

information technology; *e.g.*, permitting electronic submission of responses.

All comments must be submitted in English, or if not, accompanied by an English translation. Comments will be posted as received to <https://www.cftc.gov>. You should submit only information that you wish to make available publicly. If you wish the Commission to consider information that you believe is exempt from disclosure under the Freedom of Information Act, a petition for confidential treatment of the exempt information may be submitted according to the procedures established in § 145.9 of the Commission's regulations.¹

The Commission reserves the right, but shall have no obligation, to review, pre-screen, filter, redact, refuse or remove any or all of your submission from <https://www.cftc.gov> that it may deem to be inappropriate for publication, such as obscene language. All submissions that have been redacted or removed that contain comments on the merits of the ICR will be retained in the public comment file and will be considered as required under the Administrative Procedure Act and other applicable laws, and may be accessible under the Freedom of Information Act.

Burden Statement: The Commission is revising its burden estimate for OMB control number 3038-0076 to account for the amendments described above. Specifically, the Commission believes that the burden under this clearance will increase because the 15 DCOs subject to these requirements will be required under § 39.24(b)(11) to create and maintain minutes of each RMC meeting, and under § 39.24(b)(12) to document and provide to the RMC, at a minimum, a summary of the topics discussed and the main points raised during each meeting of the RWG. The Commission estimates a DCO will spend an average of four hours creating minutes of each RMC meeting and four hours documenting a summary of the topics discussed and the main points raised during each meeting of the RWG, which includes attending the meeting, taking notes, and putting the notes into the required format following the meeting. The Commission estimates that a DCO's RMC and RWG will each need to hold an average of six meetings per year to satisfy the § 39.24(b)(11) and (12) requirements that a DCO's RMC and RWG address all matters that could materially affect the risk profile of the DCO. Based upon the above, the estimated hour burden for this collection is calculated as follows:

Estimated number of respondents: 15.²

Estimated number of reports per respondent: 18.

Average number of hours per report: 4.

Estimated gross annual reporting burden: 1,080.

There are no capital costs or operating and maintenance costs associated with this collection.

(Authority: 44 U.S.C. 3501 *et seq.*)

Dated: July 3, 2023.

Christopher Kirkpatrick,
Secretary of the Commission.

[FR Doc. 2023-14358 Filed 7-12-23; 8:45 am]

BILLING CODE 6351-01-P

DEPARTMENT OF DEFENSE

Department of the Army

Notice of Intent To Grant Exclusive Patent License to TauMat, LLC; Silver Spring, MD

AGENCY: Department of the Army, DoD.

ACTION: Notice of intent.

SUMMARY: The Department of the Army hereby gives notice of its intent to grant to TauMat, LLC, a company having its principal place of business at 10010 Portland Place, Silver Spring, MD 20901, an exclusive license.

DATES: Written objections must be filed not later than 15 days following publication of this announcement.

ADDRESSES: Send written objections to U.S. Army Combat Capabilities Development Command Army Research Laboratory, Partnerships Support Office, FCDD-RLB-SS/Wendy Leonard, Building 4402, 6468 Integrity Ct., Aberdeen Proving Ground, MD 21005-5425 or email to ORTA@arl.army.mil.

FOR FURTHER INFORMATION CONTACT: Wendy Leonard, (410) 278-1646, E-Mail: wendy.a.leonard.civ@army.mil.

SUPPLEMENTARY INFORMATION: The Department of the Army plans to grant an exclusive license to TauMat, LLC in the following fields of use related to:

²The Commission notes that while new § 39.24(d) provides that a DCO may satisfy the requirements of paragraphs (b)(11), (b)(12), (c)(1)(iv), and (c)(3) by having rules that permit it to clear only fully collateralized positions, such DCOs are included in the total estimated number of respondents because these DCOs would still be required to develop and disclose governance arrangements required by the other provisions of § 39.24. The Commission's estimate is therefore conservative to the extent that these DCOs are not required to prepare and maintain minutes of each RMC meeting, and document and provide to the RMC, at a minimum, a summary of the topics discussed and the main points raised during each meeting of the RWG.

- Cooling and thermal energy storage associated with electronic and photonic devices.

- Cooling and thermal energy storage associated with battery/electrical storage devices during charging and discharging.

pertaining to the following;

- “Solid-State Martensitic Transformation Phase Change Material Components for Thermal Energy Storage and Transient Heat Transfer Systems”, ARL 19-02, US Patent Application No. 16/910,652, Filing Date: 06/24/2020, U.S. Publication No. 2020/0407615A1, Publication Date: 12/31/2020.
- “Solid-State Thermal Energy Storage Substrates and Methods for Same.”, ARL 22-04P, US Provisional Patent Application No. 63/521,035, Filing Date: 06/14/2023.

The prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the U.S. Army Combat Capabilities Development Command Army Research Laboratory receives written objections including evidence and argument that establish that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209(e) and 37 CFR 404.7(a)(1)(i). Competing applications completed and received by the U.S. Army Combat Capabilities Development Command Army Research Laboratory within fifteen (15) days from the date of this published notice will also be treated as objections to the grant of the contemplated exclusive license.

Objections submitted in response to this notice will not be made available to the public for inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

James W. Satterwhite Jr.,

Army Federal Register Liaison Officer.

[FR Doc. 2023-14890 Filed 7-12-23; 8:45 am]

BILLING CODE 5001-03-P

DEPARTMENT OF DEFENSE

Office of the Secretary

Notice of Five-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.

¹ 17 CFR 145.9.

SUMMARY: This notice is to advise interested parties of an additional five-year extension of the Defense Health Agency's (DHA) Evaluation of Non-United States Food and Drug Administration (FDA) Approved Laboratory Developed Tests (LDTs) Demonstration Project (hereinafter referred to as the "LDT demonstration"). The original notice was published on June 18, 2014. The LDT demonstration was effective July 18, 2014. It remained in effect for three years (July 18, 2017). A notice was published on June 20, 2017 extending the LDT demonstration for three years. The three-year extension was effective July 19, 2017, through July 18, 2020. A second notice extending the LDT demonstration for an additional three years was published on July 10, 2020. The three-year extension was effective July 19, 2020. It is scheduled to end July 18, 2023. As uncertainty remains regarding future regulatory oversight of LDTs, the LDT demonstration will now be extended for five additional years (July 18, 2028). Additionally, this notice announces the removal of preconception and prenatal carrier screening for Cystic Fibrosis (CF) from the LDT demonstration as these carrier screening tests have been added to the TRICARE Basic (*i.e.*, medical) benefit as directed by the National Defense Authorization Act (NDAA) of 2022.

DATES: The extension of this demonstration will be effective July 19, 2023. It will continue through July 18, 2028.

FOR FURTHER INFORMATION CONTACT: LaChanda Black, Defense Health Agency, (303) 676-3575, lachanda.m.black.civ@health.mil.

SUPPLEMENTARY INFORMATION: For additional information on the DHA LDT demonstration, please see 79 FR 34726-34729, 82 FR 28052, and 85 FR 41574-41575. According to title 32, Code of Federal Regulations (CFR), section 199.4(g)(15)(i)(A), TRICARE may not cost-share devices, including LDTs, that have not received FDA required device 510(k) clearance or premarket approval (referred to as "non-FDA-approved" hereafter). LDTs with FDA clearance or approval are available for cost-sharing under the TRICARE Basic (*i.e.*, medical) benefit 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. Under the LDT demonstration, DHA would allow those LDTs that met such criteria to be covered as a benefit. This demonstration also extended coverage for preconception and prenatal 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.

Effective December 27, 2021, Section 702 of the National Defense Authorization Act for Fiscal Year 2022 (NDAA FY 2022), codified at 10 U.S.C. 1079(a)(19), extended TRICARE Basic (*i.e.*, medical) benefit coverage for preconception and prenatal carrier screening tests for Cystic Fibrosis, Spinal Muscular Atrophy, Fragile X Syndrome, Tay-Sachs Disease, Hemoglobinopathies, and conditions linked with Ashkenazi Jewish descent. As a result, preconception and prenatal carrier screening for CF will be removed from the LDT demonstration as it is now incorporated into the TRICARE Basic (*i.e.*, medical) benefit.

Non-FDA-approved LDTs covered under the LDT demonstration are available for cost-sharing for eligible TRICARE beneficiaries only when performed by laboratories that are assessed and certified or 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/cleared 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 biennial surveys evaluate whether the laboratory has verified or established 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. However, CLIA certification does not assure a device is safe and effective for its intended use or impose any type of post-market surveillance or adverse event reporting requirements.

For the TRICARE Overseas Program (TOP), an exception to the requirement for CLIA certification for overseas laboratories continues. This is due to the majority of overseas laboratories not

having CLIA certification. As with the notice published at 85 FR 41574, this notice restates 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. Nonetheless, LDTs are complex and do have some risks associated with their use. For example, inaccurate tests may place patients at otherwise avoidable risk. While laboratories that offer LDTs are subject to the Federal Food, Drug, and Cosmetic Act (FFDCA), the FDA has generally exercised enforcement discretion towards LDTs, such that it has generally not enforced applicable provisions under the FFDCA and FDA regulations with respect to LDTs. TRICARE's regulatory requirement at 32 CFR 199.4(g)(15)(i)(A) requires LDTs covered in the TRICARE Program to be FDA-approved or cleared, if required under FFDCA. Further, as mentioned above, the FDA generally exercises enforcement discretion for most LDTs, and most laboratories offering LDTs do not submit their devices to the FDA for review. Therefore, most LDTs do not satisfy the requirements at 32 CFR 199.4(g)(15), that the safety and efficacy of these devices be established in order to permit cost-sharing. As a result, TRICARE is unable to cost share for such LDTs.

However, in some instances, LDTs are important and necessary tests and in many instances, there are no FDA-approved/cleared alternatives. Therefore, the TRICARE Program has endeavored to evaluate LDTs through its demonstration project initiated in 2014. Although ongoing for more than eight 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 medically necessary and appropriate LDTs that are found to otherwise meet TRICARE criteria for coverage, including requirements for safety and effectiveness.

While the DoD had hoped that another LDT demonstration extension would not be required, uncertainty remains regarding future regulatory oversight of LDTs. In the absence of any

change in the oversight of LDTs at this time, the DoD has determined that continuation of the LDT demonstration for an additional five years is necessary to provide TRICARE beneficiaries and their health care providers with seamless access to safe and effective, medically necessary tests, as determined by TRICARE, to support health care decisions and treatment.

Health care costs projected for the LDT demonstration over the five-year extension (Fiscal Year (FY) 2023–FY 2028) are \$198.8 million (M) and \$2.1M in administrative costs for all contracts combined. Because all managed care support contractors currently have systems in place for the LDT demonstration, no additional start-up costs are anticipated for this five-year extension.

During the next five 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 tests that meet TRICARE requirements for safety and effectiveness. Based on the results of the demonstration evaluation, and status of the regulatory oversight of LDTs, a recommendation will be made on whether to modify 32 CFR 199.4(g)(15) to permit TRICARE cost-sharing of non-FDA approved LDTs that are found to meet TRICARE requirements for safety and effectiveness. Our intent is for the LDT demonstration to conclude at the end of this five-year extension. 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 LDT demonstration, as appropriate, and the DoD will ensure compliance with applicable federal law and regulations.

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

Dated: July 7, 2023.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2023–14809 Filed 7–12–23; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2023–SCC–0059]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Request for Title IV Reimbursement or Heightened Cash Monitoring 2 (HCM2)

AGENCY: Federal Student Aid (FSA), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act (PRA) of 1995, the Department is proposing an extension without change of a currently approved information collection request (ICR).

DATES: Interested persons are invited to submit comments on or before August 14, 2023.

ADDRESSES: Written comments and recommendations for proposed information collection requests should be submitted within 30 days of publication of this notice. Click on this link www.reginfo.gov/public/do/PRAMain to access the site. Find this information collection request (ICR) by selecting “Department of Education” under “Currently Under Review,” then check the “Only Show ICR for Public Comment” checkbox. *Reginfo.gov* provides two links to view documents related to this information collection request. Information collection forms and instructions may be found by clicking on the “View Information Collection (IC) List” link. Supporting statements and other supporting documentation may be found by clicking on the “View Supporting Statement and Other Documents” link.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Beth Grebeldinger, 202–377–4018.

SUPPLEMENTARY INFORMATION: The Department 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: Request for Title IV Reimbursement or Heightened Cash Monitoring 2 (HCM2).

OMB Control Number: 1845–0089.

Type of Review: An extension without change of a currently approved ICR.

Respondents/Affected Public: Private Sector; State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 564.

Total Estimated Number of Annual Burden Hours: 564.

Abstract: 34 CFR part 668—Student Assistance General Provisions, Subpart K—Cash Management (§ 668.162) establishes the rules and procedures for a participating institution to request, maintain, disburse, and manage the Title IV (TIV) program funds. Institutions must complete and submit a Form 270 to request TIV program funds while participating under the Reimbursement and Heightened Cash Monitoring payment methods as explained in § 668.162(c) and (d). We are requesting an extension of the currently approved information collection. There have been no changes to the information requested or the form since its prior approval in September 2020.

Dated: July 10, 2023.

Kun Mullan,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2023–14885 Filed 7–12–23; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Tests Determined To Be Suitable for Use in the National Reporting System for Adult Education

AGENCY: Office of Career, Technical, and Adult Education, Department of Education.

ACTION: Notice.

SUMMARY: The Secretary announces tests, test forms, and delivery formats that the Secretary determines to be suitable for use in the National Reporting System for Adult Education (NRS). This notice relates to the approved information collections under OMB control numbers 1830–0027 and 1830–0567.