Interim Joint Committee on Health and Welfare

Minutes of the 5th Meeting of the 2007 Interim

November 19, 2007

The 5th meeting of the Interim Joint Committee on Health and Welfare was held on Monday, November 19, 2007, at 10:00 AM, in Room 129 of the Capitol Annex. Senator Julie Denton, Co-Chair, called the meeting to order at 10:15 AM, and the secretary called the roll.

Present were:

Members: Senator Julie Denton, Co-Chair; Representative Tom Burch, Co-Chair; Senators Charlie Borders, Perry B. Clark, Denise Harper Angel, Joey Pendleton, Dick Roeding, Ernesto Scorsone, Dan Seum, Katie Stine, and Johnny Ray Turner; Representatives James R. Comer, Jr., Robert R. Damron, Bob M. DeWeese, David Floyd, Joni L. Jenkins, Reginald Meeks, Ruth Ann Palumbo, Kathy W. Stein, and Addia Wuchner.

Guest Legislator: Representative Jimmie Lee.

Guests: Paul Trickel, Nick Sauer, David E. Clark, and Robert E. Stone, Kentucky HIV/ AIDS Planning and Advisory Council; Thomas C. Tucker, PhD, MPH, Chair, Department of Epidemiology, Associate Director for Cancer Control and Director, Kentucky Cancer Registry, University of Kentucky; Carol Steltenkamp, MD, Co-Chair, Kentucky e-Health Network Board and Chief Medical Information Officer, University of Kentucky HealthCare; Tara Ryan, Senior Director, State Policy, PhRMA; Jim Zechman; Kevin Kavanagh, MD, MS; Chris Corbin, Executive Director, Melissa Adkisson, Division Director, Office of Health Policy, Cabinet for Health and Family Services; Elizabeth Caywood, Department for Community Based Services, Cabinet for Health and Family Services; Sue Thomas Cox, Kambe Lattimore, Trista Chapman, Karin Bosh, and Sigga Jagne, Department for Public Health, Cabinet for Health and Family Services; Amy Moore and Karen Cooke, Department for Aging and Independent Living, Cabinet for Health and Family Services; Bernie Vonderheide, Kentuckians for Nursing Home Reform; Bill Doll, Kentucky Medical Association; Whitney Jones, Elizabeth Muelle,

Angela Champion, and Bill Beam, Colon Cancer Prevention Project; Jennifer Redmond and Katie Bathje, Kentucky Cancer Consortium; Jackyln Nee, Kentucky Cancer Registry; John M. Bennett, University of Kentucky; Wanda Jones; Jean Claiborne; Sarah S. Nicholson, Kentucky Hospital Association; Patty Dempsey, the Arc of Kentucky; Ann Joseph; The Kentucky Task Force on Hunger and Covering Kentucky Kids and Families; and Donna G. Brown, Kentucky Association of Chiropractors and the Kentucky Association of Health Care Facilities.

LRC Staff: Murray Wood, CSA; Barbara Baker, Miriam Fordham, DeeAnn Mansfield, Ben Payne, and Gina Rigsby.

Tara Ryan, State Policy Senior Director, PhRMA, reported on prescription drug safety and pedigree legislation. She reported that in 1988 the Prescription Drug Manufacturing Act (PDMA) was passed to require licensing for drug wholesalers and some sort of pedigree. Because of the complexity of issues involved in the distribution of prescription drugs in the United States, the final regulations for the PDMA did not come out until 1999. In 2006, the pedigree provisions were finalized and the federal regulations were released. Because of a lawsuit, the Food and Drug Administration is enjoined from regulating the prescription drug movement nationwide. The purpose of the pedigree requirement is to ensure that drugs that leave the manufacturer can be tracked until they are dispensed to the consumer. She said that all the stakeholders in the system have been working together to come up with legislation that will work. The federal law states that everyone has to document a pedigree except the manufacturer or their authorized distributors of record. Authorized distributors may distribute drugs to wholesalers for repackaging. Federal law only requires wholesalers to have a pedigree to go back to the last authorized distributor of record. The problem is that since authorized distributors do not have to have a pedigree, the continuity of the chain of distribution is lost. States want legislation that regardless where the drug left the chain of distribution, it has to keep the pedigree.

Senator Denton asked how many states currently have pedigree legislation. Ms. Ryan said approximately 22 states. Ms. Ryan stated that there are three major wholesale distributors in the United States and each state could have hundreds of secondary wholesale distributors. The problem is some of the secondary wholesaler distributors are not legitimate.

Representative Burch asked if the pedigree legislation is exactly the same in all 22 states,

and if it is not, does it cause problems. Ms. Ryan said the legislation is not the same. There is the potential to cause problems if the normal distribution channel is not the same in the states. She said that most companies and manufacturers think it is better to have something rather than nothing in place. Representative Burch said that if the purpose of the legislation is safety, there should be continuity in the language in all 50 states. He asked about manufacturers located in the United States who have drugs outside of the United States and brought into the United States for distribution. Ms. Ryan said that regardless of where they are located companies that make FDA-approved drugs still come through the FDA system. If an individual purchases a drug in a pharmacy in another country, there is no way to know if those drugs are safe.

Representative Burch asked how drugs are tracked if 22 states have different laws. She stated that they are tracked at the federal level until they get to the states and then they are tracked based on the labeling requirements. He asked about the number of counterfeit drugs and the number of deaths from these drugs. Ms. Ryan said she did not have this information because the cause of death may not be attributed to the drug. He stated that the solution should start at the federal level. Ms. Ryan said that the PDMA passed in September, 2007 have a requirement for serialization at the individual packet level (electronic pedigree) that has to be implemented within 30 months. He asked if the pedigree requirement would increase the price of the drugs, and she said that she did not have that information.

Senator Denton said that if the group develop legislation that all parties can agree to, maybe it could be adopted in the rest of the states so that it could be more uniform. Representative Burch asked if the patients have been involved in the process, and Ms. Ryan said that the patients do not understand the complexity of the distribution system. He asked if the pedigree legislation will be financially beneficial to the interested parties, and Ms. Ryan said pedigree legislation is not a financial enhancement to the industry but a safety precaution. Senator Denton said it is strictly consumer protection legislation.

Representative Damron asked about penalties for individuals who purchase drugs and bring them back to the United States. Ms. Ryan said pedigree only covers drugs that leave an FDA-approved manufacturer and goes through the U.S. system. She said there is an allowance for individuals. He asked what states along the northern borders have passed pedigree legislations. She stated Vermont has required study on electronic pedigree, but she would provide a complete list and map for the committee.

A motion to adopt the minutes was made by Senator Pendleton, seconded by Senator Borders, and adopted by voice vote.

Paul Trickle, Chair, Policy and Promotion Committee, and Robert Stone, Chairman, Kentucky HIV/AIDS Planning Advisory Council (KHPAC) gave an overview on the annual council report. Mr. Trickle stated that due to limited resources, statewide HIV/AIDS surveillance efforts are undermined and the state's ability to obtain adequate federal funding is impacted, and the ability to effectively identify and direct preventative and care services to the populations at highest risk are impeded. Although the KHPAC year-end report recommends an allocation of $100,000 in state funds to be directed to statewide core surveillance activities, they support the Department for Public Health's HIV/AIDS Branch request for $250,000. The increased need was identified after the branch conducted a more recent and extensive evaluation of all required activities. Federal funding of HIV/AIDS prevention and care services depends on the number of reported HIV/AIDS cases, and the KHPAC recognizes that increased state funding of HIV/AIDS surveillance is imperative to assure appropriate levels of federal funding.

He stated that studies indicate that HIV rates are 14 times higher in correctional settings than in the general United States population, and, HIV testing of inmates is an important step in reducing the spread of the disease. A comprehensive HIV testing protocol for correctional settings should be developed and implemented for inmates upon admission, upon an inmate's request, as warranted by an inmate's known engagement in risky behaviors, and prior to release. The KHPAC supports the Department for Public Health's HIV/AIDS Branch's request for $3.5 million to support HIV and Hepatitis C initiatives for Kentucky correctional facilities. The funds would be used for the following three immediate needs within Kentucky's correctional settings: 1) a collaborative, comprehensive educational program for inmates and correctional staff; 2) an HIV and Hepatitis testing program; and 3) an HIV discharge planning program.

Representative Meeks asked about the number of inmates infected with HIV and Hepatitis C and about the process of notifying family members, staff, and other inmates of a positive result from testing. Mr. Trickle stated because there is no comprehensive testing program for inmates, there is no clear identification of the numbers within Kentucky's correctional settings. There are no protocols to report an inmate's status to correctional staff or families.

Representative Burch asked if Kentucky's HIV/AIDS cases have increased or decreased.

Karin Bosh, Epidemiologist, HIV/AIDS Branch, Department for Public Health, Cabinet for Health and Family Services, stated that the AIDS incident rates have stayed level over the past several years. In 2004, HIV name-based reporting was implemented and statistics on the rates of HIV infection have not been released.

Thomas C. Tucker, PhD, MPH, Chair, Department of Epidemiology, Associate Director for Cancer Control, and Director, Kentucky Cancer Registry, University of Kentucky, and Whitney F. Jones, MD, Colon Cancer Prevention Project, Clinical Professor of Medicine, gave a presentation on colon cancer in Kentucky. Dr. Tucker stated that colon cancer is the third most commonly occurring cancer and the second leading cause of death from cancer in the United States. Colon cancer is also the second leading cause of death from cancer in Kentucky. When a population is adequately screened, pre-cancerous lesions are found and removed before they become cancer. This reduces the incidence rate. When a population is adequately screened, more colon cancer cases are diagnosed at an early stage when they can be treated more successfully. This improves the survival rate. He stated that approximately half of all colon cancer cases are diagnosed with late stage disease each year in Kentucky. It costs an average of $30,000 to treat each case of early stage colon cancer and an average of $120,000 to treat each case of late stage colon cancer. Increased colon cancer screening will find the disease before it becomes cancer and the cost of treatment is reduced to the only the cost of the colonoscopy procedure.

Dr. Jones stated increased rates of colon cancer combined with low screening rates equals a high impact on colon cancer in Kentucky. A colonoscopy for all Kentuckians over age 50 is the most clinically effective and the most cost effective strategy. There is a consensus among Kentucky Cancer Consortium partners that a statewide screening program for colon cancer is needed. Their recommendation is that the 2008 the General Assembly create the Kentucky Colon Cancer Screening Act and appropriate funding for the development and implementation of a statewide screening program modeled after the Kentucky Women's Cancer Screening Program.

Representative DeWeese asked about the cost of implementing the Kentucky Colon Cancer Screening Act. Dr. Jones stated approximately $10 million per year. Representative DeWeese stated that funding prevention, wellness, and early treatment programs is an investment because of the money Kentucky would save in the long run by not having to treat late state diseases.

Representative Burch asked about the screening process. Dr. Jones stated that they would

support all the American Cancer Society guidelines that promote colorectal cancer screenings as the least expensive strategy, because it only requires a colonoscopy every ten years for most people and provides the benefit of primary prevention.

Representative Meeks asked if there would be a sufficient number of doctors statewide to provide the screenings. If not, what would be done to increase the number of doctors. Dr. Tucker stated that he conducted a study on the capacity to provide colorectal screenings with the Kentucky Medical Association two years ago, and found there are enough doctors statewide to conduct the screenings.

Jim Zechman, Alternative Medicine Integration (AMI) Group, LLP, gave an overview on the integration of alternative medicine with conventional medicine. The AMI integrates wellness, prevention, and complementary alternative medicine with conventional medical care to create integrated health care delivery systems. The AMI believes alternative medical practitioners provide a model of wellness, which is missing from our current health care system that is designed to treat disease. Through better information, better communication, better alternatives and a better attitude, the AMI has developed a model that strives to create a healthier patient at tremendous cost savings to everyone involved.

Carol Steltenkamp, MD, Co-Chair, Kentucky e-Health Network Board, and Chief Medical Information Officer, University of Kentucky HealthCare, gave an overview of e-Health in Kentucky. Dr. Steltenkamp stated Senate Bill 2 enacted in the 2005 Regular Session required the development and implementation of a statewide Kentucky e-Health Network (KeHN). House Bill 185 enacted in the 2007 Regular Session gave the KeHN Board the authority to create a public-private nonprofit corporation to facilitate the development and operations of the KeHN. Three entities were created with distinct roles: 1) The Kentucky e-Health Network Board - policy and oversight; 2) The Kentucky Healthcare Infrastructure Authority - research and guidance; and 3) The Kentucky e-Health Corporation - operations. She stated the objective is that by 2011, all Kentuckians will have health information available electronically in a statewide e-Health network for instant access anywhere. Currently, only about 25 percent of Kentucky doctors use electronic health records, and only 80 percent of claims are submitted electronically.

The current e-Health projects are the Kentucky e-Health Summit, the e-Prescribing Partnerships in Kentucky (ePPIK) Grant Program, Privacy and Security Collaboration, the statewide e-Health study, and the Kentucky Health Information Partnership (K-HIP). She stated the Kentucky e-Health Action Plan published in April 2007, had the following

objectives: 1) foster improvement in quality of care and health outcomes while containing health care costs; 2) facilitate a statewide health information exchange (HIE); 3) foster consumer empowerment through health information technology (HIT) and HIE; 4) foster increased use of information technology; 5) facilitate and collaborate with local HIE efforts; 6) collaborate with federal and interstate e-health efforts; and 7) link e-Health with economic development efforts. The action plan is available at www.ehealth.ky.gov. The action plan also recommends additional funding in the amount of $17.3 million.

Representative Lee asked if the $17.3 million would be one-time or recurring money each year of the biennium. Dr. Steltenkamp stated most would be one-time funding to get the portal built with some recurring costs. She stated that the private sector may have to assume some of the cost to continue the exchange of the portal. Representative Lee asked if she anticipated having a commitment from private entities to accept some expenses, and she said anticipated by that 2008 they would be able to come back with private payor money on board with the Medicaid Transformation grant monies to build the portals.

Representative Stein stated most doctors say it is more efficient to have electronic records. Dr. Steltenkamp said that providers do not want to have to go to several places to find patient information.

Senator Roeding said that the hospitals in Northern Kentucky, Ohio, Indiana, and West Virginia fund HealthBridge. Dr. Steltenkamp stated HealthBridge is a national model.

The following administrative regulations were referred to the committee for consideration: **201 KAR 13:080** - establishes a procedure for the operation and inspection of an optical establishment ***(Amended at ARRS)***; **910 KAR 1:240** - establishes the certification process for assisted-living communities ***(Amended at ARRS)***; **921 KAR 2:016** - sets forth the standards of need for and the amount of a Kentucky Transitional Assistance Program payment ***(Amended at ARRS)***; **921 KAR 2:050** - establishes the time and manner of payments for the Kentucky Transitional Assistance Program and Kentucky Works and also establishes the time and manner of State Supplementation payments and Mental Illness or Mental Retardation (MIMR) Supplement Program payments ***(Amended at ARRS)***; and **922 KAR 2:180** - establishes requirements for providers to participate in the Child Care Assistance Program and the application procedures ***(Amended at ARRS)***.

Bernie Vonderheide, Kentuckians for Nursing Home Reform, stated that 910 KAR 1:240, the administrative regulation on certification of assisted living communities, provides for

the certification process of assisted living communities but does not mandate quality care in the facilities. It provides for criminal background checks of employees but does not mandate random drug checks. The administrative regulation sets annual inspections of assisted living facilities but no way to provide inspection results them to the public. It provides no oversight of services being offered to residents. He asked that the administrative regulation be deferred so providers and consumers could work together to improve it.

Kevin T. Kavanagh, MD, MS, and Chris L. Corbin, Executive Director, and Melissa Adkisson, Division Director, Office of Health Policy, Cabinet for Health and Family Services, gave an presentation on transparency in healthcare. Dr. Kavanagh stated that transparency should be present in either consumer drive healthcare system or a single payer system. Transparency is needed in all aspects of healthcare: healthcare facilities, physicians, and pharmacies. Four main key factors to monitor in healthcare facilities are: 1) registered nursing staff; 2) infection rates; 3) bed ulcers formations or skin care; and 4) mortality rates. According to a 1995 article in the Journal of the American Medical Association, nurses are responsible for 86 percent of all interceptions of medical errors. The Cabinet for Health and Family Services is prevented from accrediting hospitals that have had full accreditation from the Joint Commission on Accreditation of Healthcare Organizations on or before July 15, 2002 per KRS 216B.185(1).

Mr. Corbin stated that the cabinet collects approximately 600,000 de-identified inpatient records (UB-92s) annually from all Kentucky hospitals and collects outpatient surgical data from hospitals and some ambulatory surgery centers. The information collected includes charges, volume, and average length of stay for the most commonly performed elective procedures. The information is comparable by facility and by state median and average. Since March, 2007, the website includes outcome data on selected inpatient procedures and conditions, and allows consumers to compare Kentucky hospitals based on outcome data. The website is healthdata.chfs.ky.gov.

Representative Burch asked if information on infection rates is important to include in the data collected, and Mr. Corbin stated that infection rates are included in the patient safety indicators, but the reliability of the information is questionable. Ms. Adkisson stated the inpatient data is always going to be questionable because of the way information is coded.

Representative Stein asked if the same analysis is available for nursing home information. Mr. Corbin stated the legislation currently only requires hospitals and ambulatory surgery

centers to provide this information utilizing the standard billing instrument. It is something that could be considered.

Senator Roeding asked why emergency room overutilization data was not included. Mr. Corbin stated that it is very difficult to separate the emergency room claim from the outpatient claim.

There being no further business, a motion to adjourn at 12:17 p.m. was made, seconded, and adopted by voice vote.