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.


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 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; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*

**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 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; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)*
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 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; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)

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 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; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)

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 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; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA; readopted filed Nov 13, 2019, 3:14 p.m.: 20191211-IR-410190391RFA)

Rule 2. State Traumatic Injury Registry (Repealed)
(Repealed by Indiana 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 Department of Health; 410 IAC 21-3-1; filed Jul 8, 2002, 1:55 p.m.: 25 IR 3757; readopted filed Jul 14, 2008, 2:14 p.m.: 20080806-IR-410080355RFA; readopted filed Sep 10, 2014, 2:08 p.m.: 20141008-IR-410140299RFA; readopted filed Sep 10, 2020, 2:11 p.m.: 20201007-IR-410200404RFA)

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 Department of Health; 410 IAC 21-3-2; filed Jul 8, 2002, 1:55 p.m.: 25 IR 3757; readopted filed Jul 14, 2008, 2:14 p.m.: 20080806-IR-410080355RFA; readopted filed Sep 10, 2014, 2:08 p.m.: 20141008-IR-410140299RFA; readopted filed Sep 10, 2020, 2:11 p.m.: 20201007-IR-410200404RFA)

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 Department of Health; 410 IAC 21-3-3; filed Jul 8, 2002, 1:55 p.m.: 25 IR 3757; readopted filed Jul 14, 2008, 2:14 p.m.: 20080806-IR-410080355RFA; readopted filed Sep 10, 2014, 2:08 p.m.: 20141008-IR-410140299RFA; readopted filed Sep 10, 2020, 2:11 p.m.: 20201007-IR-410200404RFA)

410 IAC 21-3-4 "Registry" defined
Authority: IC 16-38-4-7
Affected: IC 16-38-4

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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 Department of Health; 410 IAC 21-3-5; filed Jul 8, 2002, 1:55 p.m.: 25 IR 3758; readopted filed Jul 14, 2008, 2:14 p.m.: 20080806-IR-410080355RFA; readopted filed Sep 10, 2014, 2:08 p.m.: 20141008-IR-410140299RFA; readopted filed Sep 10, 2020, 2:11 p.m.: 20201007-IR-410200404RFA)

410 IAC 21-3-6 "Stillbirth" defined (Repealed)

Sec. 6. (Repealed by Indiana Department of Health; filed Mar 30, 2005, 3:00 p.m.: 28 IR 2356)

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.
(17) Audiologists.

(Indiana Department of Health; 410 IAC 21-3-7; filed Jul 8, 2002, 1:55 p.m.: 25 IR 3758; filed Sep 26, 2006, 10:00 a.m.: 20061025-IR-410050256RFA; readopted filed Jul 14, 2008, 2:14 p.m.: 20080806-IR-410080355RFA; readopted filed Sep 10, 2014, 2:08 p.m.: 20141008-IR-410140299RFA; readopted filed Sep 10, 2020, 2:11 p.m.: 20201007-IR-410200404RFA)

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, except a pervasive developmental disorder or a fetal alcohol spectrum disorder, listed in section 9 of this rule that:
(A) has been diagnosed in a child before that child's third birthday; or
(B) was diagnosed at the time of a child's death up to three (3) years of age.
(2) A pervasive developmental disorder or a fetal alcohol spectrum disorder listed in section 9 of this rule that was diagnosed before a child's fifth birthday.
(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.

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. A condition of a chronic nature, including:
   (A) central nervous system hemorrhage; or
   (B) infection of the central nervous system; that may result in a need for long term health care.
5. A pervasive developmental disorder.
6. A fetal alcohol spectrum disorder.
7. Any other severe disability that is recognized:
   (A) in a child after birth; and
   (B) before the child becomes three (3) years of age.

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<th>ICD-9-CM Codes</th>
<th>Name</th>
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<td>Neoplasms</td>
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<td>216-216.9</td>
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<td>230-234</td>
<td>Neoplasms</td>
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<td>Dyshormonogenic goiter</td>
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<td>250</td>
<td>Diabetes mellitus</td>
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<td>Other testicular dysfunction</td>
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<td>279</td>
<td>Disorders involving the immune mechanism</td>
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<td>282</td>
<td>Hereditary hemolytic anemias</td>
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<td>284.0</td>
<td>Constitutional aplastic anemia</td>
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<td>286.0-286.5</td>
<td>Coagulation defects</td>
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<td>287.3</td>
<td>Primary thrombocytopenia</td>
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<td>288</td>
<td>Diseases of white blood cells</td>
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<td>289.6</td>
<td>Familial polycythemia</td>
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<td>299.00-299.99</td>
<td>Pervasive developmental disorders including autism, childhood disintegrative disorder, Asperger's syndrome, Rett syndrome, and pervasive developmental disorders not otherwise specified</td>
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<td>Cerebral degenerations usually manifest childhood</td>
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<td>335</td>
<td>Anterior horn cell disease</td>
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<td>Muscular dystrophies and myopathies</td>
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Indiana Administrative Code  Page 6
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<td>365.14</td>
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<td>378</td>
<td>Strabismus and other disorders of binocular eye movement</td>
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**Congenital anomalies**

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*(Indiana Department of Health; 410 IAC 21-3-9; filed Jul 8, 2002, 1:55 p.m.: 25 IR 3758; filed Mar 30, 2005, 3:00 p.m.: 28 IR 2355; filed Sep 26, 2006, 10:00 a.m.: 20061025-IR-410050256FRA; readopted filed Jul 14, 2008, 2:14 p.m.: 20080806-IR-410080355RFA; readopted filed Sep 10, 2014, 2:08 p.m.: 20141008-IR-410140299RFA; readopted filed Sep 10, 2020, 2:11 p.m.: 20201007-IR-410200404RFA)*