The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Committee on Fiscal Policy

BILL:	CS/SB 524
INTRODUCER:	Appropriations Committee on Health and Human Services and Senator Harrell
SUBJECT:	Newborn Screenings
DATE:	April 21, 2025
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Morgan	Brown	HP	**Favorable**
2.	Gerbrandt	McKnight	AHS	**Fav/CS**
3.	Morgan	Siples	FP	**Favorable**

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 524 amends s. 383.14, F.S., to require the Florida Department of Health (DOH) to revise its newborn screening rules to require the screening of newborns for Duchenne muscular dystrophy at the appropriate age, beginning January 1, 2027.

The bill has a significant negative fiscal impact on state expenditures. However, the bill is subject to legislative appropriation. **See Section V., Fiscal Impact Statement.**

The bill takes effect July 1, 2025.

II. Present Situation:

Newborn Screening

Newborn screening (NBS) is a preventive public health program provided in every state to identify, diagnose, and manage newborns at risk for selected disorders that, without detection and treatment, can lead to permanent developmental and physical damage or death. The federal government produces a standardized list of conditions that it recommends every newborn be

screened for, but each state determines which conditions and screenings to include in its own NBS program.[1]

Federal Recommendations for NBS

The U.S. Department of Health and Human Services (HHS) Advisory Committee on Heritable Disorders in Newborns and Children (Advisory Committee) was established to reduce morbidity and mortality in newborns and children who have, or are at risk for, heritable disorders. The Advisory Committee advises the Secretary of HHS on the most appropriate application of universal NBS tests, technologies, policies, guidelines, and standards.[2]

The federal Recommended Uniform Screening Panel (RUSP) is a list of disorders recommended by the Secretary of HHS, based on advice from the Advisory Committee, for states to screen as part of their NBS program. The inclusion of a disorder in the RUSP is determined based on evidence supporting the potential net benefit of screening, the ability of states to screen for the disorder, and the availability of effective treatments. Adding a condition to the RUSP usually takes three to four years; it is a multistep process beginning with the submission of a nomination package for review by the Advisory Committee, which might or might not result in a recommendation to include the condition in the RUSP. Anyone can nominate a condition for inclusion by completing a nomination package. The RUSP currently includes screening for 36 core conditions and 26 secondary conditions.

Duchenne muscular dystrophy has been nominated for inclusion in the RUSP but has not been recommended by Advisory Committee.[3]

The Florida NBS Program

The Florida NBS Program (NBS Program) was initially established in 1965 to screen newborns for a single condition, phenylketonuria.[4] The NBS Program has since evolved to screen for a wide range of congenital conditions. The NBS program is housed within the Department of Health (DOH) and serves to promote the screening of all newborns for metabolic, hereditary, and congenital disorders known to result in significant impairment of health or intellect.[5]

The NBS Program attempts to screen all newborns to identify, diagnose, and manage newborns at risk for select disorders that, without detection and treatment, can lead to permanent

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[1] Health Resources & Services Administration, Advisory Committee on Heritable Disorders in Newborns and Children, *History of the ACHDNC, available at* https://www.hrsa.gov/sites/default/files/hrsa/advisory-committees/heritable-disorders/hrsa-timeline-interactive.pdf (last visited Mar. 22, 2025).

[2] Health Resources & Services Administration, *Advisory Committee on Heritable Disorders in Newborns and Children, available at* https://www.hrsa.gov/advisory-committees/heritable-disorders (last visited Mar. 22, 2025).

[3] *Id.*

[4] *See*, Tatiana Wing, R.C. Philips Research and Education Unit, *Newborn Screening Update* (2020), *available at* https://genetics.pediatrics.med.ufl.edu/wordpress/files/2019/11/RCPU-Newborn-screening-update.pdf (last visited Mar. 22, 2025); Watson, S., Lloyd-Puryear, M., & Howell, R. (2022), *The Progress and Future of US Newborn Screening*, International Journal of Neonatal Screening, 8:41, *available at* https://doi.org/10.3390/ijns8030041 (last visited Mar. 22, 2025). Phenylketonuria (PKU) is a rare inherited disorder that causes an amino acid called phenylalanine to build up in the body resulting in dangerous symptoms unless a specific diet is adhered to. PKU was the first inheritable condition for which a relatively simple and repeatable blood test was able to be conducted at a high enough throughput to enable population-level screening.

[5] Section 383.14, F.S.

developmental and physical damage or death.[6] Parents and guardians may decline the screenings.[7]

The Florida Genetics and Newborn Screening Advisory Council (GNSAC) advises the DOH on disorders to be included in Florida's panel of screened disorders and the procedures for collecting and transmitting specimens.[8] The Florida NBS Program currently screens for 37 core conditions and 23 secondary conditions, nearly all of which are screened through the collection and testing of blood spots. Hearing screening, critical congenital heart disease, and targeted testing for congenital cytomegalovirus are completed at the birthing facility through point of care (POC) testing.[9]

Under current law, when a new condition is added to the federal RUSP, the GNSAC is required to consider the condition and make a recommendation to the DOH as to whether the condition should be included in the state NBS panel within one year.[10] GNSAC reviews the recommendations to ensure:[11]

- The state's readiness to screen, diagnose, and treat the condition;
- The condition is known to result in significant impairment in health, intellect, or functional ability if not treated before clinical signs appear;
- The condition can be detected using screening methods accepted by current medical practice;
- The condition can be detected prior to the infant becoming two weeks of age, or at the appropriate age as indicated by accepted medical practice;
- After screening for the disorder, reasonable cost benefits can be anticipated through a comparison of tangible program costs with those medical, institutional, and special educational costs likely to be incurred by an undetected population; and
- When screening for a condition, sufficient pediatric medical infrastructure is available.

The Florida NBS Program involves coordination across several entities, including the Bureau of Public Health Laboratories Newborn Screening Laboratory (state laboratory), the DOH's Children's Medical Services Newborn Screening (CMS NBS) Follow-up Program, referral centers, birthing centers, and physicians throughout the state. Health care providers in hospitals, birthing centers, perinatal centers, county health departments, and school health programs provide screening as part of the multilevel NBS Program screening process.[12]

Health care providers in hospitals and birthing centers collect drops of blood from the newborn's heel on a standardized specimen collection card, which is then sent to the state laboratory for testing.[13] POC testing is used at the birthing facility to screen for the conditions which cannot be

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[6] Florida Department of Health, *Florida Newborn Screening 2022 Protocols* (Mar. 15, 2022), *available at* https://floridanewbornscreening.com/wp-content/uploads/NBS-Protocols-2022-FINAL.pdf (last visited Mar. 22, 2025).
[7] Section 383.14, F.S.; Rule 64C-7.008, F.A.C. The health care provider must attempt to get a written statement of objection to be placed in the medical record.
[8] Section 383.14, F.S.
[9] Florida Department of Health, *2025 Agency Legislative Bill Analysis, HB 1089* (Mar. 12, 2025) (on file with the Senate Committee on Health Policy).
[10] *Supra* note 9.
[11] *Supra* note 10.
[12] *Supra* note 9.
[13] Florida Department of Health, Florida Newborn Screening Program, *What is Newborn Screening?, available at* https://floridanewbornscreening.com/parents/what-isnewborn-screening/ (last visited Mar. 22, 2025). *See also,* Florida

screened for with blood spot testing such as. pulse oximetry tests for critical congenital heart defect and hearing screening to detect hearing loss.[14]

Screening results are released to the newborn's health care provider and in the event of an abnormal result, the baby's health care provider, or a nurse or specialist from the CMS NBS Follow-up Program, provides follow-up services and referrals for the child and his or her family.[15]

The DOH is authorized to charge and collect a fee not to exceed $15 per live birth occurring in a hospital or birth center to administer the NBS Program. The DOH must calculate the annual assessment for each hospital and birth center and then quarterly generate and mail each hospital and birth center a statement of the amount due. The DOH bills hospitals and birth centers quarterly using vital statistics data to determine the amount to be billed. The DOH is authorized to bill third-party payers for the screening tests and bills insurers directly for the cost of the screening.[16] The DOH does not bill families that do not have insurance coverage.[17]

Duchenne Muscular Dystrophy

Duchenne muscular dystrophy (DMD), the most common form of muscular dystrophy, is a condition that causes skeletal and heart muscle weakness that quickly gets worse with time. Symptoms usually begin by the age of six years, and the condition mainly affects boys. Currently, no cure exists, so treatment involves managing symptoms and improving quality of life.[18]

DMD is caused by a change or mutation in the gene that gives instructions for a protein called dystrophin. Dystrophin is a critical part of the dystrophin-glycoprotein complex (DGC), which plays an important role as a structural unit of muscle. In DMD, both dystrophin and DGC proteins are missing, which ultimately leads to the death (necrosis) of muscle cells. People with DMD have less than five percent of the normal quantity of dystrophin needed for healthy muscles.[19]

As an individual with DMD becomes older, the individual's muscles cannot replace the dead cells with new ones, and connective and adipose (fat) tissue gradually replaces muscle fibers.[20]

Department of Health, Florida Newborn Screening, *Specimen Collection Card*, *available at* http://floridanewbornscreening.com/wp-content/uploads/Order-Form.png (last visited Mar. 22, 2025).

[14] Florida Department of Health, *2024 Agency Legislative Bill Analysis, HB 499* (Feb. 7, 2024) (on file with the Senate Committee on Health Policy).

[15] *Id*.

[16] Section 383.145, F.S.

[17] Section 383.14, F.S.

[18] Cleveland Clinic, *Duchenne Muscular Dystrophy (DMD)*, *available at* https://my.clevelandclinic.org/health/diseases/23538-duchenne-muscular-dystrophy-dmd#symptoms-and-causes (last visited Mar. 22, 2025).

[19] *Id*.

[20] *Id*.

DMD Symptoms

Symptoms of DMD most often appear between the ages of two and four years, though symptoms can present as early as infancy or be noticed later in childhood. DMD causes muscle weakness that progressively worsens, so common symptoms include:[21]

- Progressive muscle weakness and atrophy (loss of muscle bulk) beginning in the child's legs and pelvis.
- Calf muscle hypertrophy (increase in muscle size).
- Difficulty climbing up stairs.
- Difficulty walking that becomes progressively worse.
- Frequent falls.
- Waddling gait.
- Toe walking.
- Fatigue.
- Cardiomyopathy (disease of the heart muscle).
- Breathing difficulties and shortness of breath.
- Cognitive impairment.
- Delayed speech and language development.
- Developmental delay.
- Scoliosis (spine curvature).
- Short stature (height).

DMD affects approximately one in 3,600 male live-born infants. About 2.5 to 20 percent of girls who are DMD carriers may have symptoms that are milder than the typical case.[22]

DMD Diagnosis and Testing

A health care provider will likely perform a physical, neurological, and muscle exam on a child experiencing symptoms of DMD, asking detailed questions related to symptoms and medical history, and order the following tests:[23]

- Creatine Kinase (CK) Blood Test – The muscles release CK when damaged, so elevated levels may indicate DMD. Levels typically peak by age two and can be more than 10 to 20 times above the normal range.
- Genetic Blood Test – A genetic blood test looking for a complete or near-complete absence of the dystrophin gene can confirm the diagnosis of DMD.
- Muscle Biopsy – A child's provider may take a small sample of muscle tissue from a muscle in the child's thigh or calf. A specialist will review the sample under a microscope to look for signs of DMD.

[21] *Id*.
[22] Cleveland Clinic, *Duchenne Muscular Dystrophy (DMD), available at* https://my.clevelandclinic.org/health/diseases/23538-duchenne-muscular-dystrophy-dmd#symptoms-and-causes (last visited Mar. 22, 2025).
[23] Cleveland Clinic, *Duchenne Muscular Dystrophy (DMD), available at* https://my.clevelandclinic.org/health/diseases/23538-duchenne-muscular-dystrophy-dmd#symptoms-and-causes (last visited Mar. 22, 2025).

- Electrocardiogram (EKG) – As DMD almost always affects the heart, a child's provider will likely perform an EKG to look for characteristic signs of DMD and to check the health of the child's heart.

DMD Management and Treatment

Currently, there is no cure for DMD, so the main goal of treatment is to manage symptoms and improve quality of life. Supportive therapies for DMD include:[24]

- Corticosteroids – Corticosteroids, such as prednisolone and deflazacort, are beneficial for delaying muscle strength loss, improving lung function, delaying scoliosis, slowing the progression of cardiomyopathy and prolonging survival.
- Medication to Treat Cardiomyopathy – Early treatment with angiotensin-converting enzyme (ACE) inhibitors and/or beta-blockers may slow the progression of cardiomyopathy and prevent the onset of heart failure.
- Physical Therapy – The main goal of physical therapy for DMD is to prevent contractures, permanent tightening of the muscles, tendons and skin. This usually involves certain stretching exercises.
- Surgery to Help Treat Scoliosis and Contractures – Surgery to release contractures may be necessary for severe cases. Surgery to correct scoliosis may improve lung and breathing function.
- Exercise – A child's health care provider will likely recommend gentle exercise to avoid muscle atrophy due to lack of use. This is usually a combination of swimming and recreation-based exercises.
- Mobility Aids – Braces, canes, wheelchairs, etc.
- Tracheostomy and Assisted Ventilation for Respiratory Failure.

With improvement in supportive care, the life expectancy of DMD has significantly improved over the past few decades. There are also many new drugs currently undergoing clinical testing that show promise in treating DMD. Some newer treatments employing "exon skipping" (patching over a missing or mutated part of the dystrophin gene) have recently received federal Food and Drug Administration (FDA)[25] approval. These treatments are applicable only to a minority of cases with specific mutations. Although these treatments increase dystrophin protein amount in muscle, meaningful gain in strength and physical function has not yet been shown.[26]

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[24] *Id*.

[25] The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. The FDA also provides accurate, science-based health information to the public. USAGov, *Food and Drug Administration (FDA),* available at https://www.usa.gov/agencies/food-and-drug-administration#:~:text=The%20Food%20and%20Drug%20Administration,and%20products%20that%20emit%20radiation. (last visited Mar. 22, 2025).

[26] Cleveland Clinic, *Duchenne Muscular Dystrophy (DMD), available at* https://my.clevelandclinic.org/health/diseases/23538-duchenne-muscular-dystrophy-dmd#symptoms-and-causes (last visited Mar. 22, 2025).

DMD Prevention and NBS

As DMD is an inherited condition, there is no prevention and about a third of cases occur randomly without a family history of the condition.[27] Genetic counseling is an option that exists to provide information to concerned families about how genetic conditions affect the family, determining the risk for developing or passing on certain conditions.[28] In some situations, prenatal testing may be able to diagnose DMD in early pregnancy.[29]

Newborn screening has been proposed as a method for ensuring early diagnosis of DMD. Advocates for NBS for DMD point to evidence suggesting that emerging DMD therapies might prove to be most effective if initiated before the onset of symptoms.[30,31] Furthermore, delayed diagnosis of DMD leads to lost opportunities for genetic counseling, implementation of appropriate standards of care, access to newly approved disease-modifying medications, and participation in clinical trials. However, there are ethical, legal, and social concerns related to the development and implementation of newborn screening for DMD. These concerns include the limited treatment options available, whether both males and females should be screened, and the high rate of false-positives resulting from the first-tier diagnostic test.[32]

Newborn screening for DMD has been adopted in several states; it has been implemented in Minnesota and Ohio, and New York and Massachusetts are in the planning phases.[33] The method of screening is similar to the conventional diagnostic method for suspected cases of DMD. A blood spot test is conducted to measure CK levels, followed by a confirmatory genetic test. One of the primary concerns with this screening method is the relatively high frequency of elevated CK levels in newborns that are unrelated to DMD, leading to false positives and unnecessary genetic testing.[34]

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[27] *Id*.
[28] Cleveland Clinic, *Genetic Counseling*, *available at* https://my.clevelandclinic.org/health/articles/23086-genetic-counseling (last visited Mar. 22, 2025).
[29] *Supra* note 30.
[30] Birnkrant, D. J., Bushby, K., Bann, C. M., Apkon, S. D., Blackwell, A., Brumbaugh, D., Case, L. E., Clemens, P. R., Hadjiyannakis, S., Pandya, S., Street, N., Tomezsko, J., Wagner, K. R., Ward, L. M., Weber, D. R., & DMD Care Considerations Working Group (2018), *Diagnosis and management of Duchenne muscular dystrophy, part 1: diagnosis, and neuromuscular, rehabilitation, endocrine, and gastrointestinal and nutritional management*, The Lancet, Neurology, 17(3), 251–267, *available at* https://doi.org/10.1016/S1474-4422(18)30024-3 (last visited Mar. 22, 2025).
[31] Parent Project Muscular Dystrophy, *Newborn Screening Action Center*, *available at* https://www.parentprojectmd.org/advocacy/newborn-screening-action-center/ (last visited Mar. 22, 2025).
[32] Thomas, S., Conway, K. M., Fapo, O., Street, N., Mathews, K. D., Mann, J. R., Romitti, P. A., Soim, A., Westfield, C., Fox, D. J., Ciafaloni, E., & Muscular Dystrophy Surveillance, Tracking, and Research Network (MD STARnet) (2022), *Time to diagnosis of Duchenne muscular dystrophy remains unchanged: Findings from the Muscular Dystrophy Surveillance, Tracking, and Research Network*, 2000-2015, Muscle & nerve, 66(2), 193–197, *available at* https://doi.org/10.1002/mus.27532 (last visited Mar. 22, 2025).
[33] *Supra* note 35.
[34] *Birnkrant, D. J., Bushby, K., Bann, C. M., Apkon, S. D., Blackwell, A., Brumbaugh, D., Case, L. E., Clemens, P. R., Hadjiyannakis, S., Pandya, S., Street, N., Tomezsko, J., Wagner, K. R., Ward, L. M., Weber, D. R., & DMD Care Considerations Working Group (2018), Diagnosis and management of Duchenne muscular dystrophy, part 1: diagnosis, and neuromuscular, rehabilitation, endocrine, and gastrointestinal and nutritional management, The Lancet, Neurology, 17(3), 251–267, available at https://doi.org/10.1016/S1474-4422(18)30024-3 (last visited Mar. 22, 2025).*

RUSP Nomination Not Approved

DMD was nominated for inclusion in the RUSP by the Parent Project Muscular Dystrophy[35] and the Muscular Dystrophy Association.[36] The process began in February 2023, but a pause in the review process was requested by the nominators after the Advisory Committee determined there was insufficient evidence to move forward and requested additional information regarding the diagnostic process and clinical utility.[37] The RUSP is largely restricted to neonatal-onset disorders for which early treatment shows improved outcome. DMD differs from the majority of conditions included on the RUSP because onset does not occur until later in childhood.[38]

III. Effect of Proposed Changes:

The bill amends s. 383.14, F.S., to require, subject to legislative appropriation, the Department of Health (DOH) to adopt and enforce rules requiring every newborn in the state to be screened for Duchenne Muscular Dystrophy (DMD) at the appropriate age, beginning January 1, 2027.

The bill takes effect July 1, 2025.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

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[35] Parent Project Muscular Dystrophy, *available at* https://www.parentprojectmd.org/ (last visited Mar. 22, 2025).
[36] Muscular Dystrophy Association, *available at* https://www.mda.org/ (last visited Mar. 2, 2025).
[37] U.S. Department of Health and Human Services, *Advisory Committee on Heritable Disorders in Newborns and Children, Chair Letter to DMD Nominators* (2023), *available at* https://www.hrsa.gov/sites/default/files/hrsa/advisory-committees/heritabledisorders/resources/chair-letter-dmd-nominators.pdf (last visited Mar. 22, 2025); Health Resources & Services Administration, *Summary of Nominated Conditions to the Recommended Uniform Screening Panel* (2024), available at https://www.hrsa.gov/sites/default/files/hrsa/advisory-committees/heritable-disorders/rusp/summary-nominated-conditions.pdf (last visited Mar. 22, 2025).
[38] *Supra* note 38.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

The bill is subject to legislative appropriation. The Department of Health estimates a total cost of $2.7 million to implement the provisions of the bill:

- Three laboratory personnel - $272,202 recurring.
- Laboratory Testing Supplies - $984,000 recurring.
- Information Technology Updates - $75,000 nonrecurring.
- Expense - $81,532 ($57,784 recurring, $23,748 nonrecurring).
- Registered Nurse Consultant - $117,759 recurring.
- Specialty Care for Out-of-Range Results - $1,148,469 recurring:
  - Geneticist – 0.5 FTE
  - Genetics Counseling – 1 FTE
  - Dietician – 0.5 FTE
  - Social Worker – 0.5 FTE.[39]

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends section 383.14 of the Florida Statutes.

IX. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Appropriations Committee on Health and Human Services on April 10, 2025:
The committee substitute provides that the bill is subject to legislative appropriation.

[39] Florida Department of Health, 2025 Agency Legislative Bill Analysis, HB 1089 (Mar. 12, 2025) (on file with the Senate Committee on Health Policy).

B. Amendments:

None.