



Proposed Amendments to 105 CMR 302.000: Congenital Anomalies Registry

Public Health Council
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Background: Congenital Anomalies Registry

- MA conducts statewide surveillance according to guidelines and standards from the Centers for Disease Control and Prevention (CDC) and the National Birth Defects Prevention Network (NBDPN).
- The primary focus of the program is on major structural congenital anomalies.
- In 2012-2013, the program ascertained 3,590 cases with at least one congenital anomaly for a prevalence rate of 248.9/10,000 live births.

Data Utilization

Data from the Congenital Anomalies Registry is used for:

- Basic monitoring (e.g. produce reports and fact sheets, contribute to national estimates)
- Public health practice (e.g. identifying service needs, community assessments)
- Research studies (e.g. National Birth Defects Prevention Study)

An example:

- Assessed timing of diagnosis of critical congenital heart defects (CCHD) to establish a baseline for evaluation of the impact in MA of newborn screening for CCHD using pulse oximetry¹

¹ Liberman RF et al. Delayed Diagnosis of Critical Congenital Heart Defects: Trends and Associated Factors. Pediatrics 2014;134:e373.

Registry Authority

- The registry is:
 - Required by state statute (G.L. c.111, s 67E)
 - Facilitated by DPH regulations (105 CMR 302: Congenital Anomalies Registry)

Proposed Amendments

- 302.005: Definitions

Amended the definition of Health Care Facility to cover facilities that provide treatment and diagnostic services or both to any or all of the following: pregnant woman, newborns, and/or children up to age three.

- 302.010: Information Required to Be Reported (A) (B) (C)

Removed diagnostic codes, which are subject to change. Current reportable codes are provided in subregulatory guidance.

Proposed Amendments cont.

- 302.020: Data Collection Manual

Removed language related to revising manual in consultation with the Advisory Committee, to coincide with change in section 302.090.

- 302.050: Medical Records Abstraction (A)(C)(D)

Removed language related to inspecting records only during standard business hours because some facilities prefer that abstractors come off hours when there is more space available.

Removed language related to obtaining IRB approval before collecting non-surveillance data because this is standard policy for research activities and this language is included in the related statute G.L. c. 111, s. 67E.

Proposed Amendments cont.

- 302.060: System for Coding Diagnoses

Removed language related to the number of digits in the coding system because the number of digits changes with coding system changes.

- 302.070: Confidentiality (A) (F) (G)

Removed requirement about the age of passports that can be used as a valid ID since passports are valid for 10 years.

- 302.090: Advisory Committee

Revised language to make the establishment of an advisory committee optional, which will afford the committee more flexibility to meet when necessary.

Recommendation/Next Steps

- Bureau of Family Health and Nutrition has conducted a comprehensive review of 105 CMR 302: Congenital Anomalies Registry and recommends these proposed amendments.
- Following this presentation to the Public Health Council, a public hearing and comment period will be held.
- A summary of public comments and any changes to the proposed amendments will be presented at a subsequent meeting of the Public Health Council.