

105 CMR: DEPARTMENT OF PUBLIC HEALTH

105 CMR 302.000: CONGENITAL ANOMALIES REGISTRY

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302.001: Purpose

The purpose of 105 CMR 302.000 is to facilitate the maintenance of a statewide Congenital Anomaly Registry within the department of public health for the reporting of congenital anomalies.

302.002: Authority

105 CMR 302.000 is promulgated pursuant to M.G.L. c. 111, §§ 67E, 24B and 202.

302.003: Citation

105 CMR 302.000 et seq. shall be known and may be cited as 105 CMR 302.000: Congenital Anomalies Registry.

302.004: Effective Date

The reporting requirements of 105 CMR 302.000 shall apply to all cases diagnosed on or after February 6, 2009.

302.005: Definitions

As used in 105 CMR 302.000, the following words have the following meanings:

Abstractor means an official or agent of the department authorized by the commissioner to abstract and record individually identifiable health information from patient medical records for the Congenital Anomalies Registry.

Birth Defect see congenital anomaly.

Commissioner means the commissioner of the department of public health.

Congenital Anomaly or Birth Defect means structural, functional or biochemical abnormality, regardless of cause, and irrespective of any known genetic or environmental association(s), whether manifest prenatally, at delivery or at a later date up to three years of age, and that may interfere with normal growth or development.

Congenital Anomalies Registry means the central databank containing collected, classified and coded stored data relating to reported diagnoses of congenital anomalies.

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Department means the Department of Public Health.

Diagnosis means a physician's opinion, derived from physician observation, procedures or tests of a patient, which identifies a congenital anomaly or birth defect.

Fetal Death means a death that is required to be reported to the department pursuant to M.G.L. c.111, § 202.

Health Care Facility means any facility or institution located in the commonwealth, whether public or private, proprietary or not for profit, including but not limited to hospitals and other outpatient facilities such as clinics that provide treatment and/or diagnostic services to pregnant women, newborns and children up to three years of age.

Incidence means the frequency of a new occurrence of a congenital anomaly over a period of time and in relation to the population in which it occurs. Incidence is expressed as a rate, commonly a number of new cases during a prescribed time in a unit of population.

Individually Identifiable Health Information means information that is a subset of health information, including demographic information, and is created or received by the department and relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual, and that identifies the individual or with respect to which there is a reasonable basis to believe the information can be used to identify the individual.

Patient Identifiers means confidential information that can be attributed to a specific individual including but not limited to name, date of birth, address, geocode, telephone number, medical record number, health plan beneficiary number, and health identification number.

Physician means any licensed physician who makes a diagnosis.

Report means an official notice to the department of a diagnosis of a congenital anomaly in writing, by facsimile, or by electronic means.

302.010: Information Required to be Reported Regarding Congenital Anomalies

(A) The commissioner shall require the reporting of diagnoses made by physicians prenatally, at delivery and up to three years of age as the commissioner considers necessary and appropriate for the prevention and early detection of congenital anomalies or to facilitate epidemiological investigation and health surveillance of the incidence and prevalence of congenital anomalies in the commonwealth. Each report shall include the following data categories:

- (1) Mother identifiers and demographics;
- (2) Child (birth to three) or fetal death identifiers and demographics;
- (3) Provider and facility identifiers;
- (4) Specific congenital anomaly identification;
- (5) Diagnosis; and
- (6) Other information as necessary to identify the patient and ensure accuracy and completeness.

Reports shall be in the form specified in 105 CMR 302.025 and shall be in accordance with the current data collection manual as specified in 105 CMR 302.020. Reports may be subject to verification for accuracy or supplementation for completeness by medical records abstractors under 105 CMR 302.050 and 302.080.

(B) The following diagnoses are considered necessary and appropriate for the prevention and early detection of congenital anomalies or to facilitate epidemiological investigation and health surveillance of the incidence and prevalence of congenital anomalies in the commonwealth:

- (1) Central nervous system ICD9 Codes 740.00-742.99;
- (2) Eye and ear ICD9 Codes 743.00-744.99;

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- (3) Cardiovascular ICD9 Codes 745.00-747.99;
- (4) Respiratory ICD9 Codes 748.00-748.99;
- (5) Orofacial/gastrointestinal ICD9 Codes 749.00-751.99;
- (6) Genitourinary ICD9 Codes 752.00-753.99;
- (7) Musculoskeletal ICD9 Codes 754.00-756.99;
- (8) Integument ICD9 Codes 757.00-757.99;
- (9) Chromosomal and Other Syndromes ICD9 Codes 758.00-759.99;
- (10) Other anomalies outside designated congenital anomalies ICD9 Codes 279.11, 524.00-524.19, 658.80, 524.00, 760.71; 760.75, 760.79 and 762.80;
- (11) Fetal death and abnormalities from maternal record ICD9 Codes 632, 634.00-634.92, 653.6, 653.70-653.73, 655.0, 655.1, 655.2, 655.3, 655.8, 655.9, 656.40, 656.41, 656.43, 658.80-658.83, 761.8, V27.1, V27.3, V27.4, V27.6, V27.7, V27.9, V32.0-V32.2, V35.0-V35.2, and V36.0-V36.2; and
- (12) Others as identified in the data collection manual maintained pursuant to 105 CMR 302.020.

(C) Every diagnosis of a congenital anomaly detected prenatally, at delivery, or within the first three years of life is required to be reported to facilitate epidemiological investigation and health surveillance of the incidence and prevalence of congenital anomalies in the commonwealth.

- (1) A diagnosis regarding a Massachusetts resident is required to be reported by a Massachusetts physician treating a resident child up to three years of age, irrespective of whether the birth occurred inside or outside of Massachusetts.
- (2) A diagnosis regarding a non-resident child who may come to Massachusetts for specialty treatment, evaluation or consultation is not required to be reported.

302.020: Data Collection Manual

The Congenital Anomalies Registry shall maintain a data collection manual that identifies the discrete data items to be reported and the diagnoses required to be reported under 105 CMR 302.010, which manual shall be available upon request to all reporting physicians. The manual shall be revised periodically in accordance with national congenital anomaly surveillance standards and commonwealth-specific requirements and in consultation with the advisory committee established under 105 CMR 302.090. The manual shall include instructions that prohibit the collection of social security numbers. The manual also shall include instructions to record information relating to any pregnancy loss that is not a fetal death as a pregnancy loss and to record whether such pregnancy loss is case control surveillance eligible for the Centers for Disease Control and Prevention.

302.025: Report Form

Each report shall be submitted on a paper form or in an electronic format approved by the Commissioner. The Commissioner may amend the report form or format as necessary in accordance with national congenital anomaly surveillance standards and commonwealth-specific requirements and in consultation with the advisory committee established under 105 CMR 302.090.

302.030: Time for Reporting

All information required to be reported by 105 CMR 302.010 shall be reported to the Congenital Anomalies Registry within 30 days of the date of diagnosis of a congenital anomaly.

302.040: Physician Reporting Requirements

(A) Any physician who makes a diagnosis of a congenital anomaly prenatally, at delivery or between birth and up to three years of age shall report such diagnosis to the department.

(B) No physician is required to make a duplicate report under 105 CMR 302.040(A) if he or she has been informed that another physician made the diagnosis and has already reported to the department the required information or if he or she is seeing the child for reasons other than for the purpose of making a diagnosis of a congenital anomaly.

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(C) Health care facilities and physician practice groups may act as agents for individual physicians by submitting the report directly to the department; however, the reporting requirement remains the responsibility of the physician who makes the diagnosis.

(D) All diagnoses shall be classified and coded as directed by the commissioner using one of the systems for coding specified in 105 CMR 302.060.

302.050: Medical Records Abstraction

(A) Qualifications and Training. Abstractors shall have the qualifications and training, as determined by the commissioner, to accurately review and abstract records for the Congenital Anomalies Registry and shall maintain confidentiality at all times. Individuals selected as abstractors shall meet the minimum qualifications as defined by the commissioner.

(B) Purpose. When a physician or his or her agent has made a report to the Congenital Anomalies Registry but has not provided complete information that the commissioner requires for reporting, trained abstractors shall be given access to those parts of a medical record as are necessary to obtain information required to be reported and to verify the accuracy of reported information.

(C) Access to Medical Records.

(1) When a reported diagnosis occurs in Massachusetts in the office of a physician or in a licensed facility with a maternal-newborn service, neonatal intensive care unit, special care nursery service, continuing care nursery service, pediatric service, pediatric intensive care unit or with a medical specialty service as defined in 105 CMR 130.020 and when a physician or his or her agent has not provided complete information that the commissioner requires for reporting, abstractors shall be given access to those parts of the medical record which are necessary to obtain information required to be reported and to verify the accuracy of reported information. Abstractors shall provide advance notice of an intention to inspect records and shall schedule the inspection during standard business hours.

(2) Information from medical records of children and their parents relating to diagnostic information regarding congenital anomalies diagnosed prenatally, at delivery and up to three years of life that is required to be reported to the department is subject to abstraction without patient consent.

(D) Abstraction of Information Beyond Mandated Items. Before abstracting or recording any information that is in addition to items specified on the report form approved by the Commissioner under 105 CMR 302.025, department officials shall obtain the approval of a duly constituted institutional review board that reviews and approves, and thereafter annually re-approves, a research protocol submitted to it by the department. The research protocol shall specify how such records shall be reviewed, how information from them shall be abstracted and reported, the exact information to be recorded, and how the information will be used, maintained and kept confidential.

302.060: System for Coding Diagnoses

The Congenital Anomalies Registry shall use a medically recognized system for coding including but not limited to the most recent version of the International Classification of Diseases, Clinical Modification, established by the United States Center for Health Statistics, and/or the International Classification of Diseases, established by the World Health Organization; and/or the six-digit modified British Pediatric Association system (BPA/ICD).

302.070: Confidentiality

(A) The department shall require for reporting, and abstractors shall collect, no more information than the commissioner considers necessary and appropriate to conduct epidemiological surveys and to develop appropriate preventative treatment and control measures for congenital anomalies. The department shall not require reporting of social security numbers. To the extent that patient identifiers are necessary to eliminate duplicate reporting, the department shall collect the minimum amount of data necessary to accomplish that task.

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(B) The contents of any reports, records or information submitted to the Congenital Anomalies Registry shall be solely for the use of the department and shall not be open to public inspection or constitute a public record, or be disclosed except as specified in 105 CMR 302.070(D) and (G).

(C) The department shall maintain the confidentiality of reports or information submitted to the Congenital Anomalies Registry and shall not disclose such reports or any information or patient identifiers which because of name, identifying number, mark or description can be readily associated with a particular individual, except as specified in 105 CMR 302.070(D) and (G).

(D) A report submitted to the Congenital Anomalies Registry concerning a particular individual and any other information that would indicate whether or not the named individual is listed in the Congenital Anomalies Registry shall be disclosed after redacting information pertaining to any third person other than the physician who made or reported the diagnosis:

- (1) to the particular individual upon:
 - (a) receipt of a written request which is signed by the individual; and
 - (b) presentation by the individual of identification deemed suitable by the department;
- (2) if the individual is a minor, to his parent upon:
 - (a) receipt of a written request which is signed by the parent; and
 - (b) receipt of a certified copy of the individual's birth certificate listing the requester as one of the child's parents; and
 - (c) presentation by the parent of identification deemed suitable by the department;
- (3) if the particular individual has a court-appointed guardian, or if the individual is deceased, to the court-appointed guardian, or to the executor or administrator of the particular individual's estate or to the decedent's adult child upon:
 - (a) receipt of a written request which is signed by the guardian or executor or administrator or child as applicable; and
 - (b) receipt of a certified copy of the court order which appoints the guardian, executor, or administrator; and
 - (c) presentation by the guardian, executor or administrator or child of identification deemed suitable by the department; and
- (4) to an attorney designated by the individual, parent, court-appointed guardian, executor or administrator upon:
 - (a) receipt of a written request and authorization for the release of information signed by the individual, parent, guardian, executor or administrator as applicable; and
 - (b) presentation by the attorney of identification deemed suitable by the department including in the case where the attorney is designated by a parent a certified copy of the individual's birth certificate and in the case where the attorney is designated by a guardian, executor or administrator a certified copy of the court order which appoints the guardian, executor, or administrator.

(E) Every written request for the disclosure of information submitted pursuant to 105 CMR 302.070(D) shall be signed by the person making the written request and such signature shall be either:

- (1) witnessed by an employee of the department who has been designated to witness such requests;
or
- (2) notarized by a notary public.

(F) Any person required pursuant to 105 CMR 302.070(D) to present suitable identification shall present a valid, non-expired driver's license; a valid, non-expired passport issued within the last five years; or other valid, non-expired government-issued document which contains both a picture of the person and the signature or mark of the person. An adult child applying for information about a deceased parent under 105 CMR 302.070(D)(3) shall present documentary evidence of the parent's death and the parent-child relationship including:

- (1) a certified copy of the parent's death record; and
- (2) a certified copy of the requestor's own birth record listing the requestor's parent; and

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(3) if names appearing on proffered identity documents and birth and death certificates differ or the parent-child relationship is not readily apparent from such documents due to intervening change(s) of name, documentary evidence of a change of legal name such as a certified copy of a certificate of marriage or an attested copy of a judicial change of name decree.

(G) The commissioner may disclose information maintained by the Congenital Anomalies Registry to the principal investigator of a study or research project authorized by the commissioner to conduct an approved medical or scientific study for the purpose of the reduction of morbidity and mortality in the commonwealth, so long as the commissioner and a duly constituted institutional review board first approves that study. Such study shall require approval pursuant to M.G.L. c. 111, § 24A. However, with respect to a pregnancy loss that is not a fetal death, the department shall not disclose any medical record or individually identifiable health information or patient identifiers without written, informed consent of the patient. No such study or research project shall publish the name of any individual nor shall any such study or research project release any identifying number, mark or description which can be readily associated with an individual.

(H) The department shall maintain an audit trail that specifies each person who is given access to information from the Congenital Anomalies Registry under 105 CMR 302.070(D) and (G). The audit trail shall include the:

- (1) Name of the person authorizing access;
- (2) Name, title and organizational affiliation of each person given access;
- (3) Date(s) of access; and
- (4) Specific purpose for which the information was used.

(I) The department shall institute security procedures to prevent unauthorized individuals from accessing information maintained by the Congenital Anomalies Registry.

(J) The department shall comply with applicable statewide records retention schedules in the event that a decision is made that the information maintained or stored in connection with this registry is no longer needed. If destruction of information is authorized, all such destruction shall include standard sanitizing methods, including at a minimum US DoD5200 standard disk wiping and the degaussing of back up tapes, and destruction (shredding) of hard copies.

302.080: Quality Assurance

(A) For purposes of assuring the quality of submitted data, each physician and if applicable each health care facility and physician practice group that acts as a physician's agent for reporting shall allow the Congenital Anomalies Registry to inspect and copy such parts of a patient's medical records, paper and electronic, as are necessary to verify the accuracy and completeness of submitted data.

(B) Each physician, and/or agent, shall provide to the Congenital Anomalies Registry for inspection and copying no more than is necessary for quality assurance purposes. In order to provide only those portions of the medical records that contain specific information required to be reported under 105 CMR 302.000, the physician, and/or agent, shall employ reasonable measures to delete, mask, cross out or otherwise render illegible other parts of the patient's record.

(C) Each copy of a medical record or part thereof obtained by the Congenital Anomalies Registry:

- (1) Shall be stored securely with restricted access when not being used by the Registry; and
- (2) Shall not be re-copied by the Registry; and
- (3) Shall be destroyed promptly following verification of the corresponding reported data, or if the reported data appears to be inaccurate, following clarification or correction of reported data.

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302.090: Advisory Committee

The commissioner shall establish an advisory committee to advise the department regarding the Congenital Anomalies Registry. The advisory committee shall include representatives of the Massachusetts Chapter of the American College of Obstetricians and Gynecologists, Massachusetts Chapter of the American Academy of Pediatrics, Massachusetts Medical Society, Massachusetts Hospital Association, a certified genetic counselor, a parent of a child who has been diagnosed with a congenital anomaly, an adult who has been diagnosed with a congenital anomaly, a physician who specializes in treatment or research regarding congenital anomalies, an ethicist and others chosen by the commissioner to provide meaningful oversight.

REGULATORY AUTHORITY

105 CMR 302.000: M.G.L c. 111, §§ 67E, 24B and 202.