

INTERIM JOINT COMMITTEE ON HEALTH, WELFARE, AND FAMILY SERVICES

Minutes of the 7th Meeting of the 2019 Interim

November 18, 2019

Call to Order and Roll Call

The 7th meeting of the Interim Joint Committee on Health, Welfare, and Family Services was held on Monday, November 18, 2019, at 1:00 PM, in Room 154 of the Capitol Annex. Representative Kimberly Poore Moser, Chair, called the meeting to order, and the secretary called the roll.

Present were:

Members: Senator Ralph Alvarado, Co-Chair; Representative Kimberly Poore Moser, Co-Chair; Senators Julie Raque Adams, Tom Buford, Danny Carroll, Julian M. Carroll, Denise Harper Angel, Alice Forgy Kerr, Stephen Meredith, and Max Wise; Representatives Danny Bentley, Tina Bojanowski, Adam Bowling, George Brown Jr, Tom Burch, Deanna Frazier, Robert Goforth, Joni L. Jenkins, Scott Lewis, Mary Lou Marzian, Melinda Gibbons Prunty, Josie Raymond, Steve Riley, Steve Sheldon, Nancy Tate, Russell Webber, and Lisa Willner.

Guests: Kyle Keeney, President, Chief Executive Officer, Kentucky Life Science Council; Warren Olson, Director, Supply Chain Solutions Louisville Campus, United Parcel Service; Adam W. Bibelhauser, PMP, Director, Louisville Distribution Center Amgen; Kate Shanks, Vice President, Public Affairs, Kentucky Chamber of Commerce; Van Ingram, Executive Director, Office of Drug Control Policy, Justice and Public Safety Cabinet; Michael Rodman, Executive Director, Kentucky Board of Medical Licensure; Leanne Diakov, General Counsel, Kentucky Board of Medical Licensure; Dr. Doug Oyler, PharmD, Director, Office of Opioid Safety, University of Kentucky HealthCare; Kim Gaedeke, Chief Deputy Director, Michigan Department of Licensing and Regulatory Affairs; Marcella Wright, Deputy Executive Director, Office of Application Technology Services, Office of the Secretary, Cabinet for Health and Family Services; Steve Davis, Inspector General, Kim Lee, Pharmacist Consultant, Office of the Inspector General, Cabinet for Health and Family Services; Dr. Dan Danhauer, Chief Medical Information Officer, Owensboro Health; Ron Hatfield; Jim Acquisto, Senior Vice President, Public Affairs, Appriss; Jan Bright, Nurse Service Administrator, Henrietta Bada, MD, MPH, Contractor Supervisor, Assistant Director, Department for Public Health; Jessica Estes, Executive Director, Pamela Hagan, Deputy Executive Director, Nathan Goldman, General Counsel, Kentucky Board of Nursing; Morgan Ransdell, Staff Attorney Supervisor, Ann Tino, Nursing Investigator/Supervisor, Sue Thomas-Cox, Nurse Service Administrator,

April Thomas, Health Program Administrator, Kentucky Board of Nursing; and Jeff Wafford, Public Affairs Manager, United Parcel Service.

LRC Staff: DeeAnn Wenk, CSA, Ben Payne, Chris Joffrion, Dana Simmons, Becky Lancaster, and Sean Meloney.

Approval of the Minutes

A motion to approve the minutes of the September 30, 2019 meeting was made by Senator Buford, seconded by Senator Alvarado, and approved by voice vote.

Biologistics in Kentucky

Kyle Keeney, President, Chief Executive Officer, Kentucky Life Science Council, stated that America's biopharmaceutical companies are creating innovative new treatments to combat the diseases that impact many Kentucky families. There are more than 250 biotechnology health care products and vaccines available to patients, many for previously untreatable diseases. Biopharmaceutical companies are working with the Kentucky healthcare system to find cures for the hardest to treat conditions. There are 886 clinical trials with over 15,000 participants and approximately \$113 million invested. In Kentucky the biopharmaceutical economic impact consists of approximately 14,030 jobs at 1,212 companies with an average salary of \$72,151. Kentucky receives \$188 million a year in National Institutes of Health (NIH) funding and \$169 million in venture funding that results in \$4.9 billion in economic output. Kentucky is the hub for packaging and distributing medications to patients across America and the globe. Without the biologistics ecosystem in Kentucky, patients would not receive their medications when and where they need them. There are 7,475 jobs in Kentucky that are related to bioscience distribution. There are 720 physical locations that are involved in bioscience distribution. The largest bioscience related distribution employer in Kentucky is United Parcel Service (UPS).

Warren Olson, Director, Supply Chain Solutions Louisville Campus, United Parcel Service, stated that UPS has a large campus in Louisville with over 1.7 million square feet of healthcare-compliant warehouse space, including temperature and humidity controlled options. In Louisville, UPS has approximately 1,000 employees trained in healthcare logistics. In 2020, UPS is opening a new 450,000 square foot building that will create more than 200 new jobs. UPS distributes pharmaceuticals, vaccines, medical devices, biopharma, medical equipment, and animal health products. UPS is less than three miles from Worldport, UPS's automated, international all-points air hub. Louisville has strong interstate road access, with two-thirds of the United States population within a one day drive. UPS has over 75,000 square feet of coolers and 10,000 square feet of freezers that are used for storage. UPS has expertise in people, processes, and technology with focus on the needs of healthcare manufacturers.

Mr. Olson stated that UPS has donated \$4 million each year to Louisville area charities. UPS has 21,000 employees in Kentucky and has invested \$2.4 billion local capital project over the last two decades. UPS employees, families and friends have donated 18.7 million volunteer hours to various charities. UPS is environmentally responsibility having invested \$1 billion in alternative fuel and an advanced technology fleet. UPS has planted more than 12.5 million trees with a goal of planting 15 million by 2020.

Adam W. Bibelhauser, PMP, Director, Louisville Distribution Center Amgen, stated that the Amgen Louisville Distribution Center (LDC) has been operating since 1992 and has a total square footage of 125,000 and 12 acres of available land. Over the past four years Amgen has invested \$25 million to achieve business priorities including a secondary packaging and a tornado shelter. The majority of Amgen's products are manufactured in Puerto Rico and come to the LDC for commercial and sample distribution. The LDC manages multiple transportation carriers. The Amgen design allows for multiple packaging activities. Amgen distributes many different product brands. Amgen had six new product launches in the previous year and is growing its volume and staff accordingly. The LDC is engaged with the community through the University of Louisville, American Heart Association, Kentucky Chamber of Commerce, Greater Louisville Incorporated, Where Opportunity Knox, and Louisville Metro Parks.

Kate Shanks, Vice President, Public Affairs, Kentucky Chamber of Commerce, stated that logistics has become one of Kentucky's signature industries. Kentucky is within a day's drive of 65 percent of the United States population. The logistics industries consists of approximately 490 facilities that employ over 64,000 people. Kentuckians are delivering important medications to the world thanks to the continued growth of the biologistics industry. Companies come to Kentucky because there is access to world markets. The Chamber of Commerce advocates on behalf of businesses in the Commonwealth. The Chamber of Commerce will be working on infrastructure issues that are important to the logistics such as the network of roads, air, river ports, and railroads.

In response to questions and comments from Representative Moser, Mr. Olson stated that since starting at UPS he has seen the advent of serialization to minimize the impact of counterfeit drugs. He has seen a shift towards more personalized medicine, more biopharmaceuticals that require special handling, and more frozen or refrigerated shipments. Mr. Bibelhauser stated that he has seen a change in the differences between the logistics of moving healthcare products versus other industries. In the healthcare environment things are much more controlled, regulated, and focused on patients and quality. He stated that with the world is becoming more consumer focused, the challenge for many organizations is to balance quality, regulations, safety, and what the market requests.

In response to questions and comments from Senator Danny Carroll, Mr. Bibelhauser stated that Amgen uses UPS for all of its air shipments. Amgen uses other local carrier companies for ground shipments.

In response to questions and comments from Representative Brown, Mr. Olson stated that UPS has operations all across the state. UPS is centralized in Louisville due to the proximity to the airport and world port facility. UPS has large sortation facilities and large freight facilities throughout the state. Mr. Keeney stated that largest National Institutes of Health (NIH) recipient of federal money for research grants regarding the biopharmaceutical in the state is the University of Kentucky.

Diversion and Prescribing of Controlled Substances

Van Ingram, Executive Director, Office of Drug Control Policy, Justice and Public Safety Cabinet, stated that from 2017 to 2018 Kentucky had a 15 percent reduction in drug overdose deaths. From 2015 to 2018, there were 800,000 fewer prescriptions for opioids. There are 1,240 waived physicians in Kentucky that can prescribe buprenorphine but most are treating five or fewer patients. Buprenorphine is the number one diverted drug according law enforcement across the state. Gabapentin is another diversion drug on the rise. He stated that the prescribing of psychostimulant drugs is also rising at an alarming rate. The Kentucky Injury Prevention and Research Center issued a list of the counties with the highest risk score for overdoses. The Kentucky State Police data shows that from 2017 to 2019, heroin possession citations are down 15 percent, trafficking citations are down 12 percent, and deaths due to heroine are down 54 percent. Fentanyl trafficking arrests have gone up 73 percent in Kentucky. Methamphetamine use has also increased 11 percent. He stated that transitional housing and employment supports are just as important as treatment for people in early recovery.

Michael Rodman, Executive Director, Kentucky Board of Medical Licensure, stated that in 2015, the Kentucky Board of Medical Licensure (KBML) while completing regulations on prescribing controlled substances and Kentucky All Schedule Prescription Electronic Reporting (KASPER), developed regulations regarding buprenorphine for diversion. KBML has seen a steady stream of cases involving buprenorphine due to lack of education verses criminal activity. Leanne Diakov, General Counsel, Kentucky Board of Medical Licensure, stated that the buprenorphine regulation was created with the mindset that many physicians were prescribing buprenorphine but did not have guidance on how to prescribe buprenorphine correctly. The buprenorphine regulation has come under scrutiny because providers want to start buprenorphine treatments in other environments than originally envisioned. KBML has been working to amend the regulation to include other treatment environments and protocols.

Mr. Rodman stated that KBML is an independent agency, self-funded, that was created by the General Assembly through the Medical Practice Act in KRS Chapter 311. KBML is made up of 12 physicians and 3 consumers appointed by the governor except for

the representatives from the medical schools. The two major functions of KBML are licensure and discipline. All decisions regarding licensure and investigations are made by the KBML board members. KBML has five fulltime investigators with each covering a separate area of the state. The KBML investigators meet with state and local law enforcement agencies to coordinate and discuss how to handle cases. Mr. Rodman explained the various steps that are involved with a KBML investigation. Since 2012, the KBML board has initiated 412 investigations involving allegations of inappropriate prescribing. The numbers of prescriptions and the number of KBML investigations have gone down.

Ms. Diakov stated that in regards to the investigations and actions involving prescribing controlled substances, the disciplinary options available range from an admonishment to revocation of license. Typically the KBML board prefers to take a remedial action rather than a punitive action. The remedial action could be on online course or an additional continuing medical education (CME) class. If there is a question of clinical judgement or reasoning, a physician could be required to do more such as a clinical skills assessment. Mr. Rodman gave an overview of KBML's individual action totals from 2012 to present.

Jessica Estes, Executive Director, Kentucky Board of Nursing, stated that the Kentucky Board of Nursing (KBN) is governed under KRS Chapter 314 and 201 KAR Chapter 20. The KBN licenses and regulates approximately 90,000 nurses and manages the data base for the certified nursing assistant (CNA) program which includes 60,000 people. At the end of the fiscal year (FY) 2018-2019, there were 7,500 advanced practice registered nurses (APRNs). There are four categories of APRNs: nurse practitioners (APRN-NP), certified nurse midwives (APRN-CNM), certified registered nurse anesthetist (APRN-CRNA), and clinical nurse specialist (APRN CNS). All APRNs hold a masters or doctoral degree and national certifications. APRNs may only prescribe a controlled substance as defined and limited in KRS 314.011 (8), 314.042, and 201 KAR 20:059. The total number of APRNs in Kentucky have continued to rise each year. She stated that not all APRNs prescribe controlled substances.

Ms. Estes gave a summary of the KBN's investigation procedure. She stated that the different types of discipline for APRNs are immediate temporary suspension, unsubstantiated, letter of concern, consent decree, reprimand, limitation probation, and suspension. In regards to regarding controlled substances there were a total of 57 APRN disciplinary actions given in 2018 that included four suspensions, five license limitations or probations, nine reprimands, 24 consent decrees, three letters of concern, two immediate temporary suspensions, and 10 unsubstantiated cases. The KBN's partial year data for 2019 shows that there has been 59 discipline actions taken.

Doug Oyler, PharmD, Director, Office of Opioid Safety, University of Kentucky HealthCare, stated that 36 out of the 120 Kentucky counties rank in the 90th percentile or

higher nationally for individuals per capita living in poverty. 32 out of the 120 Kentucky counties rank in the 90th percentile or higher nationally for opioid prescriptions per capita. Nearly three out of four heroin users started with prescription opioids. The University of Kentucky HealthCare has three campuses in Lexington, Kentucky with 1,086 licensed beds. The University of Kentucky HealthCare is moving towards a new way of thinking about prescribing opioids. He stated that treatment should now start with nonsteroidal anti-inflammatory drugs (NSAIDs), acetaminophen, and non-pharmacological pain management then move to symptom-driven adjuvants and if pain persists resort to short-acting or intravenous opioids. He stated that the patients would then be weaned in the reverse order. The longer a patient is exposed to the opioids the higher the risk for developing a substance use disorder.

Dr. Oyler stated that within University of Kentucky HealthCare more than 70 percent of patients leave without an opioid. The University of Kentucky HealthCare has eliminated the use of extended release products from acute pain management. The University of Kentucky HealthCare has added leadership for system-wide expansion. The University of Kentucky HealthCare program changes have resulted in a 57 percent deduction in patients receiving high-risk regimens. On average there have been 1,300 opioid prescriptions avoided annually and 250,000 fewer opioid pills dispensed. The daily opioid dose per patients has decreased across the institution from approximately 30 per day to 28 per day. The number of patients receiving high dose regimens has also decreased. The number of individuals that are reporting no pain have gone up six to eight percent. The number of individuals that are reporting severe pain has decreased from approximately six to eight percent. The opioid initiation at the patient's hospital discharge was at 18 percent in July of 2016 and is at approximately seven percent in September of 2019. He stated that the goal isn't to minimize or eliminate opioids but to ensure that a patient's pain is treated adequately and responsibly with minimal risk.

In response to questions and comments from Representative Goforth, Mr. Rodman stated that by federal law to prescribe Suboxone a provider must complete an eight hour online course. Regulations could be changed to increase the training to minimize errors when prescribing Suboxone. Dr. Estes stated that KBN cases have increased because of how KBN has decided to handle investigations. When any complaint comes in or an investigation is started the KBN reviews the member's data regarding their controlled substance prescribing. Mr. Rodman stated that it is rare that KBML receives a complaint from a family member that a provider is over prescribing medication. Most of KBML's cases come from data analysis through KASPER or law enforcement.

In response to questions and comments from Representative Bentley, Dr. Estes stated that KBN can send data to the committee members regarding RN complaints. Mr. Ingram stated that there has been a Vivitrol program within the Department of Corrections since 2016. The challenge has been to keeping individuals engaged in the program. Mr. Ingram stated that the controlled substance that is most prescribed is also the controlled

substance that is being diverted. The increase in prescribing controlled substances has been with buprenorphine and gabapentin. Dr. Estes stated that in regards to the regulations that surround buprenorphine, it is not an easy drug to obtain for a patient. There are many requirements for the patients to receive the first prescription of buprenorphine.

Prescription Drug Monitoring Analytics

Kim Gaedeke, Chief Deputy Director, Michigan Department of Licensing and Regulatory Affairs (LARA), stated that the Michigan Automated Prescription System (MAPS) was established in 2015 within the Bureau of Professional Licensing. The Bureau of Professional Licensing licenses and regulates over 758,000 individuals that include 10 occupational licensing and regulation boards and 27 health professional licensing and regulation boards. The boards are advisory and determine sanctions. The MAPS System contains over 100 million records and the data is maintained for five years. Prescribers who dispense, pharmacies, and veterinarians are required to report dispensed controlled substance schedules two to five. She stated that there has been a decline in the total number of controlled substance prescriptions and opioid prescriptions dispensed in the last three years. Ms. Gaedeke gave an overview of the timeline regarding the MAPS history.

Ms. Gaedeke highlighted the MAPS replacement project goals. The MAPS replaced with new system software with Appriss Health's prescription monitoring program (PMP) AWA Rx E. The MAPS replacement project started in October 2016 and was completed on time and under budget. All users of the old system and new users required to register with MAPS through the PMP AWA Rx E software. She stated that LARA will continue to seek feedback from stakeholders. The project also incorporated NarxCare that allows the provider to see the data in different ways. She shared an example of the MAPS NarxCare report and described the information that can be obtained from the report. She stated that there is a resources tab that the prescribers and dispensers can use with care notes that are provided by the prescribers. She stated that MAPS was appropriated \$2.47 million to fund the project. The new MAPS time to query reports is less than one second. She gave a summary of the MAPS replacement project lessons learned regarding enhancements and integrations. She provided a list of MAPS projects and enhancements that have been completed or are in process. There are over 53,000 healthcare professionals that are integrated into the MAPS project. The future goals of MAPS is sustainability, strength, ongoing innovation, a focus on data analytics, and transformation into a clinical tool for health professionals.

Legislative Hearing on Maternal and Child Health Services Title V Block Grant

A motion to accept the block grant was made by Representative Bowling, seconded by Representative Bentley, and accepted by voice vote.

Legislative Hearing on the Preventive Health and Health Services Block Grant

A motion to accept the block grant was made by Representative Bowling, seconded by Senator Danny Carroll, and accepted by voice vote.

Kentucky All Schedule Prescription Electronic Reporting (KASPER) Update

Steve Davis, Inspector General, Office of the Inspector General (OIG), Cabinet for Health and Family Services, stated that KASPER is Kentucky's prescription drug monitoring program (PDMP). KASPER tracks Schedule II–V controlled substance prescriptions dispensed within the state as reported by pharmacies and other dispensers. KASPER provides a tool to help address the misuse, abuse, and diversion of controlled pharmaceutical substances. There are over 11 million controlled substance prescriptions reported to the system each year. There were more than 12.5 million reports or data requests processed in 2018. Dispensers have one business day to report information to KASPER. KASPER reports are available to authorized individuals 24 hours a day and typically within seconds via web access. The KASPER technology center can be modified by the KASPER team quickly and within existing budget in most cases to incorporate new initiatives, legislative changes, and new technology. Mr. Davis reviewed a list of new initiatives that are in process at this time.

Mr. Davis stated the most significant benefit of KASPER is that it is free of cost to prescribers, dispensers, researchers, health systems, and law enforcement. KASPER issues death notification letters, supplies drug conviction information, flags non-fatal drug overdoses, implemented prescriber report cards, helps to prepare for pain clinic closings, and assists in research collaborations. KASPER is undergoing a modernization to develop an entire new system and is completely federally funded by a grant.

Dr. Connie White, Senior Deputy Commissioner, Department for Public Health, Cabinet for Health and Family Services, stated that members were given list of organizations that belong to the Displaced Opioid Patient Workgroup. The workgroup can receive information quickly as to how many patients and which counties will be affected by a closure.

Dr. Dan Danhauer, Chief Medical Information Officer, Owensboro Health, stated that Owensboro Health covers most of Western Kentucky. Owensboro Health is on an Epic system and within one month of signing the contracts there was a live pilot of the system. There were four groups integrated together that included Owensboro Health, Epic, KASPER, and RxCheck. A PDMP report previously took 5 to 10 minutes for every single request. The RxCheck PDMP hub enables states to securely and efficiently share PDMP data. He stated that KASPER works and is considered a premier system.

Marcella Wright, Deputy Executive Director, Office of Application and Technology Services (OATS), Office of the Secretary, Cabinet for Health and Family Services, stated that OATS has reviewed the Appriss system multiple times. In regards to technology, the OATS will periodically look to see if there is more functionality in another system. In 2018, the OATS met with Appriss to acknowledge there would be a comparison of KASPER and Appriss. It was determined that Kentucky should stay with KASPER. The OATS uses some

products from Appriss that are integrated with KASPER. KASPER also integrates with RxCheck. She stated that the OATS contacted other states and asked questions about Appriss. The details of the questions and answers were provided in the packet given to the committee members. She stated that there are many similarities between Appriss and KASPER. The OATS reviewed functionality, technology, and costs. She stated that KASPER was found to be the best system for the Commonwealth.

Dr. White stated that Kentucky Poison Control has a dedicated opioid crisis hotline, 1-800-854-6813, for anyone with an opioid crisis or related questions.

In response to comments and questions from Senator Danny Carroll, Mr. Davis stated that Appriss is a Kentucky corporation and the OIG's supports its endeavors. KASPER is able to provide many peripheral benefits at no cost to the system. The reports generated, the integration, customer support and services provided by KASPER do not have a cost associated. He stated that there are many things that KASPER can do that Appriss cannot because KASPER is a state system. Appriss has a different business model. Dr. Danhauer stated that Owensboro Health's vendor quote was going to be \$50,000 a year with Appriss. The Owensboro Health system could not absorb the cost of Appriss. The KASPER system costs \$3,100 with full integration and has no ongoing costs.

Adjournment

There being no further business, the meeting was adjourned at 3:26 PM.