ARTICLE 21. REPORTING

Rule 1. State Cancer Registry

410 IAC 21-1-1 Definitions
Authority: IC 16-38-2-10
Affected: IC 16-38-2

Sec. 1. As used in 410 IAC 21-1:

"Cancer registry" means a mechanism by which data relating to all cases of malignant disease that occur in Indiana residents is recorded and, necessary and appropriate information is compiled concerning those cases as determined by the board, in order to conduct epidemiologic surveys of cancer and to apply appropriate preventive and control measures.

"Confirmed case" means the best evidence available for determining the nature of malignant disease using the following methods and codes: 1 = positive histology; 2 = positive exfoliative histology in the absence of positive histology; (3 is vacant) 4 = positive microscopic confirmation not otherwise specified (NOS); (5 is vacant) 6 = direct visualization without microscopic confirmation; 7 = radiography without microscopic confirmation; 8 = clinical diagnosis (other than 6 or 7) including gross examination at autopsy; and 9 = unspecified whether or not microscopically confirmed, unknown. This is a priority series with code 1 taking precedence. Each number takes priority over all higher numbers (i.e., 1 over 4, and 5 over 9 etc.).

"Data set" means all clinical, pathological *[sic.,]* therapeutic and demographic information defined in 410 IAC 21-1-3 and 410 IAC 21-1-4.

"ICD-O" means International Classification of Diseases for Oncology, 1976, World Health Organization publication, Organisation Mondiale De La Sante, 1211, Geneva 27, Switzerland.

"Indiana resident" means an individual domiciled in the state of Indiana.

"Malignant disease" means confirmed cases of cancer enumerated in the ICD-O excluding superficial, squamous and basal cell carcinomas of the skin.

"Patient" means any individual who is ill, or undergoing diagnosis or treatment for disease by a dentist, medical laboratory, physician or hospital.

"Person" means an individual, association, partnership, corporation, or governmental entity.

"State board" means the Indiana state board of health. *(Indiana State Department of Health; 410 IAC 21-1-1; filed Nov 7, 1986, 3:30 pm: 10 IR 420; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 21-1-2 General requirements
Authority: IC 16-38-2-10
Affected: IC 5-15-5.1-5; IC 16-38-2

Sec. 2. (a) All physicians, dentists, hospitals and medical laboratories shall report all confirmed cases of cancer occurring in Indiana residents who have been diagnosed or treated in Indiana, to the state board cancer registry.

(b) Any health care provider reporting to a public or private cancer registry on September 1, 1985 shall make available to the state cancer registry, all data as required under 410 IAC 21-1-3 (hospitals) or 410 IAC 21-1-4 (physicians, dentists and medical laboratories) upon the effective date of 410 IAC 21-1.

(c) The state board shall assure state cancer registry computer compatibility for any health care provider who on or before the effective date of 410 IAC 21-1 elects to transmit the required data by way of a computerized mechanism.

(d) Any health care provider who, after the effective date of 410 IAC 21-1, establishes a computerized mechanism for the purpose of transmitting abstracted data sets via computer link up, tape transfer, or direct interface, shall be responsible for assuring system compatibility with the state board cancer registry.

(e) Any health care provider who elects to transfer abstracted data sets to the state cancer registry in paper form, shall utilize an abstract form designed or approved by the state board pursuant to IC 5-15-5.1-5.

(f) All manually prepared data sets shall be mailed or delivered by the health care provider to the state cancer registry.

(g) All health care providers not reporting to a public or private cancer registry on September 1, 1985, shall begin submitting data on cases diagnosed on or after January 1, 1987 to the state cancer registry as set out in 410 IAC 21-1-3 (hospitals) or 410 IAC 21-1-4 (physicians, dentists and medical laboratories), no later than six (6) months following the date of such diagnosis.

(h) Reports of confirmed cases of malignant disease shall be submitted to the state cancer registry within six (6) months

following a confirmed diagnosis. *(Indiana State Department of Health; 410 IAC 21-1-2; filed Nov 7, 1986, 3:30 pm: 10 IR 420; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 21-1-3 Hospitals
Authority: IC 16-38-2-10
Affected: IC 16-38-2

Sec. 3. (a) All hospitals shall submit abstracted data sets to the state board cancer registry which shall include but not be limited to the following data items:
(1) site code
(2) accession number
(3) sequence number
(4) accession year
(5) social security number
(6) medical record number
(7) full name (including maiden name)
(8) home address, city, county, state and zip code
(9) phone number
(10) date of birth
(11) sex
(12) race
(13) class of case
(14) admission date
(15) follow-up physician
(16) discharge date
(17) date of initial diagnosis
(18) topography code
(19) paired organ involvement
(20) histology code
(21) tumor grade
(22) diagnostic confirmation
(23) tumor size (largest dimension)
(24) number of positive nodes
(25) number of nodes examined
(26) sites of distant metastasis
(27) general summary stage
(28) TNM stage
(29) AJCC stage group
(30) TNM staging basis
(31) date and method of first course of treatment
(32) subsequent therapies/treatments (dates and methods)
(b) Available updated information regarding all elements enumerated in 410 IAC 21-1-3(a) shall be reported to the state board cancer registry each twelve (12) month period following the initial reporting of the disease. *(Indiana State Department of Health; 410 IAC 21-1-3; filed Nov 7, 1986, 3:30 pm: 10 IR 421; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 21-1-4 Physicians, dentists and medical laboratories
Authority: IC 16-38-2-10
Affected: IC 16-38-2

Sec. 4. (a) Any physician, dentist or medical laboratory who diagnoses a case of malignant disease when such case is not

referred to a hospital for further diagnosis or treatment, shall submit required data sets to the state cancer registry. Such data sets shall include but not be limited to the following available data items:

(1) patient's full name (including maiden name)
(2) patient's address (including city, county, state and zip code)
(3) social security number
(4) date of birth
(5) sex
(6) race
(7) date of diagnosis
(8) topography
(9) morphology
(10) diagnostic confirmation
(11) hospital referred to
(12) physician, dentist or laboratory license number
(13) physician, dentist or laboratory name, address and phone number

(b) Physicians, dentists and medical laboratories whose offices are located within the confines of a hospital or, who are employed or contracted by a hospital and who diagnose or treat patients for malignant disease, shall not be required to report cases of malignant disease under 410 IAC 21-1-4. Such cases shall be reported in accordance with 410 IAC 21-1-3. *(Indiana State Department of Health; 410 IAC 21-1-4; filed Nov 7, 1986, 3:30 pm: 10 IR 421; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 21-1-5 Security and confidentiality of data

Authority: IC 16-38-2-10
Affected: IC 5-14-3-10; IC 16-38-2

Sec. 5. (a) The state board shall assure confidentiality of patient record data when entering, retrieving, reviewing and utilizing such data.

(b) The state board shall take all precautions and security measures necessary in order to protect the cancer registry data from intrusion or misuse by unauthorized individuals, and to preserve the right to privacy of individual patients maintained on the registry.

(c) Pursuant to IC 5-14-3-10, any public employee or official, or any employee or officer of a contractor or subcontractor of a public agency who knowingly or intentionally discloses the identity of a patient maintained on the state cancer registry system to a person not authorized to receive such information, commits a Class A misdemeanor. Any public employee shall be disciplined in accordance with the personnel policies of the agency by which he is employed if he intentionally, knowingly, or recklessly discloses or fails to protect the identity of patients maintained on the state cancer registry system.

(d) A person who reports information to the cancer registry system in accordance with 410 IAC 21-1, is immune from any civil or criminal liability that might otherwise be imposed because of release of what is otherwise confidential information. *(Indiana State Department of Health; 410 IAC 21-1-5; filed Nov 7, 1986, 3:30 pm: 10 IR 422; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 21-1-6 Cancer registry reports

Authority: IC 16-38-2-10
Affected: IC 16-38-2

Sec. 6. (a) The state board shall make available to all hospitals licensed under IC 16-10-1 *[IC 16-10 was repealed by P.L.2-1993, SECTION 209, effective April 30, 1993.]*, a comprehensive annual report which outlines the trends of malignant disease in Indiana and focuses on specific elements of special study regarding the disease.

(b) Hospitals, physicians, dentists, laboratories and other persons may request and be provided with special reports from the state cancer registry, providing the data requested does not disclose the identity of a patient. *(Indiana State Department of Health; 410 IAC 21-1-6; filed Nov 7, 1986, 3:30 pm: 10 IR 422; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

Rule 2. State Traumatic Injury Registry (Repealed)

(Repealed by Indiana State Department of Health; filed Oct 24, 1996, 4:00 p.m.: 20 IR 752)

Rule 3. Birth Problems Registry

410 IAC 21-3-1 Applicability

Authority: IC 16-38-4-7
Affected: IC 16-38-4

Sec. 1. The definitions in this rule apply throughout this rule. *(Indiana State Department of Health; 410 IAC 21-3-1; filed Jul 8, 2002, 1:55 p.m.: 25 IR 3757)*

410 IAC 21-3-2 "Indiana resident" defined

Authority: IC 16-38-4-7
Affected: IC 16-38-4

Sec. 2. "Indiana resident" means an individual whose current address is within the state of Indiana. *(Indiana State Department of Health; 410 IAC 21-3-2; filed Jul 8, 2002, 1:55 p.m.: 25 IR 3757)*

410 IAC 21-3-3 "Person" defined

Authority: IC 16-38-4-7
Affected: IC 16-38-4

Sec. 3. "Person" means an individual, association, partnership, corporation, or government entity. *(Indiana State Department of Health; 410 IAC 21-3-3; filed Jul 8, 2002, 1:55 p.m.: 25 IR 3757)*

410 IAC 21-3-4 "Registry" defined

Authority: IC 16-38-4-7
Affected: IC 16-38-4

Sec. 4. "Registry" means the Indiana birth problems registry administered by the Indiana state department of health. *(Indiana State Department of Health; 410 IAC 21-3-4; filed Jul 8, 2002, 1:55 p.m.: 25 IR 3757)*

410 IAC 21-3-5 "Severe disability" defined

Authority: IC 16-38-4-7
Affected: IC 16-38-4

Sec. 5. "Severe disability" means a severe physical disability or developmental delay that:
(1) results from injury, infection, or disease;
(2) is chronic in nature; and
(3) requires long term health care.
(Indiana State Department of Health; 410 IAC 21-3-5; filed Jul 8, 2002, 1:55 p.m.: 25 IR 3758)

410 IAC 21-3-6 "Stillbirth" defined

Authority: IC 16-38-4-7
Affected: IC 16-38-4

Sec. 6. "Stillbirth" means a birth after twenty (20) weeks of gestation that is not a live birth. *(Indiana State Department of Health; 410 IAC 21-3-6; filed Jul 8, 2002, 1:55 p.m.: 25 IR 3758)*

410 IAC 21-3-7 Persons required to report
Authority: IC 16-38-4-7
Affected: IC 16-38-4

Sec. 7. The following persons shall report a diagnosed birth problem to the birth problems registry:
(1) Hospitals.
(2) Birthing centers.
(3) Health facilities.
(4) Physicians.
(5) Psychiatric hospitals.
(6) Dentists.
(7) Oral surgeons.
(8) Registered or licensed practical nurses.
(9) Midwives.
(10) Optometrists.
(11) Podiatrists.
(12) Chiropractors.
(13) Physical therapists.
(14) Psychologists.
(15) Local health departments.
(16) Health maintenance organizations.
(Indiana State Department of Health; 410 IAC 21-3-7; filed Jul 8, 2002, 1:55 p.m.: 25 IR 3758)

410 IAC 21-3-8 Reporting requirements
Authority: IC 16-38-4-7
Affected: IC 16-38-4

Sec. 8. (a) The following shall be reported by a person who must report as required by section 7 of this rule to the registry:
(1) Every birth problem listed in section 9 of this rule that has been diagnosed in a child before that child's second birthday.
(2) Every birth problem listed in section 9 of this rule that was diagnosed at the time of a child's death up to two (2) years of age or at expulsion or extraction of a fetus after twenty (20) weeks of gestation.
(b) Reports to the registry must be made within sixty (60) days of diagnosis.
(c) Only diagnoses of birth problems in children who are Indiana residents shall be reported.
(d) The registry shall provide the required forms for birth problems reporting. *(Indiana State Department of Health; 410 IAC 21-3-8; filed Jul 8, 2002, 1:55 p.m.: 25 IR 3758)*

410 IAC 21-3-9 Reportable birth problems
Authority: IC 16-38-4-7
Affected: IC 16-38-4

Sec. 9. The following categories, along with those conditions identified in the International Classification of Diseases–Ninth Revision, Clinical Modification, 1998 (ICD-9-CM), are birth problems:
(1) A structural deformation.
(2) A developmental malformation.
(3) A genetic, inherited, or biochemical disease.
(4) Birth weight less than two thousand five hundred (2,500) grams.
(5) A condition of a chronic nature, including central nervous system hemorrhage or infection of the central nervous system, that may result in a need for long term health care.
(6) Stillbirth.
(7) Any other severe disability that is recognized in a child after birth and before the child becomes two (2) years of age.

(8) ICD-9-CM Codes	Name
155–208	Neoplasms
216–216.9	Neoplasms
230–234	Neoplasms
246.1	Dyshormonogenic goiter
250	Diabetes mellitus
257.8	Other testicular dysfunction
279	Disorders involving the immune mechanism
282	Hereditary hemolytic anemias
284.0	Constitutional aplastic anemia
286.0–286.5	Coagulation defects
287.3	Primary thrombocytopenia
288	Diseases of white blood cells
289.6	Familial polycythemia
330	Cerebral degenerations usually manifest childhood
335	Anterior horn cell disease
359	Muscular dystrophies and myopathies
362.21	Retrolental fibroplasia
362.7	Hereditary retinal dystrophies
365.14	Glaucoma of childhood
378	Strabismus and other disorders of binocular eye movement
379.51	Congenital nystagmus
524.0–524.1	Anomalies of jaw
	Congenital anomalies
740–742	Central nervous system
743–744	Orofacial
745–747	Cardiovascular
748	Respiratory
749–750.29	Orofacial
750.3–751	Gastrointestinal
752–753	Genitourinary
754–756	Musculoskeletal
757	Integument
758	Chromosome and syndromes
759	Other and unspecified congenital anomalies

(Indiana State Department of Health; 410 IAC 21-3-9; filed Jul 8, 2002, 1:55 p.m.: 25 IR 3758)

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