

DEPARTMENT OF HEALTH AND SOCIAL SERVICES

DIVISION OF PUBLIC HEALTH

Family Health Services

Statutory Authority: 16 Delaware Code, Sections 122(1), 122(3)h, and 203(a)(1) (16 Del.C. §§122(1), 122(3)h & 203(a)(1))
16 DE Admin. Code 4103

PROPOSED

PUBLIC NOTICE

4103 Inherited Metabolic Disorders

Pursuant to 16 Del.C. §122(1), §122(3)h & §203(a)(1), the Department of Health and Social Services, Division of Public Health is proposing to repeal Regulation 4103 Inherited Metabolic Disorders and intends to hold the regulation open for public comment per Delaware law. The repeal is necessary because the Division of Public Health no longer has designated funding for formula and cannot guarantee formula availability.

Copies of the proposed regulation are available for review in the October 1, 2024 issue of the *Delaware Register of Regulations*, accessible online at: <http://regulations.delaware.gov> or by calling the Division of Public Health at (302) 744-4951.

Public comments will be accepted until 4:30 PM on November 1, 2024. Comments will be accepted in written form via email to DHSS_DPH_regulations@delaware.gov, or by U.S. mail to the following address:

Vicki Schultes, Hearing Officer
Division of Public Health
417 Federal Street
Dover, DE 19901

4103 Inherited Metabolic Disorders

~~Delaware Code 201 provides for the assistance with the cost of treatment of children with birth defects. Inherited Metabolic Disorders are one such birth defect for which a fund has been established to assist with the cost of treatment.~~

~~1.0 Purpose~~

~~Inherited metabolic disorders, if undetected and untreated, can result in severe mental retardation, and possibly death, in infancy. Universal screening and milk product substitution is now a standard of medical care. If a child diagnosed with an inherited metabolic disorder amenable to dietary treatment is not able to maintain a strict dietary regime throughout life the individual will likely be developmentally delayed.~~

~~The Specialty Formula Fund ("Fund") provides that certain expenses for specialty formula, in the on-going treatment of inherited metabolic disorders, may be covered through the Department of Health and Social Services, Division of Public Health, Specialty Formula Fund.~~

~~The purpose of the Fund is to assist families in meeting the high cost of special or metabolic formulas, required to treat inherited metabolic disorders. The Division of Public Health will work to coordinate services and reduce obstacles families encounter regarding information and resource referral.~~

~~Supporting individuals with special health care needs can place economic constraints on families. The cost of special formula may be prohibitive for some families. In situations where special formula has been prescribed by a physician, and not covered by insurance, there is justification to provide economic assistance under the Fund.~~

~~2.0 Definitions~~

~~"Case Review Panel" means a group composed of individuals with knowledge of inherited metabolic disorders, whose purpose is to review each newly diagnosed case involving the special formula fund.~~

~~"Inherited Metabolic Disorder," means a disorder caused by an inherited abnormality of body chemistry, which includes those disorders screened for by the state's Newborn Screening Program located within the Division of Public Health.~~

"Specialty Formula" means a milk product substitution that is intended for the therapeutic dietary treatment of inherited metabolic disorders for which nutritional requirements are established by medical evaluation.

"Specialty Formula Fund" means funds provided to the Division of Public Health by the General Assembly, for prescribed specialty formula for women of child bearing age and children with inherited metabolic disorders.

3.0 Eligibility

- 3.1 Any Delaware woman of child bearing age or child diagnosed with an Inherited Metabolic Disorder, that warrants the prescription of a specialty formula may be eligible to receive assistance through the Specialty Formula Fund if uninsured or if current insurance benefit does not include this coverage. The assistance will be based on the current Department of Health and Social Services *Ability to Pay Fee Schedule* (see attached), less the average cost of formula for a normal newborn/infant or citizen using soy based milk products annually. The Fee Schedule is adjusted annually with the revised federal poverty guidelines.
- 3.2 The Division of Public Health may provide assistance from the Fund to a woman of child bearing age or child diagnosed with an Inherited Metabolic Disorder, if:
 - 3.2.1 The specialty formula is prescribed as medically necessary for the therapeutic treatment of an Inherited Metabolic Disorder; and
 - 3.2.2 The specialty formula is administered under the direction of a physician; and
 - 3.2.3 The client's insurer does not provide benefits to cover prescribed formula for inherited metabolic disorder or there are special circumstances as determined by the Division of Public Health, Case Review Panel.

4.0 Application

- The Division of Public Health will:
 - 4.1 Staff the Case Review Panel; and
 - 4.2 Review and refer non-compliant woman of child bearing age, parents/guardians of children with an inherited metabolic disorder to appropriate agencies for follow-up; and
 - 4.3 Determine, on a case by case basis, any assistance to be provided to a woman of child bearing age or child from this fund.

5.0 Roles/Responsibilities

- 5.1 The Division of Public Health will appoint a Case Review Panel to make recommendations to assist the Division of Public Health in determining the assistance provided to a woman of child bearing age or child from this fund. This group will also act as a case management team for women of child bearing age, children and their families, if necessary, with public and private providers of health care and/or insurance providers. The members may have a background in metabolic disease. The panel may include a Geneticist, Nutritionist, Newborn Screening Program staff member, a Physician who treats metabolic disorders, and one or more community member(s). The Genetics Director will chair the Case Review Panel and the Division of Public Health will provide staff.

The Case Review Panel will meet on a regular basis to review cases and make recommendations to the Division of Public Health. All current cases will be reviewed within the first six months of initiation of the Case Review Panel. The Case Review Panel will convene, as needed, to review newly diagnosed cases.

6.0 Authorization for Payment

- 6.1 The Division of Public Health may authorize assistance prior to the review of the Case Review Panel in cases of immediate need based on physician prescription.

- 6.2 ~~The Division of Public Health may provide assistance based on the physician's prescription, recommendation of the Case Review Panel, the calculation of the quantity of formula needed, economic need, and the availability of appropriated funds.~~
- 6.3 ~~Assistance under this fund is limited to the appropriation of the General Assembly for this purpose.~~
- 6.4 ~~The Division of Public Health will reevaluate each case every year or if health benefit coverage changes.~~
- 6.5 ~~Women of child bearing age or the parent or guardian of a child receiving assistance from the Fund are obligated to contact the Division of Public Health, immediately, if any changes in status or eligibility occur.~~

7.0 Referrals

- 7.1 ~~The Division of Public Health will accept referrals from specialty hospitals, institutions, other state agencies, primary care physicians, other health care professionals, self referrals, or referrals from the family.~~
- 7.2 ~~Referrals should include the following information: client's name, parent or guardian's name, address, phone number, social security number of client, diagnosis, formula prescription type and amount per month, feeding schedule, client's age, financial information, and any pertinent medical data.~~

3 DE Reg. 529 (10/01/99)

28 DE Reg. 276 (10/01/24) (Prop.)