

1 CABINET FOR HEALTH AND FAMILY SERVICES

2 Department for Public Health

3 Division of Epidemiology and Health Planning

4 (Amended After Comments)

5 902 KAR 2:020. Reportable disease surveillance.

6 RELATES TO: KRS 211.180(1), 214.010, 214.645, 333.130

7 STATUTORY AUTHORITY: KRS 194A.050, 211.090(3), 211.180(1), 214.010[EO
8 ~~2004-726~~]

9 NECESSITY, FUNCTION, AND CONFORMITY: [~~EO 2004-726, effective July 9,~~
10 ~~2004, reorganized the Cabinet for Health and Family Services and placed the~~
11 ~~Department for Public Health under the Cabinet for Health and Family Services.~~] KRS
12 211.180(1) requires the cabinet to implement a statewide program for the detection,
13 prevention, and control of communicable diseases, chronic and degenerative diseases,
14 dental diseases and abnormalities, occupational diseases and health hazards peculiar
15 to industry, home accidents and health hazards, animal diseases which are
16 transmissible to man, and other diseases and health hazards that may be controlled.
17 KRS 214.010 requires every physician, advanced practice registered nurse, and every
18 head of family to notify the local health department of the existence of diseases and
19 conditions designated by administrative regulation of the cabinet[~~of public health~~
20 ~~importance, known to him or her~~]. This administrative regulation establishes notification
21 standards and specifies the diseases requiring immediate, urgent, priority, [~~or~~] 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) "HAI outbreak" means:~~

~~—— (a) The occurrence of two (2) or more HAIs that are epidemiologically linked or connected by person, place, or time; or~~

~~—— (b) A single case of an HAI not commonly diagnosed such as a postsurgical group A Streptococcus infection or healthcare-associated Legionella infection.]~~

~~(2) [(3)] "Health facility" is defined by KRS 216B.015(13) [means:~~

~~—— (a) A facility licensed under 902 KAR Chapter 20 and required by the Centers for Medicare and Medicaid Services (CMS) to report an HAI event or healthcare personnel influenza vaccination information to CMS using the National Healthcare Safety Network; or~~

~~—— (b) A facility licensed under KRS Chapter 216B].~~

~~(3) [(4)] "Health professional" means a professional licensed under KRS Chapters 311 through 314.~~

~~(4) [(5)] "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) [(6)] "HIV case report" means an HIV infection or AIDS diagnosis which:~~

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

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

3 ~~(6)~~~~(7)~~ “Kentucky Department for Public Health Advisory” means a notification to
4 health professionals, health facilities, and laboratories subject to this administrative
5 regulation identifying a new health threat that warrants reporting through the procedures
6 of this administrative regulation.

7 ~~(7)~~~~(8)~~ “Medical laboratory” is defined by KRS 333.020~~(3)~~~~(2)~~.

8 ~~(8)~~~~(9)~~ “National Healthcare Safety Network” or “NHSN” means the nation’s most
9 widely used healthcare-associated infection (HAI) tracking system as provided to
10 medical facilities by the Centers for Disease Control and Prevention.

11 ~~(9)~~~~(10)~~ “National reference laboratory” means a laboratory located outside of
12 Kentucky which has been contracted by a Kentucky health professional, laboratory, or
13 healthcare facility to provide laboratory testing.

14 ~~(10)~~~~(11)~~ “Outbreak” means:

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

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

18 ~~(11)~~~~(12)~~ “Pharmacist” means a professional licensed under KRS 315.010.

19 ~~(12)~~~~(13)~~ “Select agent” means a biological agent or toxin that could pose a
20 severe threat to public health, plant health, animal product, or plant product as
21 determined by the National Select Agent Registry (NSAR) at www.selectagents.gov.

22 ~~(13)~~~~(14)~~ “Veterinarian” means a professional licensed under KRS 321.181.

23 Section 2. Notification Standards.

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

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

5 (b) The diagnosis is supported by:

6 1.a. Clinical or laboratory criteria; and

7 b. Case classifications published by the Centers for Disease Control and
8 Prevention at wwwn.cdc.gov/nndss; or

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

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

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

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

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

19 (6) The reporting health professional shall furnish:

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

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

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

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

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

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

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

20 (12) The report shall include the information required by Section 4(16) of this
21 administrative regulation.

22 Section 3. Submission of Specimens to the Kentucky Department for Public
23 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 ~~[is responsible for providing]~~ 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;

1 (e) Diphtheria;

2 (f) Escherichia coli O157:H7;

3 (g) Hemolytic Uremic Syndrome (HUS) – Post Diarrheal;

4 (h) Listeriosis;

5 (i) Measles;

6 (j) Meningococcal infections;

7 (k) Rabies animal;

8 (l) Rubella;

9 (m) Salmonellosis;

10 (n) Shiga toxin-producing E. coli (STEC);

11 (o) Shigellosis;

12 (p) Tuberculosis;

13 (q) Tularemia; and

14 (r) Typhoid fever.

15 Section 4. Reporting Classifications and Methods.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

19 (a) Investigate the report and carry out public health protection measures; and

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

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

1 (12) Routine Reporting. A report made within five (5) business days, as required
2 by Sections 7, 8, 9, 11(1), 13, 14(7), and 17 of this administrative regulation, shall be
3 made electronically, by fax, or by mail to the local health department serving the county
4 in which the patient resides.

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

7 (a) Make a record of the report;

8 (b) Answer inquiries or render assistance regarding the report if requested by the
9 reporting entity; and

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

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

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

17 (a) EPID 200, Kentucky Reportable Disease Form;

18 (b) EPID 250, Kentucky Reportable MDRO Form, **until electronic reporting is**
19 **available pursuant to Section 9(1);**

20 (c) EPID 394, Kentucky Reportable Disease Form, Hepatitis Infection in Pregnant
21 Women or Child (under the age of five);

22 (d) EPID 399, Perinatal Hepatitis B Prevention Form for Infants;

23 (e) Adult HIV/AIDS Confidential Case Report form; or

1 (f) Pediatric HIV/AIDS Confidential Case Report form.

2 (16) Information to be reported. Except as provided in subsections (3) and (7) of
3 this section, a report required by this administrative regulation shall include:

4 (a) Patient name;

5 (b) Date of birth;

6 (c) Gender;

7 (d) Race;

8 (e) Ethnicity;

9 (f) Patient address;

10 (g) County of residence;

11 (h) Patient telephone number;

12 (i) Name of the reporting medical provider or facility;

13 (j) Address of the reporting medical provider or facility; and

14 (k) Telephone number of the reporting medical provider or facility.

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

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

21 (1) Anthrax;

22 (2) Botulism;

23 (3) Brucellosis (multiple cases, temporally or spatially clustered);

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

1 2. Junin virus,

2 3. Machupo virus; and

3 4. Sabia virus.

4 Section 6. Notifiable Infectious Conditions and Notifiable Non-Infectious
5 Conditions Requiring Priority Notification. Notification of the following diseases shall be
6 considered priority and shall be made within one (1) business day:

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

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

9 1. California encephalitis virus;

10 2. Jamestown Canyon virus;

11 3. Keystone virus;

12 4. La Crosse virus;

13 5. Snowshoe hare virus; and

14 6. Trivittatus viruses;

15 (b) Chikungunya virus disease;

16 (c) Eastern equine encephalitis virus disease;

17 (d) Powassan virus disease;

18 (e) St. Louis encephalitis virus disease;

19 (f) Venezuelan equine encephalitis disease;

20 (g) West Nile virus disease; and

21 (h) Western equine encephalitis virus disease;

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

23 (3) Campylobacteriosis;

- 1 (4) Cholera;
- 2 (5) Cryptosporidiosis;
- 3 (6) Dengue virus infections;
- 4 (7) Escherichia coli O157:H7;
- 5 (8) Foodborne disease outbreak;
- 6 (9) Haemophilus influenzae invasive disease;
- 7 (10) Hansen's disease (leprosy);
- 8 (11) Hantavirus infections;
- 9 (12) Hemolytic uremic syndrome (HUS), post-diarrheal;
- 10 (13) Hepatitis B, acute;
- 11 (14) Hepatitis B infection in a pregnant woman;
- 12 (15) Hepatitis B infection in an infant or a child aged five years or less;
- 13 (16) Newborns born to Hepatitis B positive mothers at the time of delivery;
- 14 (17) Influenza-associated mortality in a pregnant woman;
- 15 (18) Influenza-associated pediatric mortality;
- 16 (19) Listeriosis;
- 17 (20) Mumps;
- 18 (21) Norovirus outbreak;
- 19 (22) Pertussis;
- 20 (23) Pesticide-related illness, acute;
- 21 (24) Psittacosis;
- 22 (25) Q fever;
- 23 (26) Rabies post exposure prophylaxis;

- (27) Rubella, congenital syndrome;
- (28) Salmonellosis;
- (29) Shiga toxin-producing E. coli (STEC);
- (30) Shigellosis;
- (31) Streptococcal toxic-shock syndrome;
- (32) Streptococcus pneumoniae, invasive disease;
- (33) Tetanus;
- (34) Toxic-shock syndrome (other than Streptococcal);
- (35) Tuberculosis;
- (36) Typhoid fever;
- (37) Varicella-associated mortality;
- (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 years or less;

1 (8) Newborns born to Hepatitis C positive mothers at the time of delivery;

2 (9) Histoplasmosis;

3 (10) Lead poisoning;

4 (11) Legionellosis;

5 (12) Lyme Disease;

6 (13) Malaria;

7 (14) Spotted Fever Rickettsiosis (Rocky Mountain Spotted Fever);

8 (15) Toxoplasmosis; and

9 (16) Trichinellosis (Trichinosis).

10 Section 8. Notifiable Infectious Conditions Requiring Routine Notification by
11 Electronic Laboratory Reporting.

12 (1) Beginning October 1, 2016, notification of the following diseases shall be
13 considered routine and shall be electronically reported to the Kentucky Department for
14 Public Health through the Kentucky Health Information Exchange within five (5)
15 business days:

16 (a) Cyclosporiasis;

17 (b) Giardiasis;

18 (c) Hepatitis B laboratory test results whether reported as positive or negative;

19 (d) Hepatitis C laboratory test results whether reported as positive or negative;

20 and

21 (e) Varicella laboratory test results reported as positive for:

22 1. Isolation of varicella virus from a clinical specimen;

23 2. Varicella antigen detected by direct fluorescent antibody test;

1 3. Varicella-specific nucleic acid detected by polymerase chain reaction (PCR);

2 or

3 4. A significant rise in serum anti-varicella immunoglobulin G (IgG) antibody level

4 by a standard serologic assay.

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

6 Section 9. Multi-Drug Resistant Organisms and Other Organisms Requiring

7 Routine Notification by Electronic Laboratory Reporting.

8 (1) Beginning October 1, 2016, notification of the following diseases shall be
9 considered routine and shall be electronically reported to the Kentucky Department for
10 Public Health through the Kentucky Health Information Exchange within five (5)
11 business days:

12 (a) Vancomycin-intermediate Staphylococcus aureus (VISA), which includes S.
13 aureus cultured from any specimen that the results show a minimum inhibitory
14 concentration (MIC) of 4-8 µg/mL per standard laboratory methods;

15 (b) Vancomycin-resistant Staphylococcus aureus (VRSA), which includes S.
16 aureus cultured from any specimen that the results show a minimum inhibitory
17 concentration (MIC) of greater than or equal to 16 µg/mL per standard laboratory
18 methods;

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

1 (d) Vancomycin-resistant Enterococcus species (VRE), regardless of whether
2 identified to the species level, that is resistant to Vancomycin by standard susceptibility
3 testing methods or by results from any FDA-approved test for VRE detection from
4 specific specimen sources;

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

9 (f) Carbapenem-resistant Enterobacteriaceae (CRE) or any Enterobacteriaceae
10 species testing non-susceptible (resistant or intermediate) to imipenem, meropenem, or
11 doripenem, by standard susceptibility testing methods and resistant to all third-
12 generation cephalosporins tested;

13 (g) Extended-spectrum beta-lactamase Gram negative organisms (ESBL)
14 Enterobacteriaceae species non-susceptible (resistant or intermediate) to ceftazidime,
15 cefepime, ceftriaxone, or cefotaxime;

16 (h) Multidrug-resistant – Acinetobacter - Non-susceptibility (resistant or
17 intermediate) to at least one (1) agent in at least three (3) antimicrobial classes of the
18 following six (6) classes:

19 1. Ampicillin-sulbactam;

20 2. Cephalosporins (cefepime, ceftazidime);

21 3. β -lactam- β -lactamase inhibitor combination (piperacillin, piperacillin-
22 tazobactam);

23 4. Carbapenems (imipenem, meropenem, doripenem);

1 5. Fluoroquinolones (ciprofloxacin or levofloxacin); and

2 6. Aminoglycosides (gentamicin, tobramycin, or amikacin); and

3 (i) Multidrug-resistant Pseudomonas - Non-susceptibility, resistant or

4 intermediate, to at least one (1) agent in at least three (3) antimicrobial classes of the

5 following five (5) classes:

6 1. Cephalosporins (cefepime, ceftazidime);

7 2. β -lactam- β -lactam β -lactamase inhibitor combination (piperacillin, piperacillin-
8 tazobactam);

9 3. Carbapenems (imipenem, meropenem, doripenem);

10 4. Fluoroquinolones (ciprofloxacin or levofloxacin);

11 5. Aminoglycosides (gentamicin, tobramycin, or amikacin).

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

13 (a) Date of specimen collection;

14 (b) Source of specimen;

15 (c) Susceptibility pattern; and

16 (d) Name of the ordering health professional.

17 (3) Upon a test result performed by a medical laboratory which indicates infection

18 with an agent associated with one (1) or more of the diseases or conditions or a multi-

19 drug resistant organism specified in this section, the director of the medical laboratory

20 shall electronically report the result to the Kentucky Department for Public Health

21 through the Kentucky Health Information Exchange within five (5) days.

22 (4) The report shall include a diagnosis.

1 Section 10. Newly Recognized Infectious Agents, HAI Outbreaks, Emerging
2 Pathogens, and Pathogens of Public Health Importance.

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

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

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

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

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

14 (a) A newly-recognized infectious agent;

15 (b) An outbreak;

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

17 (d) An epidemic; or

18 (e) A non-infectious chemical, biological, or radiological agent.

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

22 (a) Suspected Staphylococcal or other foodborne intoxication; or

23 (b) Salmonellosis or other foodborne or waterborne infection.

1 (4) The local health department shall:

2 (a) Investigate the outbreak or occurrence;

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

5 (c) Make medical and environmental recommendations to prevent future similar
6 outbreaks or occurrences.

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

9 Section 11. Laboratory Surveillance. (1) Medical or national reference laboratory
10 results for the following shall be **considered routine [reported weekly]**:

11 (a) Influenza virus isolates;

12 (b) PCR-positive test results for influenza virus; and

13 (c) DNA molecular assays for influenza virus.

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

15 (3) Upon request by the Kentucky Department for Public Health, a health facility
16 laboratory or a medical laboratory shall report the number of clinical isolates and
17 information regarding the antimicrobial resistance patterns of the clinical isolates at
18 intervals no less frequently than three (3) months for the following:

19 (a) Staphylococcus aureus;

20 (b) Enterococcus species; or

21 (c) An organism specified in a request that includes a justification of its public
22 health importance.

1 Section 12. Healthcare-Associated Infection Surveillance. (1) A healthcare facility
2 in Kentucky that participates in CMS reporting programs shall authorize the CDC to
3 allow the Kentucky Department for Public Health to access health care-associated
4 infection data reported to NHSN.

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

8 (3) The Kentucky Department for Public Health may issue reports to the public
9 regarding healthcare-associated infections in aggregate data form which:

10 (a) May identify individual health care facilities; and

11 (b) Shall comply with methodology developed by the CDC and CMS for national
12 reporting of health care-associated infections.

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

15 Section 13. Human Immunodeficiency Virus (HIV) and Acquired
16 Immunodeficiency Syndrome (AIDS) Surveillance.

17 (1) A report of an HIV infection or AIDS diagnosis shall be considered routine and
18 shall be reported within five (5) business days of diagnosis on one (1) of the following
19 forms:

20 (a) Adult HIV/AIDS Confidential Case Report form; or

21 (b) Pediatric HIV/AIDS Confidential Case Report form.

22 (2) Health professionals and medical laboratories shall report:

23 (a) A positive test result for HIV infection including a result from:

1 1. 3rd generation immunoassay;

2 2. 4th generation immunoassay;

3 3. Western Blot;

4 4. PCR;

5 5. HIV-1 or HIV-2 differentiating such as Multispot;

6 6. HIV antigen;

7 7. HIV antibody;

8 8. CD4+ assay including absolute CD4+ cell counts and CD4+%;

9 9. HIV Viral Load Assay including detectable and undetectable values; or

10 10. A positive confirmatory serologic test result for HIV infection; or

11 (b) A diagnosis of AIDS that meets the definition of AIDS established within the

12 CDC guidelines.

13 (3) A case report for a resident of Jefferson, Henry, Oldham, Bullitt, Shelby,
14 Spencer, or Trimble County shall be submitted to the HIV/AIDS Surveillance Program of
15 the Louisville-Metro Health Department.

16 (4) A case report for a resident of the remaining Kentucky counties shall be
17 submitted to the HIV/AIDS Surveillance Program of the Kentucky Department for Public
18 Health, Division of Epidemiology and Health Planning.

19 (5) A case report for a person with an HIV infection without a diagnosis of AIDS
20 shall include the following information:

21 (a) The patient's full name;

22 (b) The patient's complete address;

23 (c) Date of birth using the format MMDDYYYY;

1 (d) Gender;

2 (e) Race;

3 (f) Ethnicity;

4 (g) Risk factor as identified by CDC;

5 (h) County of residence;

6 (i) Name of provider and facility submitting report including contact information;

7 (j) Specimen collected;

8 (k) Date and type of HIV test performed using the format MMDDYYYY;

9 (l) Results of CD4+ cell counts and CD4+%;

10 (m) Results of viral load testing;

11 (n) Results of PCR, HIV culture, HIV antigen, and HIV antibody, if performed;

12 (o) Results of TB testing, if available; and

13 (p) HIV status of the person's partner, spouse, or children, as applicable.

14 (6) A reports of an AIDS case shall include:

15 (a) Information in subsections (2) through (5) of this section;

16 (b) Opportunistic infections diagnosed; and

17 (c) Date of onset of illness.

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

20 (8) If the patient has not been previously reported as having an HIV infection, the
21 AIDS report shall also serve as the report of HIV infection as required by subsection (2)
22 through (5) of this section.

23 Section 14. Sexually Transmitted Disease (STD).

1 (1) ~~[A health professional or a health facility shall give]~~ Notification of ~~[if]~~ a
2 probable diagnosis of an STD as specified in subsection (4) or (7) of this section shall
3 be ~~[is]~~ made.

4 (2) The report shall provide the following information:

5 (a) Pregnancy status; and

6 (b) Clinical, epidemiologic, laboratory, and treatment information pertinent to the
7 disease.

8 (3) Upon a laboratory test result which indicates infection with an agent
9 associated with one (1) or more of the diseases or conditions specified in subsection (4)
10 and (7) of this section, a medical laboratory shall report to the Kentucky Department for
11 Public Health information required by Section 4(16) of this administrative regulation.

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

14 (a) Congenital syphilis; or

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

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

18 (a) Investigate the report;

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

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

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

3 (7) Sexually Transmitted Diseases Requiring Routine Notification. A report of the
4 following shall be considered routine and shall be made ~~[by a health professional or~~
5 ~~medical laboratory]~~ within five (5) business days ~~[to the local health department~~
6 ~~serving the county in which the patient resides]~~:

7 (a) Chancroid;

8 (b) Chlamydia trachomatis infection;

9 (c) Gonorrhea;

10 (d) Granuloma inguinale;

11 (e) Lymphogranuloma venereum; or

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

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

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

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

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

21 Section 15. Tuberculosis. (1) A pharmacist shall give notice if two (2) or more of
22 the following medications used for the initial treatment of active tuberculosis are

1 dispensed to an inpatient in a health facility or to an ambulatory patient in a health
2 facility or a pharmacy:

3 (a) Rifampin or rifabutin;

4 (b) Isoniazid;

5 (c) Pyrazinamide; and

6 (d) Ethambutol.

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

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

11 (4) The report shall include:

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

13 (b) Names of the medications dispensed.

14 Section 16. Asbestosis, Coal Worker's Pneumoconiosis, and Silicosis.

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

17 (a) Asbestosis;

18 (b) Coal worker's pneumoconiosis; or

19 (c) Silicosis.

20 (2) A report required under this section shall include the following information
21 regarding the patient:

22 (a) Name;

23 (b) Address;

1 (c) Date of birth; and

2 (d) County of residence.

3 Section 17. Reporting of Communicable Diseases in Animals. (1) A diagnosis in
4 an animal of a condition known to be communicable to humans, except for rabies, shall
5 require routine notification.

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

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

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

13 (a) Investigate the report;

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

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

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

20 Section 18. Kentucky Department for Public Health Advisory.

21 (1) If the Secretary of the Cabinet for Health and Family Services or the
22 Commissioner of the Department for Public Health determines that a disease not

1 presently listed in this administrative regulation requires reporting, the secretary or
2 commissioner may issue a Kentucky Public Health Advisory.

3 (2) The Kentucky Public Health Advisory shall include:

4 (a) Date and time the advisory is issued;

5 (b) A unique number to identify the advisory;

6 (c) Names for the disease or condition;

7 (d) A description of the disease or condition;

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

9 and

10 (f) Notification requirements including:

11 1. The notification time interval;

12 2. Methods for notification; and

13 3. Forms to be completed and submitted with the notification.

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

18 Section 19. Incorporation by Reference. (1) The following material is incorporated
19 by reference:

20 (a) Form "EPID 200, Kentucky Reportable Disease Form", 9/2014;

21 (b) Form "EPID 250, Kentucky Reportable MDRO Form", 6/2014;

22 (c) Form "EPID 394, Kentucky Reportable Disease Form, Hepatitis Infection in
23 Pregnant Women or Child (under the age of five)", 11/2013;

1 (d) Form "EPID 399, Perinatal Hepatitis B Prevention Form for Infants", 4/2012;

2 (e) Form "Adult HIV Confidential Case Report Form", 3/2013; and

3 (f) Form "Pediatric HIV Confidential Case Report Form", 3/2013.

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

7 ~~[Notification Standards. (1) A health professional licensed under KRS Chapters~~
8 ~~311 through 314, and a health facility licensed under KRS Chapter 216B, shall give~~
9 ~~notification pursuant to subsection (3) of this section, if:~~

10 ~~(a) The health professional makes a probable diagnosis of a disease specified in~~
11 ~~Section 2, 3, or 4 of this administrative regulation; and~~

12 ~~—(b) The diagnosis is supported by:~~

13 ~~—1. "Case Definitions for Infectious Conditions under Public Health Surveillance"; or~~

14 ~~—2. A reasonable belief that the disease is present.~~

15 ~~—(2)(a) A single report by a hospital of a condition diagnosed by a test result from the~~
16 ~~hospital laboratory shall constitute notification on behalf of the hospital and its~~
17 ~~laboratory.~~

18 ~~—(b) A hospital may designate an individual to report on behalf of the hospital's~~
19 ~~laboratory and the hospital's clinical facilities.~~

20 ~~—(3) The notification shall be given to the:~~

21 ~~—(a) Local health department serving the jurisdiction in which the patient resides; or~~

22 ~~—(b) Department for Public Health.~~

23 ~~—(4) The reporting professional shall furnish the:~~

1 ~~—(a) Name, birthdate, address, county of residence, and telephone number of the~~
2 ~~patient; and~~

3 ~~—(b) Clinical, epidemiologic, and laboratory information pertinent to the disease.~~

4 ~~—(5) Upon the confirmation of a laboratory test result which indicates infection with an~~
5 ~~agent associated with one (1) or more of the diseases or conditions specified in Section~~
6 ~~2, 3, or 4 of this administrative regulation, the director of a clinical laboratory licensed~~
7 ~~under KRS Chapter 333 shall:~~

8 ~~—(a) Report the result to the:~~

9 ~~—1. Local health department serving the jurisdiction in which the patient resides; or~~

10 ~~—2. Department for Public Health; and~~

11 ~~—(b) Report the patient's name, birthdate, address, and county of residence; and~~

12 ~~—Section 2. Diseases Requiring Urgent Notification. (1) Notification pursuant to~~
13 ~~Section 1(3) of this administrative regulation of the following diseases shall be made~~
14 ~~within twenty four (24) hours:~~

15 ~~—(a) Anthrax;~~

16 ~~—(b) Botulism;~~

17 ~~—(c) Brucellosis;~~

18 ~~—(d) Campylobacteriosis;~~

19 ~~—(e) Cryptosporidiosis;~~

20 ~~—(f) Cholera;~~

21 ~~—(g) Diphtheria;~~

22 ~~—(h) Escherichia coli O157:H7;~~

23 ~~—(i) Escherichia coli, shiga toxin positive;~~

- 1 ~~—(j) Encephalitis, California group;~~
- 2 ~~—(k) Encephalitis, Eastern equine;~~
- 3 ~~—(l) Encephalitis, St. Louis;~~
- 4 ~~—(m) Encephalitis, Venezuelan equine;~~
- 5 ~~—(n) Encephalitis, Western;~~
- 6 ~~—(o) Encephalitis, West Nile Virus;~~
- 7 ~~—(p) Hansen's Disease;~~
- 8 ~~—(q) Hantavirus infection;~~
- 9 ~~—(r) Hemophilus influenzae invasive disease;~~
- 10 ~~—(s) Hepatitis A;~~
- 11 ~~—(t) Listeriosis;~~
- 12 ~~—(u) Measles;~~
- 13 ~~—(v) Meningococcal infections;~~
- 14 ~~—(w) Pertussis;~~
- 15 ~~—(x) Plague;~~
- 16 ~~—(y) Poliomyelitis;~~
- 17 ~~—(z) Psittacosis;~~
- 18 ~~—(aa) Q fever;~~
- 19 ~~—(bb) Rabies, animal;~~
- 20 ~~—(cc) Rabies, human;~~
- 21 ~~—(dd) Rubella;~~
- 22 ~~—(ee) Rubella syndrome, congenital;~~
- 23 ~~—(ff) Salmonellosis;~~

1 ~~—(gg) Shigellosis;~~
2 ~~—(hh) Syphilis, primary, secondary, early latent or congenital;~~
3 ~~—(ii) Tetanus;~~
4 ~~—(jj) Tularemia;~~
5 ~~—(kk) Typhoid fever;~~
6 ~~—(ll) Vibrio parahaemolyticus;~~
7 ~~—(mm) Vibrio vulnificus;~~
8 ~~—(nn) Yellow fever.~~
9 ~~—(2) Weekend or evening urgent notification.~~
10 ~~—(a) If health department personnel cannot be contacted directly, notification shall be~~
11 ~~made by electronic submission or by telephone to an emergency number provided by~~
12 ~~the local health department or the Department for Public Health.~~
13 ~~—(b) For the protection of patient confidentiality, this notification shall include:~~
14 ~~—1. The name of the condition being reported; and~~
15 ~~—2. A telephone number that can be used by the department to contact the reporting~~
16 ~~professional.~~
17 ~~—(3) Upon receipt of a report for a disease specified in subsection (1) of this section,~~
18 ~~the local health department shall:~~
19 ~~—(a) Immediately notify the Department for Public Health; and~~
20 ~~—(b) Assist the department in carrying out a public health response as instructed.~~
21 ~~—Section 3. Diseases Requiring Priority Notification. (1) Notification pursuant to~~
22 ~~Section 1(3) of this administrative regulation of the following diseases shall be made~~
23 ~~within one (1) business day:~~

- 1 ~~—(a) Group A streptococcal infection, invasive;~~
- 2 ~~—(b) Hepatitis B, acute;~~
- 3 ~~—(c) Hepatitis B infection in a pregnant woman or a child born in or after 1992;~~
- 4 ~~—(d) Mumps;~~
- 5 ~~—(e) Toxic shock syndrome;~~
- 6 ~~—(f) Tuberculosis.~~
- 7 ~~—(2) Upon receipt of a report for a disease or condition specified in subsection (1) of~~
- 8 ~~this section, a local health department:~~
- 9 ~~—(a) Shall investigate the report and carry out public health measures appropriate to~~
- 10 ~~the disease or condition;~~
- 11 ~~—(b) Shall notify the Department for Public Health of the case, in writing, within five (5)~~
- 12 ~~business days; and~~
- 13 ~~—(c) May seek assistance from the Department for Public Health.~~
- 14 ~~—Section 4. Diseases Requiring Routine Notification. (1) Notification pursuant to~~
- 15 ~~Section 1(3) of this administrative regulation of the following diseases shall be made~~
- 16 ~~within five (5) business days:~~
- 17 ~~—(a) Chancroid;~~
- 18 ~~—(b) Chlamydia trachomatis infection;~~
- 19 ~~—(c) Ehrlichiosis;~~
- 20 ~~—(d) Gonorrhea;~~
- 21 ~~—(e) Granuloma inguinale;~~
- 22 ~~—(f) Hepatitis C, acute;~~
- 23 ~~—(g) Histoplasmosis;~~

- 1 ~~—(h) Lead poisoning;~~
2 ~~—(i) Legionellosis;~~
3 ~~—(j) Lyme Disease;~~
4 ~~—(k) Lymphogranuloma venereum;~~
5 ~~—(l) Malaria;~~
6 ~~—(m) Rabies postexposure prophylaxis;~~
7 ~~—(n) Rocky Mountain Spotted Fever;~~
8 ~~—(o) Streptococcus pneumoniae, drug-resistant invasive disease;~~
9 ~~—(p) Syphilis, other than primary, secondary, early latent or congenital; and~~
10 ~~—(q) Toxoplasmosis.~~
11 ~~—(2) Upon receipt of a report for a disease or condition specified in subsection (1) of~~
12 ~~this section, a local health department shall:~~
13 ~~—(a) Make a record of the report;~~
14 ~~—(b) Answer inquiries or render assistance regarding the report if requested by the~~
15 ~~reporting entity; and~~
16 ~~—(c) Forward the report to the Department for Public Health within three (3) business~~
17 ~~days.~~
18 ~~— Section 5. Outbreaks or Unusual Public Health Occurrences. (1) If, in the judgment~~
19 ~~of a health professional licensed under KRS Chapters 311 through 314, or a health~~
20 ~~facility licensed under KRS Chapter 216B, an unexpected pattern of cases, suspected~~
21 ~~cases, or deaths which may indicate a newly recognized infectious agent, an outbreak,~~
22 ~~epidemic, related public health hazard or an act of bioterrorism, such as smallpox,~~
23 ~~appears, a report shall be made immediately by telephone to the:~~

1 ~~— (a) Local health department where the professional is practicing or where the facility~~
2 ~~is located; or~~

3 ~~— (b) Department for Public Health.~~

4 ~~— (2) An instance of suspected staphylococcal or other foodborne intoxication or an~~
5 ~~instance of salmonellosis or other foodborne or waterborne infection shall be reported~~
6 ~~within one (1) business day, and shall include all known information about the persons~~
7 ~~affected.~~

8 ~~— (3) The local health department:~~

9 ~~— (a) Shall investigate the outbreak or occurrence;~~

10 ~~— (b) Shall carry out public health measures appropriate to the disease or condition~~
11 ~~involved;~~

12 ~~— (c) Shall make medical and environmental recommendations appropriate to prevent~~
13 ~~future similar outbreaks or occurrences; and~~

14 ~~— (d) May seek assistance from the Department for Public Health.~~

15 ~~— Section 6. Laboratory Surveillance. (1)(a) In addition to the reports required by~~
16 ~~Sections 1 through 4 of this administrative regulation, laboratory results shall be~~
17 ~~reported weekly for influenza virus isolates.~~

18 ~~— (b) The report shall include the:~~

19 ~~— 1. Name, birthdate, address, and county of residence of the person with the~~
20 ~~disease; and~~

21 ~~— 2. Specific laboratory information pertinent to the result.~~

22 ~~— (c) The format of the report shall be an alphabetical listing of each person for whom~~
23 ~~a report is submitted.~~

1 ~~—(2) Upon request by the Department for Public Health, a clinical laboratory within a~~
2 ~~hospital licensed under KRS Chapter 216B, or a laboratory licensed under KRS Chapter~~
3 ~~333, shall report:~~

4 ~~—(a) The numbers of isolates and information regarding the antimicrobial resistance~~
5 ~~patterns of the isolates;~~

6 ~~—(b) At intervals agreed upon between the laboratory and the department, not less~~
7 ~~frequently than three (3) months, for the following:~~

8 ~~—1. Staphylococcus aureus;~~

9 ~~—2. Enterococcus species; or~~

10 ~~—3. Other organism specified in a request that includes a justification of the public~~
11 ~~health importance of the organism.~~

12 ~~—Section 7. Human Immunodeficiency Virus (HIV) and Acquired Immunodeficiency~~
13 ~~Syndrome (AIDS) Surveillance. (1) Physicians and Medical Laboratories shall report:~~

14 ~~—(a)1. A positive test result for HIV infection including a result from:~~

15 ~~—a. Elisa;~~

16 ~~—b. Western Blot;~~

17 ~~—c. PCR;~~

18 ~~—d. HIV antigen; or~~

19 ~~—e. HIV culture;~~

20 ~~—2. CD4+ assay including absolute CD4+ cell counts and CD4+%;~~

21 ~~—3. HIV detectable Viral Load Assay; and~~

22 ~~—4. A positive serologic test result for HIV infection; or~~

1 ~~—(b) A diagnosis of AIDS that meets the definition of AIDS established within the~~
2 ~~Centers for Disease Control and Prevention (CDC) guidelines and reported in the:~~
3 ~~—1. "Adult HIV/AIDS Confidential Case Report Form," or~~
4 ~~—2. "Pediatric HIV/AIDS Confidential Case Report Form."~~
5 ~~—(2) An HIV infection or AIDS diagnosis shall be reported within five (5) business~~
6 ~~days and, if possible, on the "Adult HIV/AIDS Confidential Case Report form" or the~~
7 ~~"Pediatric HIV/AIDS Confidential Case Report form."~~
8 ~~—(a) A report for a resident of Jefferson, Henry, Oldham, Bullitt, Shelby, Spencer, and~~
9 ~~Trimble Counties shall be submitted to the HIV/AIDS Surveillance Program of the~~
10 ~~Louisville Metro Health Department.~~
11 ~~—(b) A report for a resident of the remaining Kentucky counties shall be submitted to~~
12 ~~the HIV/AIDS Surveillance Program of the Kentucky Department for Public Health, or as~~
13 ~~directed by the HIV/AIDS project coordinator.~~
14 ~~—(3) A report for a person with HIV infection without a diagnosis of AIDS shall include~~
15 ~~the following information:~~
16 ~~—(a) The patient's full name;~~
17 ~~—(b) Date of birth, using the format MMDDYY;~~
18 ~~—(c) Gender;~~
19 ~~—(d) Race;~~
20 ~~—(e) Risk factor, as identified by CDC;~~
21 ~~—(f) County of residence;~~
22 ~~—(g) Name of facility submitting report;~~
23 ~~—(h) Date and type of HIV test performed;~~

1 ~~—(i) Results of CD4+ cell counts and CD4+%;~~
2 ~~—(j) Results of viral load testing;~~
3 ~~—(k) PCR, HIV culture, HIV antigen, if performed;~~
4 ~~—(l) Results of TB testing, if available; and~~
5 ~~—(m) HIV status of the person's partner, spouse or children.~~
6 ~~—(4) Reports of AIDS cases shall include the information in subsections (1) through~~
7 ~~(3) of this section; and~~
8 ~~—(a) The patient's complete address;~~
9 ~~—(b) Opportunistic infections diagnosed; and~~
10 ~~—(c) Date of onset of illness.~~
11 ~~—(5) (a) Reports of AIDS shall be made whether or not the patient has been~~
12 ~~previously reported as having HIV infection.~~
13 ~~—(b) If the patient has not been previously reported as having HIV infection, the AIDS~~
14 ~~report shall also serve as the report of HIV infection.~~
15 ~~—Section 8. Reporting of Communicable Diseases in Animals. (1) Upon arriving at a~~
16 ~~probable diagnosis in an animal of a condition known to be communicable to humans, a~~
17 ~~veterinarian licensed under the provisions of KRS Chapter 321 shall report the~~
18 ~~occurrence within one (1) business day to:~~
19 ~~—(a) The local health department in which the animal is located; or~~
20 ~~—(b) If the local health department cannot be reached, the Department for Public~~
21 ~~Health.~~
22 ~~—(2) Upon the confirmation of a laboratory test result which indicates infection of an~~
23 ~~animal with an agent associated with a condition known to be communicable to~~

1 ~~humans, the director of a clinical laboratory licensed under KRS Chapter 333 shall,~~
2 ~~within one (1) business day, report the result to the:~~
3 ~~—(a) Local health department serving the jurisdiction in which the animal is located; or~~
4 ~~—(b) Department for Public Health.~~
5 ~~—(3) The local health department:~~
6 ~~—(a) Shall investigate the report and carry out public measures for the control of~~
7 ~~communicable diseases appropriate to the condition;~~
8 ~~—(b) Shall notify the Department for Public Health of the occurrence, in writing, within~~
9 ~~five (5) business days; and~~
10 ~~—(c) May seek assistance from the Department for Public Health.~~
11 ~~—Section 9. Asbestosis, Coal Worker's Pneumoconiosis, and Silicosis. (1) A reporting~~
12 ~~provider shall submit the following information relating to a person diagnosed with~~
13 ~~asbestosis, coal worker's pneumoconiosis, or silicosis:~~
14 ~~—(a) Name;~~
15 ~~—(b) Address;~~
16 ~~—(c) Birthdate; and~~
17 ~~—(d) County of residence.~~
18 ~~—(2) A reporting provider shall submit the required information to the department~~
19 ~~within three (3) months following the diagnosis.~~
20 ~~—Section 10. Incorporation by Reference. (1) The following material is incorporated by~~
21 ~~reference:~~
22 ~~—(a) "Case Definitions for Infectious Conditions under Public Health Surveillance,~~
23 ~~MMWR, May 2, 1997, Volume 46, Number RR-10", published by the Epidemiology~~

~~Program Office, Centers for Disease Control and Prevention, Public Health Service,
U.S. Department of Health and Human Services, Atlanta, Georgia;~~

~~— (b) "Adult HIV/AIDS Confidential Case Report (CDC 50.42A, Revised January,
2003)"; and~~


~~— (c) "Pediatric HIV/AIDS Confidential Case Report form (CDC 50.42B, Revised
January, 2003)"; and~~

~~— (d) "Control of Communicable Diseases Manual 17th Edition, An Official Report of
the American Public Health Association, American Public Health Association,
Washington, D.C., 2000".~~

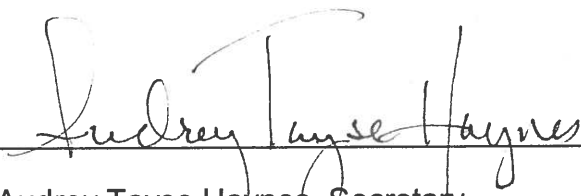
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law, at the Department for Public Health, 275 East Main Street, Frankfort, Kentucky
40621, Monday through Friday, 8 a.m. to 4:30 p.m.]~~

1 902 KAR 2:020

Reviewed:

 12/10/14
Stephanie Mayfield Gibson, MD, FCAP Date
Commissioner Department for Public Health

APPROVED

 12/12/14
Audrey Tayse Haynes, Secretary Date
Cabinet for Health and Family Services

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Regulation: 902 KAR 2:020

Contact Person: Sandy Kelly, (502) 564-3418, ext. 4241

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation establishes notification standards and specifies the diseases requiring immediate, urgent, priority, routine, or general notification, in order to facilitate rapid public health action to control diseases, and to permit an accurate assessment of the health status of the Commonwealth.

(b) The necessity of this administrative regulation: KRS 211.180 requires the cabinet to implement a statewide program for the detection, prevention and control of diseases. This regulation outlines the process and methods of reporting and surveillance of diseases of concern for the public's health.

(c) How this administrative regulation conforms to the content of the authorizing statutes: KRS 211.180 requires the cabinet to collect disease data and KRS 214.010 requires every physician, Advanced Practice Registered Nurse or household to notify the local health department of the existence of diseases and conditions of public health importance. This regulation outlines the appropriate way to report and collect this information including what should be reported.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation will assist in the effective administration of the statutes that require the cabinet to collect disease data and protect the health of the public. The process for what things to report when, how and where are outlined to give clear guidance to those entities required to report.

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

(a) How the amendment will change this existing administrative regulation: This administrative regulation was amended in response to comments received primarily to clarify the requirements. References to other sections within the regulation were made, a few definitions were amended to delete repetitive language, and amendments were made to comply with KRS 13A.

(b) The necessity of the amendment to this administrative regulation: This administrative regulation was amended in response to comments received to make it easier to understand and find requirements. Amendments were also required to comply with KRS 13A.

(c) How the amendment conforms to the content of the authorizing statutes: These amendments clarify what is required by the authorizing statutes.

(d) How the amendment will assist in the effective administration of the statutes: This amendment assists in effective administration of the statutes as it clarifies definitions and requirements and makes the administrative regulation easier to read and comply with.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: Kentucky hospitals and healthcare facilities, Kentucky physicians, state and national laboratories, local health departments, the Kentucky Department for Public Health and any Kentucky citizen exposed to or potentially exposed to a reportable disease will be affected by this regulation.

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

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: The amendments made to this administrative regulation in response to comments:

No additional actions are required as a result of the amendments made to this administrative regulation in response to comments.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): No additional costs are required as a result of the amendments made to this administrative regulation in response to comments.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): No additional actions are required as a result of the amendments made to this administrative regulation in response to comments. The amendments only make this administrative regulation easier to read and comply with.

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

(a) Initially: There will be no fiscal impact to the administrative body from implementation of this amendment.

(b) On a continuing basis: There will be no fiscal impact to the administrative body from implementation of this amendment.

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

disease surveillance program using state general funds. No additional funding will be necessary to implement this amended regulation.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: There will be no new fees nor increase to existing fees due to this amendment.

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees: No fees are established either directly or indirectly by this amendment.

(9) TIERING: Is tiering applied? Tiering was not appropriate in this administrative regulation because the regulation applies equally to all those individuals or entities regulated by it.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

Regulation No: 902 KAR 2:020

Contact Person: Sandy Kelly

Phone Number: (502) 564-3418, ext. 4241

1. What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? Local health departments and the Kentucky Department for Public Health will be impacted by this administrative regulation.

2. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 211.180, 214.010, 214.645, and 333.130

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

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? No revenue will be generated by this amendment in the first year.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? No revenue will be generated by this amendment for subsequent years.

(c) How much will it cost to administer this program for the first year? Reporting and data surveillance is occurring. Therefore, there will be no additional costs in the first year to administer this program due to this amendment.

(d) How much will it cost to administer this program for subsequent years? The amendment to this regulation will create no additional costs in subsequent years.

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

Revenues (+/-):

Expenditures (+/-):

Other Explanation:

STATEMENT OF CONSIDERATION RELATING TO
902 KAR 2:020. Reportable disease surveillance.
Department for Public Health

Amended After Comments

- (1) A public hearing on 902 KAR 2:020, scheduled for November 21, 2014, at 9:00 a.m. at the Cabinet for Health Services Auditorium, Health Services Building, was canceled due to no one requesting a public hearing. However, written comments were received during the public comment period.
- (2) The following people submitted written comments via the public comment process:

<u>Name and Title</u>	<u>Agency/Organization/Entity/Other</u>
Kevin T. Kavanagh, MD, MS	Health Watch USA
Elizabeth G. Cobb Vice President, Health Policy	Kentucky Hospital Association
Janet Justice Sr. Director of Regulatory Affairs	Kentucky Association of Health Care Facilities
Mary Newton, RN, BSN Infection Preventionist	Flaget Memorial Hospital
Susan Wurth, MSN, APRN, CNS-BC Infection Control Practitioner/Coordinator	Baptist Health Paducah
Dee Anderson, MSN, RN, CIC Infection Preventionist	Baptist Hospital Lexington
Jean Moore Director, Infection Prevention and Control	Norton Healthcare
Mary Martin, RN, CIC	St Joseph Martin
Tammy Merrill, BSN, RN, CIC Infection Control Coordinator	Baptist Health Madisonville

Stacy L. England, RN, BSN, MHA Middlesboro ARH Hospital
Community Chief Nursing Officer/Patient Safety Officer

- (3) The following people from the promulgating administrative body responded to the written comments:

Name and Title

Agency/Organization/Entity/Other

Laura Begin
Regulation Coordinator

Department for Public Health
Cabinet for Health and Family
Services

SUMMARY OF COMMENTS AND AGENCY'S RESPONSES

(1) Subject: Support

(a) Comment: Kevin T. Kavanagh, MD, MS, provided the following comment:

"I would like to offer my support for the revisions in Regulation 902.2.020 on the reporting of dangerous pathogens to the State Health Department. Over the last two years Kentucky has been featured in national news regarding both a very deadly strain of MRSA outbreak and CRE outbreak, along with having the fourth highest rate of MRSA Bacteremia in the 50 states (Data from Hospital Compare in the Healthcare Associated Infection Section.) All of this is just some of the evidence which points to the need for engagement with the Kentucky State Health Dept. for a more accurate and complete tracking system... Centralized data collection and a coordinated effort to confront this problem is needed. I would thus, strongly recommend the approval of this regulation as submitted."

(b) Cabinet's Response: The Cabinet acknowledges this comment.

(a) Comment: Elizabeth G. Cobb, Kentucky Hospital Association, provided the following comment:

"KHA is supportive of the Kentucky Department for Public Health utilizing the existing HAI reporting mechanism to better understand the scope of the HAI challenges in Kentucky healthcare facilities and to create accessible statewide reports. Use of the NHSN data in a manner which is consistent with national reporting programs ensures there is reliable and comparative data at both the state and national levels. The NHSN uses strict measure definitions which are vetted by national experts and stakeholder in infection prevention. KHA applauds the Kentucky Department for Public Health for recognizing the value in using this information rather than duplicating the process – and the burden – in the state."

(b) Cabinet's Response: The Cabinet acknowledges this comment.

(2) Subject: Regulation should be broken up into several regulations

(a) Comment: Elizabeth G. Cobb, Kentucky Hospital Association, provided the following comment:

"The regulation by its subject matter is long, intricate and at times confusing – all leading to potential inconsistent interpretation and adoption by providers. KHA strongly suggests the regulation would be more organized if broken into several regulations. We suggest creating a chapter on reportable disease surveillance with separate regulations within. Specifically, we recommend having the following separate regulations within a chapter devoted to reportable disease surveillance:

1. Section 1 – Definitions

2. Section 2 – Notification Standards
3. Sections 3 and 4
4. Sections 5 through 17
5. Sections 18 and 19”

Comment: Mary Newton, Flaget Memorial Hospital, Stacy England, Middlesboro ARH Hospital, Susan Wurth, Baptist Health Paducah, Dee Anderson, Baptist Hospital Lexington, Jean Moore, Norton Healthcare, Mary Martin, St Joseph Martin, and Tammy Merrill, Baptist Health Madisonville, provided the following comment:

“I am particularly concerned with: The overall size and scope of the regulation. We support breaking the regulation into smaller, more readable regulations...”

- (b) Cabinet's Response: The Cabinet does not concur. The Cabinet believes that providing all requirements in one place is most efficient and easiest to locate and read. As drafted, all reportable disease requirements may be found in this one administrative regulation. The format of this administrative regulation is consistent with other administrative regulations and consistent with the previous version of this regulation.

(3) Subject: Definitions

- (a) Comment: Kevin T. Kavanagh, MD, MS, provided the following comment:
“The regulation better defines what an outbreak is, which to some, including myself, believe has cause laxity in our dangerous pathogens reporting system. Some may ignore the necessity for public safety and state that this change will be too cumbersome for providers. However, it is far less cumbersome than that of other states which require reporting of all infections, not just outbreaks.”

- (b) Cabinet's Response: The Cabinet concurs. For clarification, in response to another comment received, the definition of “Outbreak” is being amended to specify that “cases” includes healthcare-associated infections (HAIs) and to include the alternative definition of, “a single case of an HAI not commonly diagnosed.”

- (a) Comment: Elizabeth G. Cobb, Kentucky Hospital Association, provided the following comments:

“KHA is supportive of the additions of definitions to the regulation and we feel this helps to clarify some requirements. Definitions 2 (HAI Outbreak) and 10 [sic] (Outbreak) are redundant. KHA recommends the definition of ‘HAI Outbreak’ be removed. The definition of ‘HAI’ has been added as has the definition of an ‘outbreak.’ It is not necessary to include ‘HAI Outbreak’ itself as it is consistent with the existing two separate definitions. The ‘Outbreak’ definition should be modified to show that even one case of an infection that

is unexpected to the facility should be reported to public health. A small facility that has an unexpected case of a disease might consider that an outbreak or at the very least an event critical enough to report. Section 1(2) b allows for one case to be reported for such as group A Streptococcus or Legionella. We would recommend language to make it more clear that any facility that diagnoses a patient with a disease that is not common for that facility may report that infection. This can be done by not suggesting types of cases but ending the sentence after 'not commonly diagnosed.'

- (b) Cabinet's Response: The Cabinet concurs. The administrative regulation has been amended to delete definition (2) and amend the definition of "Outbreak" to include the alternative definition of, "a single case of an HAI not commonly diagnosed." The Cabinet is also specifying that "cases" includes HAIs and clarifying that a single case of any HAI not commonly diagnosed is required by ending the definition after "not commonly diagnosed."
- (a) Comment: "KHA recommends clarifying the definition of a facility in simpler terms. KRS Chapter 216B provides the standard definition of a health facility in the Commonwealth of Kentucky."
- (b) Cabinet's Response: The Cabinet concurs and is amending the definition to cite only the KRS.
- (4) Subject: Tracking of reporting
- (a) Comment: Elizabeth G. Cobb, Kentucky Hospital Association, provided the following comment:

"KHA recommends the regulation be amended to include a process for appropriate tracking of reporting by healthcare facilities. ...It has come to our attention that hospitals have made reports in the past via telephone, consistent with regulatory requirements, to local health departments and those reports were not properly documented to the Kentucky Department for Public Health. There have been assertions that hospitals or other providers may be underreporting incidents but because there is no tracking process required of the local health departments when reports are made, there is a significant lack of reliable documentation as to the volume of reporting. KHA strongly recommends language be added to the 12regulation that upon receipt of a report by a health facility, a local public health official or official from the Kentucky Department for Public Health receiving the report shall assign the report a tracking number which confirms the report has been made and documented. A tracking number should be assigned for every reported infection and provided to the facility or provider making the report at the time the report is made."

Comment: Mary Newton, Flaget Memorial Hospital, Stacy England,

Middlesboro ARH Hospital, Susan Wurth, Baptist Health Paducah, Dee Anderson, Baptist Hospital Lexington, Jean Moore, Norton Healthcare, Mary Martin, St Joseph Martin, and Tammy Merrill, Baptist Health Madisonville, provided the following comment:

"I am particularly concerned with: Ability to confirm and track reports. We concur with the request by KHA to implement a tracking process so that health care provider representatives making a report in compliance with the regulation receive a tracking number upon reporting to either local or state public health.."

- (b) Cabinet's Response: The Cabinet does not concur. The national database used for reporting healthcare associated infections is controlled by the Centers for Disease Control and Prevention (CDC). The Kentucky Department for Public Health would have access to the database, but would not own it. Multidrug-resistant organisms and the National Electronic Disease Surveillance System will have assigned tracking numbers with which facilities may keep track. The creation of the Department's own tracking system for all reports would be an excessive administrative and financial burden.

(5) Subject: Increase in burden of reporting

- (a) Comment: Elizabeth G. Cobb, Kentucky Hospital Association, provided the following comments:

"The proposed changes to this regulation result in an increase in the burden of reporting by adding to the levels of reporting from four levels to six levels. Additionally, laboratory reporting is also added along with reporting of MDROs through the Kentucky Health Information Exchange. These changes substantially increase the reports being made by healthcare facilities. Kentucky Department for Public Health should consolidate the two levels 'urgent' and 'Priority'."

- (b) Cabinet's Response: The Cabinet does not concur. The Cabinet does not believe increasing the levels of reporting increases a burden in reporting, as reporting was required anyway. The difference between urgent and priority reporting is that urgent reporting requires notification made by telephone using an emergency number if local health department personnel cannot be contacted directly ("weekend, evening, or holiday"), whereas priority reporting does not require this.

- (a) Comment: "We request Kentucky Department for Public Health consolidate duplicative reporting that would be required under the proposed regulation by providers and laboratories. We ask the Kentucky Department for Public Health to revisit the requests for data and to streamline the reporting mechanism to be sure that if a health facility has a medical laboratory, the facility would not be required to submit multiple reports to public health

regarding the same infection or disease case."

Comment: Janet Justice, Kentucky Association of Health Care Facilities, provided the following comment:

"In summary, KAHCF respectfully requests that in any and all situations in which a laboratory test confirms a specified disease, specified condition or infection, as referenced in this amended regulation, the laboratory performing the test have the sole responsibility for reporting and that that reporting would completely fulfill the regulatory requirement."

- (b) Cabinet's Response: The Cabinet concurs in part. Section 2 contains "Notification Standards." Section 2(2) allows a single report by a health facility from its laboratory to constitute notification on behalf of the facility and its laboratory and Section 2(3) allows a health facility to designate an individual to report on behalf of the health facility's laboratory, pharmacy, and other clinical entities. Therefore, the Cabinet does not believe it requires one facility to report duplicate information. There are instances when notification may be required by different entities, but those notifications would contain different information. The Cabinet has the resources to resolve any duplicate information. The Cabinet would rather receive the same information more than once than have possibly no information reported.
- (a) Comment: Elizabeth G. Cobb, Kentucky Hospital Association, provided the following comments:

"The requirement under Section 2(7) for Medical Laboratories is particularly onerous. First, it creates duplicative reporting by health facilities if you have an infection preventionist or other healthcare provider designee reporting an infection and the medical laboratory reporting the same information. Additionally, some of the data required to be reported by a Medical Laboratory or a National Reference Laboratory is not readily available to a laboratory. Ethnicity may be an example of data that is not readily available to all providers or laboratories. Additionally, section 2(10) makes reporting requirements for National Reference Laboratories which may not be located in Kentucky and for which Kentucky regulation does not have jurisdiction. This means healthcare facilities would be required to renegotiate contracts with national reference laboratories to require reporting to public health. This could result in unnecessary costs when healthcare facilities are already required to make the same reports."
- (b) Cabinet's Response: The Cabinet acknowledges this comment. As noted above, Section 2(2) states that a report from a health facility's laboratory shall constitute notification from the facility and laboratory. Also, Section 2(3) allows relief from duplicate reporting. A clarification is being made in Section 2(10) to specify that the national reference laboratory will do the reporting of a positive laboratory result for a reportable disease. Electronic reporting will ease the process for laboratories even more once it becomes available. The

Cabinet agrees that healthcare facilities would be required to renegotiate contracts with national reference laboratories to require reporting to public health, but renegotiating is required anyway because the list of diseases has changed.

- (a) Comment: "There is the potential for it to appear there are a greater number of patients with MDROs when it may actually be a patient being readmitted. What assurances are there in this regulation that duplicate reporting will be identified or controlled for?"
- (b) Cabinet's Response: As stated above, the Cabinet has the resources to resolve duplicate reporting and prefers this over possibly no reporting being done.
- (a) Comment: "Sections 10(2), (7) and (10) are in conflict with each other with regards to what person or entity is responsible for making a report. The regulation should clearly describe what entity makes a report in each instance of reporting."
- (b) Cabinet's Response: The Cabinet acknowledges this comment. Section 10 does not have a subpart (7) or (10) so the Cabinet is not sure what parts were considered for this comment, but believes the regulation does clarify who makes a report in each instance of reporting.
- (a) Comment: "While the proposal seemingly takes some reporting burdens off the infection preventionist(s) in a hospital, some hospitals have suggested it would increase the burden for laboratory personnel and information technology staff in their hospital. We understand from our hospitals that much work must be undertaken by a hospital to set up electronic reporting. If the level of reporting to the exchange was not in the original scope of work established with a vendor, it will require additional charges. Data vendors also update data systems on a regular basis and hospital IT must test and update any programs built against the system each time updates occur to ensure that the programs written to meet the requirement still function. Finally, hospital representatives have indicated that infection prevention staff will be required to review and validate laboratory data prior to pushing that data to the Kentucky Health Information Exchange. This is a time consuming and costly proposal."
- (b) Cabinet's Response: The Cabinet acknowledges this comment. The 2009 American Recovery and Reinvestment Act included incentive programs from Medicare and Medicaid to provide payments to eligible hospitals and eligible professionals for implementing electronic health records. The Kentucky Health Information Exchange (KHIE) currently has signed participation agreements with a total of 685 provider organizations, which includes 72 organizations representing 110 hospitals in the state. At this time, 82% of

the hospitals in Kentucky are live and actively submitting data to KHIE across multiple feeds, including immunization, syndromics surveillance, and electronic lab reporting. KHIE is well equipped to work with a multitude of vendors as they currently work with 111 distinct vendors. This represents the strong footprint KHIE has in the state and their competence with successful public health reporting. The Cabinet urges hospitals to take advantage of available incentives for electronic reporting and avoid payment adjustments from Medicare, in which a hospital that takes care of Medicare patients will receive a penalty of 1% on their Medicare payments with increasing penalties every year.

- (a) Comment: Janet Justice, Kentucky Association of Health Care Facilities, provided the following comments:

"In Section 2 of the amended regulation, the burden of giving notice of a 'probable diagnosis of a disease' is on 'health professionals and facilities.' Although the amended regulation allows a 'health facility' to designate 'an individual to report on behalf of the health facility's laboratory, pharmacy, and the health facility's other clinical entities,' the regulatory mandate in Section 2 is for both a 'health professional' and a 'health facility' to report a probable diagnosis of a disease. KAHCF believes that this dual reporting requirement will cause confusion and may cause unintentional noncompliance of the reporting requirements especially in the nursing facility environment. In the nursing facility setting, the medical director is usually not an employee of the nursing facility. Additionally, in the nursing facility setting, the laboratory and other clinical entities may be contractors and not a unit within the legal structure of the nursing facility. Direct reporting by the 'health professional' will ensure more consistent and accurate reporting. KAHCF recommends that the regulation be revised to require that the 'health professional' and not the 'health facility' be responsible for reporting probable diagnosis of a disease under the regulation."

Comment: "Section 13 currently places the responsibility of reporting a positive test for HIV infection on both a health professional and a medical laboratory. Again, KAHCF firmly believes that requiring multiple entities or individuals to report the same diagnosis of the same person causes confusion and may result in unintentional non-compliance of the reporting requirements."

Comment: "Additionally, one individual or entity should be made responsible for reporting rather than possibly two or more, as this will cause confusion among the parties. As referenced above, a treating 'health professional' should always have the responsibility of reporting a diagnosis of a disease over a 'health facility.'"

Comment: Mary Newton, Flaget Memorial Hospital, Stacy England, Middlesboro ARH Hospital, Susan Wurth, Baptist Health Paducah, Dee

Anderson, Baptist Hospital Lexington, Jean Moore, Norton Healthcare, Mary Martin, St Joseph Martin, and Tammy Merrill, Baptist Health Madisonville, provided the following comments:

"I am particularly concerned with: Consolidating data submission. Hospital infection preventionists and other staff working in data collection and submission are overwhelmed with the scope of data requirements at the national and state levels. We ask that you reconsider the requirements for submission in this regulation which requires duplicated reporting by health care providers within the same organization (i.e. designated individuals, laboratories, electronic reporting); and The opportunity for over-reporting of infectious disease events or incidences. Throughout the regulation there are opportunities for over-reporting through duplication of reports, collection of information from pharmacists and the collection of MDRO lab data. We request the Department for Public Health implement processes within the regulation to ensure that incidence of disease and infection are not over-reported."

- (b) Cabinet's Response: The Cabinet does not concur. As noted above, Section 2(2) and (3) give reporting relief for a health facility, where applicable. The Cabinet also does not believe that requiring both health professionals and facilities to report will cause unintentional noncompliance of the reporting requirements. Only requiring one of these to do so is more likely to result in noncompliance. Also, notices from different entities may contain different information. This requirement is not new, as the previous version of this administrative regulation required notification by a health professional and a health facility.

(6) Subject: Reporting ambiguity

- (a) Comment: Elizabeth G. Cobb, Kentucky Hospital Association, provided the following comments:

"An immediate report is required for specified diseases requires a follow up communication via electronic or fax submission. The regulation does not indicate what information should be submitted via electronic communication or fax. We request the Cabinet clarify what information is to be submitted and if there is a corresponding form that should be used for reporting. If there is a form to be used, the regulation should indicate more clearly how healthcare providers can access that form. Finally, the regulation should indicate that a public health official will assign the report a tracking number as confirmation the report has been received and for future reference. The tracking number should be provided to the healthcare entity or provider upon making the report."
- (b) Cabinet's Response: The Cabinet does not concur. "Section 4. Reporting Classifications and Methods" contains the reporting classifications, such as "immediate", and how the reporting is to be made. Section 4(15) states that,

"A report submitted by fax or by mail shall be made using one of the following reporting forms:..." and then lists the forms through which reporting is accomplished. Section 19 also contains the forms and how they may be obtained. However, for further clarification, the Cabinet is amending Section 4 to include a reference to the required material in Section 2(6). The Cabinet will not create a new tracking system, as detailed in Comment Subject (4).

- (a) Comment: "Immediate Reporting is required for incidents identified in Section 10. KHA noted inconsistent language in Section 10(3) which states 'priority' reporting for a list of diseases. We ask that the final regulation clarify the reporting requirements among all levels, especially as it relates to section 10."
- (b) Cabinet's Response: The Cabinet concurs. Section 4(1) is amended as, "A report required by Section 10(1) and (2) of this administrative regulation..."
- (a) Comment: Janet Justice, Kentucky Association of Health Care Facilities, provided the following comments:
"902 KAR 2:020, Section 2(10) requires that 'upon a test result performed by a 'national reference laboratory' which indicates infection with an agent associated with one (1) or more of the disease or conditions specified in Section 3, 5, 6, 7, 8, 10, 13, 14, 15, or 16 of the 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 be responsible to ensure that the result is reported to the local health department serving the jurisdiction in which the patient resides.' Although KAHCF understands that the Commonwealth of Kentucky... may or may not have jurisdiction over an 'out of state' laboratory, KAHCF firmly believes that placing the responsibility of reporting on possibly three different individuals or entities causes confusion and may result in unintentional noncompliance of the reporting requirements. KAHCF believes that the responsibility of reporting the disease shall be with the laboratory. KAHCF requests that Section 2(10) be revised to mirror Section 2(7), which requires that the laboratory report the disease after the laboratory test confirms the disease."
- (b) Cabinet's Response: The Cabinet concurs. The intent of this subsection was to make the national reference laboratory responsible for reporting. This subsection is amended to clarify that the national reference lab reports the result.
- (a) Comment: "Section 14(1) requires that either 'a health professional or a health facility' give notification of a probable diagnosis of an STD as specified in the amended regulation. Again, KAHCF firmly believes that requiring multiple entities or individuals to report the same diagnosis of the same person causes confusion and may result in unintentional non-

compliance of the reporting requirement. KAHCF recommends that Section 14(1) be amended to require the health professional who diagnosed the probable diagnosis of an STD disease be responsible for reporting the disease, not the health facility."

- (b) Cabinet's Response: The Cabinet concurs in part. Giving different entities the opportunity to report without the requirement is likely to cause confusion and may result in unintentional noncompliance, therefore this is further amended. However, Section 2 already contains the notification standards that say both, "a health professional and a health facility shall give notification..." Therefore, to eliminate repetitive language and be consistent with Section 13, the specific language of who does the reporting will be deleted from Section 14(1) and (7).

(7) Subject: Reporting forms

- (a) Comment: Elizabeth G. Cobb, Kentucky Hospital Association, provided the following comment:
"The regulation references six forms, including EPID 250 for MDRO reporting. MDRO reporting is covered under Section 9 and is required to be reported electronically through the Kentucky Health Information Exchange. If the MDRO form is to be used for an HAI Outbreak, it should be noted within the regulation. The regulation should also identify minimum information to be required. If all information is required in an initial report, it may delay reporting."
- (b) Cabinet's Response: The Cabinet concurs that there is ambiguity regarding the EPID 250 form. The Cabinet is amending Section 4(15)(b) as, "EPID 250, Kentucky Reportable MDRO Form, until electronic reporting is available pursuant to Section 9(1)." The information required is contained in Section 9.

(8) Subject: Information reported

- (a) Comment: Elizabeth G. Cobb, Kentucky Hospital Association, provided the following comment:
"Hospitals and laboratories do not always have complete information submitted by a patient. If a healthcare facility is submitting a specimen to a reference laboratory, sometimes only a limited amount of data about the patient is collected. What is the minimum amount of information that should be submitted without delaying a report?"
- (b) Cabinet's Response: The requirements in this administrative regulation are the minimum amount of information that should be submitted and are consistent with the previous version of this administrative regulation.

(9) Subject: Electronic reporting

(a) Comment: Kevin T. Kavanagh, MD, MS, provided the following comment:
"In addition, the Regulation gives the Kentucky Health Dept. much needed access to data which has been submitted to the National Healthcare Safety Network, and provides for electronic laboratory reporting of dangerous pathogens to the Kentucky Health Dept. in the future. Neither of these latter two provisions should impose a significant burden on the providers."

(b) Cabinet's Response: The Cabinet concurs.

(a) Comment: Elizabeth G. Cobb, Kentucky Hospital Association, provided the following comments:
"KHA has consulted member hospitals regarding the proposed changes to require electronic reporting of specified infections and diseases via the Kentucky Health Information Exchange beginning October 1, 2016. We have noted a number of potential problems. Hospital responses to questions regarding readiness to meet the proposed requirement for electronic reporting in 2016 vary widely across the commonwealth. We understand the deadline is built upon Centers for Medicare and Medicaid Services (CMS) meaningful use requirements. It should be noted that meaningful use is a *voluntary* program under CMA and because numerous challenges continue with both hospitals and vendors, CMS has delayed meaningful use deadlines multiple times. We believe the deadline for connections and laboratory data submission of laboratory data to an information exchange under meaningful use requirements is also likely be further delayed. Hospital representatives have indicated concerns regarding the ability to meet the deadline. The progress in meaningful use varies significantly across the commonwealth and there are some independent and small hospitals that may have a difficult time meeting the October 1, 2016 deadline."

(b) Cabinet's Response: The Cabinet acknowledges this comment. As stated previously, the 2009 American Recovery and Reinvestment Act included incentive programs from Medicare and Medicaid to provide payments to eligible hospitals and eligible professionals for implementing electronic health records. Although the federal incentive program is voluntary, Congress mandated payment adjustments to be applied annually to Medicare eligible hospitals that are not meaningful users of certified electronic health records technology, in which a hospital that takes care of Medicare patients will receive a penalty of 1% on their Medicare payments with increasing penalties every year. In Kentucky, all except one hospital is eligible for the incentive program and subject to payment adjustments if not using this technology. The Kentucky Health Information Exchange (KHIE) currently has signed participation agreements with a total of 685 provider organizations, which includes 72 organizations representing 110 hospitals in the state. At this time, 82% of the hospitals in Kentucky are live and actively

submitting data to KHIE across multiple feeds, including immunization, syndromics surveillance, and electronic lab reporting. KHIE is well equipped to work with a multitude of vendors as they currently work with 111 distinct vendors. This represents the strong footprint KHIE has in the state and their competence with successful public health reporting. The Cabinet urges hospitals to take advantage of available incentives for electronic reporting and avoid payment adjustments.

- (a) Comment: "KHA requests that a committee or task force be convened in the interim between adoption of the regulation and the October 1, 2016 implementation of this section. The committee should include representation from the Kentucky Health Information Exchange and representation of all stakeholders impacted by the proposed requirement. The committee should look more closely at the readiness of all impacted providers to meet the proposed requirements and the group should also study the financial, man hours and other resources related to meeting the requirement. The Committee or Task force should advise the Kentucky Department for Public Health on how to implement electronic laboratory reporting in the least burdensome and costly manner."
- (b) Cabinet's Response: The Cabinet does not concur. Individuals representing Norton Healthcare, Frankfort Regional Hospital, University of Louisville Hospital, Kentucky One/St. Joseph, Kentucky Hospital Association, Kentucky Board of Pharmacy, Kentucky Pharmacists Association, and the Kentucky Department for Public Health all contributed to the drafting of this amended administrative regulation.

(10) Subject: Submittal ambiguity

- (a) Comment: Elizabeth G. Cobb, Kentucky Hospital Association, provided the following comments:
"Section 9(3) is confusing. All the infections listed under Section 9 are to be reported on a routine basis which is every five (5) business days. Section 9(3) states that 'upon a test result...' This language indicates reporting upon test results rather than on a 'routine' basis. KHA strongly urges the Department to modify the language in Section 9(3) to be consistent with 'Routine' reporting every five (5) days as continuous reporting would be overly burdensome."
- (b) Cabinet's Response: The Cabinet concurs. Although the title of Section 9 refers to routine notification and Section 9(1) says that "... notification of the following diseases shall be considered routine...", the Cabinet is amending Section 9(3) to include "within five (5) days".
- (a) Comment: "... the Section [10] indicates reports are made by a health facility directly to the Kentucky Department for Public Health yet Section 10(5)

states the 'local health department may seek assistance from the Kentucky Department for Public Health.' We ask that you clarify to which department, state or local, reports are made under Section 10."

- (b) Cabinet's Response: The Cabinet does not concur. Section 10, subpart (1), states that for the incidents listed, the Kentucky Department for Public Health shall be telephoned immediately. Subparts (2) and (3) state that for the incidents listed under them, the local health department in the county... shall be reported to.

(11)Subject: Influenza reporting

- (a) Comment: Elizabeth G. Cobb, Kentucky Hospital Association, provided the following comment:
"According to hospital representatives consulted, hospitals and other providers are currently asked to report influenza data to the state laboratory. As the volume of influenza patients peaks, the state laboratory asks for reporting to the state laboratory to cease as they become overburdened. Based on this information, KHA recommends this section be modified as written below..."
- (b) Cabinet's Response: The Cabinet acknowledges this comment. Influenza reports are not sent to the state laboratory, although specimens sometimes are. The number of specimens is sometimes requested to be reduced, but influenza reports are not. The Cabinet agrees that the proposed language is ambiguous about who reports are sent to and is amending the language to state that these reports will be classified as "routine", which Section 4(12) describes as made within five business days to the local health department serving the county in which the patient resides.

(12)Subject: Finalized data

- (a) Comment: Elizabeth G. Cobb, Kentucky Hospital Association, provided the following comment:
"KHA's recommended changes are to ensure that only finalized data is accessed and used for state-level reports... Often changes or additions are made to data up until the deadline implemented by CMA for the quality incentive program. If data is accessed prior to the deadline and finalization date, there is a potential for the Kentucky Department for Public Health to access erroneous data and build reports inconsistent with those CMS distributes. KHA recommends the language below..."
- (b) Cabinet's Response: The Cabinet does not concur. Section 12(3)(b) states that state-level reports shall comply with methodology developed by the CDC and CMS for national reporting of health care-associated infections. This methodology presently requires data to be finalized.

(13) Subject: Tuberculosis

- (a) Comment: Elizabeth G. Cobb, Kentucky Hospital Association, provided the following comment:

"A new provision is proposed in the regulation requiring pharmacists to provide notification to the health department if they dispense two medications usually used for the treatment of active tuberculosis. Any reference to medications administered for tuberculosis treatment should be consistent with CDC protocol of tuberculosis treatment. KHA recommends removing the requirement for pharmacists to make such a report. Healthcare facilities and providers are required to report cases of tuberculosis. Having pharmacists also reporting when certain medications are dispensed would result in duplicated reporting efforts. Furthermore, physicians should be actively reporting cases of tuberculosis. If there is a failure to report, physicians and other healthcare providers should be educated on their requirements. What is the value of having pharmacists report when providers diagnosing a tuberculosis case should be reporting? And how would the Department for Public Health accurately assess the number of tuberculosis cases if they are receiving duplicative reports from Pharmacists and providers on the same patients."

- (b) Cabinet's Response: The Cabinet does not concur. Section 2(3) states that 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. The Kentucky Board of Pharmacy and Kentucky Pharmacists Association were consulted in the amending of this administrative regulation. This amendment was made to ensure there are no delays in the reporting of tuberculosis and, as mentioned previously, the Cabinet has the resources to resolve duplicate data if it were to receive any.

(14) Subject: Confirmation of specimens or clinical isolates

- (a) Comment: Elizabeth G. Cobb, Kentucky Hospital Association, provided the following comment:

"We would like confirmation that public health would like specimens or clinical isolates for all the diseases outlined in Section 5. This seems overly burdensome for facilities and expensive for laboratories, especially reference laboratories."

- (b) Cabinet's Response: The Cabinet does not concur. The Cabinet confirms that it is requiring the specimens or clinical isolates for diseases outlined in subsection (5) of Section 3, not Section 5.

SUMMARY OF STATEMENT OF CONSIDERATION
AND
ACTION TAKEN BY PROMUGATING ADMINISTRATIVE BODY

The Department for Public Health is amending this administrative regulation in response to public comments received.

Page 1

Statutory Authority

Line 7

After "211.180(1)", insert "**, 214.010**".

Page 2

Section 1(2)

Lines 6 through 10

Delete subsection (2) in its entirety.

Renumber subsequent definitions.

Page 2

Section 1(3)

Lines 11 through 16

After "'Health facility'", insert "**is defined by KRS 216B.015(13)**".

Delete the following:

means: (a) A facility licensed under 902 KAR Chapter 20 and required by the Centers for Medicare and Medicaid Services (CMS) to report an HAI event or healthcare personnel influenza vaccination information to CMS using the National Healthcare Safety Network; or
(b) A facility licensed under KRS Chapter 216B

Page 3

Section 1(8)

Line 7

After "KRS 333.020", insert "**(3)**".

Delete "(2)".

Page 3

Section 1(11)

Lines 14 and 15

After "'Outbreak' means", insert "**: (a)**".

After "more cases", insert "**, including HAIs,**".

After "place, or time", insert the following:

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

Page 5

Section 2(10)

Lines 11 and 12

After "that referred the test to the national reference laboratory shall", delete "be responsible to".

After "result is reported", insert the following:

by the national reference laboratory

Page 6

Section 3(3)

Line 7

After "A submitting laboratory", insert "**shall provide**".

Delete "is responsible for providing".

Page 7

Section 4(1)

Line 12

After "required by Section 10", insert "**(1) and (2)**".

Page 9

Section 4(12)

Line 21

After "8, 9,", insert "**11(1),**".

Page 10

Section 4(15)(b)

Line 14

After "Reportable MDRO Form", insert the following:

, until electronic reporting is available pursuant to Section 9(1)

Page 11

Section 4(16)(k)

Line 9

After "provider or facility", insert the following:

. (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.

Delete the semicolon.

Page 18

Section 9(1)(h)5.

Line 18

After "levofloxacin);", insert "**and**".

Page 18

Section 9(1)(h)6.

Line 19

After "amikacin);", insert "**and**".

Page 19
Section 9(3)
Line 15

After "Information Exchange", insert "**within five (5) days**".

Page 21
Section 11(1)
Line 4

After "following shall be", insert "**considered routine**".
Delete "reported weekly".

Page 24
Section 14(1)
Line 17

After "(1)", delete the following:
A health professional or a health facility shall give
After "Notification", insert "**of**".
Delete "if".

Line 18
After "diagnosis of an STD", insert "**as**".
After "of this section", insert "**shall be**".
Delete "is".

Page 25
Section 14(7)
Lines 19 through 21

After "and shall be made", delete the following:
by a health professional or medical laboratory
After "five (5) business days", delete the following:
to the local health department serving the county in which the patient
resides