



# KY Hepatitis Connections

On behalf of the KY Adult Viral Hepatitis Prevention and Control Program, we wish you and your family a wonderful holiday season! Inside our December 2014 Edition of the KY Hepatitis Connections you will find current information about viral hepatitis, opportunities for viral hepatitis continuing professional education and information about educational materials available. See all the exciting things happening here in Kentucky!

Please feel free to forward and/or copy and distribute to other professionals in your network. Your knowledge and input are greatly valued, as we are committed to keeping you up to date on shared progress in the medical community on viral hepatitis and its impact on our families throughout the Commonwealth. We hope you enjoy our newsletter.

Kathy Sanders, RN MSN

## REMINDER:

### CABINET FOR HEALTH AND FAMILY SERVICES

#### Department for Public Health

#### Division of Epidemiology and Health Planning

COMMENT ON PROPOSED REGULATION CHANGED: 902 KAR 2:020. Reportable disease surveillance

Attached with this newsletter is the filed regulation for reportable disease surveillance. The instructions for public comment are found on page 43 of the regulation. You must submit your comments per these instructions and not to the individual sections/programs such as HAI Prevention.

#### PUBLIC COMMENT PERIOD:

You may submit written comments on the proposed administrative regulation. You may submit written comments regarding this proposed administrative regulation until close of business on **December 1, 2014**. Send written comments on the proposed administrative regulation to:

CONTACT PERSON: Tricia Orme, Office of Legal Services, 275 East Main Street 5 W-B, Frankfort, KY 40601, Phone: 502-564-7905, Fax: 502-564-7573, [Tricia.Orme@ky.gov](mailto:Tricia.Orme@ky.gov).

## HEPATITIS IN KENTUCKY:

Please see the link below YOUTH AT RISK: HEROIN, HEP C and the PRESCRIPTION PAINKILLER EPIDEMIC released last week:

[http://www.hepmag.com/articles/youth\\_heroin\\_hepatitis\\_c\\_2502\\_26174.shtml](http://www.hepmag.com/articles/youth_heroin_hepatitis_c_2502_26174.shtml)

Kentucky is mentioned as one of the five states experiencing the worst HCV outbreaks among young people, with Northern Kentucky highlighted as one of the “hot spots”. Of special note: using the approach of don’t share needles is just not enough, as the latest research shows that cookers, swabs, tourniquets and other paraphernalia can spread the HCV virus.

## HCV: IN THE NEWS:

### Few infants tested for HCV after birth, more perinatal testing needed

Very few infants in Philadelphia were tested for hepatitis C virus infection after birth despite mothers who reported being positive for the infection, according to data presented at ID Week 2014.

“Repetitive and conclusive testing of pregnant women and infants in their first 18 months is necessary to identify vertical transmission of HCV and initiate infected infants into care,” the researchers wrote in the abstract.

Researchers from the Philadelphia Department of Public Health, including Danica Kuncio, MPH, hepatitis surveillance epidemiologist, utilized HCV antibody and RNA tests reported since 2002 to identify maternal and infant testing for HCV. Datasets were matched to birth certificates between January 2011 and July 1, 2014 to detect infants born to mothers infected with HCV and to determine if infant testing for the infection occurred. Researchers compared the anticipated rate of 5% for HCV sero-positivity among the infants.

A total of 6,259 females between the ages of 12 and 44 were reported as positive for HCV infection. Of those females, there were 1,065 infants born in Philadelphia during the study period to women positive for HCV. Only 1,017 infants survived and 66 were tested for HCV. There were 41 children in the registry that matched to the birth certificates for the study period, but their mothers were not in the registry. Overall, 10% of all infants (n=107) born to HCV positive women were tested for HCV. Twelve percent of 18 month-old infants underwent HCV testing. Six infants tested positive for HCV RNA.

“This data shows that an insufficient number of infants are being tested for HCV after birth, likely resulting in a pool of chronically infected children whose disease remains unmonitored.” the researchers wrote in the abstract.

If a 5% rate of HCV sero-positivity among infants born to mothers positive for HCV was assumed, 47 more infants would be expected to develop HCV infection.

“Efforts need to be made to bridge the gap in testing for these infants born to HCV positive mothers,” Kuncio told *Healio.com/Hepatology*. “[The Philadelphia Department of Public Health] intends on launching a pilot program to better ensure screening for perinatal HCV in Philadelphia.” –  
*by Melinda Stevens*

<http://www.healio.com/hepatology/hepatitis-c/news/online/%7Ba2855634-0df1-430f-a8d1-8a80a9318c00%7D/few-infants-tested-for-hcv-after-birth-more-perinatal-testing-needed?ecp=5FF3B6D7-4120-47B9-B533-70B7305523EF>

## Networking strategy may decrease HCV prevalence among injection drug users

In a new study, researchers in Australia found that using a social network-based approach to treating injection drug users with hepatitis C virus infection led to decreased hepatitis C virus prevalence and increased efficacy of treatment over time.

“Though it is unrealistic to assume that we can observe the entire network of an [injection drug user], we suggest that HCV infection is highly likely to arise from an injector’s network, even if not from the observed network,” the researchers wrote.

Researchers enrolled a cohort of injection drug users in Melbourne, Australia, between 2005 and 2007 to determine how a person’s social network can affect HCV transmission. Using the snowball sampling method, 258 nodes from 258 participants were included and represented 524 injection drug users overall.

To test their theory on a larger population, researchers generated 100 networks with 20 sub-networks, which contained 524 injection drug users each, using the “fixed-node number and Pnet’s standard Metroplis-hastings [Markov chain Monte Carlo]” model for the final analysis.

Read More: [http://www.healio.com/hepatology/hepatitis-c/news/online/%7Ba1310771-b14a-42c9-9da4-98597f628017%7D/networking-strategy-may-decrease-hcv-prevalence-among-injection-drug-users?sc\\_trk=internalsearch](http://www.healio.com/hepatology/hepatitis-c/news/online/%7Ba1310771-b14a-42c9-9da4-98597f628017%7D/networking-strategy-may-decrease-hcv-prevalence-among-injection-drug-users?sc_trk=internalsearch)

## HCV epidemic emerging in young, non-urban injection drug users

New data indicate a rising incidence of hepatitis C infection among young, primarily white, non-urban people who inject drugs, according to CDC researchers

“A comprehensive approach is needed to address the increases in HCV infection among young persons,” the researchers wrote in *Clinical Infectious Diseases*. “Both CDC and the United States Preventive Services Task Force recommend HCV testing for persons with a history of [injection drug use]. The majority of young persons with recent HCV infection in supplemental case follow-up interacted with clinical providers, drug or alcohol rehabilitation, or prison systems — venues where HCV testing and prevention can be focused.”

The researchers used national surveillance data from 2006 to 2012 to examine HCV trends among people aged 30 years or younger.

## What If I Give My Baby Hepatitis C?

It's a common concern for women diagnosed with hepatitis C: Will I pass the disease onto my child? Luckily, only 5 or 6 percent of mothers with hepatitis C pass the disease along to their babies, said Dr. Naim Alkhouri, a pediatric gastroenterologist at the Cleveland Clinic.

Still, the American Liver Foundation (ALF) estimates there are between 23,000 and 46,000 children in the United States living with hepatitis C. New medications with cure rates close to 100 percent and relatively few side effects have revolutionized hepatitis C treatment for adults, but not much has changed for children.

Gastroenterologists still treat hepatitis C-infected children with interferon and twice-daily, oral ribavirin. This was standard for adult treatment too, until the U.S. Food and Drug Administration (FDA) approved sofosbuvir (Sovaldi) last year.

Read More: <http://www.healthline.com/health-news/what-if-i-give-my-baby-hepatitis-c-110314>

## New Prescription Regimen Produces Hepatitis C Virus Sustained Virologic Response in Liver Transplant Patients

A new drug regimen produced high sustained virologic response (SVR) rates in a small group of liver transplant patients with recurrent hepatitis C virus genotype 1 infection. The report was published online Nov. 12 in the New England Journal of Medicine.

The new treatment, which included the drugs ABT-450, ombitasvir, and dasabuvir (with or without ribavirin), was administered to patients over a 24 week period. Researchers say this regimen's side effect rate and risk of transplant rejection appears to be much lower than for treatment with interferon. – The new three-drug regimen led to a SVR 97 percent of the time in 34 people who'd had a liver transplant, but didn't have cirrhosis. The SVR rate was 96 percent in patients with cirrhosis, the researchers said. The current study was a phase 2 clinical trial, and the new regimen is still considered investigational, according to the researchers. –

Read more: <http://www.hcplive.com/articles/New-Prescription-Regimen-Produces-Hepatitis-C-Virus-Sustained-Virologic-Response--in-Liver-Transplant-Patients#sthash.HKFwxMbM.SwWHT2IJ.dpuf>

## The American Journal of Medicine Launches Hepatitis C Resource Center

The American Journal of Medicine (AJM) announces the availability of an original, comprehensive, online Hepatitis C Resource Center dedicated to providing primary care providers and specialists with the latest information on the screening, diagnosis, treatment, and management of Hepatitis C (HCV). Elsevier, a world-leading provider of scientific, technical, and medical information products and services, publishes AJM.

In a survey of primary care physicians (PCPs) who had screened and/or cared for HCV patients within the last six months, 60 percent confirmed they were not very confident or only somewhat confident when screening patients for chronic HCV infection. AJM and Elsevier Multimedia Publishing commissioned the survey, which was conducted by Metrics for Learning, LLC.

"The mandate for population-based screening and the lack of confidence of PCPs to screen highlights an opportunity that can be addressed in our healthcare system by appropriate education," said Edward Lebovics, MD, FACP, AGAF, FACG, FAASLD, Division of Gastroenterology and Hepato-biliary Diseases at New York Medical College. Dr. Lebovics is guest editor of the Resource Center.

The survey found that PCPs have misconceptions about who to screen, the risk of progression of liver disease and available therapies. Dr. Lebovics emphasized the shortage of educational resources to provide healthcare practitioners with the latest information on the screening, diagnosis, treatment, and management of HCV.

Read More: <http://www.prnewswire.com/news-releases/the-american-journal-of-medicine-launches-hepatitis-c-resource-center-282694851.html>

## New Agents Show Promise in Cirrhosis

BOSTON -- Hepatitis C (HCV) patients with cirrhosis are tough to treat. And those who have previously failed therapy are especially difficult.

But 24 weeks of treatment with a newly approved drug combination, sofosbuvir and ledipasvir (Harvoni), cured 97% of patients in a double-blinded, controlled trial, according to Marc Bourliere, MD, of the Saint Joseph Hospital in Marseilles, France.

And adding a third drug -- the relatively inexpensive, nonspecific antiviral ribavirin -- allowed investigators to get similar outcomes with just 12 weeks of therapy, Bourliere reported in a late-breaker session at the American Association for the Study of Liver Diseases annual meeting.

Read More: <http://www.medpagetoday.com/Gastroenterology/Hepatitis/48612>

## **Decision Memo for Screening for Hepatitis C Virus (HCV) in Adults (CAG-00436N)**

The Centers for Medicare & Medicaid Services (CMS) has determined the following:

The evidence is adequate to conclude that screening for Hepatitis C Virus (HCV), consistent with the grade B recommendations by the U.S. Preventive Services Task Force (USPSTF), is reasonable and necessary for the prevention or early detection of an illness or disability and is appropriate for individuals entitled to benefits under Part A or enrolled under Part B, as described below.

Therefore, CMS will cover screening for HCV with the appropriate U.S. Food and Drug Administration (FDA) approved/cleared laboratory tests, used consistent with FDA approved labeling and in compliance with the Clinical Laboratory Improvement Act (CLIA) regulations, when ordered by the beneficiary's primary care physician or practitioner within the context of a primary care setting, and performed by an eligible Medicare provider for these services, for beneficiaries who meet either of the following conditions.

1. A screening test is covered for adults at high risk for Hepatitis C Virus infection. "High risk" is defined as persons with a current or past history of illicit injection drug use; and persons who have a history of receiving a blood transfusion prior to 1992. Repeat screening for high risk persons is covered annually only for persons who have had continued illicit injection drug use since the prior negative screening test.
2. A single screening test is covered for adults who do not meet the high risk as defined above, but who were born from 1945 through 1965.

The determination of "high risk for HCV" is identified by the primary care physician or practitioner who assesses the patient's history, which is part of any complete medical history, typically part of an annual wellness visit and considered in the development of a comprehensive prevention plan. The medical record should be a reflection of the service provided.

For the purposes of this national coverage determination (NCD), a primary care setting is defined by the provision of integrated, accessible health care services by clinicians who are accountable for addressing a large majority of personal health care needs, developing a sustained partnership with patients, and practicing in the context of family and community. Emergency departments, inpatient hospital settings, ambulatory surgical centers, independent diagnostic testing facilities, skilled nursing facilities, inpatient rehabilitation facilities, clinics providing a limited focus of health care services, and hospice are examples of settings not considered primary care settings under this definition.

### **Gilead Announces Patient Assistant Program:**

Gilead has announced a patient assistant program to assist individuals with or without insurance with co-pays and the cost of Harvoni and Sovaldi. Practitioners can refer patients to call 1-855-7-MYPATH (1-855-769-7284) to register over the phone or visit: <http://www.mysupportpath.com>

## American Academy of HIV Medicine Launches Institute for Hepatitis C

The American Academy of HIV Medicine (AAHIVM) announces the creation of the new AAHIVM Institute for Hepatitis C. The AAHIVM board of directors recently voted unanimously to create the Institute to spearhead current and future AAHIVM programs and activities focused on HCV. The Institute's goal is to advance hepatitis C (HCV) care through education, professional development, and advocacy. Vice chair of the AAHIVM board of directors, Dr. Margaret Hoffman-Terry, will serve as the director of the institute.

A recent survey of AAHIVM members in Ryan White clinics, community health centers, private practices, and academic and/or hospital settings confirmed that HIV practitioners are caring for significant numbers of patients with HCV. Findings from that survey show that approximately 1 in 4 patients currently being seen by an AAHIVM member or credentialed HIV Specialist is infected with Hepatitis C (with or without HIV co-infection). In addition, 81 percent of clinician respondents felt that they have the proper clinical knowledge and education to expertly treat HCV infection. However, 92 percent of the respondents expressed a desire for even more professional support in this area.

"It is clear that HIV providers are more engaged in HCV care than ever before," says James M. Friedman, executive director of AAHIVM. "We are excited to offer our members a new, more complete focus on HCV through the new Institute, and more opportunities to increase their professional development and engagements on this important issue."

The Institute for Hepatitis C will have a visual presence on the AAHIVM website, housing the latest scientific and medical information on HCV, including prevention, and testing information, relevant research, treatment protocols and innovations, FDA treatment approval announcements and alliances and partnerships. The Institute will also house and underwrite AAHIVM's ongoing advocacy work related to promoting better access to HCV treatments.

"AAHIVM is launching this new Institute to build upon our past initiatives and lead the way in Hepatitis C testing, prevention, care and treatment outcomes throughout the country," says Zelalem Temesgen, MD, AAHIVS, of the Mayo Clinic and Chair of the AAHIVM board of directors. "Our goal is to ensure that HIV treaters are prepared to meet the new challenges of HCV care with as much success as they've had in combatting the HIV epidemic for the last 30 years."

As part of the Institute, AAHIVM is also launching a monthly, practice-focused e-newsletter on hepatitis C, The HIV/HCV Resource, which will be co-edited by Margaret Hoffman-Terry, MD, FACP, AAHIVS of Lehigh Valley Hospital, and Mark Sulkowski, MD, from John Hopkins University School of Medicine. The newsletter will be sent electronically to AAHIVM members and credentialed providers and posted within the AAHIVM Institute for Hepatitis C portal of the Academy website.

<http://www.infectioncontroltoday.com/news/2014/11/american-academy-of-hiv-medicine-launches-institute-for-hepatitis-c.aspx>

## HCV: Clinical Trials:

For the latest hepatitis C drug studies, recruitment, and evaluations:

<http://www.clinicaltrials.gov/ct2/results?term=hepatitis+c&Search=Search>

## Patient Assistance and Co-Pay Programs for Viral Hepatitis Drugs

Pharmaceutical companies offer Patient Assisted programs and co-pay programs to help offset costs and save money on hep C treatment.

Read More:

[http://www.hepmag.com/articles/hepatitis\\_paps\\_copays\\_20506.shtml?utm\\_source=newsletter09\\_15&utm\\_medium=TJ11&utm\\_campaign=lesson](http://www.hepmag.com/articles/hepatitis_paps_copays_20506.shtml?utm_source=newsletter09_15&utm_medium=TJ11&utm_campaign=lesson)

## Hepatitis B Vaccination in Diabetes Care

Did you know? People living with diabetes, ages 23-59, may have approximately a TWO-FOLD increased risk of HBV infection compared to those without diabetes.

In 2011, the Center for Disease Control and Prevention (CDC) and Advisory Committee on Immunization Practices (ACIP) issued the following recommendations:

- Adults with Diabetes 19 to 59 should be vaccinated against HBV as soon as feasible after diagnosis Adults age 60 and older with diabetes should be vaccinated against HBV at the discretion of the treating healthcare provider based on the likelihood of acquiring HBV infection.

See the full Hepatitis B and Diabetes Report at the end of the newsletter.



## HEPATITIS C Voluntary Reporting:

### Hepatitis C: Perinatal and Children Aged Five Years or Less. Update on the Project for Voluntary Reporting in Kentucky.

Health care providers are asked to report voluntarily:

- all HCV-positive pregnant women;
- all infants born to HCV-positive women; and
- all HCV-positive infants and children 5 years old and younger seen in birthing hospitals, medical practices and clinics

Routine testing for HCV is not recommended for all pregnant women. Pregnant women with a known risk factor for HCV infection should be offered counseling and testing. Data from the CDC states that approximately 6 out of every 100 infants born to HCV infected woman become infected. The risk is greater, 2 to 3 times, if the woman is co-infected with HIV. There is currently no HCV treatment approved for pregnant women.

<http://www.cdc.gov/std/treatment/2010/hepc.htm>

Infants born to HCV-positive mothers should be tested for HCV infection. Children born to HCV-positive mothers can be tested with the HCV RNA tests at 2 months of age or older (at a routine well-child visit) or HCV antibody testing can be done at 18 months of age (wait until 18 months of age to avoid detecting maternal antibody).

<http://www.cdc.gov/hepatitis/hcv/hcvfaq.htm>

There are no FDA approved HCV treatments for young children. This month, a clinical trial announcement was made to study these young children/ adolescents and the treatment of HCV:

<http://www.hivandhepatitis.com/hcv-treatment/approved-hcv-drugs/4859-sofosbuvir-ribavirin-to-be-studied-in-children-with-hepatitis-c>

Thank you for your continued support of this project and your ongoing assistance to report pregnant women and children aged five years and less who are infected with hepatitis C virus (HCV), and seen in birthing hospitals, medical practices, and clinics throughout the Commonwealth in your communities.

Please continue to report any HCV-positive individuals in the above categories. Complete and fax the reporting form at the end of this newsletter. Please note the new fax number:

**Please fax forms to 502-696-3803**

If you have additional questions or concerns, please call Kathy Sanders, RN, MSN at 502-564-3261, ext. 4236 or Julie Miracle, RN, BSN at 502-564-4478, ext. 4260.



## **Viral Hepatitis Prevention Program Staff:**

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1 CABINET FOR HEALTH AND FAMILY SERVICES

2 Department for Public Health

3 Division of Epidemiology and Health Planning

4 (Amendment)

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)~~[EO 2004-~~  
8 ~~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,

1 or general notification, in order to facilitate rapid public health action to control diseases,  
2 and to permit an accurate assessment of the health status of the Commonwealth.

3 Section 1. Definitions.

4 (1) “Authorize” means to confer rights to the Kentucky Department for Public  
5 Health in the NHSN database at the healthcare facility level.

6 (2) “HAI outbreak” means:

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

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

11 (3) “Health facility” means:

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

16 (b) A facility licensed under KRS Chapter 216B.

17 (4) “Health professional” means a professional licensed under KRS Chapters 311  
18 through 314.

19 (5) “Healthcare-associated infection” or “HAI” means an infection acquired by a  
20 person while receiving treatment for a separate condition in a health care setting.

21 (6) “HIV case report” means an HIV infection or AIDS diagnosis which:

22 (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           (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           (8) “Medical laboratory” is defined by KRS 333.020(2).

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           (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           (11) “Outbreak” means two (2) or more cases that are epidemiologically linked or  
15 connected by person, place, or time.

16           (12) “Pharmacist” means a professional licensed under KRS 315.010.

17           (13) “Select agent” means a biological agent or toxin that could pose a severe  
18 threat to public health, plant health, animal product, or plant product as determined by  
19 the National Select Agent Registry (NSAR) at [www.selectagents.gov](http://www.selectagents.gov).

20           (14) “Veterinarian” means a professional licensed under KRS 321.181.

21           Section 2. Notification Standards.

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

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

3 (b) The diagnosis is supported by:

4 1.a. Clinical or laboratory criteria; and

5 b. Case classifications published by the Centers for Disease Control and  
6 Prevention at [wwwn.cdc.gov/nndss](http://wwwn.cdc.gov/nndss); or

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

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

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

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

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

17 (6) The reporting health professional shall furnish:

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

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

21 (7) Medical Laboratories. Upon a laboratory test result which indicates infection  
22 with an agent associated with one (1) or more of the diseases or conditions specified in  
23 Section 3, 5, 6, 7, 8, 10, 13, 14 15, or 16 of this administrative regulation, the laboratory

1 shall report the result to the local health department serving the county in which the  
2 patient resides.

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

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

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

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

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

18 Section 3. Submission of Specimens to the Kentucky Department for Public  
19 Health Division of Laboratory Services. (1) A medical laboratory and a national  
20 reference laboratory in receipt of diagnostic specimens originating from the  
21 Commonwealth of Kentucky shall send specimens or clinical isolates for diseases  
22 outlined in subsection (5) of this section to the Division of Laboratory Services for  
23 primary or confirmatory testing and related studies.

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

5           (3) In the event that culture attempts do not produce a clinical isolate, the direct  
6 specimen, submitted in the appropriate preservative, shall be sent to the Division of  
7 Laboratory Services. A submitting laboratory is responsible for providing the name of  
8 the etiologic agent detected by the non-culture technique at the time of specimen  
9 submission.

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

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

16           (a) Botulism;

17           (b) Brucellosis;

18           (c) Campylobacteriosis;

19           (d) Cholera and diseases caused by other Vibrio species;

20           (e) Diphtheria;

21           (f) Escherichia coli O157:H7;

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

23           (h) Listeriosis;

- 1        (i) Measles;
- 2        (j) Meningococcal infections;
- 3        (k) Rabies animal;
- 4        (l) Rubella;
- 5        (m) Salmonellosis;
- 6        (n) Shiga toxin-producing E. coli (STEC);
- 7        (o) Shigellosis;
- 8        (p) Tuberculosis;
- 9        (q) Tularemia; and
- 10       (r) Typhoid fever.

11       Section 4. Reporting Classifications and Methods.

12       (1) Immediate reporting. A report required by Section 10 of this administrative  
13 regulation to be made immediately shall be:

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

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

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

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

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

22       (3) Weekend, evening, or holiday immediate notification. If local health  
23 department personnel cannot be contacted directly, notification shall be made by

1 telephone using an emergency number provided by the local health department or the  
2 Kentucky Department for Public Health.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3           (a) Make a record of the report;

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

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

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

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

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

14           (b) EPID 250, Kentucky Reportable MDRO Form;

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

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

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

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

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

22           (a) Patient name;

23           (b) Date of birth;

- 1        (c) Gender;
- 2        (d) Race;
- 3        (e) Ethnicity;
- 4        (f) Patient address;
- 5        (g) County of residence;
- 6        (h) Patient telephone number;
- 7        (i) Name of the reporting medical provider or facility;
- 8        (j) Address of the reporting medical provider or facility; and
- 9        (k) Telephone number of the reporting medical provider or facility;

10        Section 5. Notifiable Infectious Conditions Requiring Urgent Notification.

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

- 13        (1) Anthrax;
- 14        (2) Botulism;
- 15        (3) Brucellosis (multiple cases, temporally or spatially clustered);
- 16        (4) Diphtheria;
- 17        (5) Hepatitis A, acute;
- 18        (6) Measles;
- 19        (7) Meningococcal infections;
- 20        (8) Novel influenza A virus infections;
- 21        (9) Plague;
- 22        (10) Poliomyelitis;
- 23        (11) Rabies, animal;

- 1           (12) Rabies, human;
- 2           (13) Rubella;
- 3           (14) Severe Acute Respiratory Syndrome-associated Coronavirus (SARS-CoV)
- 4 disease;
- 5           (15) Smallpox;
- 6           (16) Tularemia;
- 7           (17) Yellow fever; and
- 8           (18) Viral hemorrhagic fevers due to:
  - 9           (a) Crimean-Congo Hemorrhagic Fever virus;
  - 10           (b) Ebola virus;
  - 11           (c) Lassa virus;
  - 12           (d) Lujó virus;
  - 13           (e) Marburg virus; or
  - 14           (f) New world arenaviruses including:
    - 15           1. Guanarito virus;
    - 16           2. Junin virus,
    - 17           3. Machupo virus; and
    - 18           4. Sabia virus.
- 19           Section 6. Notifiable Infectious Conditions and Notifiable Non-Infectious
- 20 Conditions Requiring Priority Notification. Notification of the following diseases shall be
- 21 considered priority and shall be made within one (1) business day:
  - 22           (1) Arboviral diseases, neuroinvasive and non-neuroinvasive, including:
    - 23           (a) California serogroup virus diseases, including diseases caused by:

- 1        1. California encephalitis virus;
- 2        2. Jamestown Canyon virus;
- 3        3. Keystone virus;
- 4        4. La Crosse virus;
- 5        5. Snowshoe hare virus; and
- 6        6. Trivittatus viruses;
- 7        (b) Chikungunya virus disease;
- 8        (c) Eastern equine encephalitis virus disease;
- 9        (d) Powassan virus disease;
- 10       (e) St. Louis encephalitis virus disease;
- 11       (f) Venezuelan equine encephalitis disease;
- 12       (g) West Nile virus disease; and
- 13       (h) Western equine encephalitis virus disease;
- 14       (2) Brucellosis (cases not temporally or spatially clustered);
- 15       (3) Campylobacteriosis;
- 16       (4) Cholera;
- 17       (5) Cryptosporidiosis;
- 18       (6) Dengue virus infections;
- 19       (7) Escherichia coli O157:H7;
- 20       (8) Foodborne disease outbreak;
- 21       (9) Haemophilus influenzae invasive disease;
- 22       (10) Hansen's disease (leprosy);
- 23       (11) Hantavirus infections;

- 1        (12) Hemolytic uremic syndrome (HUS), post-diarrheal;
- 2        (13) Hepatitis B, acute;
- 3        (14) Hepatitis B infection in a pregnant woman;
- 4        (15) Hepatitis B, infection in an infant or a child aged five years or less;
- 5        (16) Newborns born to Hepatitis B positive mothers at the time of delivery;
- 6        (17) Influenza-associated mortality in a pregnant woman;
- 7        (18) Influenza-associated pediatric mortality;
- 8        (19) Listeriosis;
- 9        (20) Mumps;
- 10       (21) Norovirus outbreak;
- 11       (22) Pertussis;
- 12       (23) Pesticide-related illness, acute;
- 13       (24) Psittacosis;
- 14       (25) Q fever;
- 15       (26) Rabies post exposure prophylaxis;
- 16       (27) Rubella, congenital syndrome;
- 17       (28) Salmonellosis;
- 18       (29) Shiga toxin-producing E. coli (STEC);
- 19       (30) Shigellosis;
- 20       (31) Streptococcal toxic-shock syndrome;
- 21       (32) Streptococcus pneumoniae, invasive disease;
- 22       (33) Tetanus;
- 23       (34) Toxic-shock syndrome (other than Streptococcal);

- 1       (35) Tuberculosis;
- 2       (36) Typhoid fever;
- 3       (37) Varicella-associated mortality;
- 4       (38) Vibriosis; and
- 5       (39) Waterborne disease outbreak.

6       Section 7. Notifiable Infectious Conditions and Notifiable Non-Infectious  
7       Conditions Requiring Routine Notification. Notification of the following diseases shall be  
8       considered routine and shall be made within five (5) business days:

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

1           (16) Trichinellosis (Trichinosis).

2           Section 8. Notifiable Infectious Conditions Requiring Routine Notification by  
3 Electronic Laboratory Reporting.

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

8           (a) Cyclosporiasis;

9           (b) Giardiasis;

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

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

12          and

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

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

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

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

17          or

18           4. A significant rise in serum anti-varicella immunoglobulin G (IgG) antibody level  
19 by a standard serologic assay.

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

21          Section 9. Multi-Drug Resistant Organisms and Other Organisms Requiring  
22 Routine Notification by Electronic Laboratory Reporting.

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

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

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

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

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

21 (e) Clostridium difficile (C. difficile) identified from a positive laboratory test result  
22 for a C. difficile toxin A or B, (includes molecular assays [PCR] or toxin assays) or a

1 toxin-producing organism detected by culture or other laboratory means performed on a  
2 stool sample;

3 (f) Carbapenem-resistant Enterobacteriaceae (CRE) or any Enterobacteriaceae  
4 species testing non-susceptible (resistant or intermediate) to imipenem, meropenem, or  
5 doripenem, by standard susceptibility testing methods and resistant to all third-  
6 generation cephalosporins tested;

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

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

13 1. Ampicillin-sulbactam;

14 2. Cephalosporins (cefepime, ceftazidime);

15 3.  $\beta$ -lactam- $\beta$ -lactamase inhibitor combination (piperacillin, piperacillin-  
16 tazobactam);

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

18 5. Fluoroquinolones (ciprofloxacin or levofloxacin);

19 6. Aminoglycosides (gentamicin, tobramycin, or amikacin);

20 (i) Multidrug-resistant Pseudomonas - Non-susceptibility, resistant or  
21 intermediate, to at least one (1) agent in at least three (3) antimicrobial classes of the  
22 following five (5) classes:

23 1. Cephalosporins (cefepime, ceftazidime);

1           2.  $\beta$ -lactam- $\beta$ -lactam  $\beta$ -lactamase inhibitor combination (piperacillin, piperacillin-  
2 tazobactam);

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

4           4. Fluoroquinolones (ciprofloxacin or levofloxacin);

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

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

7           (a) Date of specimen collection;

8           (b) Source of specimen;

9           (c) Susceptibility pattern; and

10          (d) Name of the ordering health professional.

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

16          (4) The report shall include a diagnosis.

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

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

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

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

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

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

7           (a) A newly-recognized infectious agent;

8           (b) An outbreak;

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

10          (d) An epidemic; or

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

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

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

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

17          (4) The local health department shall:

18          (a) Investigate the outbreak or occurrence;

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

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

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

3           Section 11. Laboratory Surveillance. (1) Medical or national reference laboratory  
4 results for the following shall be reported weekly:

5           (a) Influenza virus isolates;

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

7           (c) DNA molecular assays for influenza virus.

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

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

13           (a) Staphylococcus aureus;

14           (b) Enterococcus species; or

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

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

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

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

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

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

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

8           Section 13. Human Immunodeficiency Virus (HIV) and Acquired  
9 Immunodeficiency Syndrome (AIDS) Surveillance.

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

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

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

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

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

17           1. 3<sup>rd</sup> generation immunoassay;

18           2. 4<sup>th</sup> generation immunoassay;

19           3. Western Blot;

20           4. PCR;

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

22           6. HIV antigen;

23           7. HIV antibody;

1           8. CD4+ assay including absolute CD4+ cell counts and CD4+%;  
2           9. HIV Viral Load Assay including detectable and undetectable values; or  
3           10. A positive confirmatory serologic test result for HIV infection; or  
4           (b) A diagnosis of AIDS that meets the definition of AIDS established within the  
5 CDC guidelines.

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

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

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

- 14           (a) The patient's full name;
- 15           (b) The patient's complete address;
- 16           (c) Date of birth using the format MMDDYYYY;
- 17           (d) Gender;
- 18           (e) Race;
- 19           (f) Ethnicity;
- 20           (g) Risk factor as identified by CDC;
- 21           (h) County of residence;
- 22           (i) Name of provider and facility submitting report including contact information;
- 23           (j) Specimen collected;

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

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

3 (m) Results of viral load testing;

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

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

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

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

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

9 (b) Opportunistic infections diagnosed; and

10 (c) Date of onset of illness.

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

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

16 Section 14. Sexually Transmitted Disease (STD).

17 (1) A health professional or a health facility shall give notification if a probable  
18 diagnosis of an STD specified in subsection (4) or (7) of this section is made.

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

20 (a) Pregnancy status; and

21 (b) Clinical, epidemiologic, laboratory, and treatment information pertinent to the  
22 disease.

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

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

7 (a) Congenital syphilis; or

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

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

11 (a) Investigate the report;

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

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

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

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

22 (a) Chancroid;

23 (b) Chlamydia trachomatis infection;

1           (c) Gonorrhea;  
2           (d) Granuloma inguinale;  
3           (e) Lymphogranuloma venereum; or  
4           (f) Syphilis, other than primary, secondary, early latent or congenital.  
5           (8) Upon receipt of a report for a disease or condition specified in subsection (7)  
6 of this section, a local health department shall:

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

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

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

13           Section 15. Tuberculosis. (1) A pharmacist shall give notice if two (2) or more of  
14 the following medications used for the initial treatment of active tuberculosis are  
15 dispensed to an inpatient in a health facility or to an ambulatory patient in a health  
16 facility or a pharmacy:

17           (a) Rifampin or rifabutin;

18           (b) Isoniazid;

19           (c) Pyrazinamide; and

20           (d) Ethambutol.

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

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

3           (4) The report shall include:

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

5           (b) Names of the medications dispensed.

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

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

9           (a) Asbestosis;

10          (b) Coal worker's pneumoconiosis; or

11          (c) Silicosis.

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

14          (a) Name;

15          (b) Address;

16          (c) Date of birth; and

17          (d) County of residence.

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

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

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

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

6           (a) Investigate the report;

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

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

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

13           Section 18. Kentucky Department for Public Health Advisory.

14           (1) If the Secretary of the Cabinet for Health and Family Services or the  
15 Commissioner of the Department for Public Health determines that a disease not  
16 presently listed in this administrative regulation requires reporting, the secretary or  
17 commissioner may issue a Kentucky Public Health Advisory.

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

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

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

21           (c) Names for the disease or condition;

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

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

2 and

3 (f) Notification requirements including:

4 1. The notification time interval;

5 2. Methods for notification; and

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

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

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

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

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

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

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

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

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

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

1           ~~[Notification Standards. (1) A health professional licensed under KRS Chapters~~  
2 ~~311 through 314, and a health facility licensed under KRS Chapter 216B, shall give~~  
3 ~~notification pursuant to subsection (3) of this section, if:~~

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

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

7           ~~—1. "Case Definitions for Infectious Conditions under Public Health Surveillance"; or~~  
8           ~~—2. A reasonable belief that the disease is present.~~

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

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

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

15           ~~—(a) Local health department serving the jurisdiction in which the patient resides; or~~  
16           ~~—(b) Department for Public Health.~~

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

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

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

21           ~~—(5) Upon the confirmation of a laboratory test result which indicates infection with an~~  
22 ~~agent associated with one (1) or more of the diseases or conditions specified in Section~~

1 ~~2, 3, or 4 of this administrative regulation, the director of a clinical laboratory licensed~~  
2 ~~under KRS Chapter 333 shall:~~

3 ~~—(a) Report the result to the:~~

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

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

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

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

10 ~~—(a) Anthrax;~~

11 ~~—(b) Botulism;~~

12 ~~—(c) Brucellosis;~~

13 ~~—(d) Campylobacteriosis;~~

14 ~~—(e) Cryptosporidiosis;~~

15 ~~—(f) Cholera;~~

16 ~~—(g) Diphtheria;~~

17 ~~—(h) Escherichia coli O157:H7;~~

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

19 ~~—(j) Encephalitis, California group;~~

20 ~~—(k) Encephalitis, Eastern equine;~~

21 ~~—(l) Encephalitis, St. Louis;~~

22 ~~—(m) Encephalitis, Venezuelan equine;~~

23 ~~—(n) Encephalitis, Western;~~

- 1 —(o) Encephalitis, West Nile Virus;
- 2 —(p) Hansen's Disease;
- 3 —(q) Hantavirus infection;
- 4 —(r) Hemophilus influenzae invasive disease;
- 5 —(s) Hepatitis A;
- 6 —(t) Listeriosis;
- 7 —(u) Measles;
- 8 —(v) Meningococcal infections;
- 9 —(w) Pertussis;
- 10 —(x) Plague;
- 11 —(y) Poliomyelitis;
- 12 —(z) Psittacosis;
- 13 —(aa) Q fever;
- 14 —(bb) Rabies, animal;
- 15 —(cc) Rabies, human;
- 16 —(dd) Rubella;
- 17 —(ee) Rubella syndrome, congenital;
- 18 —(ff) Salmonellosis;
- 19 —(gg) Shigellosis;
- 20 —(hh) Syphilis, primary, secondary, early latent or congenital;
- 21 —(ii) Tetanus;
- 22 —(jj) Tularemia;
- 23 —(kk) Typhoid fever;

- 1    ~~—(ll) Vibrio parahaemolyticus;~~
- 2    ~~—(mm) Vibrio vulnificus;~~
- 3    ~~—(nn) Yellow fever.~~
- 4    ~~—(2) Weekend or evening urgent notification.~~
- 5    ~~—(a) If health department personnel cannot be contacted directly, notification shall be~~  
6 ~~made by electronic submission or by telephone to an emergency number provided by~~  
7 ~~the local health department or the Department for Public Health.~~
- 8    ~~—(b) For the protection of patient confidentiality, this notification shall include:~~
- 9    ~~—1. The name of the condition being reported; and~~
- 10   ~~—2. A telephone number that can be used by the department to contact the reporting~~  
11 ~~professional.~~
- 12   ~~—(3) Upon receipt of a report for a disease specified in subsection (1) of this section,~~  
13 ~~the local health department shall:~~
- 14   ~~—(a) Immediately notify the Department for Public Health; and~~
- 15   ~~—(b) Assist the department in carrying out a public health response as instructed.~~
- 16   ~~—Section 3. Diseases Requiring Priority Notification. (1) Notification pursuant to~~  
17 ~~Section 1(3) of this administrative regulation of the following diseases shall be made~~  
18 ~~within one (1) business day:~~
- 19   ~~—(a) Group A streptococcal infection, invasive;~~
- 20   ~~—(b) Hepatitis B, acute;~~
- 21   ~~—(c) Hepatitis B infection in a pregnant woman or a child born in or after 1992;~~
- 22   ~~—(d) Mumps;~~
- 23   ~~—(e) Toxic shock syndrome;~~

- 1    ~~—(f) Tuberculosis.~~
- 2    ~~—(2) Upon receipt of a report for a disease or condition specified in subsection (1) of~~  
3    ~~this section, a local health department:~~
- 4    ~~—(a) Shall investigate the report and carry out public health measures appropriate to~~  
5    ~~the disease or condition;~~
- 6    ~~—(b) Shall notify the Department for Public Health of the case, in writing, within five (5)~~  
7    ~~business days; and~~
- 8    ~~—(c) May seek assistance from the Department for Public Health.~~
- 9    ~~—Section 4. Diseases Requiring Routine Notification. (1) Notification pursuant to~~  
10   ~~Section 1(3) of this administrative regulation of the following diseases shall be made~~  
11   ~~within five (5) business days:~~
- 12   ~~—(a) Chancroid;~~
- 13   ~~—(b) Chlamydia trachomatis infection;~~
- 14   ~~—(c) Ehrlichiosis;~~
- 15   ~~—(d) Gonorrhea;~~
- 16   ~~—(e) Granuloma inguinale;~~
- 17   ~~—(f) Hepatitis C, acute;~~
- 18   ~~—(g) Histoplasmosis;~~
- 19   ~~—(h) Lead poisoning;~~
- 20   ~~—(i) Legionellosis;~~
- 21   ~~—(j) Lyme Disease;~~
- 22   ~~—(k) Lymphogranuloma venereum;~~
- 23   ~~—(l) Malaria;~~

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

1 ~~within one (1) business day, and shall include all known information about the persons~~  
2 ~~affected.~~

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

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

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

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

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

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

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

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

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

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

19 ~~—(2) Upon request by the Department for Public Health, a clinical laboratory within a~~  
20 ~~hospital licensed under KRS Chapter 216B, or a laboratory licensed under KRS Chapter~~  
21 ~~333, shall report:~~

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

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

3 ~~— 1. Staphylococcus aureus;~~  
4 ~~— 2. Enterococcus species; or~~  
5 ~~— 3. Other organism specified in a request that includes a justification of the public~~  
6 ~~health importance of the organism.~~

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

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

10 ~~— a. Elisa;~~  
11 ~~— b. Western Blot;~~  
12 ~~— c. PCR;~~  
13 ~~— d. HIV antigen; or~~  
14 ~~— e. HIV culture;~~

15 ~~— 2. CD4+ assay including absolute CD4+ cell counts and CD4+%;~~  
16 ~~— 3. HIV detectable Viral Load Assay; and~~  
17 ~~— 4. A positive serologic test result for HIV infection; or~~

18 ~~— (b) A diagnosis of AIDS that meets the definition of AIDS established within the~~  
19 ~~Centers for Disease Control and Prevention (CDC) guidelines and reported in the:~~

20 ~~— 1. "Adult HIV/AIDS Confidential Case Report Form," or~~  
21 ~~— 2. "Pediatric HIV/AIDS Confidential Case Report Form."~~

1 ~~— (2) An HIV infection or AIDS diagnosis shall be reported within five (5) business~~  
2 ~~days and, if possible, on the "Adult HIV/AIDS Confidential Case Report form" or the~~  
3 ~~"Pediatric HIV/AIDS Confidential Case Report form."~~

4 ~~— (a) A report for a resident of Jefferson, Henry, Oldham, Bullitt, Shelby, Spencer, and~~  
5 ~~Trimble Counties shall be submitted to the HIV/AIDS Surveillance Program of the~~  
6 ~~Louisville-Metro Health Department.~~

7 ~~— (b) A report for a resident of the remaining Kentucky counties shall be submitted to~~  
8 ~~the HIV/AIDS Surveillance Program of the Kentucky Department for Public Health, or as~~  
9 ~~directed by the HIV/AIDS project coordinator.~~

10 ~~— (3) A report for a person with HIV infection without a diagnosis of AIDS shall include~~  
11 ~~the following information:~~

12 ~~— (a) The patient's full name;~~

13 ~~— (b) Date of birth, using the format MMDDYY;~~

14 ~~— (c) Gender;~~

15 ~~— (d) Race;~~

16 ~~— (e) Risk factor, as identified by CDC;~~

17 ~~— (f) County of residence;~~

18 ~~— (g) Name of facility submitting report;~~

19 ~~— (h) Date and type of HIV test performed;~~

20 ~~— (i) Results of CD4+ cell counts and CD4+%;~~

21 ~~— (j) Results of viral load testing;~~

22 ~~— (k) PCR, HIV culture, HIV antigen, if performed;~~

23 ~~— (l) Results of TB testing, if available; and~~

1     ~~—(m) HIV status of the person's partner, spouse or children.~~

2     ~~—(4) Reports of AIDS cases shall include the information in subsections (1) through~~  
3     ~~(3) of this section; and~~

4     ~~—(a) The patient's complete address;~~

5     ~~—(b) Opportunistic infections diagnosed; and~~

6     ~~—(c) Date of onset of illness.~~

7     ~~—(5) (a) Reports of AIDS shall be made whether or not the patient has been~~  
8     ~~previously reported as having HIV infection.~~

9     ~~—(b) If the patient has not been previously reported as having HIV infection, the AIDS~~  
10    ~~report shall also serve as the report of HIV infection.~~

11    ~~—Section 8. Reporting of Communicable Diseases in Animals. (1) Upon arriving at a~~  
12    ~~probable diagnosis in an animal of a condition known to be communicable to humans, a~~  
13    ~~veterinarian licensed under the provisions of KRS Chapter 321 shall report the~~  
14    ~~occurrence within one (1) business day to:~~

15    ~~—(a) The local health department in which the animal is located; or~~

16    ~~—(b) If the local health department cannot be reached, the Department for Public~~  
17    ~~Health.~~

18    ~~—(2) Upon the confirmation of a laboratory test result which indicates infection of an~~  
19    ~~animal with an agent associated with a condition known to be communicable to~~  
20    ~~humans, the director of a clinical laboratory licensed under KRS Chapter 333 shall,~~  
21    ~~within one (1) business day, report the result to the:~~

22    ~~—(a) Local health department serving the jurisdiction in which the animal is located; or~~  
23    ~~—(b) Department for Public Health.~~

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

2    ~~—(a) Shall investigate the report and carry out public measures for the control of~~

3    ~~communicable diseases appropriate to the condition;~~

4    ~~—(b) Shall notify the Department for Public Health of the occurrence, in writing, within~~

5    ~~five (5) business days; and~~

6    ~~—(c) May seek assistance from the Department for Public Health.~~

7    ~~—Section 9. Asbestosis, Coal Worker's Pneumoconiosis, and Silicosis. (1) A reporting~~

8    ~~provider shall submit the following information relating to a person diagnosed with~~

9    ~~asbestosis, coal worker's pneumoconiosis, or silicosis:~~

10   ~~—(a) Name;~~

11   ~~—(b) Address;~~

12   ~~—(c) Birthdate; and~~

13   ~~—(d) County of residence.~~

14   ~~—(2) A reporting provider shall submit the required information to the department~~

15   ~~within three (3) months following the diagnosis.~~

16   ~~—Section 10. Incorporation by Reference. (1) The following material is incorporated by~~

17   ~~reference:~~

18   ~~—(a) "Case Definitions for Infectious Conditions under Public Health Surveillance,~~

19   ~~MMWR, May 2, 1997, Volume 46, Number RR-10", published by the Epidemiology~~

20   ~~Program Office, Centers for Disease Control and Prevention, Public Health Service,~~

21   ~~U.S. Department of Health and Human Services, Atlanta, Georgia;~~

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

23   ~~2003)"; and~~

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

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

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

1 902 KAR 2:020

Reviewed:

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Stephanie Mayfield Gibson, MD, FCAP                      Date  
Commissioner Department for Public Health

APPROVED

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

## PUBLIC HEARING AND PUBLIC COMMENT PERIOD:

A public hearing on this administrative regulation shall, if requested, be held on, November 21, 2014, at 9:00 a.m. in the Health Services Auditorium, Health Services Building, First Floor, 275 East Main Street, Frankfort, Kentucky. Individuals interested in attending this hearing shall notify this agency in writing by November 14, 2014, five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. The hearing is open to the public. Any person who attends will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to attend the public hearing, you may submit written comments on the proposed administrative regulation. You may submit written comments regarding this proposed administrative regulation until close of business on December 1, 2014. Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to:

CONTACT PERSON: Tricia Orme, Office of Legal Services, 275 East Main Street 5 W-B, Frankfort, KY 40601, Phone: 502-564-7905, Fax: 502-564-7573, [Tricia.Orme@ky.gov](mailto:Tricia.Orme@ky.gov).

## 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 amendment outlines which diseases are to be reported and how, including electronic reporting through the Kentucky Health Information Exchange. This amendment updates the prior regulation to allow for newly discovered organisms, diseases and viruses. The amendment also outlines a process whereby the Kentucky Department for Public Health can access data already being submitted electronically by hospitals and healthcare facilities so public health concerns can be more easily recognized and addressed.

(b) The necessity of the amendment to this administrative regulation: This amendment is necessary due to the ever changing state of diseases and their impact on the health of the community. Further, the implementation of the Kentucky Health Information Exchange allows data to be shared among reporting facilities, the CDC, and the

Kentucky Department for Public Health. This amendment guides the sharing of this data.

(c) How the amendment conforms to the content of the authorizing statutes: This amendment makes specific what diseases are to be reported and how, therefore helping to clarify what is required by the statute.

(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 the diseases to be reported and how they are to be reported. Because the regulation had not been amended in many years, several diseases, organisms, and materials of grave concern for the health of the public were not included in the current reporting requirements.

(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: Kentucky hospitals and healthcare facilities will be required to permit the Department for Public Health access to data they are reporting to the federal government. However, since they are currently reporting these diseases to the federal government, there will be no extra work or expense incurred by the hospitals or facilities. Hospitals and healthcare facilities are already working to connect with the Kentucky Health Information Exchange and will use that as the tool for sharing data with federal and state officials. A phase-in period has been provided in this amended regulation to allow hospitals and healthcare facilities time to implement electronic reporting, which is not required until October of 2016. Kentucky physicians will experience minimal change in reporting requirements as they are currently required to report diseases on a federal and state level. There will be new modes of reporting with which the physicians must become familiar. However, education/training will be provided by state staff and regional epidemiologists to assist with the reporting.

Because laboratories are currently required to report diseases on the state and federal level, they will experience minimal change in required action. Local health departments will see no change in their duties under this regulation as they are currently receiving disease reports and working with the cabinet to investigate risks to the public health.

A Kentucky citizen exposed or potentially exposed to reportable diseases is, at present, required to report this exposure to the local health department in the county in which he resides. This has not been changed under the amendment to the regulation.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): There is no additional fiscal impact resulting from this amendment as hospitals, health professionals, and healthcare facilities currently report this information to the CDC.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): Local health departments, the cabinet, health professionals, and healthcare facilities will have a better opportunity to cooperate to identify dangerous diseases and their infection patterns and identify possible large-scale threats. Working together will afford more protections for Kentuckians who will benefit as health officials are better able to identify dangerous disease patterns and outbreaks and address those as quickly as possible.

(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? No, tiering was not applied.

## 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:

COMMONWEALTH OF KENTUCKY  
CABINET FOR HEALTH AND FAMILY SERVICES  
DEPARTMENT FOR PUBLIC HEALTH

902 KAR 2:020

Summary of Material Incorporated by Reference

1. "EPID 200, Kentucky Reportable Disease Form", 9/2014 is used to report communicable diseases to the Kentucky Department for Public Health. This form contains 2 pages.
2. "EPID 250, Kentucky Reportable MDRO Form", 6/2014 is used to report multi-drug resistant organisms to the Kentucky Department for Public Health. This form contains 1 page.
3. "EPID 394, Kentucky Reportable Disease Form, Hepatitis Infection in Pregnant Women or Child (under the age of five)", 11/2013 is used to report perinatal hepatitis B and C to the Kentucky Department for Public Health. This form contains 1 page.
4. "EPID 399, Perinatal Hepatitis B Prevention Form for Infants", 4/2012 is used to report and identify needed prevention for hepatitis B for babies of pregnant women. This form contains 1 page.
5. "Adult HIV Confidential Case Report Form", 3/2013 is used to report HIV in adults to the Kentucky Department for Public Health. This form contains 4 pages.
6. "Pediatric HIV Confidential Case Report Form", 3/2013 is used to report HIV in pediatric cases for children from birth to age 17 years old. This form contains 4 pages.

There are a total of 13 pages incorporated by reference in this administrative regulation.

# Diabetes and Hepatitis B Vaccination

## Information for Diabetes Educators



### What is hepatitis B?

Hepatitis B is a contagious liver disease that results from infection with the hepatitis B virus.

When first infected, a person can develop an “acute” infection, which can range in severity from a very mild illness with few or no symptoms to a serious condition requiring hospitalization. **Acute** hepatitis B refers to the first 6 months after someone is infected with the hepatitis B virus. Some people are able to fight the virus and clear the infection. For others, the infection remains and leads to a “chronic,” or lifelong, illness. **Chronic** hepatitis B refers to the illness that occurs when the hepatitis B virus remains in a person’s body. Over time, the infection can cause serious damage to the liver and lead to complications such as liver failure or liver cancer.

### How is hepatitis B spread?

The hepatitis B virus is usually spread when blood or other body fluids from a person infected with the hepatitis B virus enters the body of someone who is not infected. Hepatitis B can be spread through sharing needles, syringes, or other injection equipment. In addition, the hepatitis B virus can spread through sexual contact and from an infected mother to her baby during childbirth.

### Why is hepatitis B relevant to people with diabetes?

Among people living with diabetes, the hepatitis B virus has been spread through contact with infectious blood. People living with diabetes are at increased risk for hepatitis B if they share blood glucose meters, fingerstick devices or other diabetes-care equipment such as syringes or insulin pens.

### How infectious is the hepatitis B virus?

The hepatitis B virus is 50 – 100 times more infectious than HIV which makes it easily transmitted.

The hepatitis B virus can survive outside the body at least a week. During that time, the virus can still cause infection if it enters the body of a person who is not infected.

### How has transmission occurred in healthcare facilities?

CDC has investigated numerous hepatitis B outbreaks in people with diabetes in assisted living, long-term care facilities and nursing homes. Modes of transmission are believed to have occurred from:

- Use of blood glucose meter for more than one resident without cleaning and disinfection between uses
- Failure to consistently wear gloves and perform hand hygiene between fingerstick procedures
- Use of the same fingerstick devices for more than one resident
- Cross-contamination of clean supplies with contaminated blood glucose monitoring equipment used by home health agencies
- Use of the same injection equipment such as a syringe or insulin pen for more than one person
- Failure to maintain separation of clean and contaminated podiatry equipment
- Improper sterilization of contaminated podiatry equipment
- Failure to perform environmental cleaning and disinfection between podiatry patients



## Why should people with diabetes be vaccinated?

People living with type 1 or type 2 diabetes mellitus have higher rates of hepatitis B than the general population. Some of the cases of hepatitis B have occurred in individuals with diabetes whose equipment came in contact with infected blood, or who had contact with the virus through breaks in the skin. This has happened through improper reuse and sharing of glucose monitoring equipment or other diabetes care equipment. Transmission has occurred among people with diabetes who reside in assisted living facilities when several people received glucose monitoring in close succession.

CDC now recommends the hepatitis B vaccine for adults with diabetes.

## What is the recommendation for vaccinating adults younger than 60 years of age?

In 2011, the Centers for Disease Control and Prevention and the Advisory Committee on Immunization Practices (ACIP) released new guidelines that recommend hepatitis B vaccination for all unvaccinated adults with diabetes who are younger than 60 years of age. Vaccination should occur as soon as possible after diagnosis of diabetes; vaccination should also be given to adults diagnosed with diabetes in the past.

## What is the recommendation for vaccinating adults 60 years and older?

For unvaccinated adults with diabetes who are 60 years and older, the ACIP recommends hepatitis B vaccination at the discretion of their health care provider. As with other vaccines, the effectiveness of the hepatitis B vaccine decreases with age. Decisions to vaccinate should include the patient's likelihood of acquiring hepatitis B, including the need for assisted blood-glucose monitoring, and overall health status. Hepatitis B vaccination may provide partial, if not full protection for many older adults with diabetes.

## What is the recommendation for vaccinating children living with diabetes?

In the United States, the hepatitis B vaccine is now part of the routine childhood vaccination schedule. In 1991, CDC and the ACIP recommended that all children and adolescents be vaccinated for hepatitis B. Estimates of vaccine coverage among infants and children are now over 90%.

## What should diabetes educators tell their patients about hepatitis B?

Diabetes educators should provide their clients or patients with the following information on how to protect themselves from getting the hepatitis B virus:

- Prevent exposure to hepatitis B and other blood borne pathogens by not sharing equipment such as blood glucose monitors or other diabetes care equipment.
- The best way to prevent hepatitis B is by getting vaccinated. CDC recommends hepatitis B vaccination for all unvaccinated adults with diabetes younger than 60 years of age.
- If you think you have already been vaccinated, confirm with your doctor.
- The hepatitis B vaccine is given as a series of 3 shots over a period of 6 months (0, 1, 6 month schedule). The entire series is needed for long-term protection.
- If you have not received the hepatitis B vaccine series talk to your doctor about getting vaccinated.

## For more information visit:

- **Diabetes:** <http://www.cdc.gov/diabetes/>
- **Viral Hepatitis:** <http://www.cdc.gov/hepatitis/>
- **CDC's hepatitis B vaccination recommendation for adults with diabetes mellitus is available at** <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6050a4.htm>

# HEPATITIS B VACCINATION IN DIABETES CARE:

Awareness, Priorities and Action  
among Diabetes Educators  
and Adults with Diabetes

A Report by the American Association  
of Diabetes Educators and GSK



## I. Overview

The hepatitis B virus (HBV) remains a public health concern globally. The infectious virus can lead to serious disease, including liver cancer and cirrhosis and can even lead to death.<sup>1A, 2A, 2B</sup> Despite a declining incidence from 2000 to 2011, there are still thousands of new cases of HBV in the U.S. annually.<sup>3A</sup> According to the Centers for Disease Control and Prevention (CDC), there were an estimated 18,000 new HBV infections in the U.S. in 2012,<sup>3A, 3B</sup> with as many as 1.4 million people infected with the virus.<sup>4A</sup>

For the 29.1 million Americans living with diabetes,<sup>5A</sup> there is a higher rate of HBV compared to the general population.<sup>1B</sup> It is also believed that acute HBV infection progresses to chronic infection more often among older persons with diabetes compared to those without diabetes,<sup>2C</sup> and there is some evidence that diabetes imparts a higher HBV case fatality rate.<sup>2D</sup>

## Recommendations for HBV Vaccination in People with Diabetes

The CDC and the Advisory Committee on Immunization Practices (ACIP) issued recommendations for HBV vaccination in people with diabetes after considering evidence that HBV outbreaks among people with diabetes in healthcare facilities are related to assisted glucose monitoring.<sup>2E</sup> Additional factors that informed the recommendations include results of blood tests from a national survey that found people 18 years and older with diabetes are at higher risk of exposure to HBV,<sup>2F, 2G</sup> diabetes as a risk factor among those with acute HBV,<sup>6A</sup> and an increased risk of nonalcoholic chronic liver disease in people with diabetes.<sup>7A</sup>

The CDC recommends vaccination for:

- Adults with diabetes 19 through 59 years as soon as feasible after diagnosis.<sup>2H, 2I</sup>
- Adults with diabetes aged 60 years or older at the discretion of the treating healthcare provider based on the likelihood of acquiring hepatitis B infection,<sup>2H</sup> including:
  - o Risk associated with increased need for assisted blood glucose monitoring in long-term care facilities.<sup>2J</sup>
  - o Likelihood of experiencing complications or chronic sequelae from hepatitis B infection.<sup>2J</sup>
  - o Likelihood of immune response to vaccination.<sup>2J</sup>

According to the CDC, HBV vaccination may provide partial, if not full, protection for many older adults with diabetes.<sup>1C</sup>

### What is the ACIP?

The ACIP is a group of medical and public health experts who develop recommendations on how to use vaccines to control diseases in the U.S.<sup>8A</sup> The ACIP holds meetings each year at the CDC in Atlanta to make vaccine recommendations. The ACIP's recommendations are forwarded to the CDC's Director for approval. Once the ACIP's recommendations have been approved by the CDC Director, they are published in the CDC's "Morbidity and Mortality Weekly Report (MMWR)" and represent the official CDC recommendations for immunizations in the U.S.<sup>8B</sup>

Despite these recommendations, less than one-third (28.6 percent) of adults age 19 - 59 with diabetes in the U.S. have been vaccinated against HBV.<sup>9A</sup> This low vaccination rate brings to light an unmet need for increased awareness and education regarding the HBV vaccine among adults with diabetes and providers.

The American Association of Diabetes Educators (AADE) is a multi-disciplinary professional membership organization with more than 14,000 professional members dedicated to improving diabetes care through education. AADE encourages HBV vaccination as a component of diabetes care.<sup>10A</sup>

## A Missed Opportunity

Following the CDC recommendations, AADE issued a position statement on vaccines, including the HBV vaccine, and conducted a webinar with the CDC on the topic. Despite these and other efforts, there has been little shift in HBV vaccination rates among people who have diabetes.

To understand this issue in greater depth and explore potential solutions, AADE and global healthcare company GSK commissioned an online survey of 1,000 AADE members. The goals of the survey were to determine: the level of awareness among diabetes educators of the CDC recommendations to vaccinate adults with diabetes; how diabetes educators typically inform their patients; and what level of awareness exists among AADE members' patients about vaccinations, and the HBV vaccination specifically.

The survey was conducted by Reckner, a national consumer opinion research company, for AADE and GSK. The survey was fielded between August 21 and September 2, 2014.

## II. What is Hepatitis B and How Can Vaccination Help Prevent It?

### Hepatitis B

Hepatitis B is a liver disease that results from infection with the hepatitis B virus.<sup>1D</sup> It is 50 to 100 times more infectious than HIV.<sup>1E</sup> HBV is transmitted by exposure to blood or other body fluids of an infected person through sharing needles, syringes or other injection equipment; through sexual contact; and from an infected mother to her baby during childbirth.<sup>1F</sup> The HBV virus can survive outside the body for at least a week, during which time it can still cause infection.<sup>1G</sup>

Symptoms can range from mild to severe, including abdominal pain, dark urine, fever, joint pain, loss of appetite, nausea and vomiting, weakness and fatigue, and jaundice.<sup>11A</sup>



### COMPLICATIONS OF HBV

When first infected, a person can develop an "acute" infection, which can range from a very mild illness with few or no symptoms to a serious condition requiring hospitalization.<sup>1H</sup> Some people are able to fight the virus and clear the infection, but for others, the infection leads to a "chronic" or lifelong illness.<sup>1H</sup> Chronic HBV infection is associated with high morbidity and mortality<sup>2A</sup> and may lead to cirrhosis and liver cancer.<sup>2B</sup>

### Vaccines Are Available

For most people, HBV vaccination consists of a series of three injections administered intramuscularly to create a protective antibody response.<sup>1I</sup> People with diabetes should talk to their healthcare provider about when and how to get vaccinated.<sup>1J</sup>

The first HBV vaccine became commercially available in the U.S. in 1982.<sup>12A</sup> For people in whom the vaccination series was started but not completed, the CDC recommends that they talk to their healthcare provider.<sup>13A</sup>



### MANY ADULTS MAY BE AT RISK

Routine HBV vaccination of children was implemented in 1991 per the CDC recommendations, starting with the first dose at birth and completion of the series of shots by age six months to 18 months. Therefore, those born before 1991 are less likely to have been vaccinated against HBV.<sup>12B, 14A</sup>

## People with Diabetes at Increased Risk

Recent evidence suggests that people with diabetes, ages 23-59 years, may have approximately a two-fold increased risk of HBV infection compared to those without diabetes.<sup>6B</sup>

### MODES OF TRANSMISSION AMONG ADULTS WITH DIABETES

The CDC has investigated numerous HBV outbreaks in people with diabetes and found that the modes of transmission include:<sup>\*1K</sup>



Use of a blood glucose meter for more than one patient without cleaning and disinfection between uses.



Use of the same injection equipment, such as a syringe or insulin pen, for more than one person.



Failure to consistently wear gloves and perform hand hygiene between finger stick procedures.



Failure to maintain separation of clean and contaminated podiatry equipment.



Use of the same finger stick devices for more than one patient.



Improper sterilization of contaminated podiatry equipment.



Cross-contamination of clean supplies with contaminated blood glucose monitoring equipment used by home health agencies.



Failure to perform environmental cleaning and disinfection between podiatry patients.

\*Case reports from assisted living, long-term care facilities and nursing homes.

## The CDC Recommendations: Rationale and Driving Factors

The CDC considered the available evidence before making its HBV vaccination recommendations for people with diabetes. This evidence includes the fact that since 1996, a total of 29 outbreaks of HBV infection in one or multiple long-term care facilities, including nursing homes and assisted living facilities, were reported to the CDC; of these, 25 involved adults with diabetes receiving assisted blood glucose monitoring. These outbreaks prompted a Hepatitis Vaccines Work Group to evaluate the risk for HBV infection among all adults with diagnosed diabetes. Based on the Work Group findings, the CDC issued its recommendations in 2011.<sup>2E</sup>



### WHAT INFORMED THE CDC RECOMMENDATIONS?

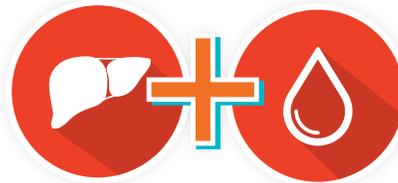
#### National Health and Nutrition Examination Survey (NHANES), 1999-2010:



**60%** MORE SERUM ANTIBODIES FOR HBV CORE ANTIGEN

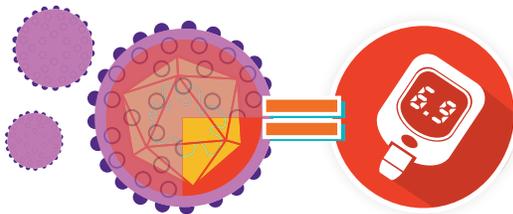
Adults with diabetes had a 60 percent higher prevalence of serum antibodies for HBV core antigen compared to those without diabetes.<sup>2F</sup>

#### Relationship between diabetes and chronic liver disease:



Diabetes is associated with increased underlying nonalcoholic fatty liver disease (NAFLD) compared to those without diabetes.<sup>7A</sup>

#### Virus characteristics:



HBV is highly infectious, can live on surfaces outside the body for up to a week,<sup>16</sup> and can be transmitted in minute amounts of blood, (e.g., on shared blood glucose monitoring devices).<sup>2G</sup>

#### Infection control lapses:



Infection control breaches related to blood glucose monitoring have been documented in long-term care facilities, hospitals, community health centers, ambulatory surgi-centers, private offices, homes and health fairs.<sup>2K</sup>

# SURVEY RESULTS

## III. Diabetes Educators See Patient Education / Awareness Gap

### Patient Awareness of Vaccines in General and HBV Risk

Our survey showed, despite the increased risk for HBV among people with diabetes, the recommendations from the CDC and education from third-party organizations (e.g., AADE), patient awareness remains low. Our survey found that diabetes educators recognize a lack of awareness and concern among their patients about recommended vaccinations in general, and HBV vaccination specifically:

- More than half (52 percent) of educators believe their patients do not understand the importance of recommended vaccinations in general.
- Fifty-four percent say their adult patients with diabetes are not aware that “as a person with diabetes, it is even more important that I get my vaccinations.”
- Only 29 percent say their patients are aware of the recommended vaccinations for them.

People with diabetes also remain unaware of their increased risk for HBV, according to diabetes educators.

- Just 18 percent of educators say that “my adult patients know that people with diabetes have an increased risk of HBV.”

### Patient Awareness of HBV Vaccine and the CDC Recommendations

- According to 52 percent of diabetes educators, their patients do not know that the CDC has recommendations for the HBV vaccine for people with diabetes.
- Only 15 percent say their patients know about the CDC’s recommendations regarding HBV vaccinations.
- Meanwhile, just 14 percent say that “my adult patients understand the importance of the HBV vaccine.”

This perceived lack of patient awareness suggests that people with diabetes may not be following through in getting the recommended vaccinations, including for HBV. According to diabetes educators, just 15 percent report that their adult patients get their vaccinations as recommended.

## IV. Diabetes Educator Priorities and Awareness

Our survey found that diabetes educators place greater importance on lifestyle and behavioral management compared to vaccines when working with their patients. When asked, “as a diabetes educator, what are your priorities for your patients with diabetes?”:

- Seventy-two percent say that setting goals and improving patient self-care habits are their priorities.
- Sixty-four percent cite providing tools and resources for diabetes management as their priority.
- Diet/exercise and regular doctor visits were each cited as priorities by 60 percent of educators.
- Just seven percent say that receiving the recommended vaccinations is a priority they have for their patients.

When asked which vaccinations they recommend to their adult patients, diabetes educators mentioned HBV least often, behind influenza, pneumococcal, zoster and diphtheria/tetanus/pertussis (DTaP). This is not surprising given that we also found educators to have low awareness of the CDC’s recommendations. When asked: “The CDC recommends the hepatitis B vaccination for which adults with diabetes?,” more than half (52 percent) say they do not know.

### Diabetes Educator Disconnect Between Priorities and Beliefs

We found a disconnect in that, per the survey, while diabetes educators place a lower priority on dedicating education session time to the HBV vaccine, the majority (79 percent) say they believe it is very important or important (34 percent and 45 percent, respectively) for adults with diabetes to be vaccinated against HBV. Given time limitations and the fact that there are so many other topics to cover with patients, vaccines, at the moment, may often have a tough time competing to be a priority in diabetes education. Thus, new ways of thinking about this issue and alternative solutions for engaging people with diabetes on this topic and moving them to take action are needed in order to change the paradigm surrounding vaccination.

### Where Do Diabetes Educators Turn for Information?

When seeking information and guidelines for vaccines, most diabetes educators turn to government agencies (69 percent) and professional organizations (67 percent). Just over 20 percent report that they are “very active” and 32 percent are “somewhat active” in seeking out and staying up to date on vaccines information and/or guidelines issued by government agencies and recognized healthcare authorities.

Here again we found a disconnect: more than half of diabetes educators are staying active in seeking vaccines information, yet they are not educating their patients about HBV vaccination. This anomaly points to the existing barriers in educating their patients about HBV vaccination and the limited time that educators spend with patients, which forces them to place greater priority on other issues.

## V. Barriers to Vaccines Education



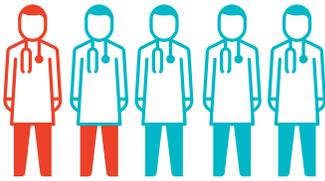
### DIABETES EDUCATORS FACE COMPETING PRIORITIES

When we looked at specific barriers to patient awareness about HBV vaccination, we found that:

**39%** PATIENT CARE

**23%** PRACTICE/CLINIC

When asked, "What are the barriers to your educating adult patients on the hepatitis B vaccination?," (33 percent) cited no barriers, while of the remaining 67 percent, the two most commonly cited barriers are the need to focus on other priorities in patient care (39 percent) and that the practice/clinic in which the diabetes educator works does not emphasize the HBV vaccine (23 percent).

**21%** 

More than one in five educators (21 percent) report that they lack the time to discuss the vaccine with their patients.

## VI. Call to Action: Increasing Awareness

Although the CDC recommendations were made three years ago, the barriers that diabetes educators face have largely remained the same. Thus, most educators have not made changes to the way in which they educate their patients about HBV: 74 percent say they have not changed their patient education efforts around HBV vaccination over the last three years, even though they agree that it is very or somewhat important (80 percent) for adult patients with diabetes to be educated about HBV.

### Recommendations for Raising Awareness and HBV Vaccination Rates

#### Diabetes Educator Recommendations

Due to the barriers previously noted, there needs to be increased awareness of the CDC recommendations among diabetes educators and people with diabetes. Further, individuals should be better informed about their risk for HBV and the available vaccination options.

Our survey shows that diabetes educators could be doing more to both inform people with diabetes about HBV and to encourage them to get vaccinated. So how can we turn the tide? We asked educators what they think would be the best ways to increase HBV vaccination rates and responses included:

- The overwhelming majority (85 percent) say doctors/prescribers should proactively discuss vaccinations with their patients.
- Sixty-eight percent believe it is important to have healthcare professionals other than doctors (e.g., diabetes educators, nurses and dietitians) proactively discuss vaccination with patients.
- A broad public service or other awareness campaign directed to adult patients with diabetes was cited by 51 percent of educators.

## AADE Recommendations

AADE believes that everyone in the diabetes community, including our members who are on the frontline with patients, is responsible for encouraging patients to stay up to date on recommended vaccinations, including HBV vaccination. For AADE, that starts with actively encouraging our members who say they currently do not educate their patients on the HBV vaccine (38 percent) to commit to providing vaccines education to patients. This includes identifying the best ways for diabetes educators to highlight vaccinations during patient visits.

AADE is committed to exploring a variety of strategies, including:

### Stakeholder Outreach

- Connect with fellow members of the diabetes community and other healthcare groups to explore joint initiatives to increase vaccination rates among people with diabetes.
- Provide guidance to other immunization-focused stakeholders on how to communicate to people with diabetes.
- Convene focus groups with people who have diabetes. Gain insight into why they don't, in general, get vaccinated, and what would motivate them to change this behavior.

## Awareness Building and Resource Creation

- Reinforce the CDC adult vaccination recommendations and AADE's practice documents on vaccinations through a variety of AADE communication vehicles.
- Create and distribute provider tools and patient take-home materials. As noted in the report, diabetes educators have a wide variety of topics they must cover within a limited time. Giving providers a tool such as a vaccines checklist would encourage them to cover the topic. And, providing patients with easy-to-digest take-home materials would allow diabetes educators to cover the importance of vaccines and be able to reinforce that message after the education session.
- Include immunization status and guidance in the 2015 update of AADE's Curriculum for Diabetes Education.

All of the strategies above would take into account recommendations from the National Vaccine Advisory Committee (NVAC). In their March/April 2014 report, "[Recommendations from the National Vaccine Advisory Committee: Standards for Adult Immunization Practice](#)," the NVAC outlines the roles and standards for immunizing and non-immunizing providers, public health departments and professional healthcare-related associations/organizations regarding routine vaccinations for adults in the U.S.<sup>15A</sup>

## The following recommendations from the NVAC continue to inform AADE's thinking about ways to increase HBV vaccination rates among people with diabetes:

### Standards for Non-immunizing Providers:<sup>15B</sup>

A healthcare provider's recommendation and offer of vaccine during the same visit is one of the most important predictors of vaccination receipt among adults. There needs to be increased emphasis on the role of all providers, including non-immunizing providers, to assess immunization status and recommend needed vaccines, and this should be included in clinical training programs. The NVAC's standards for non-immunizing providers include:

- Routinely assess the immunization status of patients.
- Strongly recommend needed vaccine(s).
- Establish referral relationships with immunizing providers and refer patients to these providers.
- Follow up to confirm that patients have received the recommended vaccine(s) and encourage the vaccine provider to document vaccination in the patient's medical record.

### Standards for Professional Healthcare-Related Associations/Organizations:<sup>15C</sup>

- Provide immunization education and training of members, including trainees.
- Provide resources and assistance to implement protocols and other systems that incorporate vaccine needs assessment and vaccination or referral into routine practice.
- Encourage members to be up to date on their own immunizations.
- Assist members in staying up to date on immunization information and recommendations.
- Partner with other immunization stakeholders to educate the public.
- Seek out collaboration opportunities with other immunization stakeholders.
- Collect and share best practices for immunization.
- Advocate policies that support adult immunization standards.

## VII. Conclusion

Three years after the CDC issued its recommendations, less than one-third of American adults with diabetes have been vaccinated,<sup>9A</sup> despite the increased risk of HBV in this population. Diabetes educators perceive that patient awareness about the importance of the vaccine is low, but as our survey shows, educators are finding it challenging to engage their patients with diabetes in dialogue about HBV.

Barriers, including lack of time and competing priorities, force diabetes educators to make decisions about what they will discuss with patients in the limited time they spend with each patient. However, given their one-on-one and group interactions with patients, educators are a crucial starting point to help move the needle by emphasizing the importance of HBV vaccination.

With the benefit of key public health stakeholders already emphasizing the importance of adult vaccination, and the defined population of people with diabetes, we have the opportunity to change the paradigm around HBV education. This means making HBV vaccination a topic of conversation between patients with diabetes and their healthcare team. It means helping those who say they do not educate their patients with diabetes on the HBV vaccine to commit to taking steps to inform their patients with diabetes about the need for vaccinations. And it means exploring ways to highlight vaccinations during patient visits. To that end, AADE is issuing a call to action that employs strategies including: stakeholder outreach by connecting with fellow members of the diabetes community and other healthcare groups, providing guidance to other immunization- focused stakeholders, as well as convening focus groups with people who have diabetes; reinforcing the CDC adult vaccination recommendations and AADE's practice documents on vaccinations; creating and distributing provider tools and patient take-home materials; and including immunization status and guidance in the 2015 update of AADE's Curriculum for Diabetes Education.

Lowering the incidence of HBV in this at-risk population requires that HBV vaccination be a part of the standard of care for people with diabetes. A commitment among all players in the diabetes community to improve communication around HBV will help raise awareness and advance this effort for people with diabetes.

*GSK provided funding and editorial assistance for this program. The recommendations in this document are those of AADE.*

## References

1. CDC.gov. "Diabetes and Hepatitis B Vaccination." Available at: [http://www.cdc.gov/diabetes/pubs/pdf/hepb\\_vaccination.pdf](http://www.cdc.gov/diabetes/pubs/pdf/hepb_vaccination.pdf)
  - A. Page 1, Paragraph 2, Lines 6-7.
  - B. Page 2, Paragraph 1, Lines 1-2.
  - C. Page 2, Paragraph 3, Line 5.
  - D. Page 1, Paragraph 1, Lines 1-2
  - E. Page 1, Paragraph 5, Line 1.
  - F. Page 1, Paragraph 3, Lines 1-4.
  - G. Page 1, Paragraph 6, Lines 1-2.
  - H. Page 1, Paragraph 2, Lines 1-7.
  - I. Page 2, Paragraph 5, Lines 8-9
  - J. Page 2, Paragraph 5, Lines 10.
  - K. Page 1, Paragraph 7.
2. CDC.gov. "Use of hepatitis B vaccination for adults with diabetes mellitus: recommendations of the Advisory Committee on Immunization Practices (ACIP)." Available at: <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6050a4.htm>
  - A. Page 1, Paragraph 1, Lines 1-2.
  - B. Page 2, Paragraph 3, Lines 12-13.
  - C. Page 2, Paragraph 3, Lines 7-9.
  - D. Page 2, Paragraph 3, Lines 5-6.
  - E. Page 1, Paragraph 1, Lines 2-7.
  - F. Page 2, Paragraph 2, Lines 1- 5.
  - G. Page 4, Paragraph 1, Lines 1-4.
  - H. Page 3, Paragraph 5, Lines 3-7
  - I. Page 4, Paragraph 2, Lines 1-2
  - J. Page 4, Paragraph 4, Lines 1-6.
  - K. Page 2, Paragraph 5, Lines 7-10.
3. CDC.gov. "Viral hepatitis surveillance-United States, 2012." Available at: <http://www.cdc.gov/hepatitis/Statistics/2012Surveillance/Commentary.htm#hepB>
  - A. Page 13, Paragraph 3, Lines 1-3.
  - B. Page 2, Paragraph 1, Lines 6-7.
4. CDC.gov. "Surveillance For Viral Hepatitis - United States, 2012." Available at: <http://www.cdc.gov/hepatitis/statistics/2012surveillance/commentary.htm#techRef09>
  - A. Page 5, Paragraph 1, Lines 5-7.
5. CDC.gov. "National Diabetes Statistics Report, 2014." Available at: <http://www.cdc.gov/diabetes/pubs/statsreport14.htm>
  - A. Page 1, Paragraph 2, Line 1.
6. Reilly ML, Schillie SF, Smith E, et al. "Increased Risk of Acute Hepatitis B among Adults with Diagnosed Diabetes Mellitus." Available at: <http://dst.sagepub.com/content/6/4/858>
  - A. Page 9, Paragraph 2, Lines 1-2.
  - B. Page 1, Paragraph 3, Lines 4-5.
7. CDC.gov. "Transmission of Hepatitis C Virus through Transplanted Organs and Tissue-Kentucky and Massachusetts, 2011."
  - A. Page 14, Paragraph 2, Lines 1-5.
8. CDC.gov. "Advisory Committee on Immunization Practices." Available at: <http://www.cdc.gov/vaccines/acip/about.html>
  - A. Page 1, Left Column, Paragraph 1, Lines 1-3.
  - B. Page 1, Right Column, Paragraph 2 and 3.
9. CDC.gov. "Noninfluenza vaccination coverage among adults-United States, 2012." Available at: <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6305a4.htm>
  - A. Page 3, Paragraph 5, Lines 4-5.
10. American Association of Diabetes Educators. "Vaccination Practices for Hepatitis B, Influenza and Pneumococcal Disease for People with Diabetes." Available at: [http://www.diabeteseducator.org/export/sites/aade/\\_resources/pdf/research/Vaccination\\_Position\\_Statement\\_2012.pdf](http://www.diabeteseducator.org/export/sites/aade/_resources/pdf/research/Vaccination_Position_Statement_2012.pdf)
  - A. Page 2, Paragraph 3, Lines 9-10.
11. Mayo Clinic. "Hepatitis B Symptoms." Available at <http://www.mayoclinic.org/diseases-conditions/hepatitis-b/basics/symptoms/con-20022210>
  - A. Page 1, Paragraph 1, Lines 3-11.
12. CDC.gov. "Achievements in Public Health: Hepatitis B Vaccination-United States 1982- 2002." Available at: <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5125a3.htm>
  - A. Page 1, Paragraphs 3 and 7.
  - B. Page 2, Paragraph 4, Lines 1-3.
13. CDC.gov. "Hepatitis B FAQs for the Public." Available at: <http://www.cdc.gov/hepatitis/b/bfaq.htm>
  - A. Page 9, Paragraph 8, Lines 1-3.
14. CDC.gov. "Recommended immunization schedule for persons aged 0 through 18 years-United States, 2014." Available at: <http://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html>
  - A. Table 1
15. National Vaccine Advisory Committee. "Recommendations from the National Vaccine Advisory Committee: Standards for Adult Immunization Practice." Available at: <http://www.publichealthreports.org/issueopen.cfm?articleID=3145>
  - A. Page 1, Paragraph 1, Line 1.
  - B. Page 4, Figure 1, Lines 6-8.
  - C. Page 4, Figure 1, Lines 12-21.



# Kentucky Reportable Disease Form

**Department for Public Health  
Division of Epidemiology and Health Planning  
275 East Main St., Mailstop HS2E-A  
Frankfort, KY 40621-0001**

**Hepatitis Infection in Pregnant Women or Child (under the age of five)  
Fax Form to 502-696-3803**

**DEMOGRAPHIC DATA**

|                     |                   |  |       |   |                     |  |
|---------------------|-------------------|--|-------|---|---------------------|--|
| Patient's Last Name |                   | First  | M.I.  | Date of Birth   | Age                 | Gender<br><input type="checkbox"/> M <input type="checkbox"/> F <input type="checkbox"/> Unk |
| Address             |                   | City   | State | Zip   | County of Residence |  |
| Phone Number        | Patient ID Number | Ethnic Origin<br><input type="checkbox"/> His. <input type="checkbox"/> Non-His. |       | Race<br><input type="checkbox"/> W <input type="checkbox"/> B <input type="checkbox"/> A/PI <input type="checkbox"/> Am.Ind. <input type="checkbox"/> Other |                     |  |

**DISEASE INFORMATION**

|   |                                   |   |                           |
|---|-----------------------------------|---|---------------------------|
| Describe Clinical Symptoms:   | Date of Onset:<br>/ /             | Jaundice:<br><input type="checkbox"/> Yes <input type="checkbox"/> No | Date of Diagnosis:<br>/ / |
| Is Patient Pregnant? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, # wks _____ | Expected Date of Delivery:<br>/ / | Name of Hospital for Delivery:  |                           |
| Physician Provider Name:<br>Address:<br>Phone:  |                                   |   |                           |

**LABORATORY INFORMATION**

| Hepatitis Markers    | Results   | Date of test | Viral Load<br>*if applicable | Name of Laboratory |
|----------------------|---|--------------|------------------------------|--------------------|
| HBsAg                | <input type="checkbox"/> Pos <input type="checkbox"/> Neg | / /          |                              |                    |
| IgM anti-HBc         | <input type="checkbox"/> Pos <input type="checkbox"/> Neg | / /          |                              |                    |
| HBeAg                | <input type="checkbox"/> Pos <input type="checkbox"/> Neg | / /          |                              |                    |
| IgM anti-HAV         | <input type="checkbox"/> Pos <input type="checkbox"/> Neg | / /          |                              |                    |
| HCV Antibody         | <input type="checkbox"/> Pos <input type="checkbox"/> Neg | / /          |                              |                    |
| HCV RNA Confirmation | <input type="checkbox"/> Pos <input type="checkbox"/> Neg | / /          |                              |                    |

**SERUM AMINOTRANSFERASE LEVELS**

| Patient        | Reference | Date of test | Name of Laboratory |
|----------------|-----------|--------------|--------------------|
| AST (SGOT) U/L | U/L       | / /          |                    |
| ALT (SGPT) U/L | U/L       | / /          |                    |

|   |  |
|---|--|
| Mother: Hepatitis Risk Factors<br><input type="checkbox"/> IDU <input type="checkbox"/> Multiple Sexual Partners <input type="checkbox"/> Tattoos <input type="checkbox"/> STD<br><input type="checkbox"/> HIV <input type="checkbox"/> Foreign Born/ Country _____<br><input type="checkbox"/> Exposure to known HBV/HCV Pos contact   | Child: Hepatitis Risk Factors<br><input type="checkbox"/> Mother HBV Pos <input type="checkbox"/> Household member exposure HBV Pos<br><input type="checkbox"/> Mother HCV Pos <input type="checkbox"/> Household member exposure HCV Pos<br><input type="checkbox"/> Foreign Born / Country _____ |
| Mother: Hepatitis A vaccination history: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Refused Dates Given: / /<br>Hepatitis B Vaccination history: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Refused<br>If yes, how many doses <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 Year completed: / /    |  |
| Child: Hepatitis A vaccination history: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Refused Dates Given: / /<br>Hepatitis B Vaccination history: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Refused Dates Given: / /<br>Was PEP Infant of Positive HBV mother given at birth? <input type="checkbox"/> Yes <input type="checkbox"/> No |  |

