Secretary of the Army and based upon the subject matters under consideration.

Subcommittee members, if not full-time or permanent part-time Federal employees, shall be appointed as experts or consultants, pursuant to 5 U.S.C. 3109, to serve as special government employee members. Those individuals who are full-time or permanent part-time Federal employees will be appointed, pursuant to 41 CFR 102–3.130(a), to serve as RGE members.

With the exception of reimbursement for official Task Force-related travel and per diem, subcommittee members shall serve without compensation.

All subcommittees operate under the provisions of FACA, the Sunshine Act, governing Federal statutes and regulations, and established DoD policies and procedures.

The Designated Federal Officer (DFO), pursuant to DoD policy, shall be a full-time or permanent part-time DoD employee, and shall be appointed in accordance with established DoD policies and procedures.

In addition, the DFO is required to be in attendance at all meetings of the Task Force and any subcommittees, for the entire duration of each and every meeting; however, in the absence of the DFO, a properly approved Alternate DFO, duly appointed to the Task Force according to established DoD policies and procedures, shall attend the entire duration of all meetings of the Task Force or its subcommittees.

The DFO or the Alternate DFO, shall call all meetings of the Task Force and its subcommittees; prepare and approve all meeting agendas; and adjourn any meeting when the DFO, or the Alternate DFO, determines adjournment to be in the public interest or required by governing regulations or DoD policies and procedures.

Pursuant to 41 CFR 102–3.105(j) and 102–3.140, the public or interested organizations may submit written statements to Missouri River (North Dakota) Task Force membership about the Task Force's mission and functions. Written statements may be submitted at any time or in response to the stated agenda of planned meeting of Missouri River (North Dakota) Task Force.

All written statements shall be submitted to the DFO for the Missouri River (North Dakota) Task Force, and this individual will ensure that the written statements are provided to the membership for their consideration. Contact information for the Missouri River (North Dakota) Task Force DFO can be obtained from the GSA's FACA Database—*http://www.facadatabase.gov/.* The DFO, pursuant to 41 CFR 102–3.150, will announce planned meetings of the Missouri River (North Dakota) Task Force. The DFO, at that time, may provide additional guidance on the submission of written statements that are in response to the stated agenda for the planned meeting in question.

Dated: June 12, 2014.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2014–14165 Filed 6–17–14; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Defense Health Agency Evaluation of Non-United States Food and Drug Administration; 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 Title 10, United States Code, Section 1092, entitled Defense Health Agency (DHA) Evaluation of Non-United States Food and Drug Administration (FDA) Approved Laboratory Developed Tests (LDTs) Demonstration Project. The demonstration project is intended to further evaluate whether it is feasible for the Department of Defense (DoD) to review LDTs not yet examined by the FDA to determine if they meet TRICARE's requirements for safety and effectiveness according to the hierarchy of reliable evidence (32 CFR 199.4(g)(15)(i)(C) and 32 CFR 199.2(b)), or TRICARE's rare disease policy (32 CFR 199.4(g)(15)(ii)) in the case of LDTs used in the diagnosis or medical management of a rare disease (32 CFR 199.2(b)), and allow those that do to be covered as a benefit under the TRICARE Program. The demonstration project will evaluate feasible alternatives to support modifications to 32 CFR 199.4(g)(15)(i)(A) to allow coverage for non-FDA approved LDTs that otherwise meet the TRICARE requirements for safety and effectiveness. The Department currently has an ongoing demonstration project to test this same provision for LDTs with a Center for Medicare and Medicaid Services (CMS) national or local coverage determination that were submitted by laboratories for consideration for coverage under TRICARE. However, this new demonstration is being conducted in order to be able to evaluate the feasibility of establishing a cost-effective and efficient way to review an expanded pool of non-FDA approved LDTs prioritized based on their potential high utilization and clinical utility within the TRICARE population. This new demonstration project will also extend coverage for prenatal and preconception cystic fibrosis carrier screening, when provided in accordance with the American College of Obstetricians and Gynecologists guidelines in order to allow DoD to establish whether there is a benefit to offering such testing to TRICARE beneficiaries.

DATES: This demonstration will be effective July 18, 2014. This demonstration will remain in effect for three years.

ADDRESSES: Defense Health Agency, Attn: Clinical Support Division, 7700 Arlington Blvd., Falls Church, VA 22040.

FOR FURTHER INFORMATION CONTACT: Jim Black, Clinical Support Division, Defense Health Agency, Telephone (703) 681–0068.

SUPPLEMENTARY INFORMATION:

A. Background

1. LDTs

According to 32 CFR 199.4(g)(15)(i)(A), TRICARE may not cost-share medical devices including LDTs if the tests are non-FDA cleared or approved; that is, they have not received FDA medical device 510(k) clearance or premarket approval. For purposes of this demonstration, LDTs that are not FDA cleared or approved will hereinafter be referred to as non-FDA approved for brevity purposes. Under the current regulation cited above, LDTs that have been identified as non-FDA approved are summarily denied.

An LDT is an in vitro diagnostic (IVD) that is designed, manufactured, and used within a single laboratory. In the past, these tests were relatively simple tests used within a single laboratory, usually at a local large hospital or academic medical center, to diagnose rare diseases or for other uses to meet the needs of a local patient population. The FDA has exercised enforcement discretion in that the agency has generally not enforced applicable provisions under the Federal Food, Drug, and Cosmetic Act (FFDCA) and its regulations with respect to LDTs.

The 1976 Medical Device Amendments modified the FFDCA to provide for a comprehensive system for the regulation of medical devices. The term ''device'' is defined broadly in 21 U.S.C. 321(h) to include: ''an

instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part or accessory, which is * * * intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease.'' Medical devices include IVDs.

FDA regulations in 21 CFR 809.3 define ''in vitro diagnostic products'' 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.'' As explained above, LDTs are a subset of IVDs. 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 Analyte Specific Reagents (ASRs) rule was published in 1997 (21 CFR 864.4020), classifying most ASRs (ASRs are considered to be the ''active ingredients'' of tests) as Class I devices. The intent was to ensure the quality of the test components and to continue enforcement discretion for LDTs.

During the 2000s, LDTs became more complex at an increasingly fast pace. In response, the FDA issued draft guidance in 2007 relating to In Vitro Diagnostic Multivariate Index Assays, a particularly complex category of tests. Final guidance has yet to be published. In July 2010, the FDA held a public meeting to discuss the agency's oversight of LDTs. In announcing the public meeting, the FDA explained:

> At the same time as LDTs are becoming more complex, diagnostic tests are playing an increasingly important role in clinical decision making and disease management, particularly in the context of personalized medicine. However, LDTs that have not been properly validated for their intended use put patients at risk. Risks include missed diagnosis, wrong diagnosis, and failure to receive appropriate treatment. . . . [and] some diagnostics critical for patient care may not be developed in a manner that provides a reasonable assurance of safety and effectiveness.
>
> (75 FR 34463–34464)

The FDA has continued its policy of enforcement discretion over LDTs and no new draft or final guidance on the regulation of LDTs has been issued since the enactment of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012.

Laboratories are assessed and accredited under minimum 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 evaluate whether the laboratory has determined the analytical validity of the tests they offer, 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. CLIA certification does not, however, assure a device is safe and effective for its intended use, or impose any type of postmarket surveillance or adverse event reporting requirements.

On December 27, 2011, the DoD published a notice in the **Federal Register** (76 FR 80905–80907), announcing the TRICARE Evaluation of Centers for Medicare and Medicaid Services (CMS) Approved Laboratory Developed Tests (LDTs) Demonstration Project. LDTs for this demonstration were limited to only those that had a CMS national or local coverage determination and significantly informed clinical decision making for surveillance, surgical interventions, chemotherapy, or radiation therapy for cancer. This three year demonstration will continue until it expires or is terminated via separate notice and LDTs covered under the current demonstration will continue to be covered. The demonstration project was based on interested laboratories submitting their LDTs for consideration. Limited participation from industry in the demonstration served as a constraining factor and did not provide sufficient data for the DoD to make an affirmative decision regarding the feasibility of developing a cost-effective and efficient method of reviewing non-FDA approved LDTs under TRICARE's requirements for safety and efficacy.

2. TRICARE Coverage of Cystic Fibrosis Testing

In general, the TRICARE program has been, and continues to be, a benefit program based on medical necessity. The current TRICARE maternity benefit is limited to coverage of medically necessary services and supplies associated with maternity care in accordance with 32 CFR 199.4(e)(16). Further, TRICARE covers genetic testing that is medically necessary and appropriate in the diagnosis and/or treatment of a disease and when the results of the test will influence the medical management of the individual or pregnancy. Routine genetic testing, including carrier screening, that does not influence a beneficiary's medical management is specifically excluded from TRICARE coverage.

For cystic fibrosis (CF) testing in particular, TRICARE covers CF testing when performed as part of a newborn screening panel as part of well-child care. TRICARE will also cover diagnostic genetic testing for CF when it is performed on individuals to confirm a clinical diagnosis that is already suspected. TRICARE does not, however, cover pre-conception CF carrier screening for couples planning a pregnancy, pre-implantation CF screening of embryos, or prenatal CF screening of pregnant women since the results do not assist in the medical management of the patient or pregnancy. Awareness that a fetus is at increased risk of having CF, in and of itself, does not usually change the management of labor, delivery, and the neonatal period. Additionally, newborn screening panels, which are performed shortly after birth, include tests for a number of conditions including CF, and are a TRICARE covered benefit.

Notwithstanding current TRICARE benefit limitations, the Department of Defense is aware of the widespread acceptance the American College of Obstetricians and Gynecologists (ACOG) guidelines of carrier screening for CF have received. Carrier screening for CF has been widely recognized and commonly provided as part of routine obstetric practice.

B. Demonstration Project Description

1. Review of LDTs

Consequently, the DoD will initiate a new and expanded demonstration project to test whether non-FDA approved LDTs meet TRICARE's requirements for safety and effectiveness in order to permit TRICARE cost-sharing. 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 this demonstration. The new demonstration project will evaluate the feasibility of establishing a cost-effective and efficient way to review an expanded pool of non-FDA approved LDTs. For example,

LDTs evaluated under the new demonstration are not limited to those associated with cancer and do not require a CMS national or local coverage determination. Further, consideration of specific gene testing as part of the ongoing demonstration project, discussed above, does not also prevent consideration under the new demonstration project.

Non-FDA approved LDTs will be prioritized and reviewed for analytical validity, clinical validity, and clinical utility. LDT reviews will be based on the TRICARE hierarchy of reliable evidence, as defined below, to determine whether the specific test is proven safe and effective for TRICARE cost-sharing purposes.

Reliable evidence is defined in 32 CFR 199.2(b) and includes: ''(i) Well-controlled studies of clinically meaningful endpoints, published in refereed medical literature; (ii) Published formal technology assessments; (iii) The published reports of national professional medical associations; (iv) Published national medical policy organization positions; and (v) The published reports of national expert opinion organizations.'' The definition goes on to state, ''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.''

There may also be non-FDA approved LDTs reviewed under the new demonstration project for use in the diagnosis or medical management of a rare disease. In accordance with 32 CFR 199.2(b), TRICARE defines a rare disease as any disease or condition that has a prevalence of less than 200,000 persons in the United States. Due to the rare nature of the condition and lack of clinical research, the hierarchy of reliable evidence as described previously may not be met. In accordance with 32 CFR 199.4(g)(15)(ii), benefits for rare diseases are reviewed on a case-by-case basis. In reviewing proposed benefits for rare diseases under the new demonstration, consistent with TRICARE's rare disease policy, a proposed LDT for a rare disease may be reviewed for analytical validity, clinical validity, and clinical utility from any or all of the following sources to determine if the proposed LDT for a rare disease is considered safe and effective for TRICARE cost-sharing purposes: (i) Trials published in refereed medical literature; (ii) Formal technology assessments; (iii) National medical policy organization positions; (iv) National professional associations; and, (v) National expert opinion organizations.

The DoD's Laboratory Joint Working Group (LJWG) will be responsible for prioritizing and reviewing the non-FDA approved LDTs for the new demonstration. Representatives are appointed by the Assistant Secretary of Defense (Health Affairs) and are comprised of government clinical and policy professionals (DoD employees and Active Duty Service Members). Reliable evidence reviews may also be performed by a third party with the appropriate expertise and recommendations provided to the LJWG.

The LJWG will prioritize the LDTs based on their potential high utilization and high clinical utility within the TRICARE population based on existing direct and purchased care data. LDTs used for non-covered conditions or tests related to unproven treatments will not be eligible for coverage and thus will not be reviewed under the new demonstration or recommended by the LJWG. Selected LDTs will be evaluated using the hierarchy of reliable evidence or rare disease policy as outlined above. By majority vote, the LJWG will recommend approval or disapproval to the Director, DHA, or designee. Approved LDTs will be available for cost-sharing under the new demonstration.

2. LDT Coverage Decisions Under the New Demonstration

Non-FDA approved LDTs determined to meet TRICARE's requirements for safety and effectiveness according to the hierarchy of reliable evidence or rare disease policy, and otherwise meet TRICARE criteria for coverage, will be recommended to the Director, DHA, or designee, for decision for approval for cost-sharing during the new demonstration period. The effective date for coverage of specific LDTs approved under the new demonstration project will be the later of: (1) January 1, 2013; or (2) the date on which there is sufficient reliable evidence to determine that the specific LDT is proven safe and effective for TRICARE cost-sharing purposes. LDTs that have been approved by the Director, DHA, or designee, under the new demonstration, as well as LDTs that have been evaluated under the new demonstration and found to lack sufficient reliable evidence of safety and efficacy and thus remain excluded from coverage, will be appropriately documented in the TRICARE Operations Manual (TOM) following existing processes. Additional information on payment methodologies will be included in the operational procedures for the new demonstration and will be published in the TOM found at *http://manuals.tricare.osd.mil/*.

Decisions regarding which LDTs are reviewed under the new demonstration, including the priority of review, are not appealable. Additionally, in order to dedicate maximum resources to the review of LDTs under the new demonstration, no formal appeal rights will be extended for tests that are reviewed under the new demonstration and found to lack sufficient reliable evidence of safety and efficacy. Should the new demonstration project be deemed successful and permanent regulatory authority enacted, appeal rights will be available as provided in 32 CFR 199.10.

3. Coverage of CF Carrier Screening Under the Demonstration

This new demonstration project will also extend coverage for prenatal and preconception CF carrier screening, when provided in accordance with the ACOG guidelines. This demonstration project will allow DoD to establish whether there is a benefit to offering such testing for purposes of determining whether to permanently establish coverage as part of the family planning genetic testing benefit at 32 CFR 199.4(e)(3)(ii), the maternity benefit at 32 CFR 199.4(e)(16), or otherwise as a special benefit. By extending coverage for CF carrier screening in accordance with ACOG guidelines under this demonstration project DoD will be able to gather the necessary data to evaluate whether there is a benefit to offering such screening, including evaluating the impact on follow-on care that a patient is given based on testing results and any other identified benefits of the testing. The Director, DHA (or designee) shall issue guidelines for collection of data involving individual cases of CF carrier screening covered under this demonstration as necessary for evaluation of the benefits resulting from

such screening. This demonstration project will extend coverage for this testing from January 1, 2013 through the end of the demonstration in order to obtain sufficient data to be able to conduct a cost benefit analysis of providing this screening for our beneficiary population.

D. Implementation

The new 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, DHA. LDTs approved by the Director, DHA, or designee, during the new demonstration period will become available for cost-sharing for qualified TRICARE beneficiaries during the demonstration period when performed by CLIA certified laboratories. Should the FDA issue final guidance on LDTs and/or enforce the requirement for clearance or premarket approval for LDTs, the Director, DHA will modify or terminate the demonstration, as appropriate, and the DoD will ensure compliance with applicable federal law and regulations.

E. Evaluation

An annual evaluation of the new demonstration will be conducted 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 examination and recommendation process to assess feasibility, resource requirements, and cost-effectiveness of DHA establishing an internal safety and efficacy review process for these devices for TRICARE cost-sharing purposes. These results of the evaluation will provide an evaluation of the potential improvement of the quality of healthcare services for beneficiaries who would not otherwise have access to these safe and effective tests. Based on the results of the demonstration evaluation, a recommendation will be made on whether to modify 32 CFR 199.4(g)(15)(i)(A) to remove the restriction for non-FDA approved LDTs and permit TRICARE cost-sharing of LDTs that are found to otherwise meet TRICARE requirements for safety and effectiveness. The Department of Defense will also conduct a cost benefit analysis of providing CF carrier screening in accordance with ACOG guidelines to the TRICARE beneficiary population for purposes of determining whether to permanently establish coverage.

Dated: June 13, 2014.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2014–14247 Filed 6–17–14; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2014–ICCD–0090]

Agency Information Collection Activities; Comment Request; Report of Infants and Toddlers Receiving Early Intervention Services and of Program Settings Where Services Are Provided in Accordance With Part C

AGENCY: Office of Special Education and Rehabilitative Services (OSERS), Department of Education (ED)

ACTION: Notice

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 3501 *et seq*.), ED is proposing an extension of an existing information collection.

DATES: Interested persons are invited to submit comments on or before August 18, 2014.

ADDRESSES: Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting Docket ID number ED–2014–ICCD–0090 or via postal mail, commercial delivery, or hand delivery. If the regulations.gov site is not available to the public for any reason, ED will temporarily accept comments at *ICDocketMgr@ed.gov.* Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted; ED will ONLY accept comments during the comment period in this mailbox when the regulations.gov site is not available. Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Mailstop L–OM–2–2E319, Room 2E105, Washington, DC 20202.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Meredith Miceli, 202–245–6028.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Report of Infants and Toddlers Receiving Early Intervention Services and of Program Settings Where Services are Provided in Accordance with Part C.

OMB Control Number: 1820–0557.

Type of Review: Revision of a currently approved collection.

Respondents/Affected Public: State, Local, or Tribal Governments.

Total Estimated Number of Annual Responses: 56.

Total Estimated Number of Annual Burden Hours: 6,697.

Abstract: This data collection provides instructions and forms necessary for States to report the number of children receiving early intervention services under Part C of Individuals with Disabilities Education Act (IDEA), the settings in which these children are provided services, and the reasons by which these children exit Part C of IDEA. The form satisfies reporting requirements and is used by OSEP to monitor State agencies and for Congressional reporting.

Dated: June 13, 2014.

Stephanie Valentine,

Acting Director, Information Collection Clearance Division, Privacy, Information and Records Management Services, Office of Management.

[FR Doc. 2014–14262 Filed 6–17–14; 8:45 am]

BILLING CODE 4000–01–P