## PENNSYLVANIA

### Birth Defects Surveillance System

<table>
<thead>
<tr>
<th>State</th>
<th>Statute/Rule</th>
<th>Language Specific to Surveillance System</th>
<th>Data Sharing</th>
<th>Research Authority</th>
<th>Consent Required?</th>
<th>Dissent Allowed?</th>
</tr>
</thead>
<tbody>
<tr>
<td>PA</td>
<td>NONE</td>
<td><strong>NONE</strong></td>
<td></td>
<td></td>
<td>NO</td>
<td>NO</td>
</tr>
</tbody>
</table>

“The Department of Health today launched the Pennsylvania Environmental Public Health Tracking Network, or PA EPHTN, which will track key environmental hazards, exposures, and health problems statewide.” – “Pennsylvania Department of Health Launches New Environmental Health Tracking Tool,” Press Release, Pennsylvania Department of Health, March 9, 2009

“Pennsylvania currently does not have a birth defects surveillance system in place.” – Birth Defects state Profile – Pennsylvania, National Birth Defects Prevention Network, January 2009

Pennsylvania Birth Defects Surveillance System (under the Division of Maternal and Child Health per Pennsylvania State Genetics Profile, Snapshot of Summer 2005)

## Cancer Surveillance System

<table>
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<tr>
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<tr>
<td>PA</td>
<td>STATUTE: P.S. Title 35 Chapter 27A</td>
<td>§ 5636. Cancer registry (a) The Department of Health shall establish a system for the Statewide collection and dissemination of data on cases of cancer by anatomical site, medical and occupational history of patients, stage of disease and other data necessary to effectuate the provisions of this act as determined by the department.</td>
<td>§ 5636. Cancer Registry ... (b) Persons in charge of hospitals and laboratories shall be required by the Department of Health, in accordance with its regulations adopted with the advice of the board to report cases of cancer on forms furnished by the department.</td>
<td>§ 5636. Cancer Registry ... (e) The reports required pursuant to this act shall be confidential and not open to public inspection or dissemination. This shall not restrict the collection and analysis of data by the Department of Health or those with whom the department contracts, nor shall it restrict the department from permitting the use of the reports and data contained therein for research purposes, subject to strict supervision by the Department of Health to insure that the use of the reports is limited to specific research purposes.</td>
<td>NO</td>
</tr>
<tr>
<td>RULE: PA Code, Title 28, Chapter 27</td>
<td>§ 5634. Responsibilities of the board. ... (d) In order to implement in whole or in part the Pennsylvania Cancer Plan, the board shall recommend to the secretary the awarding of grants and contracts to qualified associations, nonprofit organizations or governmental agencies in order to plan, establish or conduct programs in cancer control or prevention, cancer education and training and cancer clinical research. (e) Grants and contracts may be recommended for: (1) Cancer registry. [emphasis added] (2) Cancer screening, detection and prevention. (3) Cancer epidemiology and bio-statistical studies. (4) Cancer community outreach programs, including, but not limited to, grants for the provision of facilities and personnel for conducting summer camps and other activities for cancer-afflicted children. (5) Cancer rehabilitation. (6) Communication and planning among cancer institutions. (7) Cancer education and information. (8) Cancer training. (9) Cancer clinical research. (f) Consistent with the Pennsylvania Cancer Plan the board shall give its first priority to funding grants and contracts relating to subsection (e)(1), (2), (3) and (4); second priority to funding grants and contracts relating to subsection (e)(5) and (6); third priority to funding grants and contracts relating to subsection (e)(7), (8) and (9).</td>
<td>§ 5637. Sunset provisions. With the exception of section 6, [FN1] [cancer registry] this act shall expire on June 30, 2016, unless otherwise extended by an act of the General Assembly.</td>
<td><strong>§ 27.31. Reporting cases of cancer.</strong> (d) Reports submitted under this section are confidential and may not be open to public inspection or dissemination. Information for specific research purposes may be released in accordance with procedures established by the Department with the advice of the Pennsylvania Cancer Control, Prevention and Research Advisory Board. (e) Case reports of cancer shall be sent to the Cancer Registry, Division of Health Statistics, Bureau of Health Statistics and Research, unless otherwise directed by the Department.</td>
<td></td>
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</tbody>
</table>

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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.*

www.cchfreedom.org
(c) The Department or its authorized representative shall be afforded physical access to all records of physicians and surgeons, hospitals, outpatient clinics, nursing homes and all other facilities, individuals or agencies providing services to patients which would identify cases of cancer or would establish characteristics of the cancer, treatment of the cancer or medical status of any identified cancer patient…. [emphasis added]

§ 27.4. Reporting cases. (a) Except for reporting by a clinical laboratory, a case is to be reported to the LMRO serving the area in which a case is diagnosed or identified unless another provision of this chapter directs that a particular type of case is to be reported elsewhere. A clinical laboratory shall make reports to the appropriate office of the Department. (b) Upon the Department’s implementation of its electronic disease surveillance system for certain types of case reports, persons who make those reports shall do so electronically using an application and reporting format provided by the Department. At least 6 months in advance of requiring a type of case report to be reported electronically, the Department will publish a notice in the Pennsylvania Bulletin announcing when electronic reporting is to begin. [emphasis added]
## Newborn Genetic Testing & Surveillance System

<table>
<thead>
<tr>
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<th>Language Specific to Genetic Testing and Surveillance System</th>
<th>Exemption</th>
<th>Research Authority</th>
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</tr>
</thead>
<tbody>
<tr>
<td>PA</td>
<td>STATUTE: Title 35 P.S. Chapter 3, Section 623</td>
<td>§ 623. Newborn Child Screening and Follow-up Program (a) In order to assist health care providers to determine whether treatment or other services are necessary to avert mental retardation, permanent disabilities or death, the department, with the approval of the Newborn Screening and Follow-up Technical Advisory Committee, shall establish a program providing for: (1) The screening tests of newborn children for the following diseases: (i) Phenylketonuria (PKU). (ii) Maple syrup urine disease (MSUD). (iii) Sickle-cell disease (hemoglobinopathies). (iv) Galactosemia. (v) Congenital adrenal hyperplasia (CAH). (vi) Primary congenital hypothyroidism. (2) Follow-up services relating to case management, referrals, confirmatory testing, assessment and diagnosis of newborn children with abnormal, inconclusive or unacceptable screening test results for the following diseases… (b.1) All laboratories performing the screening tests for newborn children shall report the results to the department for follow-up activities. (d) The department… shall establish, by periodic publication in the Pennsylvania Bulletin, changes to the lists under subsection (a)(1) and (2) of those diseases for which newborn children shall be screened and laboratory screening results reported. (f) Test results for genetic diseases listed in this section and any diseases subsequently added by the department under subsection (d) shall be subject to the confidentiality provision of the “Disease Prevention and Control Law of 1955.”</td>
<td>§ 623. Section 3. …(c) No screening test shall be performed if a parent or guardian dissents on the ground that the test conflicts with a religious belief or practice. § 28.11. Informing the parent or guardian. Prior to specimen collection, the health care provider shall provide the pregnant woman, prior to the infant’s birth, or the mother or guardian, after the infant’s birth, with a pamphlet supplied by the Department to explain the nature of the newborn screening blood tests for the diseases in §28.2 (relating to newborn diseases listed).</td>
<td>§ 28.5. Confidentiality. (a) A health care provider, testing laboratory, the Department or any other entity involved in the newborn screening program may not release any identifying information relating to any newborn child screened in the newborn screening program to anyone other than a parent or guardian of the newborn child or the health care provider for the newborn child designated by a parent or the guardian except as follows: (1) As may be necessary to provide services to the newborn child. (2) With the consent of the newborn child’s parent or guardian. (3) With the child’s consent when the child is 18 years of age or older, has graduated from high school, has married or has been pregnant. (b) Only the Department will have the authority to release or authorize the release of nonidentifying information concerning the newborn screening program.</td>
<td>NO</td>
<td>YES</td>
</tr>
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</table>

*From “Pennsylvania Screening Services for NEW BORN BABIES,” PA Dept. of Health brochure,(no date, accessed online 1/4/09): “By Pennsylvania law, your baby’s blood filter paper test cannot be used for scientific research by any laboratory without your signed permission.”*
| §521.15 Confidentiality of reports and records [Disease Prevention and Control Law of 1955] | State and local health authorities may not disclose reports of diseases, any records maintained as a result of any action taken in consequence of such reports, or any other records maintained pursuant to this act or any regulations, to any person who is not a member of the department or of a local board or department of health, except where necessary to carry out the purposes of this act. State and local health authorities may permit the use of data contained in disease reports and other records, maintained pursuant to this act, or any regulation, for research purposes, subject to strict supervision by the health authorities to insure that the use of the reports and records is limited to the specific research purposes. |

| §28.12. Religious objections. (a) A health care provider may not collect or cause to be collected, a specimen from a newborn child if the parent or guardian of the newborn child objects on the ground that the specimen collection conflicts with religious beliefs or practices held by the parent or guardian. (b) If the parent or guardian of the newborn child objects to the collection of the specimen for screening on the ground that the specimen collection conflicts with religious beliefs or practices held by the parent or guardian, the health care provider shall ensure that the recorded objection of the parent or guardian is entered into the medical record of the newborn child. The entry shall include a written statement of the objection signed by the parent or guardian. |

| "Pennsylvania and Nebraska require written consent from parents for any medical research use of these blood spots..." |

### Vaccination Surveillance System

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<tr>
<td>PA</td>
<td>NONE</td>
<td>NONE</td>
<td>&quot;Il. Notification: All participating provider practices, with the exception of those operating on behalf of the Department, must notify patients that their information will be included in the PA-SIIS. The Department is a public health authority legally authorized to receive information without patient authorization for the purpose or preventing or controlling disease. The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule states that providers may disclose protected health information to public health authorities for public health activities without authorization from the individual. These public health activities&quot;</td>
<td>&quot;All birth records from 1996 to date are electronically imported into PA-SIIS weekly.&quot; – Statewide Immunization Information System, Pennsylvania Department of Health, June 2004</td>
<td>NO</td>
<td>NO – unless clinic does not participate</td>
</tr>
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§ 510.701. Consent and confidentiality of health information

(a) Construction.--
(1) Nothing in this act [Chpt. 2A, §510.101, eHealth Information Technology Act] shall be construed to prohibit a health care provider or payer from obtaining and storing a patient's health records in electronic form or exchanging health information with another health care provider or payer in accordance with Federal law or State law other than this act.

(2) Nothing in this act shall supersede or limit any other law which requires additional consent to the release of health information or otherwise establishes greater restrictions or limitations on the release of health information.

(b) Consent.-- The authority shall promulgate a consent form including notice of a patient's ability to decline to allow exchange of the patient's electronic health information in the health information exchange. The notice shall include, at a minimum and in plain language, the following information: 

(1) Definition of a health information exchange.

(2) Explanation of the benefits of participation in the health information exchange.

(3) Explanation of the limits of the patient's ability to decline the release or exchange of the patient's health information with the health information exchange.

(4) Explanation of the manner in which the health information exchange will address privacy issues.

(5) Explanation of the manner in which an individual may decline to participate in the health information exchange.

(c) Opt-out registry.--
(1) In order to decline participation in the health information exchange, a patient must sign and date a form declining participation. If appropriate, the signature must be witnessed by the patient’s representative. Copies of the completed form shall be sent by the provider within five business days to the authority to be included in an opt-out registry.

(2) After receipt of the form, the authority shall within five business days notify health information organizations that the patient has not authorized the release of the health information.

(3) Once the patient is included in the opt-out registry, the authority shall notify the patient. The notification shall include a copy of the completed form signed by the patient or electronic notification to the patient.

(4) The patient alone shall decide to opt out of a health information exchange.

(d) Disclosure.--

(1) The authority shall retain only the health information necessary for the operation of the health information exchange. The authority may not disclose, without prior written consent of the patient, any health information that the authority or its employees, agents or contractors retain, or to which the authority or its agents or contractors have access or any other health records maintained or accessible by the authority under this act, to any person who is not an authorized employee, agent or contractor of the authority, except as required by law.

(2) Sharing health information among participants in the health information exchange shall not be considered a disclosure under paragraph (1). [emphasis added]

(3) Violations of this subsection:

(i) shall subject employees, agents and contractors to administrative discipline, including discharge and suspension; and

(ii) shall subject contractors to monetary penalties or contract revocation or suspension.

(e) Construction.--Nothing in this act may be construed to alter a proprietary interest held by any participant in any record, data or information released, accepted or included in the health information exchange, except insofar as the paperwork approved by the authority may require participants to license those interests by contract in order to allow for the free flow of information.

include preventing or controlling disease, injury, or disability; reporting disease, injury and vital events such as birth or death; and conducting public health surveillance, public health investigations and public health interventions according to the [45 CFR 164.512(b) and Disease Prevention and Control Law, 35 P.S. §521.1, et seq., and the regulations promulgated thereunder, 28 Pa. Code §27.1 et seq. (relating to communicable and non-communicable diseases)].

“According to the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule 45 CFR 164.512(b), and Disease Prevention and Control Law, Title 28 Chapter 27 Communicable and non-communicable disease regulations, protected health information may not be released or disclosed to anyone except to public health authorities for public health activities. The public health activities are defined in the PA-SIIS Confidentiality Policy (see Section II: Notification)” – Pennsylvania Statewide Immunization Information System User Agreement Acknowledgement. Accessed 12/17/08

“Yes. Providers must enter the immunization histories of all patients. Typically, immunizations histories are entered when patients present for immunizations. A complete immunization history offers key benefits such as generation of an official immunization record, calculation of immunization rates for your practice, and generation of accurate reminder/recall notifications. Entry of complete immunization histories also assists in minimizing unnecessary duplicate immunization administration.” – Frequently Asked Questions, SIIS, PA Dept of Health, accessed August 18, 2012 at [http://www.portal.state.pa.us/portal/server.pt/community/pa_statewide_immunization_information_system_(pa-siis)/14281/faqs/556461#double]