collection may be sent by any of the following methods:

- *Mail:* Joanna Reynolds, Agency Submitting Officer, U.S. International Development Finance Corporation, 1100 New York Avenue NW, Washington, DC 20527.
- *Email: fedreg@dfc.gov.*

Instructions: All submissions received must include the agency name and agency form number or OMB form number for this information collection. Electronic submissions must include the agency form number in the subject line to ensure proper routing. Please note that all written comments received in response to this notice will be considered public records.

FOR FURTHER INFORMATION CONTACT: Agency Submitting Officer: Joanna Reynolds (202) 357–3979.

SUPPLEMENTARY INFORMATION: This notice informs the public that DFC will submit to OMB a request for approval of the following information collection.

Summary Form Under Review

Title of Collection: Development Outcomes Survey (DOS).

Type of Review: New information collection.

Agency Form Number: DFC–008.

OMB Form Number: Not assigned, new information collection.

Frequency: Once per investor per project per year.

Affected Public: Business or other for-profit; not-for-profit institutions; individuals.

Total Estimated Number of Annual Number of Respondents: 800.

Estimated Time Per Respondent: 2.0 hours.

Total Estimated Number of Annual Burden Hours: 1600 hours.

Abstract: The Development Outcomes Survey (DOS) is the principal document used by the DFC to review and update a client's developmental impact profile and determine the project's compliance with environmental, labor, and economic policies, as consistent with DFC's authorizing legislation. It will be a comprehensive survey designed to track project performance as compared to their baseline data collected during the application process.

Dated: July 6, 2020.

Nichole Skoyles,

Administrative Counsel, Office of the General Counsel.

[FR Doc. 2020–14844 Filed 7–9–20; 8:45 am]

BILLING CODE 3210–02–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Notice of Three-Year Extension of Defense Health Agency Evaluation of Non-United States Food and Drug Administration Approved Laboratory Developed Tests Demonstration Project

AGENCY: Office of the Secretary, Department of Defense (DoD).

ACTION: Notice of demonstration project extension.

SUMMARY: This notice is to advise interested parties of an additional three-year extension of a demonstration project entitled Defense Health Agency (DHA) Evaluation of Non-United States Food and Drug Administration (FDA) Approved Laboratory Developed Tests (LDTs) Demonstration Project. The original notice was published on June 18, 2014. The notice extending the demonstration project for three years was published on June 20, 2017.

DATES: This extension is applicable July 19, 2020.

ADDRESSES: Defense Health Agency (DHA), 16401 East Centretech Parkway, Aurora, CO 80011–9066.

FOR FURTHER INFORMATION CONTACT: Valerie Palmer, Defense Health Agency, 303–676–3557, *valerie.a.palmer3.civ@mail.mil;* Jim Black, Defense Health Agency, 303–676–3487, *james.n.black.civ@mail.mil.*

SUPPLEMENTARY INFORMATION: For additional information on the DHA Evaluation of Non-United States FDA Approved LDTs Demonstration Project (hereinafter referred to as the ''LDT demonstration''), please see 79 FR 34726–34729 and 82 FR 28052. According to Title 32, Code of Federal Regulations (CFR), Part 199.4, paragraph (g)(15)(i)(A), TRICARE may not cost-share medical devices, including LDTs, that have not received FDA medical device 510(k) clearance or premarket approval. LDTs with FDA approval are available for cost-sharing under the TRICARE Basic Program as long as they otherwise meet TRICARE criteria for coverage.

On June 18, 2014, a notice was published in the **Federal Register** (79 FR 34726) announcing the start of the LDT demonstration initiated by the DHA to review non-FDA approved LDTs to determine if they meet TRICARE's requirements for safety and effectiveness, and otherwise meet TRICARE criteria for coverage, and allow those that do to be covered as a benefit under the demonstration. This demonstration also extends coverage for preconception and prenatal cystic fibrosis (CF) carrier screening, when provided in accordance with the most current American College of Obstetricians and Gynecologists (ACOG) guidelines. The purpose of this demonstration is to improve the quality of health care services for TRICARE beneficiaries.

Currently, non-FDA approved LDTs covered under the LDT demonstration are available for cost-sharing for qualified TRICARE beneficiaries only when performed by laboratories that are assessed and accredited under minimum quality standards set by the Centers for Medicare and Medicaid Services (CMS) under the Clinical Laboratory Improvement Amendments (CLIA) of 1988, *i.e.,* CLIA certified. CMS regulates laboratories that perform non-FDA approved 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.

The TRICARE Overseas Program (TOP) is the DoD's program for the delivery of health care support services overseas (all locations outside of the 50 United States (U.S.) and the District of Columbia). TOP provides health care coverage for all overseas beneficiaries, including Active Duty Service Members (ADSMs), eligible Reserve Component (RC) personnel, Active Duty Family Members (ADFMs) (including family members of eligible RC personnel), retired military and their respective family members, and transitional survivors. This coverage applies regardless of where the services are received. The delivery of health care services overseas represents a unique situation that cannot be effectively addressed by applying all of the standards that apply in the 50 U.S. and the District of Columbia. TOP blends many of the features of the TRICARE program in the U.S. while allowing for significant cultural differences unique to health care practices and services in

overseas locations. Cultural differences may apply to things like location of care (provider comes to the patient's home), the manner in which care is provided (services commonly done by a provider class in the U.S. may be performed by a provider assistant or physician overseas, depending on the country), or the manner in which claims are submitted to TRICARE. In some situations, TRICARE may authorize coverage for a specific service or supply under the TOP, even though the service or supply would normally be excluded from coverage by TRICARE. Such situations are expected to be rare and are noted in the TRICARE Policy Manual. The TRICARE manuals may be accessed online at *https://manuals.health.mil/.*

The current TOP contractor has noted a unique situation that only occurs overseas. Because the majority of overseas laboratories are not CLIA certified, samples for genetic testing under the LDT demonstration from TOP beneficiaries must be shipped back to the U.S. for processing at CLIA certified laboratories which can be detrimental to the beneficiary's health care. Cold chain shipment may create a sample that becomes unviable. If a new sample is needed from the beneficiary, this means they may not obtain their test results for some time, impacting their diagnosis and/or treatment. Alternatively, individuals are given travel orders to return to the U.S. for the test, an unnecessary and disruptive requirement. As a result, we are providing an exception to the requirement for CLIA certification for overseas laboratories. This notice provides that non-FDA approved LDTs covered under the LDT demonstration shall be available for cost-sharing for qualified TOP beneficiaries when performed by either CLIA certified laboratories or laboratories that are assessed by the TOP contractor to be in accordance with the host nation's credentialing/accreditation standards when those standards for credentialing/accreditation are comparable to CLIA standards.

LDTs provide an important health care capability for the TRICARE Program. LDTs are complex and do have some risks associated with their use, such as inaccurate tests placing patients at otherwise avoidable risk. While laboratories that offer LDTs are subject to the Federal Food, Drug, and Cosmetic Act (FDCA), the FDA has generally exercised enforcement discretion towards these tests, which includes not enforcing applicable provisions under the FDCA and FDA regulations. The FDA's enforcement discretion stance leaves the TRICARE Program in a difficult position because the requirement at 32 CFR 199.4(g)(15)(i)(A) requires LDTs covered in the TRICARE program to be FDA approved. As a result of the FDA's enforcement discretion, many LDTs do not receive FDA approval. LDTs are important and necessary tests and in many instances there are no FDA-approved alternatives. Therefore, the TRICARE program has endeavored to evaluate LDTs through its demonstration project initiated in 2014. Although ongoing for six years, additional work is necessary to ensure that the TRICARE program conducts the appropriate evaluation of these tests based on reliable evidence and permit TRICARE cost-sharing of LDTs that are found to otherwise meet TRICARE requirements for safety and effectiveness. The DoD has determined that continuation of the demonstration project for an additional three years is necessary to provide TRICARE beneficiaries and their health care providers with seamless access to safe and effective, medically necessary tests to support health care decisions and treatment.

During the next three years, the DHA will continue to evaluate the LDT examination and recommendation process to assess feasibility, resource requirements, and the cost-effectiveness of establishing an internal safety and efficacy review process to permit TRICARE cost-sharing for an ever-expanding pool of non-FDA approved LDTs, including tests for cancer risk, diagnosis, and treatment, blood and clotting disorders, a variety of genetic diseases and syndromes, and neurological conditions. The results of the evaluation will provide an assessment of the potential improvement of the quality of health care 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 DoD 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. Our intent is for the demonstration to conclude at the end of this three year extension and additional extensions will not need to be pursued.

The LDT demonstration continues to be authorized by 10 U.S.C. 1092.

Dated: July 7, 2020.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2020–14951 Filed 7–9–20; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

[Docket No. ED–2020–SCC–0030]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; IDEA Part B State Performance Plan (SPP) and Annual Performance Report (APR)

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, ED is proposing a revision of an existing information collection.

DATES: Interested persons are invited to submit comments on or before August 10, 2020.

ADDRESSES: Written comments and recommendations for proposed information collection requests should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection request by selecting ''Department of Education'' under ''Currently Under Review,'' then check ''Only Show ICR for Public Comment'' checkbox.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Rebecca Walawender, 202–245–7399.

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