appendix, as amended) and the governing regulations (41 CFR 102-305 through 102-30175) provide the basis for and guidance concerning the management and operations of Federal advisory committees. Typically, advisory bodies subject to FACA require open, preannounced meetings; public access to discussions, deliberations, records and documents; opportunity for the

public to provide, at a minimum, written comments; fairly balanced membership; and evaluation of conflicts of interests for certain members. Section 5(b)(2) of the FACA requires “\* \* \* the membership of the advisory committee to be fairly balanced in terms of the points of view represented and the functions to be performed by the advisory committee.”

**Forward Nominations for Membership:** This notice is a solicitation to fill a vacancy on the board. To be considered for nomination please forward a biography of the nominee describing the professional background and qualifications meeting the above stated criteria. Submissions may be by email: *RFPB@osd.mil*, or by (703) 693-5371 (Facsimile-FAX) to the Reserve Forces Policy Board’s Designated Federal Officer no later than the close of business Friday, January 27, 2012.

**Note:** Nominees must be U.S. citizens and cannot be registered federal lobbyists. Individuals appointed by the Secretary of Defense to serve on the Reserve Forces Policy Board will be appointed as experts and consultants under the authority of 5 U.S.C. 3109 to serve as special governmental employees and be required to comply with all Department of Defense ethics requirements, to include the filing of confidential financial disclosure statements. Nominees must hold or be able to qualify for a security clearance at the Secret level. In addition, those appointed will serve without compensation except for travel and per diem in conjunction with official Board business.

Dated: December 21, 2011.

**Aaron Siegel,**

*Alternate OSD Federal Register Liaison Officer, Department of Defense.*

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**BILLING CODE 5001-06-P**

## DEPARTMENT OF DEFENSE

### Office of the Secretary

#### **TRICARE Evaluation of Centers for Medicare & Medicaid Services Approved Laboratory Developed Tests Demonstration Project**

**AGENCY:** Department of Defense.

**ACTION:** Notice of Demonstration.

**SUMMARY:** This notice is to advise interested parties of a Military Health System (MHS) demonstration project under the authority of Section 1092, Chapter 55, Title 10 of the United States Code (U.S.C.), entitled TRICARE Evaluation of Centers for Medicare & Medicaid Services Approved Laboratory Developed Tests Demonstration Project. The demonstration project is intended

to determine whether it is feasible for the Department of Defense (DoD) to review Centers for Medicare and Medicaid Services (CMS) approved laboratory developed tests (LDTs), not yet examined by the United States Food and Drug Administration (FDA), to determine if they meet TRICARE requirements for safety and effectiveness according to the hierarchy of reliable evidence (32 CFR 199.2(b)) and allow those that do to be covered as a benefit under the TRICARE Program. The LDTs for this demonstration would be limited to only those that significantly inform clinical decision making for surveillance, surgical interventions, chemotherapy, or radiation therapy for cancer. The demonstration project will provide a valuation of the potential improvement of the quality of healthcare services for TRICARE beneficiaries who would not otherwise had access to these tests. In addition, the demonstration project will evaluate the need to modify 32 CFR 199.4(g)(15)(i)(A) to allow coverage for CMS approved LDTs.

Interested LDT device manufacturers, or individual (single) laboratories developing their own proprietary tests that have a CMS National Coverage Determination (NCD) or Local Coverage Determination (LCD) who desire the DoD to consider their tests for coverage under the TRICARE Program, are encouraged to submit LDTs for consideration. Submissions must include the LDT description and complete documentation (including the CMS-assigned determination number) proving CMS National Coverage Determination (NCD) or Local Coverage Determination (LCD). Submissions will only be accepted for those LDTs which are CMS approved, but have not received FDA clearance or approval LDTs will be prioritized based on the combination of potential high utilization and potential high clinical impact on TRICARE beneficiaries. If no submission is received for a LDT and TMA is aware that a NCD or LCD exists, TMA may elect to include the LDT in the prioritization process. Relevant administrative data on number of diagnoses of specific oncological diseases, procedures, treatments, and other requested data and information will be used in the prioritization process. The prioritized list will be sent to the Director, TMA for approval. The approved list will then be reviewed in numerical order beginning with the test listed as having the highest priority. Those selected for review will be evaluated to determine whether they meet the TRICARE hierarchy of reliable

evidence for safety and effectiveness as described in 32 CFR 199.4(g)(15). LDTs determined to meet TRICARE criteria for safety and efficacy will be recommended to the Director, TMA for approval for cost-sharing during the demonstration period.

**DATES:** This demonstration will be effective 30 days after publication in the **Federal Register**. This demonstration will remain in effect for three years.

**ADDRESSES:** TRICARE Management Activity (TMA), Office of the Chief Medical Officer, Attn: HB&RM 5111 Leesburg Pike, Suite 810, Falls Church, VA 22041-3206.

**FOR FURTHER INFORMATION CONTACT:** Timothy Stockdale, Office of the Chief Medical Officer, TRICARE Management Activity, telephone (703) 681-0075.

#### **SUPPLEMENTARY INFORMATION:**

##### **A. Background**

According to 32 Code of Federal Regulation (CFR) 199.4(G)(15)(i)(a) the TRICARE Management Activity (TMA) may not cost-share medical devices including laboratory developed tests (LDTs) if the tests are non-FDA approved, that is they have not received U.S. Food and Drug Administration (FDA) marketing 510(k) clearance or premarket approval. Under the current regulation cited above, LDT’s that have been identified as non-FDA approved are summarily denied. In contrast The Centers for Medicare & Medicaid Services (CMS), which is not constrained by any similar regulation, has a policy that provides a mechanism for the review and payment of LDTs meeting the CMS standard of reasonable and necessary meaning it is safe and effective, not experimental or investigational, and appropriate.

An LDT is a test developed by a single clinical laboratory that provides testing to the public but does not sell the lab kit to other labs. In the past, these tests were relatively simple tests used to diagnose or monitor diseases and other conditions within a single laboratory usually at a local large hospital or academic medical center. As a result the FDA has utilized enforcement discretion (where the FDA does not enforce some or all applicable laws and regulations on certain categories of products) of LDTs and has taken no action to remove them from the marketplace.

The 1976 Device Amendments modified the Federal Food, Drug, and Cosmetic Act (FFDCA) to provide for the regulation of medical devices. These medical devices are defined broadly in section 201(h) of 21 U.S.C. 321 to include: “an instrument, apparatus, implement, machine, continuance,