

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.

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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

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: IDEA Part B State Performance Plan (SPP) and Annual Performance Report (APR).

OMB Control Number: 1820-0624.

Type of Review: A revision of an existing information collection.

Respondents/Affected Public: Federal Government.

Total Estimated Number of Annual Responses: 60.

Total Estimated Number of Annual Burden Hours: 107,400.

Abstract: In accordance with 20 U.S.C. 1416(b)(1), not later than 1 year after the date of enactment of the Individuals with Disabilities Education, as revised in 2004 (IDEA), each State must have in place a performance plan that evaluates the State's efforts to implement the requirements and purposes of Part B and describe how the State will improve such implementation. This plan is called the Part B State Performance Plan (Part B—SPP). In accordance with 20 U.S.C. 1416(b)(2)(C)(ii) the State shall report annually to the public on the performance of each local educational agency located in the State on the targets in the State's performance plan. The State also shall report annually to the Secretary on the performance of the State under the State's performance plan. This report is called the Part B Annual Performance Report (Part B—APR). Information Collection 1820-0624 corresponds to 34 CFR 300.600-300.602. Consistent with 20 U.S.C. 1416(d)(A), the Secretary uses this information to make annual determinations on the extent to which the Lead Agency meets the requirements and purposes of IDEA.

The Department is proposing to make revisions to the approved information collection, and to establish a new 6-year SPP cycle (FFY 2020 through FFY 2025). The proposed revisions to the Part B SPP/APR, which would go into effect with States' FFY 2018 SPP/APR to

be submitted in February 2022, are focused on ensuring improved outcomes for children with disabilities, and aligning the SPP/APR with the Secretary's priorities, including elevating parent voice.

Dated: July 7, 2020.

Kate Mullan,

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

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DEPARTMENT OF EDUCATION

[Docket No. ED-2020-SCC-0028]

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

OMB Control Number: 1820-0578.

Type of Review: An extension of an existing information collection.

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

Total Estimated Number of Annual Responses: 56.

Total Estimated Number of Annual Burden Hours: 61,320.

Abstract: The Individuals with Disabilities Education Improvement Act of 2004, signed on December 3, 2004, became Public Law 108-446. In accordance with 20 U.S.C. 1416(b)(1) and 20 U.S.C. 1442, not later than 1 year after the date of enactment of the Individuals with Disabilities Education Improvement Act of 2004 (IDEA), each Lead Agency must have in place a performance plan that evaluates the Lead Agency's efforts to implement the requirements and purposes of Part C and describe how the Lead Agency will improve such implementation. This plan is called the Part C State Performance Plan (Part C—SPP). In accordance with 20 U.S.C. 1416(b)(2)(C)(ii) and 20 U.S.C. 1442 the Lead Agency shall report annually to the public on the performance of each Part C program located in the State on the targets in the Lead Agency's performance plan. The Lead Agency shall report annually to the Secretary on the performance of the State under the Lead Agency's performance plan. This report is called the Part C Annual Performance Report (Part C—APR). Consistent with 20 U.S.C. 1416(d)(A), the Secretary uses this information to make annual determinations on the extent to which the Lead Agency meets the requirements and purposes of IDEA.