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

902 KAR 2:020. Reportable disease surveillance.

RELATES TO: KRS 214.645, 214.625(5)(c)5, 214.990(1), 215.520, 216B.015, 258.065, 258.990, 311.282, 311.571, 315.010, 321.181(4), 333.020, 333.130

STATUTORY AUTHORITY: KRS 194A.050, 211.090(3), 211.180(1)(a), 214.010

NECESSITY, FUNCTION, AND CONFORMITY: KRS 211.180(1)(a) authorizes the cabinet 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 administrative regulation establishes notification standards and specifies the diseases requiring immediate, urgent, priority, routine, or general notification, in order to facilitate rapid public health action to control diseases and to permit an accurate assessment of the health status of the commonwealth.

Section 1. Definitions.

(1) "Acid fast bacilli" or "AFB" means the mycobacteria that, if stained, retains color even after having been washed in an acid solution and can be detected under a microscope in a stained smear.

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

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

(4) "Healthcare-associated infection" or "HAI" means an infection acquired by a person while receiving treatment for a separate condition in a health care setting.

(5) "Kentucky public health advisory" means a notification to health professionals, health facilities, and laboratories subject to this administrative regulation identifying a new health threat that warrants reporting through the procedures of this administrative regulation.

(6) "Laboratory-confirmed influenza" means influenza diagnosed through testing performed using:

(a) Reverse transcriptase polymerase chain reaction (RT PCR);

(b) Nucleic acid detection; or

(c) Viral culture.

(7) "Medical laboratory" is defined by KRS 333.020(3).

(8) "National Healthcare Safety Network" or "NHSN" means the nation's most widely used healthcare-associated infection (HAI) tracking system as provided to medical facilities by the Centers for Disease Control and Prevention (CDC).

(9) "National reference laboratory" means a laboratory located outside of Kentucky that is contracted by a Kentucky health professional, laboratory, or health facility to provide laboratory testing.

(10) "Novel influenza A virus" means an influenza virus that causes human infection but is different from the seasonal human influenza A virus subtypes and includes viruses predominately of avian and swine origin.

(11) "Nucleic acid amplification test" or "NAAT" means the laboratory test used to target and amplify a single deoxyribonucleic acid (DNA) or ribonucleic acid (RNA) sequence, usually for detecting a microorganism.

(12) "Outbreak" means:

(a) Two (2) or more cases, including HAIs, that are epidemiologically linked or connected by person, place, or time; or

(b) A single case of an HAI not commonly diagnosed.

(13) "Pharmacist" is defined by KRS 315.010(17).

(14) "Post-exposure prophylaxis" or "PEP" means taking an antiretroviral medicine after being potentially exposed to HIV to prevent becoming infected.

(15) "Pre-exposure prophylaxis" or "PrEP" means daily medicine intended to reduce the chance of getting HIV.

(16) "Select agent" means a biological agent or toxin that could pose a severe threat to public health, plant health, animal product, or plant product as determined by the National Select Agent Registry (NSAR) at www.selectagents.gov.

(17) "Veterinarian" is defined by KRS 321.181(4).

Section 2. Notification Standards.

(1) Health professionals and facilities.

(a) A health professional or a health facility shall give notification if:

1. The health professional or a health facility makes a probable diagnosis of a disease specified in Section 3, 6, 7, 8, 9, 12, 16, 17, 18, or 19 of this administrative regulation; and

2. The diagnosis is supported by:

a.

(i) Clinical or laboratory criteria; and

(ii) Case classifications published by the Centers for Disease Control and Prevention at https://ndc.services.cdc.gov/[~~wwwn.cdc.gov/nndss~~]; or

b. A health professional's medical opinion that the disease is present.

(b) A single report by a health facility of a condition diagnosed by a test result from the health facility's laboratory shall constitute notification on behalf of the health facility and its laboratory.

(c) A health facility may designate an individual to report on behalf of the health facility's laboratory, pharmacy, and the health facility's other clinical entities.

(d) Notification shall be given to the local health department serving the county in which the patient resides.

(e) If the local health department cannot be reached, notification shall be given to the Kentucky Department for Public Health.

(f) The reporting health professional or health facility shall submit:

1. Information required in Section 5(6) of this administrative regulation; and

2. Clinical, epidemiologic, and laboratory information pertinent to the disease including sources of specimens submitted for laboratory testing.

(2) Medical Laboratories.

(a) A laboratory test result that indicates infection with an agent associated with one (1) or more of the diseases or conditions specified in Section 3, 6, 7, 8, 9, 12, 16, 17, 18, or 19 of this administrative regulation shall be reported to the local health department serving the county in which the patient resides.

(b) If the local health department cannot be reached, notification shall be given to the Kentucky Department for Public Health.

(c) The reporting laboratory shall submit the information required in Section 5(6) of this administrative regulation.

(3) National Reference Laboratories.

(a) A test result performed by a national reference laboratory that indicates infection with an agent associated with one (1) or more of the diseases or conditions specified in Section 3, 6, 7, 8, 9, 12, 16, 17, 18, or 19 of this administrative regulation shall be reported by the director of a medical laboratory, a health facility, or the health professional that referred the test to the national reference laboratory to the local health department serving the county in which the patient resides.

(b) If the local health department cannot be reached, notification shall be given to the Kentucky Department for Public Health.

(c) The report shall include the information required by Section 5(6) of this administrative regulation.

Section 3. Submission of Specimens to the Kentucky Department for Public Health Division of Laboratory Services.

(1) A medical laboratory and a national reference laboratory in receipt of diagnostic specimens originating from the Commonwealth of Kentucky shall send direct specimens or pure clinical isolates for diseases established in subsection (5) of this section to the Division of Laboratory Services for primary or confirmatory testing and related studies.

(2) A medical laboratory or national reference laboratory using non-culture techniques to identify bacterial agents of diarrheal disease, such as enzyme immunoassays (EIAs) or molecular assays, shall attempt isolation of the etiologic agent identified. Pure clinical isolates shall be submitted to the Division of Laboratory Services.

(3) If the culture attempts do not produce a clinical isolate, the direct specimen, submitted in the appropriate preservative, shall be sent to the Division of Laboratory Services. A submitting laboratory shall provide the name of the etiologic agent detected by the non-culture technique at the time of specimen submission.

(4) A medical laboratory performing this test shall continue to follow the state's requirement for the submission of appropriate materials to the state public health laboratory.

(5) A medical or national reference laboratory shall submit pure isolates or, if not available, the direct specimen from the following diseases to the Division of Laboratory Services:

(a) Botulism, with prior approval from the Division of Epidemiology for testing;

(b) Brucellosis;

(c) Campylobacteriosis;

(d) Candida auris;

(e) Carbapenem-resistant Acinetobacter;

(f) Carbapenem-resistant Enterobacteriaceae;

(g) Carbapenem-resistant Pseudomonas;

(h) Cholera and diseases caused by other Vibrio species;

(i) Diphtheria;

(j) Escherichia coli O157:H7;

(k) Hemolytic Uremic Syndrome (HUS) – Post Diarrheal;

(l) Listeriosis;

(m) Measles;

(n) Meningococcal infections;

(o) Rabies, animal;

(p) Rubella;

(q) Salmonellosis;

(r) Shiga toxin-producing E. coli (STEC);

(s) Shigellosis;

(t) Tuberculosis (TB);

(u) Tularemia;

(v) Typhoid fever;
(w) Vancomycin-intermediate Staphylococcus aureus;
(x) Vancomycin-resistant Staphylococcus aureus; and
(y) Zika, with prior approval from the Division of Epidemiology for testing.

(6) All direct specimens or clinical isolates from enteric disease shall be submitted within seventy-two (72) hours from collection.

Section 4. Laboratory Testing and Submission of Specimens to the Division of Laboratory Services for the Identification of M. tuberculosis.

(1) For the identification of M. tuberculosis, a medical laboratory or national reference laboratory shall perform AFB smear and culture, regardless of rapid molecular testing results (NAAT).

(2) Rapid molecular testing shall be performed for the identification of M. tuberculosis on:

(a) Any diagnostic specimen with an AFB smear positive result; or

(b) Any specimen that originates from an individual with clinical or epidemiological evidence suggesting active tuberculosis.

(3) If rapid molecular testing cannot be performed by the medical laboratory or national reference laboratory, the diagnostic specimen shall be sent to the Division of Laboratory Services.

(4) A medical laboratory or national reference laboratory that has a diagnostic specimen test positive for M. tuberculosis by rapid molecular testing shall send the remainder of that specimen to the Division of Laboratory Services.

(5) Any diagnostic specimen found to be positive for M. tuberculosis by rapid molecular testing or culture testing shall be reported in accordance with Section 7 of this administrative regulation.

Section 5. Reporting Classifications and Methods.

(1) Immediate reporting.

(a) A report required by Section 12(1) and (2) of this administrative regulation to be made immediately shall be:

1. Made by telephone to the local health department serving the county in which the patient resides; and

2. Followed up by electronic or fax submission to the local health department serving the county in which the patient resides within one (1) business day.

(b) Upon receipt of a report for a disease requiring immediate reporting, the local health department shall:

1. Notify the Kentucky Department for Public Health by telephone; and

2. Assist the department in carrying out a public health response.

(c) Weekend, evening, or holiday immediate notification. If local health department personnel cannot be contacted directly, notification shall be made by telephone using an emergency number provided by the local health department or the Kentucky Department for Public Health.

(d) For the protection of patient confidentiality, a report using the emergency number shall include:

1. The name of the condition being reported; and

2. A telephone number that can be used by the department to contact the reporting health professional or health facility.

(2) Urgent reporting.

(a) A report made within twenty-four (24) hours as required by Section 6 of this administrative regulation shall be:

1. Submitted electronically, by fax, or by telephone to the local health department serving the county in which the patient resides; and

2. If submitted by telephone, followed up by electronic or fax submission to the local health department serving the county in which the patient resides within one (1) business day.

(b) Upon receipt of a report for a disease requiring urgent reporting, the local health department shall:

1. Notify the Kentucky Department for Public Health; and

2. Assist the department in carrying out a public health response.

(c) Weekend, evening, or holiday urgent notification. If local health department personnel cannot be contacted directly, notification shall be made by telephone using an emergency number provided by the local health department or the Kentucky Department for Public Health.

(d) For the protection of patient confidentiality, notification using the emergency number shall include:

1. The name of the condition being reported; and

2. A telephone number that can be used by the department to contact the reporting health professional or health facility.

(3) Priority reporting.

(a) A report made within one (1) business day as required by Section 7, 11, 12(3), 17(4), or 18 of this administrative regulation shall be:

1. Submitted electronically, by fax, or by telephone to the local health department serving the county in which the patient resides; and

2. If submitted by telephone, followed up by electronic or fax submission of a report to the local health department serving the county in which the patient resides within one (1) business day.

(b) Upon receipt of a report for a disease requiring priority reporting, a local health department shall:

1. Investigate the report and carry out public health protection measures; and

2. Notify the Kentucky Department for Public Health of the case by electronic or fax submission within one (1) business day.

(c) The reporting health department may seek assistance in carrying out public health measures from the Kentucky Department for Public Health.

(4) Routine reporting.

(a) A report made within five (5) business days, as required by Section 8, 9, 10, 13(1), 16(1), 17(7), or 20(1) of this administrative regulation, shall be made electronically, by fax, or by mail to the local health department serving the county in which the patient resides.

(b) Upon receipt of a report of a disease or condition requiring routine reporting, a local health department shall:

1. Make a record of the report;

2. Answer inquiries or render assistance regarding the report if requested by the reporting entity; and

3. Forward the report to the Kentucky Department for Public Health by electronic or fax submission of a report, or in writing within five (5) business days.

(5) General reporting. A report made within three (3) months, as required by Section 19 of this administrative regulation, shall be made electronically, by fax, or by mail.

(6) Reporting requirements.

(a) A report submitted by fax or by mail shall be made using one (1) of the following reporting forms:

1. EPID 200, Kentucky Reportable Disease Form;

2. EPID 250, Kentucky Reportable MDRO Form, to be used for priority reporting;

3. EPID 394, Kentucky Reportable Disease Form, Hepatitis Infection in Pregnant Women or Child (aged five (5) years or less);

4. EPID 399, Perinatal Hepatitis B Prevention Form for Infants;
5. Adult HIV Confidential Case Report Form; or
6. Pediatric HIV Confidential Case Report Form.

(b) Case reports may be made electronically through the Kentucky Health Information Exchange. Electronic case reports shall include the information required by paragraph (c) of this subsection.

(c) Information to be reported. Except as provided in subsections (1)(d) and (2)(d) of this section, a report required by this administrative regulation shall include:

1. Patient name;
2. Date of birth;
3. Gender;
4. Race;
5. Ethnicity;
6. Patient address;
7. County of residence;
8. Patient telephone number;
9. Name of the reporting medical provider or facility;
10. Address of the reporting medical provider or facility; and
11. Telephone number of the reporting medical provider or facility.

(d) ~~[(c)]~~ A reporting health professional shall submit the information listed in this subsection and Section 2(1)(f) of this administrative regulation.

Section 6. Notifiable Infectious Conditions Requiring Urgent Notification.

(1) Notification of the following diseases shall be considered urgent and shall be made within twenty-four (24) hours:

(a) Anthrax;
(b) Botulism;
(c) Brucellosis (multiple cases, temporally or spatially clustered);
(d) Diphtheria;
(e) Hepatitis A, acute;
(f) Measles;
(g) Meningococcal infections;
(h) Middle East Respiratory Syndrome-associated Coronavirus (MERS-CoV) disease;
(i) Multi-system Inflammatory Syndrome in Children (MIS-C);
(j) Novel influenza A virus infections;
(k) Plague;
(l) Poliomyelitis;
(m) Rabies, animal;
(n) Rabies, human;
(o) Rubella;
(p) Severe Acute Respiratory Syndrome-associated Coronavirus (SARS-CoV) disease;
(q) Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) (the virus that causes COVID-19) in accordance with subsection (2) of this section;
(r) Smallpox;
(s) Tularemia;
(t) Viral hemorrhagic fevers due to:

1. Crimean-Congo Hemorrhagic Fever virus;
2. Ebola virus;
3. Lassa virus;
4. Lujo virus;
5. Marburg virus; or
6. New world arenaviruses including:

a. Guanarito virus;
b. Junin virus;
c. Machupo virus; and
d. Sabia virus; and

(u) Yellow fever.

(2) To track the spread of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), the virus that causes COVID-19, the following reporting is required:

(a) Laboratory reports of:

1. Positive and negative test results for SARS-CoV-2 viral detection using ~~[antigen or]~~Nucleic Acid Amplification Test (NAAT), including polymerase chain reaction (PCR);

2. Positive test results for SARS-CoV-2 viral detection using antigen immunoassays; and

3. SARS-CoV-2 molecular sequencing~~[; and]~~

~~[3.] [Positive test results for IgM or IgG antibodies to SARS-CoV-2 nucleocapsid protein]~~.

(b) Health professional case report when:

1. A COVID-19 diagnosis of a patient for whom a laboratory report is not independently submitted;
2. A COVID-19 diagnosis of a patient is admitted to an inpatient medical facility; or
3. There is a COVID-19 associated mortality.

Section 7. Notifiable Infectious Conditions and Notifiable Non-Infectious Conditions Requiring Priority Notification. Notification of the following diseases or conditions shall be considered priority and shall be made within one (1) business day:

(1) Arboviral diseases, neuroinvasive and non-neuroinvasive, including:

(a) California serogroup virus diseases, including diseases caused by:

1. California encephalitis virus;
2. Jamestown Canyon virus;
3. Keystone virus;
4. La Crosse virus;
5. Snowshoe hare virus; and
6. Trivittatus viruses;

(b) Chikungunya virus disease;

(c) Eastern equine encephalitis virus disease;

(d) Powassan virus disease;

(e) St. Louis encephalitis virus disease;

(f) Venezuelan equine encephalitis disease;

(g) West Nile virus disease;

(h) Western equine encephalitis virus disease; and

(i) Zika virus disease or infection or the birth of a child to a mother who was Zika-positive or Zika-inconclusive during any stage of pregnancy or during the periconceptional period;

(2) Brucellosis (cases not temporally or spatially clustered);

(3) Campylobacteriosis;

(4) Carbon monoxide poisoning;

(5) Cholera;

(6) Cryptosporidiosis;

(7) Cyclosporiasis;

(8) Dengue virus infections;

(9) Escherichia coli O157:H7;

(10) Foodborne disease outbreak;

(11) Giardiasis;
(12) Haemophilus influenzae invasive disease;
(13) Hansen's disease (leprosy);
(14) Hantavirus infection, non-Hantavirus pulmonary syndrome;
(15) Hantavirus pulmonary syndrome (HPS);
(16) Hemolytic uremic syndrome (HUS), post-diarrheal;
(17) Hepatitis B, acute;
(18) Hepatitis B infection in a pregnant woman;
(19) Hepatitis B infection in an infant or a child aged five (5) years or less;
(20) Newborns born to Hepatitis B positive mothers at the time of delivery;
(21) Influenza-associated mortality;
(22) Legionellosis;
(23) Leptospirosis;
(24) Listeriosis;
(25) Mumps;
(26) Norovirus outbreak;
(27) Pertussis;
(28) Pesticide-related illness, acute;
(29) Psittacosis;
(30) Q fever;
(31) Rubella, congenital syndrome;
(32) Salmonellosis;
(33) Shiga toxin-producing E. coli (STEC);
(34) Shigellosis;
(35) Streptococcal toxic-shock syndrome;
(36) Streptococcus pneumoniae, invasive disease;
(37) Tetanus;
(38) Toxic-shock syndrome (other than Streptococcal);
(39) Tuberculosis;
(40) Typhoid fever;
(41) Varicella;
(42) Vibriosis; and
(43) Waterborne disease outbreak.

Section 8. Notifiable Infectious Conditions and Notifiable Non-Infectious Conditions Requiring Routine Notification. Notification of the following diseases shall be considered routine and shall be made within five (5) business days:
(1) Acute Flaccid Myelitis;
(2) Anaplasmosis;
(3) Babesiosis;
(4) Coccidioidomycosis;
(5) Creutzfeldt-Jakob disease;
(6) Ehrlichiosis;
(7) Hepatitis C, acute;
(8) Hepatitis C infection in a pregnant woman;
(9) Hepatitis C infection in an infant or a child aged five (5) years or less;
(10) Newborns born to Hepatitis C positive mothers at the time of delivery;
(11) Histoplasmosis;
(12) Laboratory-confirmed influenza;
(13) Lead poisoning;
(14) Lyme Disease;
(15) Malaria;

(16) Spotted Fever Rickettsiosis (Rocky Mountain Spotted Fever);
(17) Toxoplasmosis; and
(18) Trichinellosis (Trichinosis).

Section 9. Notifiable Infectious Conditions Requiring Routine Notification by Electronic Laboratory Reporting.

(1) Notification of the following shall be considered routine and shall be electronically reported to the Kentucky Department for Public Health through the Kentucky Health Information Exchange within five (5) business days:

(a) Hepatitis B laboratory test results, which shall:

1. Be reported as positive or negative; and
2. Include the serum bilirubin levels or serum alanine aminotransferase taken within ten (10) days of the test of a patient who has tested positive;

(b) Hepatitis C laboratory test results, which shall:

1. Be reported as positive or negative; and
2. Include the serum bilirubin levels or serum alanine aminotransferase taken within ten (10) days of the test of a patient who has tested positive; or

(c) Varicella laboratory test results reported as positive for:

1. Isolation of varicella virus from a clinical specimen;
2. Varicella antigen detected by direct fluorescent antibody test; or
3. Varicella-specific nucleic acid detected by polymerase chain reaction (PCR).

(2) Reports made pursuant to this section shall include a diagnosis.

Section 10. Multi-Drug Resistant Organisms and Other Organisms Requiring Routine Notification by Electronic Laboratory Reporting.

(1) Notification of the following diseases shall be considered routine and shall be electronically reported to the Kentucky Department for Public Health through the Kentucky Health Information Exchange within five (5) business days:

(a) Clostridioides (formerly Clostridium) difficile (C. difficile) identified from a positive laboratory test result for C. difficile toxin A or B (includes molecular assays {PCR} or toxin assays) or a toxin-producing organism detected by culture or other laboratory means performed on a stool sample;

(b) Enterobacteriaceae species resistant to ceftazidime, ceftriaxone, or cefotaxime;

(c) Methicillin-resistant Staphylococcus aureus (MRSA), which includes S. aureus cultured from any specimen that tests oxacillin-resistant, cefoxitin-resistant, or methicillin-resistant by standard susceptibility testing methods, or by a laboratory test that is FDA-approved for MRSA detection from isolated colonies. These methods may also include a positive result by any FDA-approved test for MRSA detection; and

(d) Vancomycin-resistant Enterococcus species (VRE), only those identified to the species level, that are resistant to Vancomycin by standard susceptibility testing methods or by results from any FDA-approved test for VRE detection from specific specimen sources.

(2) The report of an organism under this section shall include the:

(a) Date of specimen collection;
(b) Source of specimen;
(c) Susceptibility pattern; and
(d) Name of the ordering health professional.

(3) Upon a test result performed by a medical laboratory that indicates infection with an agent associated with one (1) or more of the diseases or conditions or a multi-drug resistant organism specified in this section, the director of the medical laboratory shall electronically report the result to the Kentucky Department for Public Health through the Kentucky Health Information Exchange within five (5) days.

(4) The report shall include a diagnosis.

Section 11. Multi-drug Resistant Organisms and Other Organisms Requiring Priority Reporting by EPID 250 and by Electronic Laboratory Reporting to the Kentucky Department for Public Health through the Kentucky Health Information Exchange within One (1) Business Day. Notification of the following diseases shall be considered priority:

(1) Candida auris - Laboratory Criteria for Diagnosis shall include:

(a) Confirmatory laboratory evidence for detection of Candida auris from any body site using either culture or a culture independent diagnostic test (for example, Polymerase Chain Reaction {PCR}); or

(b) Presumptive laboratory evidence for detection of Candida haemulonii from any body site using a yeast identification method that is not able to detect Candida auris, and either the isolate or specimen is not available for further testing, or the isolate or specimen has not yet undergone further testing;

(2) Carbapenem-resistant – Acinetobacter – Any Acinetobacter species testing resistant to imipenem, meropenem, or doripenem, with minimum inhibitory concentration (MIC) value greater than or equal to eight (8) µg/mL by standard susceptibility testing methods, or by identification of a carbapenemase using a recognized test;

(3) Carbapenem-resistant Enterobacteriaceae (CRE) – Any Enterobacteriaceae species testing resistant to imipenem, meropenem, or doripenem, with MIC value greater than or equal to four (4) µg/mL, or ertapenem with MIC value greater than or equal to two (2) µg/mL, by standard susceptibility testing methods, or by identification of a carbapenemase using a recognized test;

(4) Carbapenem-resistant – Pseudomonas – Any Pseudomonas species testing resistant to imipenem, meropenem, or doripenem, with MIC value greater than or equal to eight (8) µg/mL by standard susceptibility testing methods, or by identification of a carbapenemase using a recognized test;

(5) Vancomycin-intermediate Staphylococcus aureus (VISA), which includes S. aureus cultured from any specimen having a MIC of four (4) to eight (8) µg/mL for vancomycin per standard laboratory methods; and

(6) Vancomycin-resistant Staphylococcus aureus (VRSA), which includes S. aureus cultured from any specimen having a MIC of greater than or equal to sixteen (16) µg/mL for vancomycin per standard laboratory methods.

Section 12. Newly Recognized Infectious Agents, HAI Outbreaks, Emerging Pathogens, and Pathogens of Public Health Importance.

(1) The following shall be reported immediately by telephone to the Kentucky Department for Public Health:

(a) A suspected incidence of bioterrorism caused by a biological agent;

(b) Submission of a specimen to the Kentucky Division of Laboratory Services for select agent identification or select agent confirmation testing; or

(c) An outbreak of a disease or condition that resulted in multiple hospitalizations or death.

(2) An unexpected pattern of cases, suspected cases, or deaths that could indicate the following shall be reported immediately by telephone to the local health department in the county where the health professional is practicing or where the facility is located:

(a) A newly-recognized infectious agent;

(b) An outbreak;

(c) An emerging pathogen that may pose a danger to the health of the public;

(d) An epidemic; or

(e) A noninfectious chemical, biological, or radiological agent.

(3) A report of the following shall be considered priority and shall be reported to the local health department in the county where the health professional is practicing or where the facility is located within one (1) business day:

(a) Suspected Staphylococcal or other foodborne intoxication; or
(b) Salmonellosis or other foodborne or waterborne infection.

(4) The local health department shall:
(a) Investigate the outbreak or occurrence;
(b) Carry out public health protection measures to address the disease or condition involved; and
(c) Make medical and environmental recommendations to prevent future similar outbreaks or occurrences.

(5) The local health department may seek assistance from the Kentucky Department for Public Health.

Section 13. Laboratory Surveillance.

(1) Medical or national reference laboratory results for the following shall be considered routine:
(a) Influenza virus isolates;
(b) PCR-positive test results for influenza virus; and
(c) DNA molecular assays for influenza virus.

(2) The report shall include specific laboratory information pertinent to the result.

(3) Upon request by the Kentucky Department for Public Health, a health facility laboratory or a medical laboratory shall report the number of clinical isolates and information regarding the antimicrobial resistance patterns of the clinical isolates at intervals no less frequently than three (3) months for:
(a) Acinetobacter baumannii complex;
(b) Enterobacter cloacae complex;
(c) Enterococcus species;
(d) Escherichia coli;
(e) Klebsiella oxytoca;
(f) Klebsiella pneumoniae;
(g) Pseudomonas aeruginosa;
(h) Staphylococcus aureus; or
(i) An organism specified in a request that includes a justification of its public health importance.

(4) A facility that reports antimicrobial resistance (AR) data to the National Healthcare Safety Network (NHSN) AUR (Antimicrobial Use & Resistance) module shall meet this reporting requirement through NHSN reporting.

Section 14. Healthcare-Associated Infection Surveillance.

(1) A health facility in Kentucky that participates in Centers for Medicare and Medicaid Services (CMS) reporting programs shall authorize the CDC to allow the Kentucky Department for Public Health to access health care-associated infection data reported to NHSN.

(2) The Kentucky Department for Public Health shall preserve patient confidentiality and shall not disclose to the public any patient-level data obtained from any health care facility.

(3) The Kentucky Department for Public Health may issue reports to the public regarding healthcare-associated infections in aggregate data form that:
(a) May identify individual health care facilities; and
(b) Shall comply with methodology developed by the CDC and CMS for national reporting of health care-associated infections.

(4) The Kentucky Department for Public Health may evaluate healthcare-associated infection data for accuracy and completeness.

Section 15. Antimicrobial Use Reporting.

(1) A short-term acute-care hospital in Kentucky that participates in the CMS reporting programs shall report data on facility-wide inpatient antimicrobial use to the Kentucky Department for Public Health, Healthcare-Associated Infection/Antibiotic Resistance (HAI/AR) Prevention Program, on a quarterly basis. Critical access hospitals shall be exempt.
(2) Reporting deadlines shall be consistent with the CMS reporting program submission deadlines of data to the NHSN.
(3) The HAI/AR Prevention Program shall provide the specifications for data submission.
(4) Hospitals shall include aggregated antimicrobial use and patient day data for all inpatient units (facility-wide inpatient) included in the NHSN Laboratory-identified (LabID) MRSA Bacteremia reporting.
(5) The antimicrobial use numerator shall be days of therapy (DOTs) as defined by the NHSN Antimicrobial Use and Resistance (AUR) Module, available at https://www.cdc.gov/nhsn/pdfs/pscmanual/11pscaurcurrent.pdf.
(6) Total DOTs shall be submitted for each of the following antimicrobials:
(a) Azithromycin;
(b) Cefepime;
(c) Ceftazidime;
(d) Ceftriaxone;
(e) Ciprofloxacin;
(f) Clindamycin;
(g) Daptomycin;
(h) Ertapenem;
(i) Imipenem;
(j) Levofloxacin;
(k) Linezolid;
(l) Meropenem;
(m) Moxifloxacin;
(n) Piperacillin-tazobactam; and
(o) Vancomycin.
(7) Total DOTs for the listed drugs shall include only administrations via the intravenous and digestive tract routes.
(8) The denominator for antimicrobial use reporting shall be patient days as defined by the NHSN LabID Module available at https://www.cdc.gov/nhsn/pdfs/pscmanual/12pscmdro_cdadcurrent.pdf.
(9) A hospital that reports antimicrobial use data to the NHSN AUR Module shall meet this reporting requirement through NHSN reporting.

Section 16. Human Immunodeficiency Virus (HIV) and Acquired Immunodeficiency Syndrome (AIDS) Surveillance.
(1) All case reports shall be submitted to the HIV/AIDS Surveillance Program of the Kentucky Department for Public Health, Division of Epidemiology and Health Planning, or its designee, within five (5) business days of diagnosis on one (1) of the following forms:
(a) Adult HIV Confidential Case Report Form; or
(b) Pediatric HIV Confidential Case Report Form.
(2) Health professionals and medical laboratories shall report:
(a) A positive test result for HIV, including tests with negative or indeterminate results that are part of a diagnostic testing algorithm whose overall interpretation is positive, and results from:
1. Any HIV antibody test;
2. Any HIV antigen test;

3. Any HIV Ribonucleic acid (RNA) or Deoxyribonucleic acid (DNA) test;
4. CD4+ assay including absolute CD4+ cell counts and CD4+%;
5. HIV genetic sequencing; or
6. HIV culture; or

(b) A diagnosis of AIDS that meets the definition of AIDS established within the CDC guidelines.

(3) A negative HIV test, if available, shall be submitted with the report required by subsection (2)(a) or (b) of this section.

(4) Any request for data related to HIV infection or AIDS shall be made to the Department for Public Health, Division of Epidemiology and Health Planning.

(5) A case report for a person with an HIV infection without a diagnosis of AIDS, or HIV infection with a diagnosis of AIDS shall include:

(a) The patient's full name;
(b) The patient's complete address;
(c) Date of birth using the format MMDDYYYY;
(d) Gender;
(e) Race;
(f) Ethnicity;
(g) Risk factors as identified by CDC;
(h) County of residence;
(i) Name of provider and facility submitting report including contact information;
(j) Specimens collected;
(k) Date and type of HIV test performed using the format MMDDYYYY;
(l) Results of CD4+ cell counts and CD4+%;
(m) Results of viral load testing;
(n) Results of RNA, DNA, HIV culture, HIV antigen, and HIV antibody, if performed;
(o) Results of TB testing, if available;
(p) Any documented HIV negative test, if available;
(q) History of PrEP or PEP treatment, if available;
(r) Antiretroviral treatment, if available;
(s) HIV status of the person's partner, spouse, or children, as applicable;
(t) Current pregnancy status for females;
(u) Opportunistic infections diagnosed; and
(v) Date of onset of illness.

(6) A report of pregnancy and delivery for a female diagnosed with HIV disease shall include:

(a) All HIV diagnostic testing and results associated with the determination of HIV status of the infant, including tests with negative or indeterminate results that are part of a diagnostic testing algorithm and if final result is negative; and
(b) Any HIV treatment prescribed to an infant.

(7) A report of AIDS shall be made whether or not the patient has been previously reported as having an HIV infection.

(8) If the patient has not been previously reported as having an HIV infection, the AIDS report shall also serve as the report of HIV.

Section 17. Sexually Transmitted Disease (STD).

(1) Notification of a probable diagnosis of an STD as specified in subsection (4) or (7) of this section shall be made.

(2) The report shall provide:

(a) Pregnancy status; and
(b) Clinical, epidemiologic, laboratory, and treatment information pertinent to the disease.

(3) Upon a laboratory test result that indicates infection with an agent associated with one (1) or more of the diseases or conditions specified in subsection (4) or (7) of this section, a medical laboratory shall report to the Kentucky Department for Public Health information required by Section 5(6)(c)[(b)] of this administrative regulation.

(4) Sexually Transmitted Diseases Requiring Priority Notification. A report of the following shall be considered priority and shall be made within one (1) business day:

(a) Each pregnant female who has tested positive for syphilis regardless of stage; or

(b) Syphilis - primary, secondary, or early latent.

(5) Upon receipt of a report for a disease or condition specified in subsection (4) of this section, a local health department shall:

(a) Investigate the report;

(b) Carry out public health protection measures to address the disease or condition; and

(c) Forward the report to the Kentucky Department for Public Health within one (1) business day.

(6) The local health department may seek assistance from the Kentucky Department for Public Health.

(7) Sexually Transmitted Diseases Requiring Routine Notification. A report of the following shall be considered routine and shall be made within five (5) business days:

(a) Chancroid;

(b) Chlamydia trachomatis infection;

(c) Gonorrhea;

(d) Granuloma inguinale;

(e) Lymphogranuloma venereum; or

(f) Syphilis, other than primary, secondary, early latent, or congenital.

(8) Upon receipt of a report for a disease or condition specified in subsection (7) of this section, a local health department shall:

(a) Make a record of the report using Form EPID 200, Kentucky Reportable Disease Form;

(b) Forward the report to the Kentucky Department for Public Health within five (5) business days; and

(c) Render assistance if requested by the reporting entity or the Kentucky Department for Public Health.

Section 18. Tuberculosis.

(1) A pharmacist shall give notice if two (2) or more of the following medications used for the initial treatment of active tuberculosis are dispensed to an inpatient in a health facility or to an ambulatory patient in a health facility or a pharmacy:

(a) Ethambutol;

(b) Isoniazid;

(c) Pyrazinamide; and

(d) Rifampin or rifabutin.

(2)

(a) A report of tuberculosis shall be considered priority and shall be reported to the local health department serving the county in which the patient resides.

(b) If the local health department cannot be reached, notification shall be given to the Kentucky Department for Public Health.

(3) The report shall include:

(a) Information required in Section 5(6)(c)[(b)] of this administrative regulation; and

(b) Names of the medications dispensed.

Section 19. Asbestosis, Coal Worker's Pneumoconiosis, and Silicosis.

(1) A health professional shall report a diagnosis of the following to the Kentucky Department for Public Health within three (3) months of diagnosis:

(a) Asbestosis;
(b) Coal worker's pneumoconiosis; or
(c) Silicosis.

(2) A report required under this section shall include the information required in Section 5(6)(c)[~~(b)~~].

Section 20. Reporting of Communicable Diseases in Animals.

(1) A diagnosis in an animal of a condition known to be communicable to humans, except for rabies, shall require routine notification.

(2) A veterinarian shall report the diagnosis within five (5) business days to the local health department serving the county in which the animal is located.

(3) If a laboratory test indicates infection of an animal with an agent associated with a condition known to be communicable to humans, the director of a medical laboratory shall report the result to the local health department serving the county in which the animal is located within five (5) business days.

(4) The local health department receiving the report shall:

(a) Investigate the report;

(b) Carry out public health protection measures for the control of communicable diseases; and

(c) Forward the report to the Kentucky Department for Public Health within five (5) business days.

(5) The local health department may seek assistance from the Kentucky Department for Public Health.

Section 21. Kentucky Public Health Advisory.

(1) If the secretary of the Cabinet for Health and Family Services or the commissioner of the Department for Public Health determines that a disease not presently listed in this administrative regulation requires reporting, the secretary or commissioner shall issue a Kentucky public health advisory.

(2) The Kentucky public health advisory shall include:

(a) Date and time the advisory is issued;

(b) A unique number to identify the advisory;

(c) Names for the disease or condition;

(d) A description of the disease or condition;

(e) Recommendations for health professionals, health facilities, and laboratories; and

(f) Notification requirements including:

1. The notification time interval; and
2. Methods for notification.

(3) The duty to report by health professionals, health facilities, and laboratories pursuant to a Kentucky public health advisory shall begin upon receipt of the advisory and shall remain in effect until the advisory is rescinded by order of the secretary or the commissioner.

Section 22. Penalty. If the cabinet has cause to believe that a physician willfully neglects or refuses to notify the cabinet in accordance with this administrative regulation, pursuant to KRS 214.990(1) the cabinet shall make a referral to the appropriate professional licensing board.

Section 23. Incorporation by Reference.

(1) The following material is incorporated by reference:

(a) "EPID 200, Kentucky Reportable Disease Form", 4/2020;

(b) "EPID 250, Kentucky Reportable MDRO Form", 10/2020;

(c) "EPID 394, Kentucky Reportable Disease Form, Hepatitis Infection in Pregnant Women or Child (aged five (5) years or less)", 9/2020;

(d) "EPID 399, Perinatal Hepatitis B Prevention Form for Infants", 6/2020;
(e) "Adult HIV Confidential Case Report Form", 11/2019; and
(f) "Pediatric HIV Confidential Case Report Form", 11/2019.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Department for Public Health, 275 East Main Street, Frankfort, Kentucky 40621, Monday through Friday, 8 a.m. to 4:30 p.m. and available online at https://chfs.ky.gov/agencies/dph/dehp/idb/Pages/default.aspx.

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

APPROVED BY AGENCY: April 25, 2022
FILED WITH LRC: April 26, 2022 at 12:25 p.m.

PUBLIC HEARING AND COMMENT PERIOD: A public hearing on this administrative regulation shall, if requested, be held on July 25, 2022, 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 July 18, 2022, 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 July 31, 2022. 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 502-564-6746; 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 establishes notification standards and specifies the diseases requiring immediate, urgent, priority, routine, or general notification, in order to facilitate rapid public health action to control diseases, and to permit an accurate assessment of the health status of the commonwealth.

(b) The necessity of this administrative regulation:
KRS 211.180(1) requires the cabinet to implement and maintain a statewide program for the detection, prevention, and control of reportable 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 designated by administrative regulation of the cabinet.

(c) How this administrative regulation conforms to the content of the authorizing statutes:
This administrative regulation delineates which diseases are reportable including the urgency of the notification.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes:
This administrative regulation will allow clinicians including every physician, advanced practice registered nurse, and head of family to notify the local health department of the existence of the diseases specified in the administrative regulation.

(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 removes the requirement for healthcare facilities to submit a negative COVID-19 antigen test results, removes the requirement for reporting COVID-19 antibody test results, and allows for the submission of electronic case reporting through the Kentucky Health Information Exchange.

(b) The necessity of the amendment to this administrative regulation:
The amendment to this administrative regulation is necessary to provide relief of the administrative burden for healthcare facilities due to changes for COVID-19 case reporting requirements issued by the Secretary of the Department for Health and Human Services, and to allow healthcare facilities to utilize electronic case reporting in lieu of submitting a faxed or mailed paper form.

(c) How the amendment conforms to the content of the authorizing statutes:
KRS 211.180(1) requires the cabinet to implement and maintain a statewide program for the detection, prevention, and control of reportable 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 designated by administrative regulation of the cabinet.

(d) How the amendment will assist in the effective administration of the statutes:

The amendment to this administrative regulation provides relief of the administrative burden for healthcare providers by eliminating the requirement to report negative COVID-19 antigen test results and will allow healthcare facilities to submit case reports electronically which will provide for a better response time for case investigation.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation:

The entities affected by this administrative regulation include all health facilities as defined by KRS 216B.015(13), health professionals licensed under KRS Chapters 311 through 314, medical laboratories as defined by KRS 333.020(3), national reference laboratories contracted by Kentucky health professionals, laboratories, or healthcare facilities, pharmacists licensed under KRS Chapter 315, and veterinarians licensed under KRS Chapter 321.

(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:

Healthcare facilities will need to be aware of the change in COVID-19 reporting requirements and will need to determine if they begin using the Kentucky Health Information Exchange for case reporting.

(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. Healthcare facilities and physicians already report communicable diseases.

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

As a result of compliance, the benefits of the timely and appropriate prevention and control of communicable diseases will be afforded to all citizens of the commonwealth.

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

(a) Initially:

This is an ongoing program, there are no initial costs.

(b) On a continuing basis:

There is no increase in ongoing costs associated with the amendment to this administrative regulation.

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

The reportable disease programs affected by this administrative regulation are funded through a mix of state general fund dollars, federal dollars, and specialized grants.

(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 changes with this amended administrative regulation.

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

This emergency administrative regulation does not contain fees.

(9) TIERING: Is tiering applied?

Tiering is not applied. While the list of reportable diseases and conditions is separated by immediate, urgent, priority, routine, or general notification, all healthcare facilities and physicians are required to report any known communicable disease.

FISCAL NOTE

(1) What units, parts, or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation?

This emergency administrative regulation impacts the Division of Epidemiology and Health Planning, as well as all local health departments.

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

KRS 194A.050, 211.090(3), 211.180(1), and 214.010.

(3) Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year?

This administrative regulation does not generate revenue.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years?

This administrative regulation does not generate revenue.

(c) How much will it cost to administer this program for the first year?

There are no increased costs to administer this program in the first year.

(d) How much will it cost to administer this program for subsequent years?

There are no increased costs to administer this program in subsequent years.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-):

Expenditures (+/-):

Other Explanation:

(4) Estimate the effect of this administrative regulation on the expenditures and cost savings of regulated entities for the first full year the administrative regulation is to be in effect.

(a) How much cost savings will this administrative regulation generate for the regulated entities for the first year?

This administrative regulation will result in cost savings for those health care facilities that elect to utilize the Kentucky Health Information Exchange for submission.

(b) How much cost savings will this administrative regulation generate for the regulated entities for subsequent years?

This administrative regulation will result in cost savings for those health care facilities that elect to utilize the Kentucky Health Information Exchange for submission.

(c) How much will it cost the regulated entities for the first year?

There will be no costs to the regulated entities.

(d) How much will it cost the regulated entities for subsequent years?

There will be no costs to the regulated entities.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Cost Savings (+/-):This administrative regulation will result in cost savings for those health care facilities that elect to utilize the Kentucky Health Information Exchange for submission.

Expenditures (+/-):

Other Explanation:

(5) Explain whether this administrative regulation will have a major economic impact, as defined below.

"Major economic impact" means an overall negative or adverse economic impact from an administrative regulation of five hundred thousand dollars ($500,000) or more on state or local government or regulated entities, in aggregate, as determined by the promulgating administrative bodies. [KRS 13A.010(13)] This administrative regulation will not have a major economic impact on the regulated entities or state or local governments.