

July 1, 2014

Major General Richard W. Thomas, MD

Chief Medical Officer and Director

Defense Health Agency, Healthcare Operations Directorate

7700 Arlington Boulevard  
Falls Church, VA 22042

Dear General Thomas:

On behalf of the American Clinical Laboratory Association (“ACLA”) and our members, I am writing to express our appreciation for the recent action by the Defense Health Agency (“DHA”) to establish a demonstration project to allow for coverage of certain Laboratory Developed Tests (“LDTs”).[[1]](#footnote-1) As we discussed in our meeting with you and your team on April 22nd, we are committed to working with the DHA to ensure TRICARE beneficiaries have access to laboratory developed tests. We are writing today to make clear our desire to work with DHA in the implementation of this new demonstration project. We would like to meet with you and others at DHA in the near future to offer suggestions for how we might be of assistance during the demonstration project and to obtain a better understanding of DHA’s plans for implementation.

ACLA represents providers of clinical laboratory services, including national, regional, and esoteric laboratories. Virtually all ACLA members provide LDTs, which are laboratory tests that are developed and validated by clinical laboratories for use in-house, rather than for sale as laboratory “kits.” As DHA recognizes in its Notice, FDA exercises “enforcement discretion” with regard to LDTs, and does not require laboratories to seek premarket approval or clearance for them. ACLA was deeply concerned about DHA’s previous policy, which denied coverage and payment for some LDTs, and created a hardship for some TRICARE beneficiaries.

ACLA appreciates the decision of DHA to establish a process for coverage of LDTs that can be shown to be safe and effective. As we have discussed, LDTs are generally considered standard of care today and are an integral part of the practice of medicine, generally, and also “personalized medicine,” which allows physicians to target particular therapies to those who are most likely to benefit from them. ACLA strongly believes that if TRICARE beneficiaries were not able to access LDTs, they would be denied the same high quality medical care that is available to other patients outside the TRICARE system. We especially welcome the decision of DHA to cover prenatal and preconception cystic fibrosis carrier screening, which, as DHA notes, “is widely recognized and commonly provided as part of routine obstetric practice.” [[2]](#footnote-2)

Although the Notice did not seek comments or input from stakeholders, ACLA is writing today to offer several suggestions, which, we hope, will help facilitate the implementation of the demonstration project. First, we note that the Notice does not specify how DHA will select LDTs for review and coverage within the demo other than stating that DOD’s Laboratory Joint Working Group (LJWG) “will prioritize the LDTs based on their potential for high utilization and high clinical utility.”[[3]](#footnote-3) Our reading of the Notice leads us to believe that the LJWG has already identified a number of LDTs for coverage under the demo and we encourage DHA to publish, as soon as possible, this list of covered LDTs so that providers and patients can make informed clinical decisions based on the new coverage.

Additionally, we believe DHA should establish a clear process by which laboratories can submit applications and clinical evidence to the LJWG for determining coverage of additional tests. We note that under the previous LDT demonstration project initiated in 2012 related to tests used for the diagnosis and treatment of cancer, laboratories filed applications with the agency in order to begin the coverage process.[[4]](#footnote-4) Such a process would facilitate the collection of clinical evidence for tests identified by the LJWG; allow laboratories to apply for coverage of other clinically meaningful services; and create a clear coverage process for new laboratory services yet to be considered by DHA.

Laboratories routinely assemble this information in connection with technology assessments by other payors and we believe it would be helpful to submit this information to DHA to assist in the review process. We believe such a process will reduce the work for the Department’s LJWG, which otherwise will be tasked with researching and assembling all of this information, a process that would be arduous and time-consuming. If laboratories are permitted to assist in this effort, it will result in a faster and more efficient review process. We would like to work with you in establishing such a clinical evidence and submission process.

Finally, we also request the opportunity to meet with DHA to gain a better understanding of how it plans to implement certain aspects of this demonstration project. In particular, we would like to understand the process that DHA will determine reimbursement for those tests deemed eligible for coverage and how new LDTs that become available during the demo will be handled. For instance, a press release issued by the Department has suggested that regional contractors will have to “preapprove use” of the tests for them to be covered.[[5]](#footnote-5) This requirement was not included in the actual Notice and we are unclear what the basis would be for such a requirement and could easily result in geographic variation in reimbursement that adversely impact beneficiaries. For new LDTs, we believe an explicit application process, as noted above, would greatly reduce the burden of coverage decisions going forward and, thus, increase access for patients to the highest quality clinical laboratory services.

Major General Thomas, thank you again for your willingness to work with ACLA and our members to address coverage issues with some laboratory developed tests. We appreciate your willingness to consider our comments and look forward to hearing from you.

Sincerely,



Julie Khani

Senior Vice President

1. Notice of Demonstration, 79 Fed. Reg. at 34726 (June 18, 2014)(hereinafter “the Notice”.) [↑](#footnote-ref-1)
2. *Id*. at 34727. [↑](#footnote-ref-2)
3. *Id.* At 34728. [↑](#footnote-ref-3)
4. Notice of Demonstration, 76 Fed. Reg. at 80905-80907 (December 27, 2011). [↑](#footnote-ref-4)
5. “TRICARE Launches New Laboratory Developed Test Demonstration” (Press Release), TRICARE HEALTH PLAN, (June 18, 2014) (<http://www.health.mil/Reference-Center/Articles/2014/06/18/TRICARE-Launches-New-Laboratory-Developed-Test-Demonstration>). [↑](#footnote-ref-5)