Appendix N: Kentucky Reportable Disease Statutes and Regulations

1) 902 KAR 2:020. Disease Surveillance

2) KRS 211.180. Functions of Cabinet in Regulation of Certain Health Matters - Inspection Fees - Hearing

3) KRS 214.010. Physicians and Heads of Families to Report Diseases to Local Board of Health

4) KRS 214.020. Cabinet to Adopt Regulations and Take Other Action to Prevent Spread of Disease

5) HIPPA - Disclosures for Public Health Activities

RELATES TO: KRS 211.180(1), 214.010, 214.645, 333.130
STATUTORY AUTHORITY: KRS 194A.050, 211.090(3), 211.180(1), 214.010
NECESSITY, FUNCTION, AND CONFORMITY: KRS 211.180(1) requires 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 which are transmissible to man, and other diseases and health hazards that may 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) "Authorize" means to confer rights to the Kentucky Department for Public Health in the NHSN database at the healthcare facility level.

(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) "HIV case report" means an HIV infection or AIDS diagnosis which:

(a) Has been confirmed by laboratory test results; or

(b) Meets the definition of AIDS established within the Centers for Disease Control and Prevention (CDC) guidelines.

(6) "Kentucky Department for 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.

(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.

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

(10) "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.
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(11) "Pharmacist" means a professional licensed under KRS 315.010.

(12) "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.

(13) "Veterinarian" means a professional licensed under KRS 321.181.

Section 2. Notification Standards. (1) Health Professionals and Facilities. A health professional and a health facility shall give notification if:

(a) The health professional makes a probable diagnosis of a disease specified in Section 3, 5, 6, 7, 8, 10, 13, 14, 15, or 16 of this administrative regulation; and

(b) The diagnosis is supported by:
   1.a. Clinical or laboratory criteria; and
   b. Case classifications published by the Centers for Disease Control and Prevention at www.cdc.gov/nndss; or
   2. A health professional’s medical opinion that the disease is present.

(2) 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.

(3) 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.

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

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

(6) The reporting health professional shall furnish:

(a) Information required in Section 4(16) of this administrative regulation; and

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

(7) Medical Laboratories. Upon a laboratory test result which indicates infection with an agent associated with one (1) or more of the diseases or conditions specified in Section 3, 5, 6, 7, 8, 10, 13, 14, 15, or 16 of this administrative regulation, the laboratory shall report the result to the local health department serving the county in which the patient resides.

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

(9) The reporting laboratory shall furnish the information required in Section 4(16) of this administrative regulation.

(10) National Reference Laboratories. Upon a test result performed by a national reference laboratory which indicates infection with an agent associated with one (1) or more of the diseases or conditions specified in Section 3, 5, 6, 7, 8, 10, 13, 14, 15, or 16 of this administrative regulation, the director of a medical laboratory, a health facility, or the health professional that referred the test to the national reference laboratory shall ensure that the result is reported by the
national reference laboratory to the local health department serving the jurisdiction in which the patient resides.

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

(12) The report shall include the information required by Section 4(16) 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 specimens or clinical isolates for diseases outlined 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. 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 clinical isolates or, if not available, the direct specimen from the following diseases to the Division of Laboratory Services:

(a) Botulism;
(b) Brucellosis;
(c) Campylobacteriosis;
(d) Cholera and diseases caused by other Vibrio species;
(e) Diphtheria;
(f) Escherichia coli O157:H7;
(g) Hemolytic Uremic Syndrome (HUS) – Post Diarrheal;
(h) Listeriosis;
(i) Measles;
(j) Meningococcal infections;
(k) Rabies animal;
(l) Rubella;
(m) Salmonellosis;
(n) Shiga toxin-producing E. coli (STEC);
(o) Shigellosis;
(p) Tuberculosis;
(q) Tularemia; and
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(r) Typhoid fever.

Section 4. Reporting Classifications and Methods. (1) Immediate reporting. A report required by Section 10(1) and (2) of this administrative regulation to be made immediately shall be:

(a) Made by telephone to the local health department serving the county in which the patient resides; and

(b) 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.

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

(a) Notify the Kentucky Department for Public Health by telephone; and

(b) Assist the department in carrying out a public health response.

(3) 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.

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

(a) The name of the condition being reported; and

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

(5) Urgent Reporting. A report made within twenty-four (24) hours as required by Section 5 of this administrative regulation shall be:

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

(b) 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.

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

(a) Notify the Kentucky Department for Public Health; and

(b) Assist the department in carrying out a public health response.

(7) 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.

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

(a) The name of the condition being reported; and

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

(9) Priority Reporting. A report made within one (1) business day as required by Sections 6, 14(4), and 15 of this administrative regulation shall be:

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

(10) Upon receipt of a report for a disease requiring priority reporting, a local health department shall:
   (a) Investigate the report and carry out public health protection measures; and
   (b) Notify the Kentucky Department for Public Health of the case by electronic or fax submission within one (1) business day.

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

(12) Routine Reporting. A report made within five (5) business days, as required by Sections 7, 8, 9, 11(1), 13, 14(7), and 17 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.

(13) Upon receipt of a report of a disease or condition requiring routine reporting, a local health department shall:
   (a) Make a record of the report;
   (b) Answer inquiries or render assistance regarding the report if requested by the reporting entity; and
   (c) 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.

(14) General Reporting. A report made within three (3) months, as required by Section 16 of this administrative regulation, shall be made electronically, by fax, or by mail.

(15) A report submitted by fax or by mail shall be made using one (1) of the following reporting forms:
   (a) EPID 200, Kentucky Reportable Disease Form;
   (b) EPID 250, Kentucky Reportable MDRO Form, until electronic reporting is available pursuant to Section 9(1) of this administrative regulation;
   (c) EPID 394, Kentucky Reportable Disease Form, Hepatitis Infection in Pregnant Women or Child (aged five (5) years or less);
   (d) EPID 399, Perinatal Hepatitis B Prevention Form for Infants;
   (e) Adult HIV/AIDS Confidential Case Report form; or
   (f) Pediatric HIV/AIDS Confidential Case Report form.

(16) Information to be reported. Except as provided in subsections (3) and (7) of this section, a report required by this administrative regulation shall include:
   (a) Patient name;
   (b) Date of birth;
   (c) Gender;
   (d) Race;
   (e) Ethnicity;
   (f) Patient address;
   (g) County of residence;
   (h) Patient telephone number;
   (i) Name of the reporting medical provider or facility;
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(j) Address of the reporting medical provider or facility; and
(k) Telephone number of the reporting medical provider or facility.

(17) A reporting health professional shall furnish the information listed in subsection (16) of this section and Section 2(6)(b) of this administrative regulation.

Section 5. Notifiable Infectious Conditions Requiring Urgent Notification. Notification of the following diseases shall be considered urgent and shall be made within twenty-four (24) hours:

(1) Anthrax;
(2) Botulism;
(3) Brucellosis (multiple cases, temporally or spatially clustered);
(4) Diphtheria;
(5) Hepatitis A, acute;
(6) Measles;
(7) Meningococcal infections;
(8) Novel influenza A virus infections;
(9) Plague;
(10) Poliomyelitis;
(11) Rabies, animal;
(12) Rabies, human;
(13) Rubella;
(14) Severe Acute Respiratory Syndrome-associated Coronavirus (SARS-CoV) disease;
(15) Smallpox;
(16) Tularemia;
(17) Varicella;
(18) Viral hemorrhagic fevers due to:
   (a) Crimean-Congo Hemorrhagic Fever virus;
   (b) Ebola virus;
   (c) Lassa virus;
   (d) Lujo virus;
   (e) Marburg virus; or
   (f) New world arenaviruses including:
      1. Guanarito virus;
      2. Junin virus;
      3. Machupo virus; and
      4. Sabia virus; and
(19) Yellow fever.

Section 6. 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) Dengue virus infections;
(8) Escherichia coli O157:H7;
(9) Foodborne disease outbreak;
(10) Haemophilus influenzae invasive disease;
(11) Hansen's disease (leprosy);
(12) Hantavirus infection, non-Hantavirus pulmonary syndrome;
(13) Hantavirus pulmonary syndrome (HPS);
(14) Hemolytic uremic syndrome (HUS), post-diarrheal;
(15) Hepatitis B, acute;
(16) Hepatitis B infection in a pregnant woman;
(17) Hepatitis B infection in an infant or a child aged five (5) years or less;
(18) Newborns born to Hepatitis B positive mothers at the time of delivery;
(19) Influenza-associated mortality;
(20) Leptospirosis;
(21) Listeriosis;
(22) Mumps;
(23) Norovirus outbreak;
(24) Pertussis;
(25) Pesticide-related illness, acute;
(26) Psittacosis;
(27) Q fever;
(28) Rubella, congenital syndrome;
(29) Salmonellosis;
(30) Shiga toxin-producing E. coli (STEC);
(31) Shigellosis;
(32) Streptococcal toxic-shock syndrome;
(33) Streptococcus pneumoniae, invasive disease;
(34) Tetanus;
(35) Toxic-shock syndrome (other than Streptococcal);
(36) Tuberculosis;
(37) Typhoid fever;
(38) Vibriosis; and
(39) Waterborne disease outbreak.

Section 7. 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) Babesiosis;
(2) Coccidioidomycosis;
(3) Creutzfeldt-Jakob disease;
(4) Ehrlichiosis/Anaplasmosis;
(5) Hepatitis C, acute;
(6) Hepatitis C infection in a pregnant woman;
(7) Hepatitis C infection in an infant or a child aged five (5) years or less;
(8) Newborns born to Hepatitis C positive mothers at the time of delivery;
(9) Histoplasmosis;
(10) Lead poisoning;
(11) Legionellosis;
(12) Lyme Disease;
(13) Malaria;
(14) Spotted Fever Rickettsiosis (Rocky Mountain Spotted Fever);
(15) Toxoplasmosis; and
(16) Trichinellosis (Trichinosis).

Section 8. Notifiable Infectious Conditions Requiring Routine Notification by Electronic Laboratory Reporting. (1) Beginning October 1, 2016, 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) Cyclosporiasis;
(b) Giardiasis;
(c) Hepatitis B laboratory test results whether reported as positive or negative:
   1. Include the serum bilirubin levels taken within ten (10) days of the test of a patient who has tested positive; or
   2. Include the serum alanine aminotransferase levels taken within ten (10) days of the test of a patient who tested positive;
(d) Hepatitis C laboratory test results whether reported as positive or negative:
   1. Include the serum bilirubin levels taken within ten (10) days of the test of a patient who has tested positive; or
2. Include the serum alanine aminotransferase levels taken within ten (10) days of the test of a patient who tested positive; and
   (e) 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;
   3. Varicella-specific nucleic acid detected by polymerase chain reaction (PCR); or
   4. A significant rise in serum anti-varicella immunoglobulin G (IgG) antibody level by a standard serologic assay.

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

Section 9. Multi-Drug Resistant Organisms and Other Organisms Requiring Routine Notification by Electronic Laboratory Reporting. (1) Beginning October 1, 2016, 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) Vancomycin-intermediate Staphylococcus aureus (VISA), which includes S. aureus cultured from any specimen that the results show a minimum inhibitory concentration (MIC) of 4-8 mg/mL per standard laboratory methods;
   (b) Vancomycin-resistant Staphylococcus aureus (VRSA), which includes S. aureus cultured from any specimen that the results show a minimum inhibitory concentration (MIC) of greater than or equal to 16 mg/mL per standard laboratory methods;
   (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;
   (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;
   (e) Clostridium difficile (C. difficile) identified from a positive laboratory test result for a 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;
   (f) Carbapenem-resistant Enterobacteriaceae (CRE), which includes Escherichia coli, Klebsiella oxytoca, Klebsiella pneumonia, or Enterobacter species testing resistant to imipenem, meropenem, doripenem, or ertapenem by standard susceptibility testing methods or by production of carbapenemase by an isolate demonstrated by using a recognized test;
   (g) Cephalosporin-resistant Klebsiella, which includes Klebsiella oxytoca, Klebsiella pneumonia, or a Klebsiella species testing non-susceptible (resistant or intermediate) to ceftazidime, cefotaxime, ceftriaxone, or cefepime;
(h) Extended–spectrum beta-lactamase Gram negative organisms (ESBL) Enterobacteriaceae species non-susceptible (resistant or intermediate) to ceftazidime, cefepime, ceftriaxone, or cefotaxime;

(i) Multidrug-resistant – Acinetobacter - Non-susceptibility (resistant or intermediate) to at least one (1) agent in at least three (3) antimicrobial classes of the following six (6) classes:
1. Ampicillin-sulbactam;
2. Cephalosporins (cefepime, ceftazidime);
3. β-lactam–β-lactamase inhibitor combination (piperacillin, piperacillin-tazobactam);
4. Carbapenems (imipenem, meropenem, doripenem);
5. Fluoroquinolones (ciprofloxacin or levofloxacin); and
6. Aminoglycosides (gentamicin, tobramycin, or amikacin); and

(j) Multidrug-resistant Pseudomonas - Non-susceptibility, resistant or intermediate, to at least one (1) agent in at least three (3) antimicrobial classes of the following five (5) classes:
1. Cephalosporins (cefepime, ceftazidime);
2. β-lactam–β-lactam β-lactamase inhibitor combination (piperacillin, piperacillin-tazobactam);
3. Carbapenems (imipenem, meropenem, doripenem);
4. Fluoroquinolones (ciprofloxacin or levofloxacin); and
5. Aminoglycosides (gentamicin, tobramycin, or amikacin).

(2) The report of an organism under this section shall include the following:
(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 which 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 10. 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 which may 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 which may pose a danger to the health of the public;
(d) An epidemic; or
(e) A non-infectious 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 11. 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 the following:

(a) Staphylococcus aureus;
(b) Enterococcus species; or
(c) An organism specified in a request that includes a justification of its public health importance.

Section 12. Healthcare-Associated Infection Surveillance. (1) A healthcare facility in Kentucky that participates in 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.
The Kentucky Department for Public Health may issue reports to the public regarding healthcare-associated infections in aggregate data form which:
(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.

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

Section 13. Human Immunodeficiency Virus (HIV) and Acquired Immunodeficiency Syndrome (AIDS) Surveillance. (1) A report of an HIV infection or AIDS diagnosis shall be considered routine and shall be reported within five business days of diagnosis on one of the following forms:
(a) Adult HIV/AIDS Confidential Case Report form; or
(b) Pediatric HIV/AIDS Confidential Case Report form.
(2) Health professionals and medical laboratories shall report:
(a) A positive test result for HIV infection including a result from:
   1. 3rd generation immunoassay;
   2. 4th generation immunoassay;
   3. Western Blot;
   4. PCR;
   5. HIV-1 or HIV-2 differentiating such as Multispot;
   6. HIV antigen;
   7. HIV antibody;
   8. CD4+ assay including absolute CD4+ cell counts and CD4+%;
   9. HIV Viral Load Assay including detectable and undetectable values; or
   10. A positive confirmatory serologic test result for HIV infection; or
(b) A diagnosis of AIDS that meets the definition of AIDS established within the CDC guidelines.
(3) A case report for a resident of Jefferson, Henry, Oldham, Bullitt, Shelby, Spencer, or Trimble County shall be submitted to the HIV/AIDS Surveillance Program of the Louisville-Metro Health Department.
(4) A case report for a resident of the remaining Kentucky counties shall be submitted to the HIV/AIDS Surveillance Program of the Kentucky 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 shall include the following information:
(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 factor as identified by CDC;
(h) County of residence;
(i) Name of provider and facility submitting report including contact information;
(j) Specimen 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 PCR, HIV culture, HIV antigen, and HIV antibody, if performed;
(o) Results of TB testing, if available; and
(p) HIV status of the person's partner, spouse, or children, as applicable.

(6) A report of an AIDS case shall include:
(a) Information in subsections (2) through (5) of this section;
(b) Opportunistic infections diagnosed; and
(c) Date of onset of illness.

(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 infection as required by subsection (2) through (5) of this section.

Section 14. 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 the following information:
(a) Pregnancy status; and
(b) Clinical, epidemiologic, laboratory, and treatment information pertinent to the disease.

(3) Upon a laboratory test result which indicates infection with an agent associated with one (1) or more of the diseases or conditions specified in subsection (4) and (7) of this section, a medical laboratory shall report to the Kentucky Department for Public Health information required by Section 4(16) 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) Congenital syphilis; 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 15. 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) Rifampin or rifabutin;
(b) Isoniazid;
(c) Pyrazinamide; and
(d) Ethambutol.
(2) 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.
(3) If the local health department cannot be reached, notification shall be given to the Kentucky Department for Public Health.
(4) The report shall include:
(a) Information required in Section 4(16) of this administrative regulation; and
(b) Names of the medications dispensed.

Section 16. 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 following information regarding the patient:
(a) Name;
(b) Address;
(c) Date of birth; and
(d) County of residence.
Section 17. 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 18. Kentucky Department for 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 may 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;
2. Methods for notification; and
3. Forms to be completed and submitted with the 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 19. Incorporation by Reference. (1) The following material is incorporated by reference:
(a) Form "EPID 200, Kentucky Reportable Disease Form", 6/2016;
(b) Form "EPID 250, Kentucky Reportable MDRO Form", 6/2014;
(c) Form "EPID 394, Kentucky Reportable Disease Form, Hepatitis Infection in Pregnant Women or Child (aged five years or less)", 9/2016;
(d) Form "EPID 399, Perinatal Hepatitis B Prevention Form for Infants", 4/2012;
(e) Form "Adult HIV Confidential Case Report Form", 3/2013; and

(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. (CDS-2; 1 Ky.R. 187; eff. 12-11-1974; Am. 2 Ky.R. 464; eff. 4-14-1976; 11 Ky.R. 1518; 1786; eff. 6-4-1985; 16 Ky.R. 663; 1185; eff. 11-29-1989; 21 Ky.R. 128; eff. 8-17-1994; 23 Ky.R. 3119; 3597; 4131; eff. 6-16-1997; 27 Ky.R. 1099; 1489; eff. 12-21-2000; 29 Ky.R. 812; 1273; eff. 10-16-2002; 31 Ky.R. 873; eff. 1-4-2005; 41 Ky.R. 1213; 1674; eff. 2-26-2015; 43 Ky.R. 122, 568; eff, 11-16-2016.)

211.180 Functions of cabinet in the regulation of certain health matters -- Inspection fees -- Hearing.

(1) The cabinet shall enforce the administrative regulations promulgated by the secretary of the Cabinet for Health and Family Services for the regulation and control of the matters set out below and shall formulate, promote, establish, and execute policies, plans, and programs relating to all matters of public health, including but not limited to the following matters:

   (a) 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 which are transmissible to man, and other diseases and health hazards that may be controlled;

   (b) The adoption of regulations specifying the information required in and a minimum time period for reporting a sexually transmitted disease. In adopting the regulations the cabinet shall consider the need for information, protection for the privacy and confidentiality of the patient, and the practical ability of persons and laboratories to report in a reasonable fashion. The cabinet shall require reporting of physician-diagnosed cases of acquired immunodeficiency syndrome based upon diagnostic criteria from the Centers for Disease Control and Prevention of the United States Public Health Service. No later than October 1, 2004, the cabinet shall require reporting of cases of human immunodeficiency virus infection by reporting of the name and other relevant data as requested by the Centers for Disease Control and Prevention and as further specified in KRS 214.645. Nothing in this section shall be construed to prohibit the cabinet from identifying infected patients when and if an effective cure for human immunodeficiency virus infection or any immunosuppression caused by human immunodeficiency virus is found or a treatment which would render a person noninfectious is found, for the purposes of offering or making the cure or treatment known to the patient;

   (c) The control of insects, rodents, and other vectors of disease; the safe handling of food and food products; the safety of cosmetics; the control of narcotics, barbiturates, and other drugs as provided by law; the sanitation of schools,
industrial establishments, and other public and semipublic buildings; the sanitation of state and county fairs and other similar public gatherings; the sanitation of public and semipublic recreational areas; the sanitation of public rest rooms, trailer courts, hotels, tourist courts, and other establishments furnishing public sleeping accommodations; the review, approval, or disapproval of plans for construction, modification, or extension of equipment related to food-handling in food-handling establishments; the licensure of hospitals; and the control of such other factors, not assigned by law to another agency, as may be necessary to insure a safe and sanitary environment;

(d) The construction, installation, and alteration of any on-site sewage disposal system, except for a system with a surface discharge;

(e) Protection and improvement of the health of expectant mothers, infants, preschool, and school-age children;

(f) The practice of midwifery, including the issuance of permits to and supervision of women who practice midwifery; and

(g) Protection and improvement of the health of the people through better nutrition.

(2) The secretary shall have authority to establish by regulation a schedule of reasonable fees, not to exceed twenty dollars ($20) per inspector hour plus travel costs pursuant to state regulations for travel reimbursement, to cover the costs of inspections of manufacturers, retailers, and distributors of consumer products as defined in the Federal Consumer Product Safety Act, 15 U.S.C. secs. 2051 et seq.; 86 Stat. 1207 et seq. or amendments thereto, and of youth camps for the purpose of determining compliance with the provisions of this section and the regulations adopted by the secretary pursuant thereto. Fees collected by the secretary shall be deposited in the State Treasury and credited to a revolving fund account for the purpose of carrying out the provisions of this section. The balance of the account shall lapse to the general fund at the end of each biennium.

(3) Any administrative hearing conducted under authority of this section shall be conducted in accordance with KRS Chapter 13B.

Effective: June 20, 2005

KRS 214.010 Physicians and heads of families to report diseases to local board of health.

Every physician and advanced practice registered nurse shall report all diseases designated by administrative regulation of the Cabinet for Health and Family Services as reportable which are under his or her special treatment to the local board of health of his or her county, and every head of a family shall report any of the designated diseases, when known by him or her to exist in his or her family, to the local board or to some member thereof in accordance with the administrative regulations of the Cabinet for Health and Family Services.

Effective: July 15, 2010


214.990 Penalties

(1) Every head of a family who willfully fails or refuses and every physician who fails or refuses to comply with KRS 214.010 shall be guilty of a violation for each day he neglects or refuses to report. Repeated failure to report is sufficient cause for the revocation of a physician's certificate to practice medicine in this state.

(2) Any owner or person having charge of any public or private conveyance, including watercraft, who refuses to obey the rules and regulations made by the Cabinet for Health and Family Services under KRS 214.020 shall be guilty of a Class B misdemeanor.

(3) Any physician or other person legally permitted to engage in attendance upon a pregnant woman during pregnancy or at delivery who fails to exercise due diligence in complying with KRS 214.160 and 214.170 shall be guilty of a violation.

(4) Any person who violates any of the provisions of KRS 214.280 to 214.310 shall be guilty of a Class A misdemeanor.

(5) Any person who violates any provision of KRS 214.034 or KRS 158.035 shall be guilty of a Class B misdemeanor.

(6) Any person who violates any provision of KRS 214.420 shall be guilty of a violation. Each violation shall constitute a separate offense.

(7) Any person who knowingly violates any provision of KRS 214.452 to 214.466 shall be guilty of a Class D felony. Each violation shall constitute a separate offense.

Effective: June 20, 2005

KRS 214.020 Cabinet to adopt regulations and take other action to prevent spread of disease.

When the Cabinet for Health and Family Services believes that there is a probability that any infectious or contagious disease will invade this state, it shall take such action and adopt and enforce such rules and regulation as it deems efficient in preventing the introduction or spread of such infectious or contagious disease or diseases within this state, and to accomplish these objects shall establish and strictly maintain quarantine and isolation at such places as it deems proper.

Effective: June 20, 2005

DISCLOSURES FOR PUBLIC HEALTH ACTIVITIES

[45 CFR 164.512(b)]

Background

The HIPAA Privacy Rule recognizes the legitimate need for public health authorities and others responsible for ensuring public health and safety to have access to protected health information to carry out their public health mission. The Rule also recognizes that public health reports made by covered entities are an important means of identifying threats to the health and safety of the public at large, as well as individuals. Accordingly, the Rule permits covered entities to disclose protected health information without authorization for specified public health purposes.

How the Rule Works

General Public Health Activities. The Privacy Rule permits covered entities to disclose protected health information, without authorization, to public health authorities who are legally authorized to receive such reports for the purpose of preventing or controlling disease, injury, or disability. This would include, for example, the reporting of a disease or injury; reporting vital events, such as births or deaths; and conducting public health surveillance, investigations, or interventions. See 45 CFR 164.512(b)(1)(i). Also, covered entities may, at the direction of a public health authority, disclose protected health information to a foreign government agency that is acting in collaboration with a public health authority. See 45 CFR 164.512(b)(1)(i). Covered entities who are also a public health authority may use, as well as disclose, protected health information for these public health purposes. See 45 CFR 164.512(b)(2).

A “public health authority” is an agency or authority of the United States government, a State, a territory, a political subdivision of a State or territory, or Indian tribe that is responsible for public health matters as part of its official mandate, as well as a person or entity acting under a grant of authority from, or under a contract with, a public health agency. See 45 CFR 164.501. Examples of a public health authority include State and local health departments, the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention, and the Occupational Safety and Health Administration (OSHA).

Generally, covered entities are required reasonably to limit the protected health information disclosed for public health purposes to the minimum amount necessary to accomplish the public health purpose. However, covered entities are not required to make a minimum necessary determination for public health disclosures that are made pursuant to an individual’s authorization, or for disclosures that are required by other law. See 45 CFR 164.502(b). For disclosures to a public health authority, covered entities may reasonably rely on
a minimum necessary determination made by the public health authority in requesting the protected health information. See 45 CFR 164.514(d)(3)(iii)(A). For routine and recurring public health disclosures, covered entities may develop standard protocols, as part of their minimum necessary policies and procedures, that address the types and amount of protected health information that may be disclosed for such purposes. See 45 CFR 164.514(d)(3)(i).

Other Public Health Activities. The Privacy Rule recognizes the important role that persons or entities other than public health authorities play in certain essential public health activities. Accordingly, the Rule permits covered entities to disclose protected health information, without authorization, to such persons or entities for the public health activities discussed below.

- **Child abuse or neglect.** Covered entities may disclose protected health information to report known or suspected child abuse or neglect, if the report is made to a public health authority or other appropriate government authority that is authorized by law to receive such reports. For instance, the social services department of a local government might have legal authority to receive reports of child abuse or neglect, in which case, the Privacy Rule would permit a covered entity to report such cases to that authority without obtaining individual authorization. Likewise, a covered entity could report such cases to the police department when the police department is authorized by law to receive such reports. See 45 CFR 164.512(b)(1)(ii). See also 45 CFR 512(c) for information regarding disclosures about adult victims of abuse, neglect, or domestic violence.

- **Quality, safety or effectiveness of a product or activity regulated by the FDA.** Covered entities may disclose protected health information to a person subject to FDA jurisdiction, for public health purposes related to the quality, safety or effectiveness of an FDA-regulated product or activity for which that person has responsibility. Examples of purposes or activities for which such disclosures may be made include, but are not limited to:
  - Collecting or reporting adverse events (including similar reports regarding food and dietary supplements), product defects or problems (including problems regarding use or labeling), or biological product deviations;
  - Tracking FDA-regulated products;
  - Enabling product recalls, repairs, replacement or lookback (which includes locating and notifying individuals who received recalled or withdrawn products or products that are the subject of lookback); and
  - Conducting post-marketing surveillance.
See 45 CFR 164.512(b)(1)(iii). The “person” subject to the jurisdiction of the FDA does not have to be a specific individual. Rather, it can be an individual or an entity, such as a partnership, corporation, or association. Covered entities may identify the party or parties responsible for an FDA-regulated product from the product label, from written material that accompanies the product (known as labeling), or from sources of labeling, such as the Physician’s Desk Reference.

• **Persons at risk of contracting or spreading a disease.** A covered entity may disclose protected health information to a person who is at risk of contracting or spreading a disease or condition if other law authorizes the covered entity to notify such individuals as necessary to carry out public health interventions or investigations. For example, a covered health care provider may disclose protected health information as needed to notify a person that (s)he has been exposed to a communicable disease if the covered entity is legally authorized to do so to prevent or control the spread of the disease. See 45 CFR 164.512(b)(1)(iv).

• **Workplace medical surveillance.** A covered health care provider who provides a health care service to an individual at the request of the individual’s employer, or provides the service in the capacity of a member of the employer’s workforce, may disclose the individual’s protected health information to the employer for the purposes of workplace medical surveillance or the evaluation of work-related illness and injuries to the extent the employer needs that information to comply with OSHA, the Mine Safety and Health Administration (MSHA), or the requirements of State laws having a similar purpose. The information disclosed must be limited to the provider’s findings regarding such medical surveillance or work-related illness or injury. The covered health care provider must provide the individual with written notice that the information will be disclosed to his or her employer (or the notice may be posted at the worksite if that is where the service is provided). See 45 CFR 164.512(b)(1)(v).

**Frequently Asked Questions**

To see Privacy Rule FAQs, click the desired link below:

**FAQs on Public Health Uses and Disclosures**

**FAQs on ALL Privacy Rule Topics**

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