DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

1) Heading of the Part: Health and Hazardous Substances Registry Code

2) Code Citation: 77 Ill. Adm. Code 840

3)

Section Numbers:	Proposed Actions:
840.10	Amendment
840.20	Amendment
840.110	Amendment
840.115	Amendment
840.200	Amendment
840.210	Amendment

4) Statutory Authority: Illinois Health and Hazardous Substances Registry Act [410 ILCS 525], Section 2310-365 of the Civil Administrative Code of Illinois [20 ILCS 2310/2310-365], the Developmental Disability Prevention Act [410 ILCS 250], and the Lead Poisoning Prevention Act [410 ILCS 45].

5) A Complete Description of the Subjects and Issues Involved: This rulemaking updates Subpart B pertaining to the Illinois State Cancer Registry (ISCR) to remove the manual report form method of reporting, update codes for case finding to include ICD-10-CM Diagnosis or Procedure Codes and to update the North American Association of Central Cancer Registries data standards versions. This rulemaking also updates Subpart C pertaining to the Adverse Pregnancy Outcomes Reporting System (APORS) to modify sections describing which infants should be reported, the fields to be reported, and remove the requirement that hospitals distribute copies to local health agencies. Amendments also update the list of reportable diseases to reflect the addition of ICD-10-CM Diagnosis or Procedure codes.

6) Published studies or reports, and sources of underlying data, used to compose this rulemaking: ICD-10-CM Diagnosis or Procedure Codes

7) Will this rulemaking replace any emergency rulemaking currently in effect? No

8) Does this rulemaking contain an automatic repeal date? No

9) Does this rulemaking contain incorporations by reference? Yes

10) Are there any other proposed rulemakings pending on this Part? No

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

11) Statement of Statewide Policy Objectives: This rulemaking does not create a state mandate.

12) Time, Place and Manner in which interested persons may comment on this proposed rulemaking:

Interested persons may present their comments concerning this rulemaking within 45 days after the publication of this issue of the *Illinois Register* to:

Elizabeth Paton
Assistant General Counsel
Division of Legal Services
Illinois Department of Public Health
535 W. Jefferson St., 5th floor
Springfield, Illinois 62761

217/782-2043
e-mail: rules@idph.state.il.us

13) Initial Regulatory Flexibility Analysis:

A) Types of small businesses, small municipalities and not for profit corporations affected: It is anticipated that the amendments will have minimum impact on the regulated industry

B) Reporting, bookkeeping or other procedures required for compliance: None

C) Types of professional skills necessary for compliance: None

14) Regulatory Agenda on which this rulemaking was summarized: July 2015

The full text of the Proposed Amendments begins on the next page:

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

TITLE 77: PUBLIC HEALTH
CHAPTER I: DEPARTMENT OF PUBLIC HEALTH
SUBCHAPTER p: HAZARDOUS AND POISONOUS SUBSTANCES

PART 840
HEALTH AND HAZARDOUS SUBSTANCES REGISTRY CODE

SUBPART A: GENERAL REGISTRY PROVISIONS

Section

SUBPART B: ILLINOIS STATE CANCER REGISTRY

SUBPART C: ADVERSE PREGNANCY OUTCOMES REPORTING SYSTEM

SUBPART D: OCCUPATIONAL DISEASE REGISTRY

DEPARTMENT OF PUBLIC HEALTH

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840.APPENDIX B Instructions for APORS Reporting (Repealed)
840.EXHIBIT A Instructions for Completing Infant Discharge Record (Repealed)
840.ILLUSTRATION A Infant Discharge Record (Repealed)
840.EXHIBIT B Instructions for Completing Maternal Supplement (Repealed)
840.ILLUSTRATION B Maternal Supplement Abstract (Repealed)
840.APPENDIX C Forms and Instructions for Occupational Disease Registry (Repealed)
840.EXHIBIT A Instructions for completing The Laboratory Based Report of Adult Blood Lead Analysis (Repealed)
840.EXHIBIT B Instructions for completing the Health Department Follow-Up Report of Adult Blood Lead Level Analysis For Results of 25 mcg/dl and Above (Local Health Authorities will use this form) (Repealed)
840.ILLUSTRATION A Health Department Laboratory Report of Adult Elevated Blood Lead Analysis 25 mcg/dl and Above (Repealed)
840.ILLUSTRATION B Health Department Follow-up Report of Adult Blood Lead Level Analysis For Results of 25 mcg/dl and Above (Repealed)
840.ILLUSTRATION C Occupational Disease Registry Abstract Information from the Illinois Health Care Cost Containment Council (Repealed)

AUTHORITY: Implemented and authorized by the Illinois Health and Hazardous Substances Registry Act [410 ILCS 525], Section 2310-365 of the Civil Administrative Code of Illinois [20 ILCS 2310/2310-365], the Developmental Disability Prevention Act [410 ILCS 250], and the Lead Poisoning Prevention Act [410 ILCS 45].

SOURCE: Adopted at 10 Ill. Reg. 7842, effective May 19, 1986; amended at 12 Ill. Reg. 13173, effective August 1, 1988; amended at 14 Ill. Reg. 5495, effective April 1, 1990; amended at 17 Ill. Reg. 2319, effective February 10, 1993; amended at 24 Ill. Reg. 3685, effective February 16, 2000; amended at 31 Ill. Reg. 12207, effective August 2, 2007; amended at 36 Ill. Reg. 8379, effective May 18, 2012; amended at 40 Ill. Reg. _____, effective _____.

SUBPART A: GENERAL REGISTRY PROVISIONS

Section 840.10 Definitions

"Act" means the Illinois Health and Hazardous Substances Registry Act [410 ILCS 525].

"*Adverse pregnancy outcomes" includes but is not limited to birth defects, fetal loss, infant mortality, low birth weight, selected life-threatening conditions, and other developmental disabilities as defined* in Section 840.200 of this Part.

DEPARTMENT OF PUBLIC HEALTH

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(Section 3(1) of the Act)

"Adverse Pregnancy Outcomes Reporting System" or "APORS" means the Illinois Department of Public Health program established to compile a registry of adverse pregnancy outcomes.

"Ambulatory Surgical Treatment Center" means any facility subject to licensure pursuant to the Ambulatory Surgical Treatment Center Act [210 ILCS 5].

"Birth center" means a facility as defined under the Alternative Health Care Delivery Act and licensed by the Department under the Birth Center Demonstration Program Code (77 Ill. Adm. Code 265) to provide birth services.

"Birth defect" means a condition of abnormal development related to body structure, body function, body metabolism, or an error of body chemistry that typically is identified at birth but can be diagnosed during pregnancy or following birth. Birth defects can originate in a number of ways, including having a genetic or metabolic origin.

"Cancer" means all malignant neoplasms, regardless of the tissue of origin, including malignant lymphoma and leukemia. (Section 3(e) of the Act)

"Cancer-confirming report" means the simple biopsy, excision biopsy or surgical pathology report that confirms the morphologic (histologic) type of cancer, primary site, and the stage or extent of disease.

"Cancer incidence" means a medical diagnosis of cancer, consisting of a record of cases of cancer and specified cases of tumorous or precancerous diseases which occur in Illinois, and such other information concerning these cases as the Department deems necessary or appropriate in order to conduct thorough and complete epidemiological surveys of cancer and cancer-related diseases in Illinois. (Section 3(f) of the Act) Other information concerning cancer incidence may include, but is not limited to, diagnosis, staging, treatment, follow-up and survival information.

"Cancer surveillance" means the ongoing and systematic collection and analysis of information on new cancer cases, cancer deaths, extent of disease at diagnosis, treatment, clinical management, and survival.

"Clinical laboratory" means any clinical laboratory as defined in the Illinois

Clinical Laboratory and Blood Bank Act [210 ILCS 25].

"Company profile" includes but is not limited to the name of any company operating in the State of Illinois which generates, uses, disposes of or transports hazardous substances, identification of the types of permits issued in such company's name relating to transactions involving hazardous substances, inventory of hazardous substances handled by the *company, and the manner in which* the *hazardous substances are used, disposed of, or transported by the company.* (Section 3(j) of the Act)

"Confidential data" means Health and Hazardous Substances Registry data containing identifiers or variables that, alone or in combination, can lead to identification of individuals, physicians, or facilities (see Section 840.30(h)).

"Congenital" means present at birth, referring to certain mental or physical traits, anomalies, malformations, diseases, etc., that may be either hereditary or caused by an influence occurring during fetal development or pregnancy, up to the moment of birth.

"Council" means the Health and Hazardous Substances Coordinating Council created by the *Act.* (Section 3(c) of the Act)

"Current Procedural Terminology" or "CPT" or "Coding Index Version 2007" means the coding index developed by the American Medical Association (see Section 840.115).

"Death certificate clearance" means the process by which incident cases are added to the database through review of the cause of death on death certificates and subsequent follow-up with medical providers.

"Department" means the Illinois Department of Public Health. (Section 3(a) of the Act)

"Director" means the Director of the Illinois Department of Public Health. (Section 3(b) of the Act)

"Elevated blood lead level" means a concentration of lead in whole blood equal to or in excess of 10 micrograms per deciliter.

"Ethnicity" means the group of human kind to which an individual belongs, either Hispanic (Latino) or not Hispanic (not Latino).

"Facility" means a hospital, clinical laboratory, ambulatory surgical treatment center, independent radiation therapy center, independent pathology laboratory, reference pathology laboratory, nursing home, physician's office and/or any other diagnostic or treatment center or other entity that is required by this Part to make reports to the Department. "Facility" also includes any other institution, place or building devoted primarily to the performance of medical care or surgical procedures that is maintained by the State or local government bodies.

"Facility-identifying information" means any information, collection or grouping of data from which the identity of the facility to which it relates may be discerned, e.g., name, address or Department-assigned facility identification number.

"Fetal death" means the demise of a fetus at gestation greater than 20 weeks; the death is indicated if the fetus does not breathe or show any other evidence of life, such as beating of the heart, pulsation of the umbilical cord, or definite movement of voluntary muscles at delivery.

"Follow-up" means the reporting of or Registry-initiated obtainment of patient's survival information after the first diagnosis of the medical conditions defined by the Registry.

"Follow-up services" means medical, educational, social and family support services provided to infants and children with adverse pregnancy outcomes.

"Hazardous nuclear material" means:

> *any source or special nuclear material intended for use or used as an energy source in a production or utilization facility as defined in Sec. 11.v. or 11.cc. of the Federal Atomic Energy Act of 1954 as amended;*
>
> *any fuel which has been discharged from such a facility following irradiation, the constituent elements of which have not been separated by reprocessing;* or
>
> *any by-product material resulting from operation of such a facility.*
> (Section 3(k) of the Act)

"Hazardous substances" means a hazardous substance as defined in Section 3.215 of *the Environmental Protection Act* [415 ILCS 5]. (Section 3(h) of the Act)

"Hazardous substances incident" includes but is not limited to spill, fire or accident involving hazardous substances, illegal disposal, transportation, or use of hazardous substances, and complaints or permit violations involving hazardous substances. (Section 3(i) of the Act)

"Hospital" means any facility subject to licensure pursuant to the Hospital Licensing Act [210 ILCS 85].

"Hospital Cancer Registry" means a data collection system that monitors all types of cancer diagnosed or treated at that facility by collecting case identification, a description of the patient and the cancer, treatment and follow-up data.

~~"Infant discharge record" means documentation of one or more identified adverse pregnancy outcomes reported by a facility to the Department.~~

"Institutional review board" or "IRB" means a specially constituted review body established or designated by an institution to protect the welfare of human subjects participating in research.

"Lead hazard" means a lead-bearing substance that, because of its accessibility, poses a health hazard to humans.

"Local health authority" means the full-time official health department or board of health, as recognized by the Department, that has jurisdiction over a particular geographical area.

"mcg/d1" means micrograms per deciliter.

"Morphology" means a concise diagnostic description of a tumor that includes the kind of tumor, the behavior of the tumor (e.g., benign, in-situ, malignant, or malignant uncertain, whether primary or metastatic), and the grade or degree of differentiation of the cells.

"National Birth Defects Prevention Network" means a national organization dedicated to improving the quality of birth defect surveillance and providing technical assistance for the development of uniform methods of data collection.

"Neonatal" means related to the period immediately succeeding birth and continuing through the first 28 days of life.

"Neonate" means an infant less than 28 days of age.

"Newly diagnosed" means a condition or disease first discovered or diagnosed by a licensed physician or dentist in a resident of the State of Illinois or a non-resident receiving medical diagnosis or treatment in the State of Illinois.

"North American Association of Central Cancer Registries" or "NAACCR" means the organization that sets standards that measure a central registry's data completeness, quality and timeliness.

"Occupational disease" includes but is not limited to all occupational diseases covered by the Workers' Occupational Diseases Act [820 ILCS 310]. (Section 3 (g) of the Act)

"Other facility" means any person, organization, institution, corporation, partnership or other entity not required to be licensed as a health care facility by the State of Illinois, which maintains and operates facilities for the performance of diagnostic, laboratory or therapeutic services for the identification and treatment of cancer.

"Patient contact" means contacting patients based on collected Registry data.

"Patient-identifying information" means any information or collection or grouping of data from which the identity of the person to whom it relates may be discerned, e.g., name, address and social security number.

"*Perinatal" means the period of time between the conception of an infant and the end of the first month of life.* (Section 2(a) of the Developmental Disability Prevention Act)

"*Perinatal center" means a referral facility intended to care for the high risk patient before, during or after labor and delivery and characterized by sophistication and availability of personnel, equipment, laboratory, transportation techniques, consultation and other support services.* (Section 2(e) of the Developmental Disability Prevention Act)

"Prenatal" means preceding birth.

"Primary site" means the anatomic location in a cancer patient that identifies the site of origin of a tumor (i.e., where the cancer first began).

"Public health surveillance" means the ongoing systematic collection, analysis and interpretation of health data for purposes of improving health and safety.

"Race" means the major group of human kind to which an individual belongs, having distinct physical characteristics. These groups include, but are not limited to: American Indian or Alaska Native; Asian; Black or African American; Native Hawaiian or Other Pacific Islander; and White.

"Rapid case ascertainment" means special case-finding procedures that require early or preliminary reporting of certain types of cancer cases. The procedure may include the review of patient medical records, pathology report forms, radiology reports, laboratory reports and other diagnostic tests.

"Record uniqueness" means the quantification of the risk of a breach of confidentiality of electronic health databases, including the identifiability of cases through triangulation of information or linkage with other electronic databases.

"Regional Perinatal Network" means any number and combination of hospitals providing maternity and newborn services at a designated level of perinatal care.

"Registry" means the Illinois Health and Hazardous Substances Registry established by the Department of Public Health under Section 6 of the *Act.* (Section 3(d) of the Act)

"Work" means duties, activities or tasks that produce a product or result; that are done in exchange for money, goods, services, profit, benefit or as a volunteer; and that are legal activities in the United States.

"Work-related injury or illness" means an event or exposure in the work environment that caused or contributed to the condition or significantly aggravated a preexisting condition. Work-relatedness is presumed for injuries and illnesses resulting from events or exposures occurring in the workplace.

"Workplace fatality" means a fatality that occurs to an employee (working for pay, compensation, or profit) or volunteer (exposed to the same work hazards and

performing the same duties or functions as paid employees) while engaged in a legal work activity, or present at the site of the incident as a requirement of his or her job. A work relationship exists if an event or exposure results in a fatal injury to a person on or off the employer's premises and the person was there to work; or if the event or exposure was related to the person's work or status as an employee.

"Workplace nonfatal injury or illness" means an occupational injury resulting from a work-related event or from exposure in the work environment. Injuries or illnesses are reported if they result in lost work time; if they require medical treatment (other than first aid); or if the worker experiences loss of consciousness, restriction of work activities or motion, or is transferred to another job.

(Source: Amended at 40 Ill. Reg. _____, effective _____)

Section 840.20 Incorporated and Referenced Materials

a) The following materials are referenced in this Part:

1) State of Illinois Statutes

A) Illinois Health and Hazardous Substances Registry Act [410 ILCS 525]

B) Developmental Disability Prevention Act [410 ILCS 250]

C) Section 2310-365 of the Civil Administrative Code of Illinois [20 ILCS 2310/2310-365]

D) Lead Poisoning Prevention Act [410 ILCS 45]

E) Ambulatory Surgical Treatment Center Act [210 ILCS 5]

F) Illinois Clinical Laboratory and Blood Bank Act [210 ILCS 25]

G) Hospital Licensing Act [210 ILCS 85]

H) Freedom of Information Act [5 ILCS 140]

I) Part 21 of Article 8 of the Code of Civil Procedure, commonly known as the Medical Studies Act [735 ILCS 5/Art. 8, Part 21]

J) State Records Act [5 ILCS 160]

K) Vital Records Act [410 ILCS 535]

L) Environmental Protection Act [415 ILCS 5]

M) Workers' Occupational Diseases Act [820 ILCS 310]

N) Alternative Health Care Delivery Act [210 ILCS 3]

2) State of Illinois Rules:

A) Freedom of Information Code (2 Ill. Adm. Code 1126)

B) Practice and Procedure in Administrative Hearings (77 Ill. Adm. Code 100)

C) Hospital Licensing Requirements (77 Ill. Adm. Code 250)

D) Regionalized Perinatal Health Care Code (77 Ill. Adm. Code 640)

E) Birth Center Demonstration Program Code (77 Ill. Adm. Code 265)

3) Federal Statutes

A) Occupational Safety and Health Act of 1970 [29 USC 15]

B) The Birth Defects Prevention Act of 1998 [42 USC 201]

C) Public Health Service Act [42 USC 247b-4]

D) Federal Atomic Energy Act of 1954 [42 USC 2011]

b) The following materials are incorporated by reference in this Part:

1) Federal Regulations

A) Protection of Identity − Research Subjects, 42 CFR 2a.4(a) through ~~–~~(j), 2a.6(a) and ~~–~~(b) and 2a.7(a) through ~~–~~(b)(1) (October 1, 2009)

B) Occupational Safety and Health Standards, 29 CFR 1910.1025 (July 1, 2009)

2) Other Guidelines and Materials

A) International Classification of Diseases, 9th Revision Clinical Modification (1986), World Health Organization, Avenue Appia 20, 1211 Geneva ZT, Geneva, Switzerland

B) International Classification of Diseases for Oncology (ICD-O), Third Edition (2000), World Health Organization, Avenue Appia 20, 1211 Geneva ZT, Geneva, Switzerland

C) International Classification of Diseases, 10th Revision (1992), World Health Organization, Avenue Appia 20, 1211 Geneva ZT, Geneva, Switzerland

D) NAACCR Standards for Cancer Registries, Volume II, Data Standards and Data Dictionary, 19th ~~11th~~ Edition, October 2014 ~~April 2006~~ (effective January 2015 ~~2007~~), North American Association for Central Cancer Registries, 2050 W. Iles Ave., Suite A ~~2121 W. White Oaks Dr., Suite C~~, Springfield IL 62704

E) NAACCR Standards for Cancer Registries, Volume III, Standards for Completeness, Quality, Analysis, ~~and~~ Management, Security, and Confidentiality of Data, August 2008 ~~October 2004~~, North American Association of Central Cancer Registries, 2050 W. Iles Ave., Suite A ~~2121 W. White Oaks Dr., Suite C~~, Springfield IL 62704

F) NAACCR Standards for Cancer Registries, Volume V, Pathology Laboratory Electronic Reporting, Version 4.0 ~~2.0~~, April 2011 ~~November 2005~~, North American Association of Central Cancer Registries, 2050 W. Iles Ave., Suite A ~~2121 W. White Oaks Dr., Suite C~~, Springfield IL 62704

G) Current Procedural Terminology (CPT) Coding Index, 2007 Version, American Medical Association, P.O. Box 930876, Atlanta GA 31193

H) National Birth Defects Prevention Network (NBDPN), Guidelines for Conducting Birth Defects Surveillance, June 2004, Sever, LE, ed., 1600 Clifton Rd., Atlanta GA 30333~~:~~

I) NAACCR/NPCR Disk 7 of Fundamentals of Registry Operations: Data Collection and Coding: Race and Ethnicity Procedures for Central Registries, May 2005, North American Association of Central Cancer Registries, 2050 W. Iles Ave., Suite A,~~2121 W. White Oaks Dr., Suite, C~~ Springfield IL 62704

J) NAACCR Record Uniqueness Analysis Software Version 1.5, May 2004, North American Association of Central Cancer Registries, 2050 W. Iles Ave., Suite A~~2121 W. White Oaks Dr., Suite C~~, Springfield IL 62704

K) Public Health Reporting and National Notification for Elevated Blood Lead Levels, Position Statement 09-OH-02, June 2009, Council of State and Territorial Epidemiologists, 2872 Woodcock Blvd., Atlanta GA 30341

L) ICD-10-CM 2015: The Complete Official Codebook, American Medical Association, P.O. Box 930876, Atlanta GA 31193.

c) All incorporations by reference of federal regulations and the standards of nationally recognized organizations refer to the regulations and standards on the date specified and do not include any later amendments or editions.

(Source: Amended at 40 Ill. Reg. _____, effective _____)

SUBPART B: ILLINOIS STATE CANCER REGISTRY

Section 840.110 Information Required to be Reported

a) A facility required to submit information shall report each cancer incidence and other tumorous and precancerous disease, as specified in this Section, to the Department.

b) This information to be reported shall be provided in a format as designated by the Department ~~and may be~~ in ~~either~~ electronic ~~or paper~~ form. The electronic form must comply with the required standard. ~~The paper form will be supplied by the Department.~~ The facility tumor registrar or other person designated by the facility shall abstract information from the cancer patient's record. The information to be reported is divided into seven subject areas, each containing a particular set of information. The seven subject areas of the incidence report shall include the following:

1) Reporting Information – type of report being submitted, abstracter identification code and the date the abstract was submitted.

2) Patient Data and Resident Address − patient's full name (including maiden name, when applicable and available), Social Security number, telephone number, and residential address, including street address, city, county, state, and postal code.

3) Personal Data − patient's birthdate, age, sex, race, ethnicity, marital status, birthplace, history of tobacco and alcohol usage, history of occupation and industry, health insurance status and socio-economic status including, but not limited to, education and income.

4) Diagnosis Data − initial diagnosis date; diagnostic information; method of diagnosis; primary site; laterality; histology and behavior code; grade; stage of disease, including clinical and pathological extent of disease information; existence of other reportable primary diseases and date of diagnosis; first course cancer-directed therapy; and supporting text information for all diagnostic procedures, histology, primary site, staging and treatment.

5) Facility Data − facility identification number provided by the Department of Public Health, the medical record number, date of admission, type of reporting source, accession number (if available), case identification type, discharge date and status, class of case, and name and Illinois medical license number of attending physician.

6) Follow-Up Data − date of last follow-up or death, follow-up status, type of follow-up, names of follow-up physicians, cause of death, whether patient information is incomplete, and names and Illinois medical license numbers

of managing and treating physicians.

7) Text Documentation – description of the primary site, histology, diagnostic test results, staging, pathology results and treatment information.

c) Each patient's cancer report form shall be sent within six months after the date of diagnosis or within four months after the date of discharge from the reporting facility, whichever is sooner. Reporting facilities shall report by letter to the Department, each year by July 1, the status of the completeness of reporting of cancer incidence cases diagnosed through December of the preceding year.

d) Every hospital, clinical laboratory, ambulatory surgical treatment center, independent radiation therapy center, independent pathology laboratory, reference pathology laboratory, nursing home, physician's office and other diagnostic or treatment facility shall provide the Department or entities authorized to represent the Department with access to information from all medical, pathological, and other pertinent records and logs related to cancer diagnosis, treatment and follow-up for the purpose of quality control, rapid case ascertainment, patient follow-up and death certificate clearance. (See Section 10 of the Act.)

e) Every hospital, ambulatory surgical treatment center, clinical laboratory, independent radiation therapy center, independent pathology laboratory, reference pathology laboratory, nursing home, physician's office and other diagnostic or treatment facility shall provide access to information from all medical, pathological, and other pertinent records and logs related to cancer diagnosis and treatment for the purpose of patient record review specified for research studies or for rapid case ascertainment related to cancer prevention and control conducted by the Department and that have been approved after appropriate review by the Department for assuring protection of human subjects. (See 42 CFR 2a.4(a)-(j), 2a.6(a)-(b), 2a.7(a)-(b)(1).)

(Source: Amended at 40 Ill. Reg. _____, effective _____)

Section 840.115 Methods of Reporting Cancer Registry Information

a) All patients identified at a reporting facility, whether as an inpatient or outpatient, who meet one of the three following criteria are reportable to the Registry:

1) Patients with a newly diagnosed cancer who have, within six months after

diagnosis, received cancer-directed treatment or refused treatment.

2) Patient with cancer diagnosed through autopsy.

3) Patient diagnosed and receiving all first course treatment elsewhere and now receiving cancer-directed treatment at the reporting facility.

b) A patient is considered to have a malignant neoplasm when a licensed physician or dentist indicates that he/she does. Otherwise, the following terminology, when applied to a malignancy, shall be interpreted as indicating involvement by a cancerous tumor:

1) apparent,

2) appears to,

3) comparable with,

4) compatible with,

5) consistent with,

6) favors,

7) malignant appearing,

8) most likely,

9) presumed,

10) probable,

11) suspected,

12) suspicious for, and

13) typical of.

c) The following terminology, when applied to a malignancy without additional information, shall be interpreted as indicating non-involvement by a cancerous

tumor:

1) cannot be ruled out,

2) equivocal,

3) possible,

4) potentially malignant,

5) questionable,

6) rule out,

7) suggests, and

8) worrisome.

d) Determination of whether or not a given primary tumor is reportable shall be made by reference to the morphology codes (M-codes) of the International Classification of Diseases for Oncology (ICD-O).

e) The specified cases of tumorous or precancerous diseases that shall be reported to the Registry are:

1) benign intracranial tumors, and

2) other conditions that the facility wishes to report.

f) Cases of basal or squamous cell neoplasms of the skin shall be reported only when located in the following areas: penis, scrotum, anus, eyelid, and muco-cutaneous junctions of the lips, labia and vulva.

g) Facilities shall electronically submit the report in the NAACCR data exchange format, using the version specified by the Registry (see Section 840.20). Supporting text documentation that is sufficient to support the diagnosis, stage and treatment should be included for each case submitted.~~There are two mechanisms by which a reporting facility can report cancer cases.~~

~~1) Option #1. Electronic Reporting: Facilities that submit electronically~~

~~shall submit the report in the North American Association of Central Cancer Registries (NAACCR) data exchange format, using the version specified by the Registry (see Section 840.20). Supporting text documentation that is sufficient to support the diagnosis, stage, and treatment should be included for each case submitted.~~

~~2)~~ ~~Option #2. Manual Reporting: Facilities that submit in manual format should use the forms provided by the Registry. These facilities shall code all fields on the manual report form. Supporting text documentation that is sufficient to support the diagnosis, stage, and treatment should be included for each case submitted.~~

h) All reporting facilities are responsible for complete casefinding, which means identifying all first time reported cancer patients and completing an incidence report form for the Registry. To achieve complete case ascertainment, the following sources should be reviewed as they apply: Medical Record Disease Index (ICD-CM) or CPT Coding Index; pathology reports; cytology reports; autopsy reports; surgery and/or outpatient logs; radiation therapy and/or oncology clinic logs and appointment books; and diagnostic X-rays, nuclear medicine reports, and/or other imaging techniques.

1) Any patient's clinical record identified with any of the following ICD-9-CM Diagnosis, ICD-10-CM Diagnosis, or Procedure Codes by the Medical Record Department shall be reviewed for reportability to the Registry:

	Diagnosis Codes	Diagnosis (in preferred ICD-O-3 terminology)
A)	042	AIDS with malignancy
B)	140.0-208.9	Malignant neoplasms
C)	203.1	Plasma cell leukemia (9733/3)
D)	205.1	Chronic neutrophilic leukemia (9963/3)
E)	225.0-225.4 225.8-225.9 227.3-227.4	Benign intracranial and CNS neoplasms

F)	230.0-234.9	Carcinoma in situ
G)	237.0-237.1 237.5-237.6 237.7, 237.9	Borderline intracranial and CNS neoplasms
H)	238.4	Polycythermia erra (9950/3)
I)	238.6	Solitary plasmacytoma (9731/3)
J)	238.6	Extramedullary plasmacytoma (9734/3)
K)	238.7	Chronic Myeloproliferative disease (9960/3)
L)	238.7	Myelosclerosis with myeloid metaplasia (9961.3)
M)	238.7	Essential thrombocythemia (9962/3)
N)	238.7	Refractory cytopenia with multilineage displasia (9985/3)
O)	238.7	Myelodisplastic syndrome with 5q- syndrome (9986/3)
P)	238.7	Therapy related myelodisplastic syndrome (9987/3)
Q)	239.0-239.9	Neoplasms of unspecified behavior
R)	273.2	Gamma heavy chain disease; Franklin's disease
S)	273.3	Waldenstrom's macroglobulinemia
T)	273.9	Unspecified disorder of plasma protein metabolism (screen for potential 273.3 miscodes)

U)	284.9	Refractory anemia (9980/3)
V)	285.0	Refractory anemia with ringed sideroblasts (9982/3)
W)	285.0	Refractory anemia with excess blasts (9983/3)
X)	285.0	Refractory anemia with excess blasts in transformation (9984/3)
Y)	288.3	Hypereosinophilic syndrome (9964/3)
Z)	289.8	Acute myelofibrosis (9932/3)
AA)	V07.8	Other prophylactic chemotherapy (screen carefully for miscoded malignancies)
BB)	V07.8	Other specified prophylactic measures
CC)	V10.0-V10.9	Personal history of malignant neoplasm (review these for recurrences, subsequent primaries and/or subsequent treatment)
DD)	V58.0	Admission for radiotherapy
EE)	V58.1	Admission for chemotherapy
FF)	V66.1	Convalescence following radiotherapy
GG)	V66.2	Convalescence following chemotherapy
HH)	V67.1	Radiation therapy follow-up
II)	V67.2	Chemotherapy follow-up
JJ)	V71.1	Observation for suspected malignant neoplasm
KK)	V76-V76.9	Special screening for malignant neoplasm

LL)	92.21-92.29	Therapeutic radiology and nuclear medicine
MM)	92.21-92.29	Injection or infusion of cancer chemotherapeutic substance
NN)	C00-C43, C45-C96	Malignant neoplasms (excluding category C44), stated or presumed to be primary (of specified site) and certain specified histologies. (Note: Pilocytic/juvenile astrocytoma (M-9421) is reported with the behavior coded /3 (i.e., 9421/3 not 9421/1).)
OO)	D00-D09	In-situ neoplasms (Note: Carcinoma in situ of the cervix (CIN III-8077/2) and Prostatic Intraepithelial Carcinoma (PIN III-8148/2) are not reportable.)
PP)	D18.02	Hemangioma of intracranial structures and any site
QQ)	D18.1	Lymphangioma, any site (Note: Includes Lymphangiomas of Brain, Other parts of nervous system and endocrine glands, which are reportable.)
RR)	D32	Benign neoplasm of meninges (cerebral, spinal and unspecified)
SS)	D33	Benign neoplasm of brain and other parts of central nervous system (CNS)
TT)	D35.2-D35.4	Benign neoplasm of pituitary gland, craniopharyngeal duct and pineal gland
UU)	D42-D43	Neoplasm of uncertain or unknown behavior of meninges, brain, CNS

VV)	D44.3-D44.5	Neoplasm of uncertain or unknown behavior of pituitary gland, craniopharyngeal duct and pineal gland
WW)	D45	Polycythemia vera (9950/3)
XX)	D46	Myelodysplastic syndromes
YY)	D47.1	Chronic myeloproliferative disease
ZZ)	D47.3	Essential (hemorrhagic) thrombocythemia (9962/3))
AAA)	D47.4	Osteomyelofibrosis (9961/3)
BBB)	D47.7	Other specified neoplasms of uncertain/unknown behavior of lymphoid, hematopoietic
CCC)	D47.Z	Other neoplasms of uncertain behavior of lymphoid, hematopoietic and related tissue
DDD)	D47.9	Neoplasm of uncertain behavior of lymphoid, hematopoietic and related tissue unspecified
EEE)	D49.6, D49.7	Neoplasm of unspecified behavior of brain, endocrine glands and other CNS
FFF)	J91.0	Malignant pleural effusion
GGG)	R18.0	Malignant ascites
HHH)	Z08	Encounter for follow-up examination after completed treatment for malignant neoplasm
III)	Z12	Encounter for screening for malignant neoplasms

JJJ)	Z51.0	Encounter for antineoplastic radiation therapy
KKK)	Z51.1	Encounter for antineoplastic chemotherapy and immunotherapy
LLL)	Z85	Personal history of malignant neoplasm
MMM)	Z86.0, Z86.01, Z86.03	Personal history of in situ and benign neoplasms and neoplasms of uncertain behavior
NNN)	Z92.21, Z92.23, Z92.25, Z92.3	Personal history of antineoplastic chemotherapy, estrogen therapy, immunosuppression therapy or irradiation (radiation)
OOO)	R85.614	Cytologic evidence of malignancy on smear of anus
PPP)	R87.614	Cytologic evidence of malignancy on smear of cervix
QQQ)	R87.624	Cytologic evidence of malignancy on smear of vagina

2) All pathology and cytology reports from the facility with a positive morphologic diagnosis of cancer shall be reviewed for reportable neoplasms, including reports on inpatient and outpatient surgical resections and biopsy specimens, bone marrow biopsies, cytology specimens and autopsies.

3) Any conflict of interpretation of cancer incidence shall defer to the clinician's determination.

i) All reporting facilities shall submit the report forms on a monthly basis.

(Source: Amended at 40 Ill. Reg. _____, effective _____)

SUBPART C: ADVERSE PREGNANCY OUTCOMES REPORTING SYSTEM

Section 840.200 Adverse Pregnancy Outcome

An adverse pregnancy outcome for an infant consists of one or more of the following case criterion:

a) A diagnosis of a birth defect, made prenatally or by two years of age;.

b) A gestational age of less than 31 completed weeks (ICD-10-CM P07.21-P07.33)~~A birth weight of less than 1500 grams~~;

c) A diagnosis of fetal alcohol syndrome (ICD-9-CM 760.71 and ICD-10-CM Q86.0);

d) A fetal or neonatal death; or

e) A diagnosis of one of the following conditions made prior to discharge from the newborn hospitalization:

1) Positive toxicology for any controlled substance (except cannabis or drugs administered during labor and delivery); a maternal admission to illicit drug use (except cannabis) during the pregnancy that led to the delivery of this infant; or a diagnosis of signs of drug toxicity or withdrawal;

2) Serious infections:

A) Prenatal exposure to syphilis (ICD-9-CM V01.6 and ICD-10-CM Z20.2) or a diagnosis of congenital syphilis (ICD-9-CM 090.0-090.9 and ICD-10-CM A50.01-A53.9);

B) Prenatal exposure to hepatitis B (ICD-9-CM V01.7 and ICD-10-CM Z20.2) or a diagnosis of hepatitis B (ICD-10-CM P35.3);

C) Prenatal exposure to chlamydia (ICD-9-CM V01.8 and ICD-10-CM Z20.2) or a diagnosis of a chlamydial infection (ICD-9-CM 079.88 or 079.98 and ICD-10-CM A74.89, A74.9, or P23.1);

D) Prenatal exposure to herpes (ICD-9-CM V01.8 and ICD-10-CM Z20.2) or a diagnosis of congenital herpes (ICD-9-CM 771.2 and ICD-10-CM P35.2);

E) Group B streptococcus (ICD-9-CM 041.02 and ICD-10-CM J15.3 or P36.0);

F) Gonococcal conjunctivitis (neonatorum) (ICD-9-CM 098.40 and ICD-10-CM P39.1);

G) Congenital listeriosis (ICD-9-CM 771.2 and ICD-10-CM P37.2);

H) Congenital rubella (ICD-9-CM 771.0 and ICD-10-CM P35.0);

I) Congenital cytomegalovirus (ICD-9-CM 771.1 and ICD-10-CM P35.1);

J) Tetanus neonatorum (ICD-9-CM 771.3 and ICD-10-CM A33);

K) Septicemia of the newborn (ICD-9-CM 771.81 and ICD-10-CM P36.0-P36.9); or

L) Other congenital infections (ICD-9-CM 771.0-771.81 and ICD-10-CM P35.8, P35.9 or P37.0-P37.9).

3) Endocrine, metabolic or immune disorder:

A) Hypothyroidism (ICD-9-CM 243 and ICD-10-CM E03.0-E03.9);

B) Adrenogenital syndrome (ICD-9-CM 255.2 and ICD-10-CM E25.0-E25.9);

C) Inborn errors of metabolism (ICD-9-CM 270-273, or 275-276 and ICD-10-CM E70.0-E79.9);

D) Cystic fibrosis (ICD-9-CM 277.0 and ICD-10-CM E84.0-E84.9); or

E) Immune deficiency disorder (ICD-9-CM 279 and ICD-10-CM D80.0-D81.9).

4) Blood disorder:

A) Leukemia (ICD-9-CM 204-208 and ICD-10-CM C91.0-C95.92);

B) Hereditary hemolytic anemias (ICD-9-CM 282 and ICD-10-CM D58.0-D58.9);

C) Constitutional aplastic anemia (ICD-9-CM 284 and ICD-10-CM D61.0-D61.09); or

D) Coagulation defects (ICD-9-CM 286 and ICD-10-CM D65-D68.9).

5) Other conditions:

A) Neurofibromatosis (ICD-9-CM 237.7 and ICD-10-CM Q85.0-Q85.9);

B) Cerebral lipidoses (ICD-9-CM 330.1 and ICD-10-CM E75.4);

C) Retinopathy of prematurity (ICD-9-CM 362.21 and ICD-10-CM H35.1-H35.17);

D) Chorioretinitis (ICD-9-CM 363.2 and ICD-10-CM H30.00-H30.93);

E) Strabismus (ICD-9-CM 378 and ICD-10-CM H50.00-H50.9);

F) Endocardial fibroelastosis (ICD-9-CM 425.3 and ICD-10-CM I42.4);

G) Occlusion of cerebral arteries (ICD-9-CM 434 and ICD-10-CM I63.30-I63.59 or I66.0-I66.9);

H) Bronchopulmonary dysplasia (ICD-9-CM 770.7 and ICD-10-CM P27.1);

I) Intrauterine growth retardation (ICD-9-CM 764.9 and ICD-10-CM P05.0-P05.9);

J) Intraventricular hemorrhage grade III (ICD-9-CM 772.13 and ICD-10-CM P52.21);

K) Intraventricular hemorrhage grade IV (ICD-9-CM 772.14 and ICD-10-CM P52.22);

L) Seizures (ICD-9-CM 779.0 and ICD-10-CM P90); ~~or~~

M) Other conditions leading to more than 72~~48~~ hours on a ventilator (ICD-9-CM V46.1 and ICD-10-CM Z99.11);~~.~~

N) Conditions leading to extracorporeal membrane oxygenation (ECMO) (ICD-10-CM Z92.81)

O) Erb's Palsy (ICD-10-CM P14.0)

P) Hypoxic ischemic encephalopathy leading to cooling treatment (ICD-10-CM P91.63)

AGENCY NOTE: The products of induced abortions shall not be reported to APORS. ICD-9-CM codes will be supplanted with ICD-10 codes when the latter is adopted by the U.S. Department of Health and Human Services.

(Source: Amended at 40 Ill. Reg. _____, effective _____)

Section 840.210 Newborn Infant Case Reporting

a) Entities required to report newborn infant cases:

1) The Department requires all hospitals and birth centers licensed by the State of Illinois to report adverse pregnancy outcome information for cases identified during newborn infant hospitalization or care.

2) The Department requests, but does not require, hospitals outside Illinois and hospitals maintained by the federal government or other governmental agencies of the United States to report adverse pregnancy outcome information identified during the newborn hospital stay of infants whose mothers were Illinois residents at the time of delivery.

3) The Department requires clinical laboratories licensed by the State of Illinois to report newborn infants who have positive toxicology for controlled substances.

4) The Department requires all hospitals and birth centers that are members of an Illinois Perinatal Network to report adverse pregnancy outcome information for cases identified during newborn infant hospitalization or care.

b) Reporting newborn infant cases by hospitals:

1) Every hospital shall develop procedures and policies for identifying newborn infants who meet an APORS case criterion (see Section 840.200) and shall report these newborn infants to APORS.

2) When a newborn infant meets a case criterion (see Section 840.200) and is transferred to another hospital for a higher level of care, the hospital providing the highest level of care shall report the case.

3) Hospitals are required to report newborn infant cases in the format provided by the Department.

A) The Department will provide the hospitals with written instructions for completing an APORS report.

B~~A~~) Hospitals shall use the Department's format for APORS reports and shall report the following information:

i) Reporting hospital four-digit facility identification number, name and city and state if not Illinois;

ii) Delivery hospital four-digit facility identification number, name and city and state if not Illinois; for births that do not occur in a hospital, the location should be provided by address or by description;

iii) Infant's patient identification number;

iv) Date the infant was admitted to the reporting hospital;

v) Infant's date of birth;

vi) Infant's discharge date from the reporting hospital;

vii) Infant's ~~four-digit facility identification number and~~ first, middle and last names~~name~~;

viii) Other names by which the infant may be known;

ix) Infant's sex;

x) Infant's race;

xi) Infant's ethnicity;

xii) Whether the infant was admitted to the Intensive Care Unit;

xiii) Whether the infant was exposed to drugs (except cannabis or drugs administered during labor and delivery) prenatally and, if applicable, what type;

xiv) Birth mother's hepatitis B status;

xv) Dates and times infant's hepatitis B immunizations were provided, and type of vaccine given, if applicable;

xvi) Infant's gestational age at delivery in ~~whole~~ weeks and days;

xvii) Infant's birth weight in grams;

xviii) Infant's birth order;

xix) Pregnancy plurality;

xx) Infant's diagnoses made prior to the newborn discharge;

xxi) Birth mother's first, middle and last names~~name~~;

xxii) Birth mother's maiden name;

xxiii) Birth mother's address at delivery, including number, direction, street name, type of street, apartment number, city, state and ZIP code;

xxiv) Birth mother's county of residence at delivery;

xxv) Birth mother's medical record number;

xxvi) Birth mother's social security number;

xxvii) Birth mother's date of birth;

xxviii) Birth mother's telephone number, including the area code;

xxix) Father's first, middle and last names~~name~~;

xxx) Number of the birth mother's pregnancies, including the pregnancy resulting in this infant;

xxxi) Number of pregnancies that produced: full-term infants, premature infants, abortions (spontaneous and induced), currently living children;

xxxii) Infant's status on discharge: deceased, going home with parents or other family member, transferring to another hospital, transferring to a long-term care facility, being adopted, going to foster care, or in Department of Children and Family Services (DCFS) custody;

xxxiii) Name, city and four-digit facility identification number of facility to which child was discharged, if applicable;

xxxiv) Name and address of the person to whom the infant was discharged if the infant did not go home with the birth mother;

xxxv) Delivery type, either vaginal or caesarean section;

xxxvi) Feeding type, either breast, bottle or tube;

xxxvii) If applicable, formula type, frequency and amount;

xxxviii) Infant's discharge weight in grams;

xxxix) Infant's head circumference, in centimeters, at the time of birth;

xl) Infant's length, in centimeters, from crown to heel at the time of birth;

xli) Treatments prescribed for the infant at discharge;

xlii) Medication name, dosage and route of administration prescribed for the infant at discharge;

xliii) Other health, social and developmental concerns;

xliv) Name and telephone number (including area code) of registered nurse who can be contacted by the public health nurse making home visits to the infant;

xlv) Name, address and telephone number (including area code) of a relative, friend or other person who would know how to contact the infant's parents and the relationship of that person to the birth parents;

xlvi) Whether the infant's family has been informed that a local public health nurse will contact them to offer follow-up services in their home after the infant is discharged from the hospital;

xlvii) Name and the four-digit identification code of the local health agency that serves families in the county or city where the infant will be located;

xlviii) Indication of whether the infant or the infant's family is receiving services from a community social service agency, Division of Specialized Care For Children (DSCC), DCFS, or other agency;

xlix) Name of the infant's primary care physician;

l) Name and title of the person providing the information;

li) Date the report is completed.

~~B)~~ ~~The Department will provide the hospitals with written instructions for completing an APORS report.~~

4) Hospitals are required to fully complete all sections of the report and to send the report to the Department within seven days after the newborn infant's discharge or death.

5) When hospital-submitted reports are incomplete, the Department will contact the hospital within 30 days after receiving the report. The hospital shall supply the missing information to the Department within 30 days after receiving the request.

6) When a newborn infant is discharged, the hospital shall notify the infant's parents or legal guardian that the infant was reported to the Department and that the infant will be referred to health agencies for services.

7) Hospitals shall provide the parents or legal guardian with materials provided by DHS that explain the follow-up services that will be offered to the family.

8) Hospitals shall provide copies of the report submitted to the Department to the parents or legal guardian if requested. All other requests for copies shall be denied.

9) Hospitals shall distribute the original report and two~~three~~ copies in the following manner:

A) The original report shall be sent to the Department's Division of Epidemiologic Studies, 535 West Jefferson, 3rd Floor, Springfield, Illinois 62761;

B) ~~One copy shall be sent to the local health department or health agency in the county where the infant resides so that the infant's family can be offered follow-up public health services~~

~~C)~~ One copy shall be sent to the infant's primary care physician; and

CD) One copy shall be retained by the reporting hospital.

c) Reporting newborn infant cases by clinical laboratories:

1) Clinical laboratories are required to develop procedures and policies to report newborn infant cases of positive toxicology for controlled substances. Negative results are not reported to the Department.

2) Clinical laboratories are required to submit:

A) Infant's name (first, middle and last);

B) Infant's date of birth;

C) Residential address, including street address, city, county, state and ZIP code;

D) Unique identification number assigned by the submitting facility;

E) Name of the facility submitting the test;

F) Address of the facility submitting the test;

G) Test results, including the type of controlled substance found; and

H) Date of the test.

3) The clinical laboratory shall send the test results to the Department within seven days after the laboratory completes testing.

(Source: Amended at 40 Ill. Reg. _____, effective _____)