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) HIPAA – Disclosures for Public Health Activities

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902 KAR 2:020. Reportable disease surveillance.

RELATES TO: KRS 211.180(1), 214.010, 214.645, 215.520, 216B.015, 258.065, 258.990,

311.282, 311.571, 315.010, 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) 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, occupationaldiseases 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 regulationestablishes 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, ifstained, 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 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 laboratorytesting.

(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 andamplify 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 byperson, 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 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 thisadministrative 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 inthe 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;
(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 testpositive 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 servingthe 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 servingthe 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 orChild (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) 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.

(c) A reporting health professional shall submit the information listed in this subsection andSection 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);
(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, notification of testing results shall include both positive and negative test results.

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 orZika-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 stoolsample;

(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 PublicHealth 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 usingeither 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 siteusing 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 MIC value greater than or equal to eight (8) mg/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) mg/mL, or ertapenem with MIC value greater than or equal to two (2) mg/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) mg/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 minimum inhibitory concentration (MIC) of four (4) to eight
(8) mg/mL for vancomycin per standard laboratory methods; and

(6) Vancomycin-resistant Staphylococcus aureus (VRSA), which includes S. aureus culturedfrom any specimen having a minimum inhibitory concentration (MIC) of greater than or equal tosixteen (16) mg/mL for vancomycin per standard laboratory methods.

Section 12. Newly Recognized Infectious Agents, HAI Outbreaks, Emerging Pathogens, andPathogens 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 facilityis 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 outbreaksor 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 forthe 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 regardingthe 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 SafetyNetwork (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 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 andshall 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 regardinghealthcare-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 ofhealth 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 Centers for Medicare and Medicaid Services (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, effective January 1, 2021. Critical access hospitals shall be exempt.

(2) Reporting deadlines shall be consistent with the CMS reporting program submissiondeadlines 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 theNHSN Antimicrobial Use and Resistance (AUR) Module, available at

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 anddigestive 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 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;
10. HIV genetic sequencing; or
11. 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) The most recent 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 Departmentfor 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 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;
(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) Opportunistic infections diagnosed; and
(u) Date of onset of illness.

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

(7) 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.

Section 17. Sexually Transmitted Disease (STD). (1) Notification of a probable diagnosis ofan 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)(b) of this administrative regulation.

(4) Sexually Transmitted Diseases Requiring Priority Notification. A report of the followingshall 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) businessday.

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

(7) Sexually Transmitted Diseases Requiring Routine Notification. A report of the followingshall 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) businessdays; and

(c) Render assistance if requested by the reporting entity or the Kentucky Department forPublic 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 localhealth 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)(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 Section5(6)(b).

Section 20. Reporting of Communicable Diseases in Animals. (1) A diagnosis in an animalof 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 theresult 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 toa 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", 10/2000;
(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, Mondaythrough 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; 47 Ky.R. 200, 1039; eff. 12-15-2020.)

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 comprehensive programs relating to all matters ofpublic 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 aminimum 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 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; and

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

(2) (a) The secretary shall have authority to establish by regulation a schedule of reasonable fees. The total fees for permitting and inspection:

1. Shall be the total of the operational and administrative costs of the programs to the cabinet and to agencies as defined in KRS 211.185;

2. Beginning on March 17, 2020, until December 31, 2020, shall not increase more than twenty-five percent (25%) of the fee amount on March 17, 2020; and
3. Beginning on or after January 1, 2021, shall not increase more than five percent (5%) for each year thereafter.

(b) The fees shall include travel 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.

(c) 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 theprovisions of this section. The balance of the account shall lapse to the generalfund 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: March 17, 2020
History: Amended 2020 Ky. Acts ch. 21, sec. 5, effective March 17, 2020. – Amended 2019 Ky. Acts ch. 104, sec. 10, effective July 1, 2019. -- Amended 2018 Ky. Acts ch. 136, sec. 7, effective July 1, 2019. -- Amended 2005 Ky. Acts ch. 99, sec. 345, effective June 20, 2005. -- Amended 2004 Ky. Acts ch. 102, sec. 1, effective July 13, 2004. -- Amended 2000 Ky. Acts ch. 432, sec. 2, effective July 14, 2000. – Amended 1998 Ky. Acts ch. 426, sec. 289, effective July 15, 1998. -- Amended 1996 Ky. Acts ch. 318, sec. 104, effective July 15, 1996. -- Amended 1990 Ky. Acts ch. 443, sec. 44, effective July 13, 1990. -- Amended 1982 Ky. Acts ch. 247, sec. 9, effective July 15, 1982; and ch. 392, sec. 5, effective July 15, 1982. -- Amended 1978 Ky. Acts ch. 117, sec. 18, effective February 28, 1980. -- Amended 1976 Ky. Acts ch. 299, sec. 42. -- Amended 1974 Ky. Acts ch. 74, Art. VI, sec. 107(17). -- Amended 1972 (1st Extra. Sess.) Ky. Acts ch. 3, sec. 29. -- Created 1954 Ky. Acts ch. 157, sec. 12, effective June 17, 1954.
2020-2022 Budget Reference. See State/Executive Branch Budget, 2020 Ky. Acts ch. 92, Pt. I, G, 5, (3) at 884.

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
History: Amended 2010 Ky. Acts ch. 85, sec. 72, effective July 15, 2010. -- Amended 2005 Ky. Acts ch. 99, sec. 446, effective June 20, 2005. -- Amended 1998 Ky. Acts ch. 426, sec. 393, effective July 15, 1998. -- Amended 1974 Ky. Acts ch. 74, Art. VI, sec. 107(1) and (3). -- Amended 1968 Ky. Acts ch. 87, sec. 5. -- Recodified 1942 Ky. Acts ch. 208, sec. 1, effective October 1, 1942, from Ky. Stat. sec. 2055.

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 person who willfully violates any administrative regulation promulgated under KRS Chapter 13A 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 duediligence 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: February 2, 2021
History: Amended 2021 Ky. Acts ch. 7, sec. 23, effective February 2, 2021. Amended 2005 Ky. Acts ch. 99, sec. 470, effective June 20, 2005. – Amended 1998 Ky. Acts ch. 426, sec. 415, effective July 15, 1998. -- Amended 1992 Ky. Acts ch. 463, sec. 23, effective July 14, 1992. -- Amended 1988 Ky. Acts ch. 76, sec. 10, effective July 15,

1988. -- Amended 1986 Ky. Acts ch. 294, sec. 4, effective July 15, 1986. -- Amended 1984 Ky. Acts ch. 113, sec. 5, effective July 13, 1984. -- Amended 1978 Ky. Acts ch. 384, sec. 65, effective June 17, 1978. -- Amended 1974 Ky. Acts ch. 74, Art. VI, sec. 107(3). -- Amended 1968 Ky. Acts ch. 87, sec. 7. -- Amended 1962 Ky. Acts ch. 95, sec. 5. -- Amended 1954 Ky. Acts ch. 223, sec. 5. -- Recodified 1942 Ky. Acts ch. 208, sec. 1, effective October 1, 1942, from Ky. Stat. secs. 2049, 2055a, 2056, 2062b-3, 2062b-8, 2062d-9, 2635c-12, 3909, 4615, G.S., ch. 102, Art. II, sec. 8.

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

(1) When the Cabinet for Health and Family Services determines that an infectious or contagious disease will invade this state, it shall take necessary action andpromulgate administrative regulations under KRS Chapter 13A to prevent the introduction or spread of such infectious or contagious disease or diseases within this state.

(2) Any administrative regulation promulgated under the authority of this sectionshall:

(a) Be in effect no longer than thirty (30) days if the administrative regulation:

1. Places restrictions on the in-person meeting or functioning of the following:
   a. Elementary, secondary, or postsecondary educationalinstitutions;
   b. Private businesses or non-profit organizations;
   c. Political, religious, or social gatherings;
   d. Places of worship; or
   e. Local governments; or
2. Imposes mandatory quarantine or isolation requirements;

(b) Include the penalty, appeal, and due process rights for violations of theadministrative regulation; and

(c) Contain the public hearing and written comment period notice required byKRS 13A.270.

Effective: February 2, 2021
History: Amended 2021 Ky. Acts ch. 7, sec. 22, effective February 2, 2021. -- Amended 2005 Ky. Acts ch. 99, sec. 447, effective June 20, 2005. – Amended 1998 Ky. Acts ch. 426, sec. 394, effective July 15, 1998. -- Amended 1974 Ky.Acts ch. 74, Art. VI, sec. 107(1). -- Amended 1968 Ky. Acts ch. 87, sec. 6. – Recodified 1942 Ky. Acts ch. 208, sec. 1, effective October 1, 1942, from Ky. Stat. sec. 2049, 2056.

HIPAA – Disclosures for Public Health Activities

Downloaded from the Department for Health and Human Services Office for Civil Rights Website
http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/publichealth.html

OCR HIPAA Privacy
December 3, 2002
Revised April 3, 2003

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 (know 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

(You can also go to http://answers.hhs.gov/cgi-bin/hhs.cfg/php/enduser/std_alp.php, then select "Privacy of Health Information/HIPAA" from the Category drop down list and click the Search button.)