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.*

[FR Doc. 2011–33070 Filed 12–23–11; 8:45 am]

**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,

implant, in vitro reagent, or similar or related articles, including any component, part or accessory which is * * * intended for use in the diagnosis or disease or other conditions, or in the cure, mitigation, treatment or prevention of disease.'' Medical devices include laboratory tests also known as in vitro diagnostics (IVDs).

The FDA authority over IVDs, which includes LDTs, is defined in 21 CFR 809.33 as: ''those reagents, instruments, and systems intended for use in diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae. Such products are intended for use in the collection, preparation, and examination of specimens taken from the human body.'' The FDA has stated that clinical laboratories that develop LDTs are acting as manufacturers of medical devices and are subject to FDA jurisdiction under the FFDCA. As noted, the FDA has chosen to exercise its ''enforcement discretion'' over many LDTs and these tests are routinely sold without FDA approval.

The Analytic Specific Reagents rule was published in 1997 (21 CFR 864.4020) where FDA regulates the primary active reagents of laboratory developed tests rather than the LDTs themselves. The intent was to ensure the quality of the test components and to continue enforcement discretion for LDTs.

During the 2000's LDTs were developed and becoming more complex at an increasingly fast pace. In response FDA issued draft guidance relating to In Vitro Diagnostic Multivariate Index Assays, a particularly complex category of tests in 2007. A final rule has yet to be published. Recently in July 2011, the FDA released draft guidance on In Vitro Companion Diagnostic Devices which are devices that provide information that is essential for the safe and effective use of a corresponding therapeutic agent.

Laboratories are assessed and accredited under quality standards set by CMS under the Clinical Laboratory Improvement Amendments (CLIA) of 1988. CMS regulates laboratories that use LDTs as well as FDA approved 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 periodic inspections ensure the analytical validity of laboratory tests, 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.

In contrast to TMA, CMS regulations do not have a specific requirement that devices be FDA approved. As a result CMS policy provides a mechanism for the review and payment of non-FDA approved LDTs (Section 522 of the Benefits Improvement and Protection Act). Non-FDA approved LDTs which meet CMS's standards are approved through its National Coverage Determination (NCD) or Local Coverage Determination (LCD) process. Once a LDT receives a LCD, it is considered a nationwide Medicare covered benefit.

**B. Demonstration Project Description**

A demonstration project will be initiated by the TMA to test whether CMS approved LDTs which have not received FDA medical device 510(k) clearance or premarket approval (therefore considered non-FDA approved) are safe and effective for cost-sharing for TRICARE beneficiaries. The LDTs for this demonstration would be limited to only those that significantly inform clinical decision-making for surveillance, surgical intervention, chemotherapy, or radiation therapy for cancer. The demonstration project will be effective 30 days after publication in the **Federal Register** and will continue for three years from the effective date of the original demonstration. The demonstration project will establish a process for TRICARE to evaluate the subset of non-FDA approved LDTs currently covered by a CMS NCD or LCD.

Upon publication of this **Federal Register** notification, TMA will solicit submissions from LDT device manufacturers and individual (single) laboratories which develop their own proprietary laboratory developed tests requests for DoD coverage of their LDTs. LDTs with current FDA 510(k) clearance or premarket approval will not be considered for this demonstration project; but will continue to be considered for coverage under the current routine coverage determination process of the TRICARE Program. Submissions must include evidence of CMS LCD or NCD approval and a statement from the manufacturer or laboratory attesting that the LDT has not received FDA medical device clearance or approval for marketing. CLIA certification is also required and a copy of the certificate should be included. If a submission is not received for an eligible LDT, TMA may elect to add the LDT to the list for consideration; but a manufacturer should not assume that their product will be considered without a submission. Submissions will be accepted for 90 calendar days from the date of publication of the demonstration project in the **Federal Register**.

All submissions will be reviewed by the Department of Defense (DoD) Laboratory Joint Working Group (LJWG), appointed by the Director, TMA. The LJWG team will be comprised of government clinical and policy professionals (DoD employees or active duty service members) to include; medical specialists, clinical laboratory medicine specialists, and medical benefits specialists. The LJWG will prioritize the list of LDTs based on the potential high utilization and potential high clinical impact on TRICARE beneficiaries. Administrative information from DoD clinical information systems relating to number of diagnoses of specific oncological diseases, procedures, treatments, and other requested data and information will be used in the prioritization process. LDTs used for non-covered conditions or tests related to unproven treatments will not be eligible for coverage and thus will not be recommended by the LJWG.

The prioritized list will be submitted to the Director, TMA for approval of the test as well as its priority placement on the list. Once an approved list has been obtained, a health care technology assessment and review for analytical validity, clinical validity, and clinical utility will be conducted. All health care technology assessments will be based on the TRICARE hierarchy of reliable evidence, as defined below, for criteria for safety and efficacy. CLIA certification will meet the requirement of analytical validity. Clinical validity and clinical utility are defined in the Agency of Healthcare Research and Quality (AHRQ) report titled, ''Quality, Regulation and Clinical Utility of Laboratory-developed Molecular Tests, Project ID: LABC0707. In this report clinical validity is defined as: ''test characteristics (sensitivity, specificity, predictive values, and likelihood ratios) in other words, the accuracy with which a test predicts the presence or absence of a clinical condition or predisposition. Clinical utility is defined as: ''whether the results of the test can be used to pursue effective treatment or provide other concrete clinical benefit,'' that is the usefulness of the test and the value of the information to medical practice. These standards will be used in determining if an LDT meets the requirements for clinical validity and clinical utility.

The LJWG will conduct a review of the LDT using the evidence which

meets the hierarchy of reliable evidence as well as the evidence outlined above which meet the requirements for analytical validity, and clinical validity and utility. The definition of reliable evidence which will be used by the LJWG is defined in 32 CFR 199.2(b) and includes: ''(i) Well-controlled trials of clinically meaningful endpoints, published in refereed medical literature, (ii) Published formal technology assessments, (iii) Published reports of national medical policy organization positions, (iv) Published national professional associations, and (v) Published reports of national expert opinion organizations.'' The hierarchy of reliable evidence of proven medical effectiveness, established by (i) through (v) of this paragraph, is the order of the relative weight to be given to any particular source. With respect to clinical studies, only those reports and articles containing scientifically valid data and published in the refereed medical and scientific literature shall be considered as meeting the requirements of reliable evidence. Specifically not included in the meaning of reliable evidence are reports, articles, or statements by providers or groups of providers containing only abstracts, anecdotal evidence or personal professional opinions. Also not included in the meaning of reliable evidence is the fact that a provider or a number of providers have elected to adopt a drug, device, or medical treatment or procedure as their personal treatment or procedure of choice or standard of practice. By majority vote the LJWG would recommend approval or disapproval to the Director, TMA. Approved LDTs would be available for cost-sharing with TRICARE beneficiaries.

**C. Final Coverage Decisions**

LDTs (evaluated under the demonstration project) determined by the JLWG to meet the TRICARE hierarchy of evidence for safety and effectiveness will be recommended to the Director, TMA for decision for acceptance for cost-sharing during the demonstration period. LDTs approved by the Director, TMA for cost-sharing will follow existing processes for inclusion as a TRICARE benefit. Additional information on payment methodologies will be included in the operational procedures for this Demonstration and will be published in the TRICARE Operations Manual found at *http://manuals.tricare.osd.mil/.*

**D. Implementation**

The demonstration is effective 30 days after publication in the **Federal Register** and will continue for a period of three years from the date of the original demonstration unless terminated earlier by the Director, TMA. LDTs approved by the Director, TMA during the demonstration period will become available for cost-sharing for qualified TRICARE beneficiaries during the demonstration period. Should the FDA issue final guidance on and or enforcement of the requirement for prior marketing approval, the Director TMA will terminate the demonstration and the DoD will ensure compliance with applicable federal law and regulations.

**E. Evaluation**

An evaluation will be conducted during the third year of the demonstration period to determine how many TRICARE approved LDTs were provided to beneficiaries across all TRICARE Regions. The evaluation will also include a review of the LDT review and recommendation process. These results of the evaluation will provide a valuation of the potential improvement of the quality of healthcare services for beneficiaries who would not otherwise had access to these safe and effective tests. Based on the utilization results, a decision will be made to modify 32 CFR 199.4(g)(15)(i)(A) to remove the restriction for non-FDA approved devices and allow TRICARE cost-sharing of CMS approved LDTs determined to meet the TRICARE criteria for safety and effectiveness.

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 Prime Urgent Care 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 title 10, U.S. Code, section 1092, entitled Department Of Defense TRICARE Prime Urgent Care Demonstration Project. The demonstration project is intended to test whether allowing four visits to an urgent care center without requiring a referral from the Primary Care Manager (PCM) will improve access to urgent care including minor illness or injury for Active Duty Family Members enrolled in TRICARE Prime or TRICARE Prime Remote while reducing the overall costs of such care to the DoD. The Department currently has a demonstration to test this same provision for U.S. Coast Guard personnel. However, this demonstration is being conducted outside of the Coast Guard population in order to be able to evaluate the impact on ADFMs who tend to be a more mobile population than the Coast Guard members and their families. Current data indicates that the ADFMs frequently need urgent care while traveling to new duty stations for permanent orders or training and when traveling to temporary locations while a member is deployed. Under the demonstration, ADFMs who are enrolled in TRICARE Prime or TRICARE Prime Remote would be allowed to self-refer, without an authorization, to a TRICARE network provider such as an Urgent Care Clinic (UCC) or Convenience Center for up to four urgent care visits per year. No referral from their PCM or authorization by a Health Care Finder will be required and no Point of Service (POS) deductibles and cost shares shall apply to these four unmanaged visits. The ADFMs will be required to notify their PCM of any urgent/acute care visits to other than their PCM within 24 hours of the visit and schedule any follow-up treatment that might be indicated with their PCM. If more than the four (4) authorized urgent care visits are used, or if the beneficiary seeks care from a non TRICARE network or non TRICARE authorized provider, POS deductibles and cost shares as required by Title 32, Code of Federal Regulations, Section 199.17 (n)(3) may apply. Referral requirements for specialty care and inpatient authorizations will remain as currently required by MHS policy. At the conclusion of the demonstration, data will be analyzed to determine if use of this ability to seek urgent care without a referral is used more or less frequently by a more mobile population than a stable population in order to determine whether the overall costs to the government have decreased due to a reduced usage of emergency care facilities by this same population.

**DATES:** This demonstration will be effective 60 days from the date of this notice in the **Federal Register** for a period of thirty-six (36) months.

**ADDRESSES:** TRICARE Management Activity (TMA), Health Plan Operations, 5111 Leesburg Pike, Suite 810, Falls Church, VA 22041.

**FOR FURTHER INFORMATION CONTACT:** For questions pertaining to this