Authority: 8 U.S.C. 1521–1524

Mary C. Jones,

ACF/OPRE Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Addition of Duchenne Muscular Dystrophy to the Recommended Uniform Screening Panel

AGENCY: Health Resources and Services Administration, Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: HRSA published a **Federal Register** notice on August 14, 2025 (90 FR 39197), requesting comments from the public on the potential recommendation of adding Duchenne Muscular Dystrophy (DMD) to the Recommended Uniform Screening Panel (RUSP). After consideration of public comments and evidence-based reports, HRSA recommended to the HHS Secretary that DMD be added to the RUSP. The Secretary has accepted the recommendation as detailed in this notice. Conditions listed on the RUSP are part of the evidence-informed preventive health guidelines supported by HRSA for infants, children, and adolescents. Non-grandfathered group health plans and health insurance issuers are required to cover screenings included in these HRSA-supported comprehensive guidelines without cost-sharing (*e.g.,* copayment, co-insurance, etc.). Please see the RUSP (*https://newbornscreening.hrsa.gov/about-newborn-screening/recommended-uniform-screening-panel*) for additional information.

FOR FURTHER INFORMATION CONTACT: CDR Leticia Manning, Newborn Screening Team Lead, Division of Services for Children with Special Health Needs, Maternal and Child Health Bureau, HRSA, 5600 Fishers Lane, Rockville, Maryland 20857 or *NBSPrograms@hrsa.gov*.

SUPPLEMENTARY INFORMATION: The RUSP is a list of conditions that the Secretary of HHS recommends for states to screen as part of their state universal newborn screening (NBS) programs. Conditions on the RUSP are chosen based on evidence that supports the potential net benefit of screening, the ability of states to screen for the disorder, and the availability of effective treatments. Although states ultimately determine what conditions their NBS program will screen for, it is recommended that every newborn be screened for all conditions on the RUSP. Conditions listed on the RUSP are part of the comprehensive preventive health guidelines supported by HRSA for infants and children under section 2713 of the Public Health Service Act. Non-grandfathered group health plans and health insurance issuers are required to cover screenings included in these HRSA-supported comprehensive guidelines without charging a co-payment, co-insurance, or deductible for plan years beginning on or after the date that is 1 year from the Secretary's adoption of the condition for screening.

The Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC), now inactive, was tasked with reviewing available scientific evidence and then making recommendations to the Secretary of HHS regarding what conditions should be on the RUSP. When a condition was nominated, ACHDNC determined whether there is sufficient evidence available for early screening and refers it to the ACHDNC's Evidence Review Group (ERG). The ERG was responsible for identifying and assessing all available evidence and summarizing for ACHDNC the strength and effectiveness of the evidence found on the net benefit of screening, the ability of states to screen for the condition, and the availability of effective treatments. The ERG completed an evidence review for DMD. Following the completion of the evidence review for DMD, but prior to issuing a recommendation to the Secretary on the inclusion of DMD to the RUSP, ACHDNC was terminated.

DMD is a rare genetic condition that causes progressive muscle weakness and degeneration. Individuals eventually require a wheelchair for mobility and have a shortened lifespan. There are Food and Drug Administration-approved treatments which allow children to walk longer before needing a wheelchair and extend heart and lung functions.

Summary of Public Comments

A **Federal Register** notice sought public comment on the potential recommendation of including or not including DMD on the RUSP. HRSA requested that the respondents consider the ERG's report summary on DMD and the suitability of state NBS programs screening for DMD within the newborn period in their response. HRSA considered all public comments as part of its deliberate process along with review of the completed DMD evidence review report prior to making a recommendation to the Secretary of HHS. A total of 379 respondents commented on the inclusion of DMD on the RUSP. Of these, 366 responses (97 percent) expressed support to add DMD to the RUSP and 11 responses (3 percent) opposed its addition. The responses in support of or against adding DMD to the RUSP are summarized below.

Comments on Adding DMD to the RUSP

Ninety-seven percent of commenters (366 comments) were in favor of adding DMD to the RUSP. A variety of stakeholders, including clinicians and families, described benefits and reasons in support of adding DMD to the RUSP. A vast majority of respondents commented that by adding DMD to the RUSP, families may receive a DMD diagnosis sooner enabling access to early intervention, support services, and more treatment options. Families expressed the invaluable benefit of receiving an earlier diagnosis for their child to reduce the diagnostic odyssey due to an unknown diagnosis through progressive symptoms and the negative impacts it causes to the family's overall well-being and mental health. Families with multiple children shared that knowledge of the first child having DMD, enabled them to better prepare for, identify, and treat subsequent children with DMD leading to improved health outcomes. Other comments emphasized that if DMD is added to the RUSP, state adoption to screen for DMD will swiftly follow allowing for researchers to conduct population-level analyses of treatment efficacy.

Three percent of commenters (11 comments) were against adding DMD to the RUSP. One commenter noted that there is a high rate of false positives of the screening test which can lead to uncertainty/worry before confirmation of a negative result and there are unclear cutoff thresholds for positive/negative results. However, the screening test can have additional steps included on the same bloodspot prior to confirmatory testing, or by implementing DNA analysis, that would reduce the false positive rate.

Additional comments highlighted the lack of data that supports treatment during the newborn period is beneficial for the infant. As noted in the evidence-based review (*https://publications.aap.org/pediatrics/article/doi/10.1542/peds.2025-073192/203177/Evidence-Regarding-Duchenne-Muscular-Dystrophy?autologincheck=redirected*), treatment may improve outcomes for DMD with additional studies needed to

establish the timing of treatment. Identification of DMD in an infant would allow early monitoring to initiate treatment prior to the onset of substantial physical decline.

The final comments against adding DMD noted a lack of public health laboratory resources to pay for multi-tier molecular screening. However, HRSA notes that adding a condition to the RUSP does not require states to implement screening for conditions immediately. States determine their resource allocations for NBS screening based on their specific state budget and public health priorities.

After consideration of the evidence review report and public comments, no changes were made to the recommendation and HRSA recommended to the HHS Secretary that DMD be included for addition to the RUSP.

Acceptance of Recommendation

On December 16, 2025, the HHS Secretary accepted HRSA's recommendation. The RUSP is updated and can be accessed at the following link: *https://mchb.hrsa.gov/programs/newborn-screening*.

Thomas J. Engels,

Administrator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Substance Use Disorder Treatment and Recovery Loan Repayment Program and the Pediatric Specialty Loan Repayment Program—OMB No. 0906–0058—Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than January 21, 2026.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain*. Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Samantha Miller, the HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call (301) 443–3983.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Substance Use Disorder Treatment and Recovery Loan Repayment Program and the Pediatric Specialty Loan Repayment Program, OMB No. 0906–0058—Revision.

Abstract: The Substance Use Disorder Treatment and Recovery (STAR) Loan Repayment Program (LRP) is authorized by section 781 of the Public Health Service Act (42 U.S.C. 295h). This program allows HRSA to provide the repayment of eligible education loans to individuals working in an eligible full-time substance use disorder treatment job that involves direct treatment or recovery support of patients with or in recovery from a substance use disorder and which is located in either a Health Professional Shortage Area (HPSA) designated for Mental Health, or a county (or municipality, if not contained within any county) where the average drug overdose death rate per 100,000 people over the past 3 years for which official data is available from the state, is higher than the most recent available national average overdose death rate per 100,000 people, as reported by the Centers for Disease Control and Prevention. The Pediatric Specialty (PS) LRP is authorized by section 775 of the Public Health Service Act (42 U.S.C. 295f). This program allows HRSA to provide the repayment of education loans to eligible providers working full-time in or serving a HPSA, medically underserved area (MUA), or medically underserved population (MUP).

The Department of Health and Human Services agrees to make payment of up to $250,000 for the repayment of eligible educational loans in return for 6 years of obligated service through the STAR LRP, and up to $100,000 in return for 3 years of obligated service through the PS LRP.

Eligible disciplines for the STAR LRP include, but are not limited to physicians, psychologists, psychiatric nurses, marriage and family therapists, social workers, counselors, and substance use disorder counselors. The PS LRP may make awards to applicants participating in an accredited pediatric medical subspecialty, pediatric surgical specialty, and child and adolescent mental health subspecialty residency or fellowship employed as a pediatric medical subspecialist, pediatric surgical specialist, or child and adolescent mental health professional.

Eligible facilities or sites for the STAR LRP and PS LRP include, but are not limited to: School-Based Clinics, Community Health Centers, Inpatient Programs/Rehabilitation Centers, Federally Qualified Health Centers, Centers for Medicare & Medicaid Services-approved Critical Access Hospitals, Rural Emergency Hospitals, American Indian Health Facilities (Indian Health Service Facilities, Tribally-Operated 638 Health Programs, and Urban Indian Health Programs), inpatient rehabilitation centers, and psychiatric facilities. STAR LRP facilities must be located in a mental health HPSA or a county where the average drug overdose death rate exceeds the national average, as described above. PS LRP sites must provide pediatric medical subspecialty care, pediatric surgical specialty care, or child and adolescent mental and behavioral health care in or to a HPSA, MUA, or MUP. HRSA will approve and activate sites for the PS LRP if:

(1) The facility is already approved for the National Health Service Corps, Nurse Corps, or STAR LRP and located in or serves a HPSA, MUA or MUP; or

(2) During the PS LRP application cycle, the facility submits to HRSA the site type and the point of contact(s) to *PS_LRP_Sites@hrsa.gov*.

HRSA will review and approve eligible new facilities during the respective application cycle for the STAR LRP and the PS LRP, or upon request by a STAR LRP participant. New facilities must submit to HRSA the facility type and the recruitment contact(s). HRSA will use the information collected to determine eligibility of the facility for participants in the respective program.

Note: Despite the similarity in the titles, the STAR LRP is not the existing National Health Service Corps Substance Use Disorder Workforce LRP (OMB #0915–0127), which is authorized under Title III of the Public Health Service Act. The STAR LRP is authorized under Title VII of the Public