CABINET FOR HEALTH AND FAMILY SERVICES
Department for Public Health
Division of Epidemiology and Health Planning
(Amendment)

902 KAR 2:040. Syndromic surveillance~~[and screening of carriers and selected groups]~~.

RELATES TO: KRS 216B.015, Chapter 311 through 314 ~~[211.180, 214.010, 214.020]~~
STATUTORY AUTHORITY: KRS 211.180, 214.010~~[195.040, 211.090]~~
NECESSITY, FUNCTION, AND CONFORMITY: KRS 211.180 requires the Cabinet for Health and Family Services~~[mandates the Cabinet for Human Resources]~~ to implement a statewide program for the surveillance, detection, prevention, and control of communicable diseases,~~[.]~~ chronic diseases, and injuries. KRS 214.010 requires every physician, advanced practice registered nurse, and every head of family to notify the local health department of the existence of diseases and conditions designated by administrative regulation of the cabinet. This administrative regulation ensures~~[insures]~~ that selected individuals and groups who serve as potential sources of certain communicable diseases are under proper medical surveillance in order to prevent outbreaks of such diseases among their contacts.

Section 1. Definitions.

(1) "Admit reason" means the primary reason a patient has presented and is admitted for healthcare.

(2) "Chief complaint" means a concise statement describing the symptoms, problems, health conditions, diagnoses, or other factors that are the reason for the patient encounter.

(3) "Completeness" means the full, detailed data gathered or measured during the patient encounter that is submitted in the correct HL7 messaging segment or position that can be parsed to one of the Centers for Disease Control and Prevention's National Syndromic Surveillance Program (NSSP) Priority 1, Priority 2, or Priority 3 data elements.

(4) "Diagnosis code" means the combination of numbers and letters that reference a certain medical condition, medical procedure, symptom, or disease. Diagnosis codes should be submitted as valid International Classification of Disease-Clinical Modification or Systematized Nomenclature of Medicine-Clinical Terms (SNOMED-CT) codes with the parsed corresponding code description.

(5) "Discharge disposition" means the patient's final destination upon leaving the health facility.

(6) "Encounter" means an interaction between a patient and healthcare provider to provide healthcare service or assess the health status of a patient.

(7) "Facility type" means the type of healthcare services primarily provided by a specific healthcare provider, such as emergency, inpatient, outpatient, urgent care, primary care, or medical specialty.

(8) "Health facility" is defined by KRS 216B.015(13).

(9) "Health professional" means a professional licensed under KRS Chapters 311 through 314.

(10) "HL7 messaging" means the message format that provides a framework for the management, integration, exchange, and retrieval of electronic information across different healthcare systems.

(11) "ICD-CM code" means International Classification of Disease – Clinical Modification that healthcare professionals use to classify and code all diagnoses, symptoms, and procedures for claims processing.

(12) "Kentucky Health Information Exchange" or "KHIE" means the secure network that ensures interoperability among healthcare providers across the commonwealth.

(13) "Medical record number" or "MRN" means the person-level identifier assigned to the patient by the facility that shall:

(a) Not be changed during the encounter; and

(b) Remain consistent across multiple encounters by the same patient at the same facility.

(14) "Patient class code" means the type and manner of admission method that describes the patient interaction with the healthcare facility or provider. Acceptable, valid codes shall be E (emergency), I (inpatient), O (outpatient), B (obstetrics), P (preadmit), or R (recurring patient).

(15) "Patient class" means the level of resources needed to provide healthcare during a given patient encounter. Valid patient classes shall be direct admit, emergency, inpatient, observation patient, obstetrics, outpatient, preadmit, or recurring patient.

(16) "Syndromic surveillance" means the electronic public health surveillance system that aggregates de-identified healthcare information about patients' demographic information, symptoms, diagnoses, and other healthcare encounter-level data to assess healthcare utilization patterns and trends to identify potential imminent threats to public health in near real-time.

(17) "Systematized Nomenclature of Medicine-Clinical Terms" or "SNOMED-CT" means the standardized, international, multilingual core set of clinical healthcare terminology codes used in electronic health records to supplement ICD-CM diagnosis codes.

(18) "Timeliness" means an initial encounter message level data is submitted and received within twenty forty-eight (48) hours of when the patient encounter occurred.

(19) "Validity" means the use of informative and contextually appropriate free-text strings and proper usage of applicable syndromic surveillance code value sets available within the Centers for Disease Control and Prevention's Public Health Information Network Vocabulary Access and Distribution System (PHIN VADS).

(20) "Visit ID" means the unique numerical identifier assigned by each hospital or healthcare provider to identify each specific patient encounter.

Section 2. Required Reporting. The following data elements shall be reported to the cabinet via KHIE within forty-eight (48) hours of each patient encounter:

(1) Name, which shall be reported separately, in the following format:

(a) First name;

(b) Middle name; and

(c) Last name;

(2) Date of birth in MM/DD/YYYY format with time of birth and age in units;

(3) Gender;

(4) Race;

(5) Ethnicity;

(6) County of residence;

(7) Zip code of residence, post office box (P.O. Box) zip codes shall not be submitted;

(8) Medical record number (MRN);

(9) MRN assigning authority;

(10) Date and time of the actual patient encounter, which shall not be updated or altered in subsequent HL7 messaging updates for that patient encounter;

(11) Facility identification, including facility type;

(12) Admit reason, including a description with date and time of admission;

(13) Patient type;

(14) Patient class code;

(15) Chief complaint, which shall not include non-chief complaint related information such as screening questionnaires;

(16) Diagnosis code, which shall be:
(a) A valid ICD-CM code;
(b) A valid SNOMED-CT code with the corresponding diagnosis description and ICD-CM codes; and
(c) Submitted in the diagnosis code field;
(17) Discharge disposition including date and time of discharge;
(18) Death indicator, if applicable, including date and time of death;
(19) Visit ID - A new unique visit ID shall be assigned to the same patient, regardless of transfer status or changes to patient class or patient class code during that patient encounter; and
(20) Pregnancy status, if applicable.

Section 3. Data Submission.
(1) Health professionals and health facilities shall:
(a) Complete the electronic onboarding performed by the Kentucky Health Information Exchange (KHIE);
(b) Work directly with KHIE to establish an active, secure, electronic connection; and
(c) Actively participate with KHIE onboarding staff for ongoing data quality improvement.
(2)
(a) If the active connection required by subsection (1)(b) of this section is lost or an error in connection occurs, the health professional or health facility shall notify KHIE within one (1) business day; and
(b) Any backlog in data submission that results during a lost or errored connection shall be submitted when the connection is re-established.
(3) Syndromic surveillance data shall be submitted accordance with Centers for Disease Control and Prevention timeliness standards.
(4) Healthcare encounter data submitted shall include all required data elements listed in Section 2 of this administrative regulation. Only required data elements will be considered during assessments of data quality completeness and validity measures.
(5) Data transmitted to KHIE shall be deidentified and routed to state and national syndromic surveillance platforms on behalf of the submitting healthcare organization. ~~[Carriers. Any person who is a carrier of the infectious agents of cholera, amoebic dysentery, bacillary dysentery, diphtheria, typhoid, paratyphoid fever shall be subject to supervision of the local health department or Cabinet for Human Resources, as provided by 902 KAR 2:050. Every physician and local health department shall report such carriers immediately to the Cabinet for Human Resources.]~~

~~[Section 2.] [Selected Groups. The Cabinet for Human Resources or individual local health departments may require periodic medical examinations for selected occupational groups including barbers, beauticians, school teachers and employees, and others who come into intimate contact with the public and potentially serve as sources of infection.]~~

STEVEN J. STACK, MD, MBA, Commissioner
ERIC C. FRIEDLANDER, Secretary

APPROVED BY AGENCY: August 15, 2024
FILED WITH LRC: September 9, 2024 at 11:20 a.m.
PUBLIC HEARING AND COMMENT PERIOD: A public hearing on this administrative regulation shall, if requested, be held on November 25, 2024, at 9:00 a.m. using the CHFS Office of Legislative and Regulatory Affairs Zoom meeting room. The Zoom invitation will be emailed to each requestor the week prior to the scheduled hearing. Individuals interested in attending this virtual hearing shall notify this agency in writing by

November 18, 2024, five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. This hearing is open to the public. Any person who attends virtually will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on this proposed administrative regulation until November 30, 2024. Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to the contact person. Pursuant to KRS 13A.280(8), copies of the statement of consideration and, if applicable, the amended after comments version of the administrative regulation shall be made available upon request.

CONTACT PERSON: Krista Quarles, Policy Analyst, Office of Legislative and Regulatory Affairs, 275 East Main Street 5 W-A, Frankfort, Kentucky 40621; phone 502-564-7476; fax 502-564-7091; email CHFSregs@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact Person:Julie Brooks or Krista Quarles

(1) Provide a brief summary of:

(a) What this administrative regulation does:

This administrative regulation requires carriers of specific diseases, specifically cholera, amoebic dysentery, bacillary dysentery, diphtheria, typhoid, and paratyphoid, to be subject to supervision by local health departments or the Cabinet for Human Resources and requires every physician and local health department to report these carriers to the Cabinet for Human Resources. This administrative regulation allows the Cabinet for Human Resources or local health departments to periodically require medical examinations for people in selected occupations, specifically barbers, beauticians, schoolteachers and employees, and others who come into intimate contact with the public and potentially serve as sources of infection.

(b) The necessity of this administrative regulation:

This administrative regulation was necessary as a means of tracking carriers of the listed illnesses, and as a means to survey selected occupations for potential threats to public health.

(c) How this administrative regulation conforms to the content of the authorizing statutes:

KRS 211.180 authorizes the cabinet to implement a statewide program for the detection, prevention, and control of communicable diseases. KRS 214.010 requires every physician, advanced practice registered nurse, and every head of family to notify the local health department of the existence of diseases and conditions as designated by administrative regulation.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes:

This administrative regulation list specific diseases and occupations for surveillance.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation:

The amendment to this administrative regulation updates the name of the cabinet to the Cabinet for Health and Family Services, adds new definitions, adds syndromic surveillance requirements including the required data elements and data submission procedures to standardize reporting by health professionals and health facilities, and deletes outdated requirements for the reporting and monitoring of identified carriers of selected diseases as well as deletes the authority to require certain occupations to submit to periodic medical examinations.

(b) The necessity of the amendment to this administrative regulation:

The amendment to this administrative regulation is necessary to standardize and assure completeness of data being submitted electronically to the Kentucky Health Information Exchange for syndromic surveillance purposes. This administrative regulation requires the cabinet to implement and maintain a statewide program for the detection, prevention and control of communicable diseases. Syndromic surveillance is one method of detecting incidence of any condition, outbreak, or unusual occurrences of disease in Kentucky. The reporting of healthcare information

already occurs electronically via data feeds to the Kentucky Health Information Exchange, but the amendment to this administrative regulation will require hospitals and non-hospital agencies to submit syndromic surveillance data in a timely manner and to standardize the data that is submitted by healthcare facilities, which is often incomplete or of poor quality due to a lack of standards required by the current administrative regulation.

(c) How the amendment conforms to the content of the authorizing statutes:
KRS 211.180(1)(a) authorizes the Cabinet for Health and Family Services to implement a statewide program for the detection, prevention, and control of communicable diseases, chronic and degenerative diseases, dental diseases and abnormalities, occupational diseases and health hazards peculiar to industry, home accidents and health hazards, animal diseases that are transmissible to man, and other diseases and health hazards that can be controlled. KRS 214.010 requires every physician, advanced practice registered nurse, and every head of family to notify the local health department of the existence of diseases and conditions designated by administrative regulation of the cabinet, this amendment advances the completeness of reporting requirements as electronic reporting mechanisms progress. The amendment to this administrative regulation delineates which data elements are required and the timeliness for submitting them for syndromic surveillance purposes in conformance with KRS 211.180 and 214.010.

(d) How the amendment will assist in the effective administration of the statutes:
The amendment to this administrative regulation will allow hospital and non-hospital facilities to submit data that can be monitored for increases in syndromes, conditions, and illnesses. Ongoing analysis of this data allows for detection of public health threats, monitoring of trends for pathogens required to be reported, outbreaks, and other outcomes of interest, identification of regional or other geographic trends in disease events, and more effective targeting of healthcare and public health interventions.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation:
The amendment to this administrative regulation impacts all hospitals and non-hospital healthcare facilities that are fully onboarded with the Kentucky Health Information Exchange.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment:
Hospital and non-hospital facilities that are onboarded to the Kentucky Health Information Exchange may need to implement additional coding in order to assure complete and standard submission of required variables. All onboarded healthcare facilities are aware of the need to report electronically but have not had a standard to follow as to completeness or accuracy of data elements.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3):
The costs associated with compliance is unknown. Hospital and non-hospital facilities should already have the ability to submit syndromic surveillance data as they already submit electronic data to Kentucky Health Information Exchange (KHIE). Troubleshooting missing or incomplete data may incur additional cost but

will be pursued by the cabinet only in cases where gaps are egregious, or compliance is clearly not being worked toward.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3):

As a result of compliance, entities identified in question (3) will be more able to achieve the standards set by the Interoperability Program.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially:

No initial costs are expected for KHIE or the cabinet.

(b) On a continuing basis:

No additional ongoing costs are expected for KHIE or the cabinet.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation:

Funding for syndromic surveillance activities is a mix of state general funds and federal grant dollars.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment:

An increase in fees or funding is not necessary to implement the amendment to this administrative regulation.

(8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees:

This administrative regulation does not contain any fees.

(9) TIERING: Is tiering applied?

Tiering is not applied. The requirements of this administrative regulation are applied equally to health professionals and health facilities.

FISCAL IMPACT STATEMENT

(1) Identify each state statute, federal statute, or federal regulation that requires or authorizes the action taken by the administrative regulation.

KRS 211.180 and 214.010.

(2) Identify the promulgating agency and any other affected state units, parts, or divisions:

The Cabinet for Health and Family Services, Department for Public Health, Division of Epidemiology and Health Planning is the promulgating agency. The Kentucky Health Information Exchange in the Cabinet for Health and Family Services, Office of Inspector General will also be impacted by this administrative regulation.

(a) Estimate the following for the first year:

Expenditures:This administrative regulation will not impact expenditures in the first year.

Revenues:This administrative regulation does not generate revenue.

Cost Savings:This administrative regulation does not result in cost savings.

(b) How will expenditures, revenues, or cost savings differ in subsequent years?

There will be no change in expenditures, revenues, or cost savings in subsequent years.

(3) Identify affected local entities (for example: cities, counties, fire departments, school districts):

There are no affected local entities.

(a) Estimate the following for the first year:

Expenditures:Not applicable.

Revenues:Not applicable.

Cost Savings:Not applicable.

(b) How will expenditures, revenues, or cost savings differ in subsequent years?

Not applicable.

(4) Identify additional regulated entities not listed in questions (2) or (3):

All local hospitals and health care facilities that report syndromic surveillance data and the Kentucky Injury Prevention and Research Center at the University of Kentucky are additional regulated entities that will be impacted by this administrative regulation.

(a) Estimate the following for the first year:

Expenditures:This administrative regulation will not impact the expenditures of the additional regulated entities.

Revenues:This administrative regulation will not generate revenue for the additional regulated entities.

Cost Savings:This administrative regulation will not result in cost savings for the additional regulated entities.

(b) How will expenditures, revenues, or cost savings differ in subsequent years?

There will be no change in expenditures, revenue, or cost savings in subsequent years.

(5) Provide a narrative to explain the:

(a) Fiscal impact of this administrative regulation:

This administrative regulation will not have a significant fiscal impact. Health care facilities and hospitals are currently required to report syndromic surveillance data. This administrative regulation will ensure the accuracy and completeness of the data.

(b) Methodology and resources used to determine the fiscal impact:

The fiscal impact was determined by considering the current processes in place for reporting syndromic surveillance data.

(6) Explain:

(a) Whether this administrative regulation will have an overall negative or adverse major economic impact to the entities identified in questions (2) - (4). ($500,000 or more, in aggregate)

This administrative regulation does not have an overall negative or adverse major economic impact to the entities identified in questions (2) – (4).

(b) The methodology and resources used to reach this conclusion:

This administrative regulation does not generate revenue for any of the regulated entities or the department. Because regulated entities are currently reporting syndromic surveillance data, this administrative regulation will not impact their expenditures or result in cost savings.