902 KAR 19:010. Kentucky Birth Surveillance Registry.

RELATES TO: KRS 194A.050, 211.180, 211.651, 211.655, 211.660, 211.670, Chapter 216B

STATUTORY AUTHORITY: KRS 194A.050(1), 211.660(6)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 194A.050(1) requires the Cabinet for Health and Family Services to promulgate administrative regulations necessary to operate the programs and fulfill the responsibilities vested in the cabinet. KRS 211.660(1) requires the department to establish the Kentucky Birth Surveillance Registry based on the need to provide information on the incidence, prevalence, and trends of congenital anomalies, stillbirths and high risk conditions; provide information as to possible causes; and develop preventive strategies to reduce their incidence and the secondary complications associated with them. KRS 211.660(6) authorizes the department to implement the provisions of KRS 211.651 to 211.670 through the promulgation of administrative regulations. This administrative regulation establishes uniform procedures for collection of data for the registry.

Section 1. Definitions.

(1) "Agent" means an entity with which the department may:

(a) Contract pursuant to carrying out the duties of the registry; and

(b) Designate to act on the behalf of the registry to edit or analyze data from hospitals.

(2) "Cabinet" is defined by KRS 211.651(1).

(3) "Coding and transmission specifications" means the required data elements and codes to be included on the UB-04 CMS 1450 Form.

(4) "Department" is defined by KRS 211.651(3).

(5) "Free-standing birthing center" means a non-hospital affiliated alternative birthing center licensed under the provisions of KRS Chapter 216B.

(6) "Hospital" means an acute care hospital licensed under the provisions of KRS Chapter 216B.

(7) "Hospitalization" means the inpatient medical episode identified by a patient's birth, admission date, length of stay and discharge date, and further identified by a provider-assigned patient control number unique to that inpatient episode.

(8) "ICD-10 Code" means the International Classification of Diseases, Tenth Revision, Clinical Modification system used by physicians and other health care providers to classify and code all diagnoses, symptoms and procedures recorded in conjunction with hospital care.

(9) "Laboratory" means a medical laboratory licensed under KRS Chapter 333.

(10) "Medical record" means the patient's actual medical record maintained by a hospital's or free-standing birth center's medical record department or by a laboratory.

(11) "Record" means documentation in UB-04 data format, in paper or electronic submission, of:

(a) A hospitalization;

(b) An outpatient visit; or

(c) A laboratory result.

(12) "Registry" means the Kentucky Birth Surveillance Registry.

(13) "UB-04 data" means the standard claim format used by birthing centers, hospitals and laboratory providers to transmit a healthcare claim.

Section 2. Data Collection.

(1) Hospitalization records. A hospital shall document, in the UB-04 data format, each inpatient hospitalization of a child up to age five (5) years who is diagnosed with a congenital birth anomaly or high-risk condition, as defined by the department in accordance with KRS 211.660(2), and included in Section 5 of this administration

regulation. Each hospital shall provide to the registry the data specified in Section 6 of this administrative regulation.

(2) Outpatient and laboratory records.

(a) In accordance with KRS 211.660(3)(b), a laboratory shall maintain medical records for each child up to the age of five (5) years who has a primary diagnosis or laboratory test result indicating a congenital anomaly or high-risk condition, as defined by the department and included in Section 5 of this administrative regulation.

(b) A laboratory, and a hospital voluntarily maintaining an outpatient list as described at KRS 211.660(3)(a), shall provide the data specified in Section 6 of this administrative regulation.

(3) Access to medical records. A hospital, free-standing birthing center, or laboratory shall provide an agent of the department access to the medical record of:

(a) Patients meeting the criteria in subsections (1) or (2) of this section;

(b) An infant who dies before his or her first birthday;

(c) Any stillborn child; and

(d) Maternal prenatal medical records for a patient meeting the criteria in:

1. Subsections (1) or (2) of this section; and

2. Paragraphs (b) and (c) of this subsection.

(4) Maternal prenatal medical records shall be used to assist in determining the possible causes of congenital anomalies, stillbirths, and high risk conditions, and aid in the development of prevention strategies to reduce their incidence as authorized by KRS 211.655.

Section 3. Data Finalization and Submission.

(1) Submission of final data. Data shall be final for purposes of submission to the registry as soon as a record is sufficiently final that the provider could submit it to a payor for billing purposes, whether or not the record has actually been submitted to a payor.

(a) Finalized data shall not be withheld from submission to the registry on grounds that it remains subject to adjudication by a payor; and

(b) Data on a hospitalization shall not be submitted to the registry before the patient is discharged.

(2) Data editing.

(a) If the registry identifies a record as incomplete or invalid, the submitting hospital shall submit a corrected copy within thirty (30) days of notification.

(b) The date of notification shall be the date postmarked on the registry's mailed notice of required correction.

(c) Resubmission shall be by either electronic transmission or mailing.

(3) Transmission of records.

(a) Data submitted to the registry shall be uniformly completed and formatted according to coding and transmission specifications;

(b) Hospitals, free-standing birthing centers, and laboratories that have the capacity shall submit data on computer-readable electronic media;

(c) Hospitals, free-standing birthing centers, and laboratories shall provide backup security against accidental erasure or loss of the data until any incomplete or inaccurate records identified by the registry have been corrected and resubmitted; and

(d) Data submitted by mail shall be by certified mail or other traceable carrier, such as United Parcel Service, and be postmarked on or before the due date.

Section 4. Data Submission Timetable. Quarterly submission. A hospital, free-standing birthing center, or laboratory shall submit data at least once for each calendar quarter. A quarterly submission shall contain data from records of patients which became final during that quarter, as specified in Section 3(1) of this administrative regulation. The data shall be submitted to the registry not later than forty-five (45) days after the last day of that quarter.

(1) If the 45th day falls on a weekend or holiday, the submission due date shall become the next following working day.

(2) Outpatient data shall be submitted directly to the registry within thirty (30) days of the written request.

(3) A hospital, free-standing birthing center, or laboratory shall, within thirty (30) days of receipt of a written request from the registry, submit a medical records report for specified ICD-10 codes for a designated quarter.

Section 5. Required Reporting Conditions. Hospitals, free-standing birthing centers, and laboratories shall submit to the registry the following information with respect to all patients up to the age of five (5) years, diagnosed with the following ICD-10 codes:

(1) All congenital anomalies codes Q00-Q99, and all subcategories;

(2) Metabolic storage disorder codes D80-D82, E70-E72, E74-E83, E88, and all subcategories;

(3) Teratogens (noxious influences) codes P04.0-P04.9, and all subcategories;

(4) Zika virus disease code A92.5; and

(5) Any additional condition necessary for public health surveillance.

Section 6. Required Data Elements.

(1) UB-04 data. Hospitals and free-standing birthing centers shall ensure that each copy of UB-04 data submitted to the registry contains the following data elements:

UB-04 data FIELD #	ELEMENT NAME
8	Patient Name
9	Patient Address
10	Birth Date
11	Sex
12	Admission Date
50	Payer Name
58	Insured's Name
59	Patient Relationship (P. REL)
60	Insured's Unique ID
66	Diagnosis Codes
67	Principle Diagnosis Code
76	Attending Physician National Provider Identifier

(2) Outpatient and laboratory data. A laboratory and a hospital voluntarily maintaining a list of outpatients, in accordance with KRS 211.660(3)(a), shall ensure that the data submitted to the registry includes the following data elements: patient name, patient address, birth date, sex, principal diagnosis, other diagnoses, and reporting source.

Section 7. Incorporation by Reference.

(1) "UB-04 CMS 1450 Form", 03-01-2007, is incorporated by reference.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Birth Surveillance Registry, Division of Maternal and Child Health, Department for Public Health, 275 East Main Street, Frankfort, Kentucky 40621, Monday through Friday, 8 a.m. to 4:30 p.m.

(22 Ky.R. 1185; Am. 1480; 1604; eff. 3-7-96; 29 Ky.R. 574; 966; eff. 10-16-2002; 45 Ky.R. 2777, 3182; eff. 5-31-2019.)