Happy Thanksgiving! This is a very exciting time in the world of hepatitis C. The first interferon- and ribavirin-free therapy for everyone with HCV genotype 1 was recently approved.

Inside our November 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
HEPATITIS IN KENTUCKY:
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 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.

HEPATITIS IN KENTUCKY: IN THE NEWS

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

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.
NASTAD Conference: October 2014

On October 20th thru 22nd, representatives from Kentucky were invited to attend and present at the National Alliance of State & Territorial AIDS Directors (NASTAD) National Viral Hepatitis Technical Assistant Meeting in Washington, DC.

NASTAD’s viral hepatitis program began in 2000 with a goal of providing guidance and technical assistance to Viral Hepatitis Prevention Coordinators (VHPC) and other health department staff to strengthen the capacity of state and local health departments to develop, maintain, and enhance comprehensive viral hepatitis programs.

Dr. Doug Crall, MD, Medical Services from the Kentucky Department of Corrections presented on “Hepatitis in Jail and Prisons in Kentucky”. In his presentation, Dr. Crall discussed the importance of health departments working with jails, prisons, and the court system to reach this important high risk population impacted by HCV.

Jennifer Hunter, RN, Director of Clinical Services and Joyce Rice, RN, Epidemiology Manager with the Northern Kentucky Independent District Health Department (NKIDHD) jointly presented on “Increasing HCV Screening and Confirmatory Testing”. During their presentations, they presented NKIDHD HCV surveillance data and discussed ways to increase HCV access, screening, confirmatory testing, and programs they have implemented for HCV in the Northern Kentucky district.

Pictured Above: Jennifer Hunter, Dr. Crall, Kathy Sanders, and Joyce Rice.
HCV: IN THE NEWS:

Uncovering cases of early HCV infection in HIV-positive men

Hepatitis C virus (HCV) infects the liver, causing inflammation. Over time as HCV-related inflammation continues, parts of this vital organ degrade as healthy tissue is replaced with useless scar tissue. This can lead to an increasingly dysfunctional liver. In turn, complications can develop, including serious infections, internal bleeding, kidney dysfunction, and a greatly increased risk for liver cancer.

Increasingly effective and tolerable therapies for HCV are being licensed in Canada and other high-income countries. The earlier HCV is detected, the easier it is to treat. This is one reason that regular testing for HCV is important. Another important reason is that once HCV infection is diagnosed, HCV-positive people can take steps not to spread this infection.

Among HIV-positive MSM

For more than a decade, an outbreak of hepatitis C virus has been occurring among men who have sex with men (MSM) in Western Europe, North America, and Australia. Most of these men are HIV positive and HCV appears to have been spread through sex.


Corbin, Ky. woman charged with hepatitis exposure

CORBIN, Ky. (AP) - A Corbin woman has been indicted on charges she intentionally exposed several people to hepatitis C at a hospital.

The Times-Tribune reports that 29-year-old Tiffany Myers faces charges including second-degree assault.

Police say Myers was arrested earlier this month after she forcefully removed an IV unit from her arm Aug. 5 at Knox County Hospital, knowing she suffers from hepatitis C.

Police say she purposefully slung her infected blood across the room, potentially exposing officers and medical personnel. One nurse reported having blood land in her eye.

Police say Myers also allegedly attempted to spit on law enforcement and medical staff while they tried to restrain her.

Myers is being held at the Clay County Detention Center. It was not immediately known if she had a lawyer.

St. Louis University to test sofosbuvir/ribavirin in pediatric HCV cases

Researchers at St. Louis University will begin study enrollment to test the safety and efficacy of sofosbuvir with ribavirin to treat hepatitis C virus infection in children, according to a news release.

In a multicenter clinical study, researcher Jeffrey Teckman, MD, professor of pediatrics at SLU, will analyze the combination of sofosbuvir (Sovaldi, Gilead Sciences) and ribavirin among children aged 3 to 17 years in an effort to cure the infection while limiting side effects.

Sofosbuvir and ribavirin already is being used to treat HCV infection in adults and has shown cure rates of 90% to 100%, according to the release.

“A lot of times studies for children don’t get approved,” Teckman said in the release. “The exciting part with our study is that the medication has already been tested in adults, and we are moving rapidly to test in children.”


HIV and Hepatitis C Risk in Pregnancy and Newborns

A major public health triumph for the pediatric community has been a significant decrease in transmission of HIV, the virus that causes AIDS, from pregnant women to the baby. This is especially important for prospective adoptive parents. The decrease in rates is due to the treatment of pregnant women who are HIV+ with antiviral drugs and the elective use of Caesarean section delivery for infected women. However, drug abuse continues to be a leading factor in placing an individual at risk for HIV infection, and those families who are fostering or adopting an infant whose mother has used drugs during pregnancy have to continue to be concerned about this issue.

Risk varies based on a number of factors. In a recent study of 1,106,757 pregnancies in 955,251 women from across the country, it was found that 2856 women (0.28 percent) were HIV positive. Importantly, there were significant variations in positive rates based on regions in the country. Pregnant women in Washington DC had an HIV positive rate of 5.8 percent, those in Maryland and New York had rates at about 0.9 percent, and all other states had a prevalence rate below 0.5 percent.

Mother To Child HCV Transmission Among Three Brothers: A Long-Term Follow-Up

Abstract
Three male children were born each 2 years apart by spontaneous delivery from a mother infected with hepatitis C virus (HCV) genotype 2b, and all have been followed up after birth. The viral load in the serum of the mother was high before their deliveries, and anti-HCV antibody immunoglobulin G, which is allowed to pass through placenta, was positive in the umbilical blood of all the children. Mother-to-child transmission of HCV was confirmed in the second son, who was positive for both anti-HCV antibody and serum HCV RNA when first examined 108 days after birth, but not in the other siblings. Persistent HCV genotype 2b infection with mild elevation of the serum alanine aminotransferase level has been established in the second son for more than 14 years. The interleukin 28B (IL28B) genotype (rs8099917) of the second son showed the TG heterozygote, which is unfavorable for viral clearance, and this may predict persistent HCV infection. Among the three brothers sharing the same delivery conditions with exposure to the same virus, as well as sharing the same environment after birth, HCV infection has not been consistent, and one of them possessing the TG genotype of the IL28B gene (rs8099917) has had chronic HCV infection. These cases suggest that maternal HCV transmission does not occur so often, even among multiple children who are exposed to the same HCV with a high viral load, and that this variation might be attributable to very minor events that can impact on viral exposure in the perinatal period.


People living with HIV in the US are infrequently screened for HCV

People living with HIV are infrequently screened for hepatitis C virus (HCV) infection, according to US research published in the online edition of Clinical Infectious Diseases. The retrospective study examined screening practices at seven primary care sites between 2000 and 2011. The frequency of testing increased, but practice varied considerably between sites, in some instances individuals with high-risk behaviors’ were infrequently tested for HCV.

“Screening for incidence HCV is variable across sites and improvement in frequency of screening is also variable, highlighting the need for US-based guidelines to inform HIV practice,” write the authors.

An editorial in the same issue of the journal stresses the importance of prompt HCV diagnosis in people living with HIV.

Many people living with HIV have a high risk of infection with hepatitis C virus. Injecting drug use is a recognized risk factor for the acquisition of the HCV and there is also an epidemic of sexually transmitted HCV among gay men living with HIV in some European and US cities.

HCV antibody testing may miss recent infections in gay men living with HIV

Nucleic acid testing should be used to diagnose acute hepatitis C virus (HCV) infections in gay men living with HIV, Dutch research published in the online edition of *Clinical Infectious Diseases* shows. HCV antibodies only developed a median of 74 days after infection with the virus. Over half of people who had a successful response to HCV therapy lost their HCV antibodies during follow-up. However, there was a high rate of re-infection, and these could be reliably diagnosed using antibody testing.

“Screening for acute HCV is...preferably performed using nucleic acid testing instead of anti-HCV testing,” write the authors.

Epidemics of sexually transmitted HCV have been observed among HIV-positive gay and other men who have sex with men (MSM) in several European and US cities. Routine HIV care for people at risk of HCV should include regular HCV screens, including testing for HCV RNA and HCV antibody testing.

But the utility of antibody testing – especially for the diagnosis of acute infections – is open to question. People with HCV mono-infection typically develop antibodies within 30-70 days of infection, but there have been reports of a delayed antibody response in people with HIV co-infection.


HCV tested in space

Crew members of the International Space Station are performing experiments on crystallized hepatitis C virus proteins in microgravity conditions to identify new targets for treatment, according to a news release.

Akram Amin Abdellatif, a graduate student at the German university Technische Universität München (TUM), and Hanaa Gaber, a doctoral student at the TUM Institute of Virology, are winners of the International Space Station (ISS) Research Competition. Their prize will be to watch the ISS crew perform experiments aboard the space station using two viral proteins they had isolated from HCV genotype 4.

“The hepatitis C virus is a major problem in our home nation of Egypt,” Abdellatif said in the release. “We developed this project to learn more about the virus and find its weaknesses.”

Egypt has one of the highest rates of HCV infection in the world, affecting approximately 15% of those aged 15 to 59 years, according to the Egyptian Ministry of Health. HCV genotype 4 is prevalent in that country.

Abdellatif and Gaber’s project, “Egypt Against Hepatitis C Virus,” was one of eight chosen out of more than 600 submissions. Theirs was the only project from outside the United States to be selected and the first experiment involving Egyptian scientists to be conducted aboard the ISS. The competition is
hosted by Space Florida and NanoRacks LLC, which is supplying a limited number of special transport containers, called NanoLabs.


Challenges with pharmacotherapy of HIV/HCV co-infection

Hepatitis C virus infection is common among individuals already infected with HIV, affecting about one-third of patients. Experts anticipate this number may only increase, given the shared risk factors for acquisition of both infections. In fact, a proportional rise in the sexual transmission of HCV has been observed since ART became widely available in the mid-1990s, possibly reflecting longer duration and improved quality of life, and perhaps a perception of fewer risks associated with unprotected sexual intercourse while receiving treatment for HIV. However, blood exposure remains the most efficient mode of infection, explaining the very high incidence, more than 90%, of HCV co-infection and injection drug use in the HIV-positive population.

Besides overlapping risk factors, HIV/HCV co-infected patients are at risk for more aggressive disease, likely owing to the chronic inflammation, enhanced viral translocation, impaired T-cell response, and the baseline hepatic impairment often observed among patients infected with HIV. As a result, co-infected patients typically present with higher initial viral loads, lower rates of spontaneous viral clearance and faster progression to hepatic fibrosis and cirrhosis. For these reasons, national guidelines recommend prioritizing all co-infected patients for prompt initiation of both HIV and HCV treatment.


Ensuring Patient Access to Care in the United States and Globally

To assist eligible hepatitis C patients in the United States with access to Harvoni and Sovaldi, Gilead provides the Support Path™ program. Through this program, the majority of commercially insured patients will be able to access Harvoni and Sovaldi for a $5 co-pay per month. In addition, Support Path can help patients find alternative forms of financial assistance that may be available through independent non-profit organizations. And for eligible patients with no other insurance options, The Support Path Patient Assistance Program will provide Harvoni and Sovaldi at no charge.

http://www.gilead.com/~/media/Files/pdfs/Policy-Perspectives/ExpandingAccessToHCVTreatments10214.pdf
Gilead's Harvoni gets FDA approval for genotype 1 chronic hepatitis C treatment

US-based biopharmaceutical firm Gilead Sciences has received approval from the US Food and Drug Administration (FDA) for Harvoni (ledipasvir 90mg/sofosbuvir 400mg), the first once-daily single tablet regimen to treat chronic hepatitis C genotype 1 infection in adults.

Approved under the tradename Sovaldi in December 2013, Harvoni is a combination of the NS5A inhibitor ledipasvir and the nucleotide analog polymerase inhibitor sofosbuvir.

The FDA approval is based on data from three Phase III trials ION-1, ION-2 and ION-3, which evaluated eight, 12 or 24 weeks of treatment with Harvoni, with or without ribavirin, among nearly 2,000 genotype 1 HCV patients with compensated liver disease.

The trials included non-cirrhotic treatment-naïve patients (ION-3), cirrhotic and non-cirrhotic treatment-naïve patients (ION-1) and cirrhotic and non-cirrhotic patients who failed prior therapy with an interferon-based regimen, including regimens containing an HCV protease inhibitor (ION-2). Read More: http://www.pharmaceutical-business-review.com/news/gileads-harvoni-gets-fda-approval-for-genotype-1-chronic-hepatitis-c-treatment-131014-4401876

Patient education materials: http://hcvadvocate.org/hepatitis/easyfacts/Harvoni_e.pdf

The Affordability of Sovaldi

Sovaldi is currently one of the best medications approved to defeat the tenacious Hepatitis C virus. With a price tag of $1,000 per pill, this drug’s cost is probably its biggest caveat. The World Health Organization estimates that 130 million people have been infected with Hepatitis C, and many of those are far from able to afford the $84,000 needed for Sovaldi’s twelve weeks of treatment.

However, the price of $1,000 per pill does not seem to apply to everyone. Besides differences in what U.S. health insurers will cover, generic licensing of Sovaldi in developing countries will drastically slash its cost in certain areas.

Improving Hepatitis C treatment success rates from 75 percent up to 90 percent, Sovaldi entered the U.S. market in December 2013. The prior standard-of-care was a combination of Incivek, interferon and ribavirin over a course of 24 weeks. The side effects of this drug trio could be severe, but replacing Incivek with Sovaldi dramatically reduced the incidence of side effects – and did so in half the time. Sovaldi’s maker, Gilead Sciences, describes Sovaldi’s treatment regimens for Hepatitis C:

- Hepatitis C genotypes 1 and 4 – Sovaldi + peg-interferon alfa + ribavirin for 12 weeks
- Hepatitis C genotype 2 – Sovaldi + ribavirin for 12 weeks
- Hepatitis C genotype 3 – Sovaldi + ribavirin for 24 weeks
Paying for Sovaldi Outside the U.S

On September 15, 2014, Gilead announced plans to make Sovaldi affordable in 91 developing countries by allowing generic drug manufacturers to create a lower-cost version of the drug. The agreements allow the following seven Indian companies to make sofosbuvir (Solvadi) and the investigational single tablet regimen of ledipasvir/sofosbuvir for distribution:

1. Cadila Healthcare Ltd.
2. Cipla Ltd.
3. Hetero Labs Ltd.
4. Mylan Laboratories Ltd.
5. Ranbaxy Laboratories Ltd.
6. Seqent Scientific Ltd.
7. Strides Arcolab Ltd.

According to reports, these seven companies will be able to set their own prices for the drug and they will pay royalties to Gilead. In addition to the generic versions, Gilead will begin selling its own version of Sovaldi in India and other developing nations at about $10 per pill – 1 percent of the price it charges in the United States.

The difference in Sovaldi’s cost between the U.S. and India is enormous; $1,000 vs. $10 per pill. The implications of this differential are yet to be seen:

- Will those with Hepatitis C who can’t get their insurance company to pay for Sovaldi travel to a developing country for treatment?
- Will the low price of Sovaldi in developing countries create a ‘black market’ for the drug?
- Will pressure from the U.S. government and health insurance industry influence Gilead’s pricing?

With a success rate of 90 percent, there is no doubt that Gilead’s Sovaldi is a game-changer. Though, Sovaldi is not affordable for most Americans with Hepatitis C who are uninsured or who are unable to obtain prior authorization from their insurer.

To read the full article: http://www.hepatitiscentral.com/mt/archives/2014/10/the-affordability-of-sovaldi.html?eml=hepcen218
Glucose Abnormalities in Patients with Hepatitis C Virus Infection

Epidemiology and pathogenesis

Hepatitis C virus (HCV) infection is a major cause of chronic liver disease, affecting ∼3% of the world’s population. The disease is characterized by silent onset in most infected individuals and recent studies indicate that the rate of progression to advanced liver disease might be lower than previously assumed. If we consider that most HCV-infected persons are <50 years of age, the burden of disease associated with HCV infection is likely to increase during the next 10–20 years as this cohort reaches the age at which complications of chronic liver disease typically occur.

The prevalence of type 2 diabetes in people living in the developed world ranges from 2.0 to 9.4%, rising to 12.3% in U.S. adults between 40 and 74 years of age. The decline in mortality of people with diabetes, together with the rapidly increasing frequency of obesity and the sedentary lifestyle of the population portends a dramatic increase in the prevalence rates of type 2 diabetes. Therefore, both HCV liver disease and type 2 diabetes are two already prevalent diseases that will probably continue to increase in the next decades.

HCV mainly affects the liver, but also several tissues outside the liver have been reported to be involved, resulting in a wide spectrum of extra-hepatic manifestations. During the last decade, it has been hypothesized that diabetes could be one more of these extra-hepatic conditions attributable to HCV infection. This raises the intriguing question of whether the rise in HCV infection is contributing to the increasing prevalence of type 2 diabetes.

http://care.diabetesjournals.org/content/29/5/1140.full

IDWeek 2014: Study Shows HIV/HCV Coinfected Women Have Lower Bone Density

ART-treated women with HIV/HCV co-infection have greater deficits in some structural bone parameters compared to women with HIV only, HCV only, or neither virus, according to the results of a cross-sectional study presented at ID Week 2014 last week in Philadelphia. Among women with HCV, bone loss was most profound in those with stage 3-4 liver fibrosis or cirrhosis, which adversely effects bone health.

"Compared to healthy reference participants, the women with HIV/HCV had decreased tibia trabecular volumetric bone mineral and cortical thinning, and significant endo-cortical bone loss, a pattern observed in other inflammatory diseases," according to Vincent Lo Re of the University of Pennsylvania, who presented the study findings.

Could the Hepatitis C Virus Be Eradicated in Your Lifetime?

With the introduction of interferon free therapies, it is possible that the hepatitis C infection may be cured or even eradicated within the next 10 to 20 years.

Broadcast Med, Inc. and UAB Medicine present Brendan McGuire, MD, and his colleagues at the University of Alabama at Birmingham with their review of the changing landscape for the treatment of the hepatitis C virus (HCV).

See the presentation:

This presentation gives a review of hepatitis C, the epidemiology of the disease, complications in HCV patients and treatment, possible liver transplantation, current therapies in treating and the possibility of eradication of the disease.

HCV: Clinical Trials:

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

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:
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.


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:


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.
Perinatal Hepatitis B Prevention Program:

Julie Miracle, RN BSN

Thank you for all who are reporting pregnant women infected with Hepatitis C. The Ky Department for Public Health would like to remind providers that KY mandates that all women are screened for Hepatitis B surface antigen (HBsAg) during each and every pregnancy and that all positive results are reported to the Kentucky Department for Public Health. Over the summer the program has been visiting hospitals completing audits and educational perinatal hepatitis B visits.

Please be careful in ordering the correct test for each pregnancy. The American Academy of Pediatrics’ Red Book recommendations for PEP for an infant born to a positive HBsAg woman is found on page 384 in the 12th edition. A copy of the lab work should be on an infant’s or maternal chart so all caring for the infant can review the results. Accurate and Complete documentation leads to successful protection of the infant.

Hepatitis B vaccination at birth is the cornerstone to preventing Perinatal Hepatitis B. It is a Safe Net. Vaccination alone can prevent 85% of infection. Infant are the most vulnerable since if exposed and infected, 90% will become chronically infected with Hepatitis B.

KY’S Birthing Hospitals are doing a great job vaccinating our newborns. According to the last National Immunization Survey, KY Had the highest hepatitis B birth-dose coverage rate prior to discharge at 88%. The Immunization Action Coalition continues to recognize hospitals vaccinating over 90% of their newborns. Highlands Regional Medical Center in Prestonsburg, KY (97%) was just recently added. Congratulations! The IAC birth dose Honor Roll with other Perinatal Hepatitis B resources is http://www.immunize.org/protect-newborns/

For any questions or comments please contact:

Julie A. Miracle, RN, BSN,CPAN
Perinatal Hepatitis B Prevention Program Coordinator
(502)564-4478 ext. 4260
E-mail: Julie.Miracle@ky.gov
Viral Hepatitis Prevention Program Staff:

Robert Brawley, MD, MPH, FSHEA  
Chief, Infectious Disease Branch  
502-564-3261, ext. 4235  
Robert.Brawley@ky.gov

Kathy Sanders, RN, MSN  
Adult Viral Hepatitis Prevention Program Manager  
502-564-3261, ext. 4236  
KathyJ.Sanders@ky.gov

Julie A. Miracle, RN, BSN, CPAN  
Perinatal Hepatitis B Prevention Program Coordinator  
(502)564-4478, ext. 4260  
Julie.Miracle@ky.gov
**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

<table>
<thead>
<tr>
<th>Patient’s Last Name</th>
<th>First</th>
<th>M.I.</th>
<th>Date of Birth</th>
<th>Age</th>
<th>Gender</th>
<th>Address</th>
<th>City</th>
<th>State</th>
<th>Zip</th>
<th>County of Residence</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Phone Number</th>
<th>Patient ID Number</th>
<th>Ethnic Origin</th>
<th>Race</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Unk</th>
<th>W</th>
<th>B</th>
<th>A/PI</th>
<th>Am.Ind.</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>M</td>
<td>F</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### DISEASE INFORMATION

<table>
<thead>
<tr>
<th>Describe Clinical Symptoms:</th>
<th>Date of Onset:</th>
<th>Jaundice:</th>
<th>Date of Diagnosis:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>/ /</td>
<td>Yes/No</td>
<td>/ /</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Is Patient Pregnant?</th>
<th>Yes</th>
<th>No</th>
<th>If yes, # wks_____</th>
<th>Expected Date of Delivery:</th>
<th>Name of Hospital for Delivery:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Physician Provider Name:</th>
<th>Address:</th>
<th>Phone:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### LABORATORY INFORMATION

<table>
<thead>
<tr>
<th>Hepatitis Markers</th>
<th>Results</th>
<th>Date of test</th>
<th>Viral Load *if applicable</th>
<th>Name of Laboratory</th>
</tr>
</thead>
<tbody>
<tr>
<td>HBsAg</td>
<td>Pos</td>
<td>Neg</td>
<td>/ /</td>
<td></td>
</tr>
<tr>
<td>IgM anti-HBc</td>
<td>Pos</td>
<td>Neg</td>
<td>/ /</td>
<td></td>
</tr>
<tr>
<td>HBeAg</td>
<td>Pos</td>
<td>Neg</td>
<td>/ /</td>
<td></td>
</tr>
<tr>
<td>IgM anti-HAV</td>
<td>Pos</td>
<td>Neg</td>
<td>/ /</td>
<td></td>
</tr>
<tr>
<td>HCV Antibody</td>
<td>Pos</td>
<td>Neg</td>
<td>/ /</td>
<td></td>
</tr>
<tr>
<td>HCV RNA Confirmation</td>
<td>Pos</td>
<td>Neg</td>
<td>/ /</td>
<td></td>
</tr>
</tbody>
</table>

### SERUM AMINOTRANSFERASE LEVELS

<table>
<thead>
<tr>
<th>Patient</th>
<th>AST (SGOT) U/L</th>
<th>ALT (SGPT) U/L</th>
<th>Date of test</th>
<th>Name of Laboratory</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>U/L</td>
<td>U/L</td>
<td>/ /</td>
<td></td>
</tr>
</tbody>
</table>

### Hepatitis Risk Factors

Mother: 
- IDU
- Multiple Sexual Partners
- Tattoos
- STD
- HIV
- Foreign Born / Country

Child: 
- Mother HBV Pos
- Household member exposure HBV Pos
- Mother HCV Pos
- Household member exposure HCV Pos
- Foreign Born / Country

Mother: Hepatitis A vaccination history: Yes No Refused Dates Given: / /

Child: Hepatitis A vaccination history: Yes No Refused Dates Given: / /

Mother: Hepatitis B vaccination history: Yes No Refused

If yes, how many doses: 1 2 3 Year completed: / /

Child: Hepatitis B vaccination history: Yes No Refused Dates Given: / /

Was PEP Infant of Positive HBV mother given at birth? Yes No

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

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

NECESSITY, FUNCTION, AND CONFORMITY: [EO 2004-726, effective July 9, 2004, reorganized the Cabinet for Health and Family Services and placed the Department for Public Health under the Cabinet for Health and Family Services.] KRS 211.180(1) requires the cabinet to implement a statewide program for the detection, prevention, and control of communicable diseases, chronic and degenerative diseases, dental diseases and abnormalities, occupational diseases and health hazards peculiar to industry, home accidents and health hazards, animal diseases which are transmissible to man, and other diseases and health hazards that may be controlled.

KRS 214.010 requires every physician, advanced practice registered nurse, and every head of family to notify the local health department of the existence of diseases and conditions designated by administrative regulation of the cabinet[of public health importance, known to him or her]. This administrative regulation establishes notification standards and specifies the diseases requiring immediate, urgent, priority, [or] routine,
or general notification, in order to facilitate rapid public health action to control diseases, and to permit an accurate assessment of the health status of the Commonwealth.

Section 1. Definitions.

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

(2) “HAI outbreak” means:

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

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

(3) “Health facility” means:

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

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

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

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

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

(a) Has been confirmed by laboratory test results; or
(b) Meets the definition of AIDS established within the Centers for Disease Control and Prevention (CDC) guidelines.

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

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

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

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

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

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

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

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

Section 2. Notification Standards.

(1) Health Professionals and Facilities. A health professional and a health facility shall give notification if:
(a) The health professional makes a probable diagnosis of a disease specified in Section 3, 5, 6, 7, 8, 10, 13, 14, 15, or 16 of this administrative regulation; and

(b) The diagnosis is supported by:

1. a. Clinical or laboratory criteria; and

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

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

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

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

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

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

(6) The reporting health professional shall furnish:

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

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

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

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

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

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

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

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

Section 3. Submission of Specimens to the Kentucky Department for Public Health Division of Laboratory Services. (1) A medical laboratory and a national reference laboratory in receipt of diagnostic specimens originating from the Commonwealth of Kentucky shall send specimens or clinical isolates for diseases outlined in subsection (5) of this section to the Division of Laboratory Services for primary or confirmatory testing and related studies.
(2) A medical laboratory or national reference laboratory using non-culture techniques to identify bacterial agents of diarrheal disease, such as enzyme immunoassays (EIAs) or molecular assays, shall attempt isolation of the etiologic agent identified. Clinical isolates shall be submitted to the Division of Laboratory Services.

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

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

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

(a) Botulism;
(b) Brucellosis;
(c) Campylobacteriosis;
(d) Cholera and diseases caused by other Vibrio species;
(e) Diphtheria;
(f) Escherichia coli O157:H7;
(g) Hemolytic Uremic Syndrome (HUS) – Post Diarrheal;
(h) Listeriosis;
(i) Measles;

(j) Meningococcal infections;

(k) Rabies animal;

(l) Rubella;

(m) Salmonellosis;

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

(o) Shigellosis;

(p) Tuberculosis;

(q) Tularemia; and

(r) Typhoid fever.

Section 4. Reporting Classifications and Methods.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(7) Weekend, evening, or holiday urgent notification. If local health department personnel cannot be contacted directly, notification shall be made by telephone using an emergency number provided by the local health department or the Kentucky Department for Public Health.
(8) For the protection of patient confidentiality, notification using the emergency number shall include:

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

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

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

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

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

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

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

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

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

(12) Routine Reporting. A report made within five (5) business days, as required by Sections 7, 8, 9, 13, 14(7), and 17 of this administrative regulation, shall be made electronically, by fax, or by mail to the local health department serving the county in which the patient resides.
Upon receipt of a report of a disease or condition requiring routine reporting, a local health department shall:

(a) Make a record of the report;

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

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

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

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

(a) EPID 200, Kentucky Reportable Disease Form;

(b) EPID 250, Kentucky Reportable MDRO Form;

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

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

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

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

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

(a) Patient name;

(b) Date of birth;
(c) Gender;
(d) Race;
(e) Ethnicity;
(f) Patient address;
(g) County of residence;
(h) Patient telephone number;
(i) Name of the reporting medical provider or facility;
(j) Address of the reporting medical provider or facility; and
(k) Telephone number of the reporting medical provider or facility;

Section 5. Notifiable Infectious Conditions Requiring Urgent Notification.

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

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

Section 6. Notifiable Infectious Conditions and Notifiable Non-Infectious Conditions Requiring Priority Notification. Notification of the following diseases shall be considered priority and shall be made within one (1) business day:
(1) Arboviral diseases, neuroinvasive and non-neuroinvasive, including:
   (a) California serogroup virus diseases, including diseases caused by:
1. California encephalitis virus;

2. Jamestown Canyon virus;

3. Keystone virus;

4. La Crosse virus;

5. Snowshoe hare virus; and

6. Trivittatus viruses;

(b) Chikungunya virus disease;

(c) Eastern equine encephalitis virus disease;

(d) Powassan virus disease;

(e) St. Louis encephalitis virus disease;

(f) Venezuelan equine encephalitis disease;

(g) West Nile virus disease; and

(h) Western equine encephalitis virus disease;

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

(3) Campylobacteriosis;

(4) Cholera;

(5) Cryptosporidiosis;

(6) Dengue virus infections;

(7) Escherichia coli O157:H7;

(8) Foodborne disease outbreak;

(9) Haemophilus influenzae invasive disease;

(10) Hansen's disease (leprosy);

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

(36) Typhoid fever;

(37) Varicella-associated mortality;

(38) Vibriosis; and

(39) Waterborne disease outbreak.

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

(1) Babesiosis;

(2) Coccidioidomycosis;

(3) Creutzfeldt-Jakob disease;

(4) Ehrlichiosis/Anaplasmosis;

(5) Hepatitis C, acute;

(6) Hepatitis C infection in a pregnant woman;

(7) Hepatitis C infection, in an infant or a child aged five years or less;

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

(9) Histoplasmosis;

(10) Lead poisoning;

(11) Legionellosis;

(12) Lyme Disease;

(13) Malaria;

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

(15) Toxoplasmosis; and
(16) Trichinellosis (Trichinosis).

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

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

(a) Cyclosporiasis;

(b) Giardiasis;

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

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

and

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

1. Isolation of varicella virus from a clinical specimen;

2. Varicella antigen detected by direct fluorescent antibody test;

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

or

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

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

Section 9. Multi-Drug Resistant Organisms and Other Organisms Requiring Routine Notification by Electronic Laboratory Reporting.
(1) Beginning October 1, 2016, notification of the following diseases shall be considered routine and shall be electronically reported to the Kentucky Department for Public Health through the Kentucky Health Information Exchange within five (5) business days:

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

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

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

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

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

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

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

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

1. Ampicillin-sulbactam;

2. Cephalosporins (cefepime, ceftazidime);

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

4. Carbapenems (imipenem, meropenem, doripenem);

5. Fluoroquinolones (ciprofloxacin or levofloxacin);

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

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

1. Cephalosporins (cefepime, ceftazidime);
2. β-lactam-β-lactamase inhibitor combination (piperacillin, piperacillin-tazobactam);

3. Carbapenems (imipenem, meropenem, doripenem);

4. Fluoroquinolones (ciprofloxacin or levofloxacin);

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

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

(a) Date of specimen collection;

(b) Source of specimen;

(c) Susceptibility pattern; and

(d) Name of the ordering health professional.

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

(4) The report shall include a diagnosis.


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

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

(b) Submission of a specimen to the Kentucky Division of Laboratory Services for select agent identification or select agent confirmation testing; or
(c) An outbreak of a disease or condition that resulted in multiple hospitalizations or death.

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

(a) A newly-recognized infectious agent;

(b) An outbreak;

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

(d) An epidemic; or

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

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

(a) Suspected Staphylococcal or other foodborne intoxication; or

(b) Salmonellosis or other foodborne or waterborne infection.

(4) The local health department shall:

(a) Investigate the outbreak or occurrence;

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

(c) Make medical and environmental recommendations to prevent future similar outbreaks or occurrences.
(5) The local health department may seek assistance from the Kentucky Department for Public Health.

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

(a) Influenza virus isolates;

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

(c) DNA molecular assays for influenza virus.

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

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

(a) Staphylococcus aureus;

(b) Enterococcus species; or

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

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

(2) The Kentucky Department for Public Health shall preserve patient confidentiality and shall not disclose to the public any patient-level data obtained from any health care facility.
(3) The Kentucky Department for Public Health may issue reports to the public regarding healthcare-associated infections in aggregate data form which:

(a) May identify individual health care facilities; and

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

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

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

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

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

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

(2) Health professionals and medical laboratories shall report:

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

1. 3\textsuperscript{rd} generation immunoassay;

2. 4\textsuperscript{th} generation immunoassay;

3. Western Blot;

4. PCR;

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

6. HIV antigen;

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

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

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

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

CDC guidelines.

(3) A case report for a resident of Jefferson, Henry, Oldham, Bullitt, Shelby, Spencer, or Trimble County shall be submitted to the HIV/AIDS Surveillance Program of

the Louisville-Metro Health Department.

(4) A case report for a resident of the remaining Kentucky counties shall be

submitted to the HIV/AIDS Surveillance Program of the Kentucky Department for Public

Health, Division of Epidemiology and Health Planning.

(5) A case report for a person with an HIV infection without a diagnosis of AIDS

shall include the following information:

(a) The patient's full name;

(b) The patient's complete address;

(c) Date of birth using the format MMDDYYYY;

(d) Gender;

(e) Race;

(f) Ethnicity;

(g) Risk factor as identified by CDC;

(h) County of residence;

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

(j) Specimen collected;
(k) Date and type of HIV test performed using the format MMDDYYYY;

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

(m) Results of viral load testing;

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

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

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

(6) A report of an AIDS case shall include:

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

(b) Opportunistic infections diagnosed; and

(c) Date of onset of illness.

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

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

Section 14. Sexually Transmitted Disease (STD).

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

(2) The report shall provide the following information:

(a) Pregnancy status; and

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

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

(a) Congenital syphilis; or

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

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

(a) Investigate the report;

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

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

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

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

(a) Chancroid;

(b) Chlamydia trachomatis infection;
(c) Gonorrhea;
(d) Granuloma inguinale;
(e) Lymphogranuloma venereum; or
(f) Syphilis, other than primary, secondary, early latent or congenital.

(8) Upon receipt of a report for a disease or condition specified in subsection (7) of this section, a local health department shall:
(a) Make a record of the report using Form EPID 200, Kentucky Reportable Disease Form;
(b) Forward the report to the Kentucky Department for Public Health within five (5) business days; and
(c) Render assistance if requested by the reporting entity or the Kentucky Department for Public Health.

Section 15. Tuberculosis. (1) A pharmacist shall give notice if two (2) or more of the following medications used for the initial treatment of active tuberculosis are dispensed to an inpatient in a health facility or to an ambulatory patient in a health facility or a pharmacy:
(a) Rifampin or rifabutin;
(b) Isoniazid;
(c) Pyrazinamide; and
(d) Ethambutol.

(2) A report of tuberculosis shall be considered priority and shall be reported to the local health department serving the county in which the patient resides.
(3) If the local health department cannot be reached, notification shall be given to the Kentucky Department for Public Health.

(4) The report shall include:
(a) Information required in Section 4(16) of this administrative regulation; and
(b) Names of the medications dispensed.

Section 16. Asbestosis, Coal Worker’s Pneumoconiosis, and Silicosis.
(1) A health professional shall report a diagnosis of the following to the Kentucky Department for Public Health within three (3) months of diagnosis:
(a) Asbestosis;
(b) Coal worker’s pneumoconiosis; or
(c) Silicosis.
(2) A report required under this section shall include the following information regarding the patient:
(a) Name;
(b) Address;
(c) Date of birth; and
(d) County of residence.

Section 17. Reporting of Communicable Diseases in Animals. (1) A diagnosis in an animal of a condition known to be communicable to humans, except for rabies, shall require routine notification.
(2) A veterinarian shall report the diagnosis within five (5) business days to the local health department serving the county in which the animal is located.
(3) If a laboratory test indicates infection of an animal with an agent associated with a condition known to be communicable to humans, the director of a medical laboratory shall report the result to the local health department serving the county in which the animal is located within five (5) business days.

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

(a) Investigate the report;

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

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

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

Section 18. Kentucky Department for Public Health Advisory.

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

(2) The Kentucky Public Health Advisory shall include:

(a) Date and time the advisory is issued;

(b) A unique number to identify the advisory;

(c) Names for the disease or condition;

(d) A description of the disease or condition;
(e) Recommendations for health professionals, health facilities, and laboratories; and

(f) Notification requirements including:

1. The notification time interval;
2. Methods for notification; and
3. Forms to be completed and submitted with the notification.

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

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

(a) Form “EPID 200, Kentucky Reportable Disease Form”, 9/2014;
(b) Form “EPID 250, Kentucky Reportable MDRO Form”, 6/2014;
(c) Form “EPID 394, Kentucky Reportable Disease Form, Hepatitis Infection in Pregnant Women or Child (under the age of five)”, 11/2013;
(d) Form “EPID 399, Perinatal Hepatitis B Prevention Form for Infants”, 4/2012;
(e) Form “Adult HIV Confidential Case Report Form”, 3/2013; and
(f) Form “Pediatric HIV Confidential Case Report Form”, 3/2013.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Department for Public Health, 275 East Main Street, Frankfort, Kentucky 40621, Monday through Friday, 8 a.m. to 4:30 p.m.
Notification Standards. (1) A health professional licensed under KRS Chapters 311 through 314, and a health facility licensed under KRS Chapter 216B, shall give notification pursuant to subsection (3) of this section, if:

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

(b) The diagnosis is supported by:

1. “Case Definitions for Infectious Conditions under Public Health Surveillance”; or

2. A reasonable belief that the disease is present.

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

(b) A hospital may designate an individual to report on behalf of the hospital’s laboratory and the hospital’s clinical facilities.

(3) The notification shall be given to the:

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

(b) Department for Public Health.

(4) The reporting professional shall furnish the:

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

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

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

(a) Report the result to the:

1. Local health department serving the jurisdiction in which the patient resides; or
2. Department for Public Health; and

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

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

(a) Anthrax;

(b) Botulism;

(c) Brucellosis;

(d) Campylobacteriosis;

(e) Cryptosporidiosis;

(f) Cholera;

(g) Diphtheria;

(h) Escherichia coli O157:H7;

(i) Escherichia coli, shiga-toxin-positive;

(j) Encephalitis, California group;

(k) Encephalitis, Eastern equine;

(l) Encephalitis, St. Louis;

(m) Encephalitis, Venezuelan equine;

(n) Encephalitis, Western;
Encephalitis, West Nile Virus;

Hansen’s Disease;

Hantavirus infection;

Hemophilus influenzae invasive disease;

Hepatitis A;

Listeriosis;

Measles;

Meningococcal infections;

Pertussis;

Plague;

Poliomyelitis;

Psittacosis;

Q fever;

Rabies, animal;

Rabies, human;

Rubella;

Rubella syndrome, congenital;

Salmonellosis;

Shigellosis;

Syphilis, primary, secondary, early latent or congenital;

Tetanus;

Tularemia;

Typhoid fever;
(ll) *Vibrio parahaemolyticus*;

(mm) *Vibrio vulnificus*;

(nn) Yellow fever.

(2) Weekend or evening urgent notification.

(a) If health department personnel cannot be contacted directly, notification shall be made by electronic submission or by telephone to an emergency number provided by the local health department or the Department for Public Health.

(b) For the protection of patient confidentiality, this notification shall include:

1. The name of the condition being reported; and

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

(3) Upon receipt of a report for a disease specified in subsection (1) of this section, the local health department shall:

(a) Immediately notify the Department for Public Health; and

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

Section 3. Diseases Requiring Priority Notification. (1) Notification pursuant to Section 1(3) of this administrative regulation of the following diseases shall be made within one (1) business day:

(a) Group A streptococcal infection, invasive;

(b) Hepatitis B, acute;

(c) Hepatitis B infection in a pregnant woman or a child born in or after 1992;

(d) Mumps;

(e) Toxic shock syndrome;
(f) Tuberculosis.

(2) Upon receipt of a report for a disease or condition specified in subsection (1) of this section, a local health department:

(a) Shall investigate the report and carry out public health measures appropriate to the disease or condition;

(b) Shall notify the Department for Public Health of the case, in writing, within five (5) business days; and

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

Section 4. Diseases Requiring Routine Notification. (1) Notification pursuant to Section 1(3) of this administrative regulation of the following diseases shall be made within five (5) business days:

(a) Chancroid;

(b) Chlamydia trachomatis infection;

(c) Ehrlichiosis;

(d) Gonorrhea;

(e) Granuloma inguinale;

(f) Hepatitis C, acute;

(g) Histoplasmosis;

(h) Lead poisoning;

(i) Legionellosis;

(j) Lyme Disease;

(k) Lymphogranuloma venereum;

(l) Malaria;
(m) Rabies postexposure prophylaxis;
(n) Rocky Mountain Spotted Fever;
(o) Streptococcus pneumoniae, drug-resistant invasive disease;
(p) Syphilis, other than primary, secondary, early latent or congenital; and
(q) Toxoplasmosis.

(2) Upon receipt of a report for a disease or condition specified in subsection (1) of this section, a local health department shall:

(a) Make a record of the report;
(b) Answer inquiries or render assistance regarding the report if requested by the reporting entity; and
(c) Forward the report to the Department for Public Health within three (3) business days.

Section 5. Outbreaks or Unusual Public Health Occurrences. (1) If, in the judgment of a health professional licensed under KRS Chapters 311 through 314, or a health facility licensed under KRS Chapter 216B, an unexpected pattern of cases, suspected cases, or deaths which may indicate a newly-recognized infectious agent, an outbreak, epidemic, related public health hazard or an act of bioterrorism, such as smallpox, appears, a report shall be made immediately by telephone to the:

(a) Local health department where the professional is practicing or where the facility is located; or
(b) Department for Public Health.

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

(3) The local health department:

(a) Shall investigate the outbreak or occurrence;

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

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

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

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

(b) The report shall include the:

1. Name, birthdate, address, and county of residence of the person with the
disease; and

2. Specific laboratory information pertinent to the result.

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

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

(a) The numbers of isolates and information regarding the antimicrobial resistance
patterns of the isolates;
(b) At intervals agreed upon between the laboratory and the department, not less frequently than three (3) months, for the following:

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

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

(a)1. A positive test result for HIV infection including a result from:
   a. Elisa;
   b. Western Blot;
   c. PCR;
   d. HIV antigen; or
   e. HIV culture;
2. CD4+ assay including absolute CD4+ cell counts and CD4+%;
3. HIV detectable Viral Load Assay; and
4. A positive serologic test result for HIV infection; or

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

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

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

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

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

(a) The patient’s full name;

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

(c) Gender;

(d) Race;

(e) Risk factor, as identified by CDC;

(f) County of residence;

(g) Name of facility submitting report;

(h) Date and type of HIV test performed;

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

(j) Results of viral load testing;

(k) PCR, HIV culture, HIV antigen, if performed;

(l) Results of TB testing, if available; and
(m) HIV status of the person's partner, spouse or children.

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

(a) The patient's complete address;

(b) Opportunistic infections diagnosed; and

(c) Date of onset of illness.

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

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

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

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

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

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

(a) Local health department serving the jurisdiction in which the animal is located; or

(b) Department for Public Health.
(3) The local health department:

(a) Shall investigate the report and carry out public measures for the control of communicable diseases appropriate to the condition;

(b) Shall notify the Department for Public Health of the occurrence, in writing, within five (5) business days; and

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

Section 9. Asbestosis, Coal Worker’s Pneumoconiosis, and Silicosis. (1) A reporting provider shall submit the following information relating to a person diagnosed with asbestosis, coal worker’s pneumoconiosis, or silicosis:

(a) Name;

(b) Address;

(c) Birthdate; and

(d) County of residence.

(2) A reporting provider shall submit the required information to the department within three (3) months following the diagnosis.

Section 10. Incorporation by Reference. (1) The following material is incorporated by reference:

(a) "Case Definitions for Infectious Conditions under Public Health Surveillance, MMWR, May 2, 1997, Volume 46, Number RR-10", published by the Epidemiology Program Office, Centers for Disease Control and Prevention, Public Health Service, U.S. Department of Health and Human Services, Atlanta, Georgia;

(b) "Adult HIV/AIDS Confidential Case Report (CDC-50.42A, Revised January, 2003)"; and
(c) "Pediatric HIV/AIDS Confidential Case Report form (CDC 50.42B, Revised January, 2003)"; and


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

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

APPROVED

Audrey Tayse Haynes, Secretary
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.
(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:
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.