## Maryland

### Newborn Genetic Testing & Surveillance System

<table>
<thead>
<tr>
<th>State</th>
<th>Statute/Rule</th>
<th>Language Specific to Genetic Testing and Surveillance System</th>
<th>Exemption</th>
<th>Research Authority</th>
<th>Consent Required?</th>
<th>Dissent Allowed?</th>
</tr>
</thead>
<tbody>
<tr>
<td>MD</td>
<td>STATUTE: M.C. Title 13, Subtitle 1. RULE: 10.52.12.00 to 10.52.12.12</td>
<td>§ 13-111 Statewide system for screening newborns (a) Establishment. – The Department shall establish a coordinated statewide system for screening all newborn infants in the State for certain hereditary and congenital disorders associated with severe problems of health or development, except when the parent or guardian of the newborn infant objects.</td>
<td>§ 13-109. ...(e) Minimum Standards - Restrictions on participation.- The rules, regulations, and standards of the Department shall: (1) Require that, before an individual participates in a hereditary and congenital disorders program, the person who conducts the program shall inform the individual or, if the individual is a minor or disabled person, a parent or guardian of the person of the requirement that participation in the program be wholly voluntary and of any risk that is involved in participation;</td>
<td>10.10.13.15 Test Specimens – Use, Research, Storage, and Retention. A. Use. A permittee may use a newborn infant blood-spot from a newborn infant to test for only the conditions listed in Regulation .12C of this chapter.</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>(b) Department of Public Health laboratory to perform tests. – Except as provided in § 13-112 of this subtitle, the Department’s <strong>public health laboratory is the sole laboratory authorized to perform test</strong> on specimens from newborn infants collected to screen for hereditary and congenital disorders as determined under subsection (d)(2) of this section. [emphasis added]</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>---</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(2) Prohibit the testing of an individual for a hereditary or congenital disorder unless the individual or, if the individual is a minor or disabled person, a parent or guardian of the person:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(i) Is informed fully of the purpose of the test and the nature and consequences of being affected by a hereditary or congenital disorder or being a carrier of a hereditary disorder;</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(ii) Is given a reasonable opportunity to object, and</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(iii) Does not object to the test; and</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(3) Require unambiguous diagnostic results to be made available through a physician or other source of health care to the individual or, if the individual is a minor or disabled person, to a parent or guardian of the person.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>B. Research. A researcher may not use a Maryland newborn infant’s blood-spot or test results for research purposes unless the: (1) Research is approved in writing by the Department’s: (a) Newborn screening Program; and (b) Institutional Review Board; and (2) The researcher acknowledges in writing that the researcher will return all untested blood-spots to the Department’s public health laboratory within 6 months of completing the approved research.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>C. Storage. A permittee or researcher shall store a newborn infant blood-spot in a sealed, moisture-proof container at between 2 [degrees] and 23 [degrees] C.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### 10.52.12.03 Definitions.

...(10 Hereditary Disorders. (a) “Hereditary disorder” means a disorder that:

(i) Is transmissible through the genetic material deoxyribonucleic acid (DNA); or

(ii) Arises through the improper processing of information in the genetic material.

(b) “Hereditary disorder” includes:

(i) Hemoglobin disorders;

(ii) Metabolic disorders; and

(iii) Endocrine disorders.

(11) Metabolic disorder” means a disorder caused by a genetic alteration that results in a defect in the function of a specific enzyme, hormone, or protein, which can be detected by:

### (f) Minimum Standards - Program participation requirements and childbearing restrictions prohibited.

- The rules, regulations, and standards of the Department shall provide that a hereditary and congenital disorders program may not:

  1. Require participation in the program;

  2. Require restriction of childbearing; or

  3. Be prerequisite for eligibility for any service or other program.

### (g) Minimum Standards - Protection of program participants.

- The rules, regulations, and standards of the Department shall provide that:

  1. Each participant in a hereditary and congenital disorders program shall be:

### D. Retention.

A permittee shall:

1. Retain a newborn infant’s:

   a. Gel, produced when testing for hemoglobin disorders, for at least 90 days after testing is complete; and

   b. Blood-spot for 25 years after the blood-spot is received for screening, supplemental, or diagnostic testing; and

   (Return to the State’s public health laboratory all untested blood-spots received from the Department’s public health laboratory for supplemental of diagnostic testing within 90 days after testing is completed by the permittee.
| (a) Direct analysis of the enzyme, hormone, or protein; or (b) Testing for a substance whose metabolism is altered as a result of the defect. … | (i) Protected from undue physical or mental harm; and (ii) Informed of the nature, cost, benefits, and risks of any therapy or maintenance program available for an individual affected by a hereditary or congenital disorder; and | 10.10.13.13 Screening Test Specimens – Collection and Test Requisition. …B. Blood-Spot Collection Test Requisition Card Information. A person shall record the following information as specified on the Department-supplied blood-spot collection test requisition card: (1) Newborn infant information, including: (a) Name; (b) Date of birth; (c) Time of birth; (d) Current weight; (e) Gender; (f) Race; (g) Gestational age; (h) Birthing facility identification, including the: (i) Facility name; (ii) Facility street address, city, state, and zip code; and (iii) Newborn infant’s medical record or chart number; (i) Date and time of first feeding; (j) Type of feeding, such as: (i) Breast; (ii) Lactose- |
### §13-102 Findings

The General Assembly finds that:

1. Everyone in this State is entitled to the highest level of health care attainable and protection from inadequate health services;
2. Hereditary and congenital disorders are often costly and tragic and sometimes deadly burdens to the health and well-being of the citizens of this State;
3. Detection through screening for hereditary and congenital disorders can:
   - (i) Lead to alleviation of the disability of some hereditary and congenital disorders; and
   - (ii) Prevent the occurrence of the disability of others.

### 10.52.12.06 Pre-Test Information

Before a specimen is sent for newborn screening, a health care provider shall provide to the newborn infant’s parent or guardian an explanation of newborn screening that includes:

A. Reason for newborn screening, including the:
   - (1) Purpose of the testing; and
   - (2) Nature and consequences of being affected by a hereditary or congenital disorder or being a carrier of a hereditary or congenital disorder; and

B. Information on the pediatrician or attending physician who will be following the newborn containing:
   - (i) Formula containing no lactose;
   - (ii) Transfusion history, including transfusion date and time;
   - (l) General health status of the newborn infant; and
   - (m) The total protein and calorie intake for any newborn infant in a neonatal intensive care setting.

C. Blood-spot specimen information, including:
   - (a) Date of collection;
   - (b) Time of collection;
   - (c) Initials or other identifier of the individual who collected the specimen;

D. Mother or guardian information, including:
   - (a) Name;
   - (b) Street address, city, state and zip code;
   - (c) Telephone number where the mother or guardian may be reached;

E. Information on the pediatrician or attending physician who will be following the newborn containing:
   - (i) Formula containing no lactose;
   - (ii) Transfusion history, including transfusion date and time;
   - (l) General health status of the newborn infant; and
   - (m) The total protein and calorie intake for any newborn infant in a neonatal intensive care setting.
<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>(ii) Further the understanding of and accumulation of medical knowledge about other hereditary and congenital disorders that may lead to their eventual alleviation or cure;</td>
<td><strong>B.</strong> A parent or guardian’s right to object to having the testing performed, including: (1) Stating that newborn screening is wholly voluntary; (2) Explaining any risk involved in having newborn screening performed; and (3) Providing a reasonable opportunity to object to screening.</td>
</tr>
<tr>
<td>(4) Hereditary and congenital disorders differ in severity, in that: (i) Some have little effect on the normal functioning of an individual; and (ii) Some may be alleviated, wholly or partly, through medical intervention and treatment;</td>
<td><strong>10.52.12.07 Births in a Birthing Facility A.</strong> Specimen Collection and Screening. If the parent or guardian of the newborn infant does not object to newborn screening, the individual in charge of a birthing facility or the individual's designated representative shall:</td>
</tr>
<tr>
<td>(5) Most if not all, individual are carriers of some hereditary disorder and are substantially unaffected by that fact;</td>
<td>infant, including the physician’s: (a) Name; (b) Street address, city, state, and zip code; and (c) Telephone number; and (5) <strong>Other information</strong> that can affect the test results or the interpretation of the test results when applicable, such as that antibiotics were administered to the: (a) Mother; or (b) Newborn infant.</td>
</tr>
</tbody>
</table>

**10.52.12.03 Definitions.** … (20) "Supplemental test" means a test performed on a specimen collected from a newborn infant that is: (a) Used to detect a hereditary or congenital disorder not specified in Regulation .05 of this chapter; or (b) Not required to be performed by the Department's public health laboratory under this chapter or COMAR 10.10.13.
(6) A carrier of a hereditary disorder should not be discriminated against or stigmatized;

(7) Medical knowledge of the discovery, diagnosis, treatment, and cure of hereditary and congenital disorders is expanding rapidly and often at an uneven rate, so that hereditary and congenital disorders are discovered long before their treatment or cure can be found;

(8) Legislation designed to alleviate the problems associated with specific hereditary and congenital disorders may tend to be inflexible in the face of rapidly expanding medical knowledge;

(1) Collect a blood specimen:
(a) As set forth in:
(i) §§ C and D of this regulation; and
(ii) COMAR 10.10.13.13; and
(b) Pursuant to the procedures established in COMAR 10.10.13.14A; and

(2) Submit the collected blood specimen to the Department's public health laboratory.

10.52.12.05 Selection of Disorders for Screening. A. The Department, with the advice of the Council, shall select the disorders for which screening is required by the Newborn Screening Program: …

C. Supplemental Tests. The State's Newborn Screening Program may not request or perform a supplemental test until the public health laboratory has confirmed there is sufficient specimen to test for the required panel of disorders set forth in §B of this regulation.
(9) The policy of this State on hereditary and congenital disorders should be:
(i) Made with full public knowledge, in light of expert opinion; and
(ii) Reviewed constantly to consider changing medical knowledge and ensure full public protection;

(10) Participation in a hereditary and congenital disorders program should be wholly voluntary, and all information obtained about any individual in a hereditary and congenital disorders program should be kept confidential; and

**B. Parental Objection.**
When a parent or guardian objects to newborn screening, the individual in charge of a birthing facility or the individual's designated representative shall:

(1) Have the parent or guardian sign a form that states the parent or guardian objects to newborn screening; and

(2) Inform the Department's Follow-Up Unit by telephone, fax, or email of the objection within 12 hours after the objection.
(11) A commission is needed:
(1) To ensure that the policies and programs of this State for hereditary and congenital disorders comply with the principles established in this subtitle; and
(ii) To preserve and protect the freedom, health, and well-being of the citizens of this State from improper treatment or advice, discrimination, violation of privacy, or undue anxiety that results from any hereditary and congenital disorders program.

10.52.12.08 Births Outside a Birthing Facility … A.

(1) Provide to a parent or guardian the information that a health care provider is required to provide to a parent or guardian under Regulation .06 of this chapter;

(2) Have the parent or guardian sign a form that state the parent or guardian object to newborn screening if the parent or guardian objects;

(3) Inform the Department’s Follow-Up Unit by telephone, fax, or email of the objection within 12 hours after the objection; …
§ 13-108. Advisory Council - Specific powers as to hereditary and congenital disorder. To preserve and protect the health and welfare of the citizens of this State, the Advisory Council may:

(4) Advise the Secretary as to the need for rules, regulations, and standards for the detection and management of hereditary and congenital disorders…


(a) In general. - Subject to the requirements of this section, the Department may adopt rules, regulations, and standards for the detection and management of hereditary and congenital disorders.
(b) Consultations and consideration

(1) Before the Department adopts a rule, regulation, or standard, the Department shall consult:

(i) The public, especially communities and groups who particularly are affected by hereditary and congenital disorders programs;

(ii) Where appropriate, experts in the medical, psychological, ethical, social, and economic effects of programs for the detection and management of hereditary and congenital disorders; and

(iii) The Advisory Council…
c) Minimum standards - Access to information.

(1) The rules, regulations, and standards of the Department shall require the Department and each person who conducts a hereditary and congenital disorders program to keep in code and treat as a confidential medical record all information that is gathered in the program and identifies an individual. However, this requirement does not prevent the disclosure of information if the individual or, if the individual is a minor or disabled person, a parent or guardian of the person:

(i) Is informed of the scope of information to be released and the purpose of the release; and
(ii) Consents to the release…

10.52.12.14 Counseling.
Upon request, the Department’s Newborn Screening Follow-Up Unit shall make available to any parent or guardian of a newborn infant tested pursuant to this chapter, counseling services that:

A. Are nondirective;
B. Emphasize informing the parent or guardian; and
C. Do not require the restriction of childbearing.