### SOUTH CAROLINA

**Birth Defects Surveillance System**

<table>
<thead>
<tr>
<th>State</th>
<th>Statute/Rule</th>
<th>Language Specific to Surveillance System</th>
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<th>Research Authority</th>
<th>Consent Required?</th>
<th>Dissent Allowed?</th>
</tr>
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</table>
| SC    | STATUTE: SCCL, Title 44, Chapter 44 | SECTION 44-44-30. South Carolina Birth Defects Program established; public health monitoring and referral.  
(A) There is established the South Carolina Birth Defects Program within the Department of Health and Environmental Control to promote increased understanding of birth defects, prevent and reduce birth defects, and assist families with children who have birth defects.  
(B) As part of this program, the department shall conduct public health monitoring, make appropriate referrals and provide other interventions related to birth defects. Information obtained pursuant to this subsection must be used for:  
(1) public health and epidemiology purposes in which incidence, distribution, causes, risk factors, and trends may be studied. This data may be published and made accessible for education and research purposes. This information must be released in aggregate form only without identifying information;  
(2) referral for service and treatment purposes so that referrals of the individual child and family may be facilitated for optimal care... | 44-44-80. Access to health and medical records; confidentiality. All hospitals, health providers, birth centers, clinics, medical records departments, third party payers, laboratories, universities, and other sources of birth defects information shall provide access to all health or medical records for the purpose of surveillance and identification of birth defects in accordance with procedures promulgated by the department in regulation. This access is protected by state and federal law concerning birth defects monitoring, and confidentiality must be maintained by the department in accordance with Section 44-44-140. Individually identifiable data may not be made available to the public.  
44-44-110. Providing data to National Center for Birth Defects and Developmental Disabilities at the Centers for Disease Control and Prevention... | 44-44-60. Utilization of data. The Birth Defects Program shall concentrate on public health surveillance and monitoring birth defects. Data may be made available to persons or institutions outside the program for education, research, provision of services, and other purposes in accordance with program procedures.  
44-44-100. Use and disclosure of birth defects data. Birth defects data may be used and disclosed for the purposes of scientific research concerning causation, prevention strategies, epidemiological analysis, environmental and geographic study, and other purposes authorized by the department. | NO | NO |
### SECTION 44-44-70. Maintenance of central database; case ascertainment.

The department shall maintain a central database for the gathering of data from hospitalizations, specialty clinics, births, pregnancies, stillbirths, and pediatric deaths through age two, throughout the State, including border regions. The department shall establish procedures for active birth defect case ascertainment. The data system must be maintained to be accurate, timely, and dynamic, and the department shall institute procedures to make this system effective. The department may expand the age range for data collection as resources become available and if the department determines the additional data collection would benefit the program.

### Section C: Public Health Surveillance and Monitoring of Birth Defects

1. The Department shall conduct statewide monitoring of all major structural birth defects using active surveillance methods to ascertain cases. This monitoring may be both prenatal and postnatal (up to two years of age) and shall include live births and fetal deaths occurring in South Carolina. South Carolina Birth Defects Program Nurse Abstractors will conduct active surveillance at all hospitals in South Carolina that provide obstetrical or pediatric care for case identification and abstraction. Hospitals and other medical facilities will provide, upon request, access to medical records containing ICD-9-CM diagnostic code categories in the range of birth defects codes recommended by the Centers for Disease Control (CDC) and the National Birth Defects Prevention Network (NBDPN) for surveillance. The categories of ICD-9-CM codes for birth defects includes, but is not limited to, the following:

- a. Upon request, the Department shall have access to all records of parent(s), child, and siblings if necessary, for the purpose of identifying birth defects, including vital records, hospital medical records, physician office medical records, specialty clinic records, and discharge data, in order to identify birth defect cases. The Department shall verify the cases through records review and may include review by a physician geneticist.

- b. For the purpose of surveillance and identification of birth defects, all laboratories, universities, and other sources of birth defects information shall provide the Department access to all health, medical, or other records, upon request.

- c. Access to all records described herein may be granted in hard copy or electronically.

### Section D: Data Usage

1. Unless otherwise provided by law, all reports generated by the Department containing birth defects data will be subject to the following: Data may be provided to the National Center for Birth Defects and Developmental Disabilities at the Centers for Disease Control and Prevention to enhance scientific, epidemiological, and investigative efforts and studies.

### SECTION 44-44-140. …(B)

The department shall maintain confidentiality in regard to:

- (3) epidemiological study and reporting;
- (4) research uses; …

**61-114…Section F: Confidentiality**

These records will be kept confidential and used and released pursuant to the provisions of S.C. Code Ann. Section 44-44-140 only.
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<table>
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<tbody>
<tr>
<td>a. Central nervous system disorders</td>
<td>4. The Department may negotiate and enter into agreements and contracts with state and federal agencies, other states, universities, genetic centers and other parties, as appropriate, in order to facilitate operation of the program. These agreements and contracts may include the release of identifying data to enable the other entity to offer families assistance for prevention of recurrence of birth defects.</td>
</tr>
<tr>
<td>b. Eye and ear disorders</td>
<td>5. The Department may enter into agreements with other states, health care facilities, and other entities in order to conduct monitoring of birth defects.</td>
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<td>c. Cardiovascular disorders</td>
<td>61-114 …Section E: Referral</td>
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<tr>
<td>d. Orofacial disorders</td>
<td>1. The Department may contact a family whose child is identified as having a structural birth defect either directly or through the child's health care provider in order to offer services. Family acceptance of referrals is voluntary. Referrals shall be made in accordance with the Department guidelines and recommendations.</td>
</tr>
<tr>
<td>e. Gastrointestinal disorders</td>
<td>2. South Carolina Birth Defects Program nurse abstractors will conduct surveillance activities, to include review of medical records for documentation of physician, social work or discharge planner referral for follow-up of children with birth defects. When there is no documented evidence of follow-up, South Carolina Birth Defects Program staff may access other appropriate health and developmental systems or organizations for referral for early intervention, such as Babynet. Babynet will provide regular feedback, as requested, to South Carolina Birth Defects Program on status of birth defects cases referred.</td>
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<tr>
<td>f. Genitourinary disorders</td>
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<td>g. Musculoskeletal disorders</td>
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<td>h. Chromosomal disorders</td>
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<tr>
<td>i. Other disorders to include Fetal Alcohol Syndrome and Amniotic bands</td>
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<tr>
<td>j. ICD-9-CM codes regarding known or suspected fetal abnormality affecting management of mother.</td>
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2. The birth defects surveillance system will be implemented by phasing in additional birth defect categories until all CDC recommended types of birth defects are monitored.

3. Birth defects case abstraction information will include demographic data on the child, mother and father, if available.

4. The Department shall maintain a central database of all birth defects data gathered from hospitals, specialty clinics and other facilities, regarding births, pregnancies, stillbirths, and pediatric deaths through age two, throughout the state, including border regions.
## Cancer Surveillance System

<table>
<thead>
<tr>
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<tr>
<td>SC</td>
<td>STATUTE: SCCL, Title 44, Chapter 35, Section 44-35</td>
<td>SECTION 44-35-10. Formulation of plan for cancer prevention, detection, and surveillance programs. The Department of Health and Environmental Control, in conjunction with hospitals and entities throughout the State, shall formulate a plan for cancer prevention, detection, and surveillance programs and for care of persons suffering from cancer to meet standards of care set forth by nationally recognized and approved accrediting bodies.</td>
<td>SECTION 44-35-50. Coordination of collection and report of cancer data. The registry shall coordinate, to the fullest extent possible, with the State Budget and Control Board, Office of Research and Statistical Services, for the complete, timely, and accurate collection and reporting of cancer data.</td>
<td>SECTION 44-35-40. Confidentiality; data release protocol. Information that could identify the cancer patient must be kept strictly confidential in accordance with the administrative policy of the Department of Health and Environmental Control. This information must not be open for inspection except by the individual patient or the patient’s authorized representative. Procedures for the disclosure of confidential information to researchers for the purposes of cancer prevention, control, and research must be promulgated in regulations. The data release protocol developed in coordination with the South Carolina Budget and Control Board, Office of Research and Statistical Services, must be utilized by the registry to determine appropriate use and release of cancer registry data.</td>
<td>NO</td>
</tr>
<tr>
<td></td>
<td>RULE: Chapter 61; 61-45.</td>
<td>SECTION 44-35-20. Establishment, administration, and purpose of central cancer registry. (A) There is established the South Carolina Central Cancer Registry and, to the extent funds are available, the Department of Health and Environmental Control shall administer this as a statewide population-based registry of cancer cases with a diagnosis date after December 31, 1995. (B) The purpose of the registry is to provide statistical information that will reduce morbidity and mortality of cancer in South Carolina. This information must be used to guide cancer control effort in the State by assisting in prevention and early detection of cancer, extending the life of the cancer patient, identifying high-risk groups or areas in the State with cluster of cancer cases, and improving cancer treatment. (C) The registry shall receive, compile, analyze, and make available epidemiological and aggregate clinical cancer case information collected from all health care providers who diagnose and/or treat cancer patients in this State. The registry shall meet national standards of completeness and timeliness of case reporting and quality of data. Annual reports of aggregate cancer data must be provided to reporting facilities and physicians in the State. SECTION 44-35-30. Reporting requirements; applicable regulations. (A) A provider who diagnoses and/or treats cancer patients and does not report to a regional cancer registry shall report specific case information to the registry in accordance with regulations promulgated by the Department of Health and Environmental Control. These regulations shall include, but are not limited to, the reportable case listing, data elements to be collected, the content and design of forms and reports required by this section, the procedures for disclosure of information gathered by the registry, and other matters necessary to the administration of this section. The regulations shall include these data elements:</td>
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Updated August 2012. All state statutes and department rules originally accessed online July/Aug 2008. Statute/Rule data not inclusive. For comprehensive or updated language, access complete statute and rules online, at local library or through the state legislature.
(1) complete demographic information;
(2) occupational and industrial information to the extent available;
(3) date and confirmation of initial diagnosis;
(4) pathological information characterizing the cancer, including cancer
site and cell type, stage of disease, and initial treatment information, to
the extent available, in the medical record.
A provider participating in a regional registry is not required to report to
the Central Cancer Registry. Reporting providers must not incur
additional expense in providing information to the registry.
(B) Regional registries shall report data on behalf of providers in their
area to the Central Cancer Registry.

61-45. South Carolina Central Cancer Registry. …B. DEFINITIONS.
I. “South Carolina Central Cancer Registry (SCCCR)” means the
population-based cancer data system for the collection, storage,
maintenance, analysis, and dissemination of all cancer cases occurring
in South Carolina, diagnosed after December 31, 1995, under the
administration of the South Carolina Department of Health and
Environmental Control (DHEC). …

SECTION 44-35-70. Acquisition of laboratories, hospitals, or other
property. The Department of Health and Environmental
Control may, to the extent of and within the available funds which may be
provided, acquire laboratories, hospitals, or other property, either real
or personal, by gift, purchase, devise or otherwise, as the department considers
advisable to afford proper treatment and
care to cancer patients in this State
and to carry out the intent and purpose of
this chapter.

3. The DHEC CCAC shall advise and make
recommendations to the Department about the issues
related to cancer surveillance, including all Central
Cancer Registry activities. A subcommittee of the
CCAC called the Surveillance Subcommittee shall
have specific responsibility to determine the
appropriateness of requests for confidential data
release. Membership of this subcommittee shall
consist of statewide representation of cancer
researchers, the South Carolina Medical Association,
the South Carolina Hospital Association, and the South
Carolina Budget and Control Board Office of Research
and Statistics. Strict criteria set forth in the SCCCR
Data Release Protocol written in coordination with the
South Carolina Budget and Control Board Office of
Research and Statistics Principles and Protocol for
Release of Health Data shall be utilized to review each
data release request. This Subcommittee also assures
the DHEC Internal Review Board approval when
appropriate in order to assure protection of human
subjects.
Newborn Genetic Testing & Surveillance System

<table>
<thead>
<tr>
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</thead>
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<tr>
<td>SC</td>
<td>STATUTE: SCCL, Title 44, Chapter 37</td>
<td>SECTION 44-37-30 Neonatal testing of children; storage and availability of blood samples for future tests; confidentiality; religious exemption; violation and penalties. (A) A child born in this State, except a child born of a parent who objects on religious grounds and indicates this objection before testing on a form promulgated in regulation by the Department of Health and Environmental Control, shall have neonatal testing to detect inborn metabolic errors and hemoglobinopathies. (B) Information obtained as a result of the tests conducted pursuant to this section is confidential and may be released only to a parent or legal guardian of the child, the child’s physician, and the child when eighteen years of age or older when requested on a form promulgated in regulation by the department. (C) A blood sample obtained pursuant to this section is confidential and may be released only as the parent or legal guardian of the child from whom a blood sample was obtained, or the child if eighteen years of age or older, directs the department at the time of testing or at any time after that on a form promulgated in regulation by the department. (D)(1) Unless otherwise directed pursuant to this subsection, a blood sample obtained pursuant to this section must be stored by the department at minus 20° centigrade and may be released for purposes of confidential, anonymous scientific study. The release of a blood sample must conform with regulations 44-37-30: (A) A child born in this State, except a child born of a parent who objects on religious grounds and indicates this objection before testing on a form promulgated in regulation by the Department of Health and Environmental Control, shall have neonatal testing to detect inborn metabolic errors and hemoglobinopathies. (E) (1) A blood sample that has not been stored at minus 20° centigrade before the effective date of this section must be destroyed in a scientifically acceptable manner six months from the effective date of this section unless a parent or legal guardian of a child from whom a blood sample was obtained, or the child if eighteen years of age or older, requests return of the blood sample on a form provided by the department. …(E)(2) A blood sample stored at minus 20° centigrade pursuant to this section before the effective date of this section must be retained as prescribed in subsection (D) unless directed by the parent or legal guardian of the child from whom a blood sample was obtained to destroy or return the blood sample. 61-80 Section D – Collection of Specimen. …2…c. A specimen shall be collected from every child born in the hospital prior to release from the hospital (except when the parents object due to religious convictions) in accordance with the procedure specified in the Official Departmental Instructions. If the parent objects to the screening on the basis of religious convictions, the parent shall complete the procedure specified in the 61-80 Section F – Storage of Specimen …3. 3. The Laboratory shall store all specimens at minus 20° Centigrade and may release specimens for purposes of confidential, anonymous scientific study unless prohibited by the parents, legal guardians, or children from whom the specimens were obtained when the children are eighteen years of age or older. 4. Hospital staff or other persons who collect these specimens shall ensure that the parent’s or legal guardian’s storage choice is documented on the Blood Sample Storage Options form if the parent or legal guardian does not agree to have their child's blood specimen stored and potentially released for confidential, anonymous scientific study. In these instances, the Laboratory shall maintain all such specimens based upon the storage option chosen by the parent or legal guardian as documented on the Blood Sample Storage Options form.</td>
<td>NO</td>
<td>YES</td>
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</table>
promulgated by the department. At the time of testing or at any time after that, on a form promulgated in regulation by the department, the parent or legal guardian of the child from whom a blood sample was obtained, or the child when eighteen years of age or older, may direct the department to:
(a) return a blood sample in its entirety and any test results not less than two years after the date of testing;
(b) destroy a blood sample in a scientifically acceptable manner not less than two years after the date of the testing; or
(c) store a blood sample at minus 20° centigrade but not release the blood sample for confidential, anonymous scientific study.

(2) A blood sample released for confidential, anonymous study pursuant to this section must not contain information which may be used to determine the identity of the donor. A blood sample released pursuant to this section may contain demographic or other statistical information. If scientific study identifies genetic information that may benefit the child, the department may notify confidentially the parent or legal guardian, or the child if eighteen years of age or older, of this information.

(E)(1) A blood sample that has not been stored at minus 20° centigrade before the effective date of this section must be destroyed in a scientifically acceptable manner six months from the effective date of this section unless a parent or legal guardian of a child from whom a blood sample was obtained, or the child if eighteen years of age or older, requests return of the blood sample on a form provided by the department.

Official Departmental Instructions.

61-80 Section H-Forms

1. Religious Objection Form: The Religious Objection Form, Appendix A of this regulation, shall be completed if the parents refuse newborn screening for inborn metabolic errors and hemoglobinopathies for their child based upon religious convictions.

2. Information Release Form: The Information Release Form, Appendix B of this regulation, may be completed as needed for release of information regarding newborn screening for inborn metabolic errors and hemoglobinopathies to persons other than those specified elsewhere in this regulation.

3. Blood Sample Storage Options Form: The Blood Sample Storage Options Form, Appendix C of this regulation, shall be completed if the parents or legal guardians do not agree to have their child’s specimen stored and potentially released for confidential, anonymous scientific study.

APPENDIX A: Religious Objection Form: DHEC 1804, Newborn Screening Program, Parental Statement of Religious Objection

I am the parent or legal guardian of ________________, a child born __________ in South Carolina. I request that my child not be tested by blood spot screening in order to detect silent, deadly metabolic diseases and hemoglobinopathies. I certify this refusal is based on religious grounds. Religious grounds are the only permitted reason for refusal under South Carolina law, Section 44-37-30 (C).

Section G-Use of Stored Specimen

1. Stored blood specimens may be released for the purposes of confidential, anonymous scientific study unless prohibited by the parent, legal guardian, or child from whom the specimen was obtained when he/she is eighteen years of age or older.

2. The Department's Institutional Review Board shall approve all scientific studies that use stored blood specimens before the specimens are released.

3. Blood specimens released for scientific study shall not contain information that may be used to determine the identity of the children from whom they were obtained by the person(s) to whom the specimens are released. The Department shall code the specimens before releasing them so that the Department can identify the children from whom the blood specimens were obtained if necessary.

4. If any such scientific study identifies genetic or other information that may benefit the children from whom the specimens were obtained, the Department may confidentially provide this information to the parents, legal guardians or children from whom the specimens were obtained when the children are eighteen years of age or older.

Section 38-93-40. Confidentiality; disclosure restrictions and exceptions. (A) All genetic information obtained before or after the effective date of this chapter must be confidential and must not be disclosed to a third party in a manner that allows identification of the individual tested without first obtaining the written informed consent of that individual or a person legally authorized to consent on behalf of the individual, except that genetic information may be disclosed without consent: 

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Statute/Rule data not inclusive. For comprehensive or updated language, access complete statute and rules online, at local library or through the state legislature.

www.cchfreedom.org
A blood sample stored at minus 20° centigrade pursuant to this section before the effective date of this section must be retained as prescribed in subsection (D) unless directed by the parent or legal guardian of the child from whom a blood sample was obtained to destroy or return the blood sample.

The department shall promulgate regulations necessary for the implementation of this section. All forms must include information concerning the benefits of neonatal testing and storage of a blood sample.

A person who violates this section or the regulations promulgated pursuant to this section or who provides or obtains or otherwise tampers with a blood sample collected pursuant to this section is guilty of a misdemeanor and, upon conviction, may be fined not more than thirty thousand dollars or imprisoned for not more than three years.

Section 38-93-50. Informed consent required for genetic test; exceptions. It is unlawful to perform a genetic test an individual without first obtaining specific informed consent to the test from the individual, or a person legally authorized to consent on behalf of the individual, unless the test is performed: ... (4) pursuant to a statute or court order specifically requiring that the test be performed. (5) for diagnosis or treatment of the individual if performed by a clinical laboratory that has received a specimen referral from the individual's treating physician or another clinical laboratory. Nothing in this item may be construed so as to waive the requirement that the treating physician obtain specific informed consent in accordance with the provisions of this section.

APPENDIX C: Blood Sample Storage Options
Form: DHEC 1812, Blood Sample Storage Options, Screening for Inborn Metabolic Errors and Hemoglobinopathies ...
...IF THIS FORM IS NOT SIGNED BY A PARENT/LEGAL GUARDIAN AND/OR NONE OF THE ABOVE BOXES ARE CHECKED, THE BLOOD SAMPLE WILL BE STORED AS REQUIRED BY SC CODE ANN. Section 44-37-30 AT -20 DEGREES CENTIGRADE AND MAY BE RELEASED ONLY FOR CONFIDENTIAL, ANONYMOUS SCIENTIFIC STUDY.

NOTE TO PROVIDERS: The parent or legal guardian is not required to sign this form. However, the person who gives the brochure that explains neonatal testing and blood sample storage to the parent or legal guardian must sign this form.
<table>
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<tr>
<th>2.</th>
<th>Hospital staff or other persons who collect these blood specimens shall give the brochure produced by the Department that explains newborn screening for inborn metabolic errors and hemoglobinopathies to the parent or legal guardian as a means of informing them of the benefits of screening and blood specimen storage. Hospital staff or other persons who collect these blood specimens shall indicate that the brochure was given to the parent or legal guardian by documenting in the appropriate space on the Blood Sample Storage Options Form…</th>
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<tr>
<td></td>
<td>I release and hold harmless the South Carolina Department of Health and Environmental Control, the hospital or other facility at which the birth occurred, the person(s) responsible for the collection of the blood spots, and any other person or entity relying on this objection, for any injury, illness and/or consequences, including the death of my child, which may result to my child as the result of my refusal of blood spot screening.</td>
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<tr>
<td></td>
<td>Parent: __________ Date: __________</td>
</tr>
<tr>
<td></td>
<td>Witness: __________</td>
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Vaccination Surveillance System

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<tr>
<td>SC</td>
<td>STATUTE: Title 44, Chapter 29</td>
<td><strong>SECTION 44-29-40.</strong> Department of Health and Environmental Control shall have general supervision of vaccination, screening and immunization; statewide immunization registry. <em>(language adding registry became law in 2010 without Governor’s signature)</em></td>
<td>“Immunization Registry: This successful ongoing partnership with the medical community aims to continue increasing the number of health care providers who participate in a fully operational population-based immunization registry. This partnership is a critical component of the immunization project’s public health infrastructure…”</td>
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</table>

(A) The Department of Health and Environmental Control shall have general direction and supervision of vaccination, screening, and immunization in this State. The Department of Health and Environmental Control has the authority to promulgate regulations concerning vaccination, screening, and immunization requirements.

(B) The department shall establish a statewide immunization registry and shall promulgate regulations for the implementation and operation of the registry. All health care providers shall report to the department the administration of any immunization in a manner and including such data as specified by the department. The department may make immunization information available to persons and organizations in accordance with state and federal disclosure and reporting laws. The department may seek enforcement of this section and issue civil penalties in accordance with Section 44-1-150.

**SECTION 44-29-50.** Any person who shall fail, neglect or refuse to comply with any regulation of the Department of Health and Environmental Control relating to vaccination, screening or immunization shall be deemed guilty of a misdemeanor and upon conviction shall be fined not more than one hundred dollars or be imprisoned for not more than thirty days.

**SECTION 44-1-140.** Department may promulgate and enforce rules and regulations for public health.

The Department of Health and Environmental Control may make, adopt, promulgate and enforce reasonable rules and regulations from time to time requiring and providing:

…(10) For the care, segregation and isolation of persons having or suspected of having any communicable, contagious or infectious disease;

…(12) For the thorough investigation and study of the causes of all diseases, epidemic and otherwise, in this State, the means for the prevention of contagious disease …