INTERIM JOINT COMMITTEE ON HEALTH, WELFARE, AND FAMILY SERVICES

Minutes of the 4th Meeting of the 2022 Interim

October 26, 2022

Call to Order and Roll Call

The 4th meeting of the Interim Joint Committee on Health, Welfare, and Family Services was held on Wednesday, October 26, 2022, at 11:00 AM, in Room 149 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, Karen Berg, Danny Carroll, Denise Harper Angel, Jason Howell, Alice Forgy Kerr, Stephen Meredith, Michael J. Nemes, and Max Wise; Representatives Danny Bentley, Tom Burch, Ryan Dotson, Daniel Elliott, Ken Fleming, Deanna Frazier Gordon, Melinda Gibbons Prunty, Josie Raymond, Steve Riley, Scott Sharp, Steve Sheldon, Nancy Tate, Russell Webber, Susan Westrom, and Lisa Willner.

Guests: Shanna Babalonis, PhD, Director, Kentucky Cannabis Center; Bart Hardin, Director of Government Relations, University of Kentucky; Nancy Galvagni, President, Kentucky Hospital Association; Monalisa Tailor, MD, President, Kentucky Medical Association; Cori Meadows, Deputy Vice President, Director of Advocacy, Kentucky Medical Association; Tim Mullett, MD, Medical Director, Markey Cancer Center Network Development, Markey Cancer Center, University of Kentucky HealthCare; Jill Kolesar, PharmD, Professor, College of Pharmacy, University of Kentucky; Michael Gieske, MD, Director, Lung Cancer Screening, St. Elizabeth Healthcare; Tony Remington, MBA, Chief Executive Officer, Gravity Diagnostics; Leah Phillips, Lung Cancer Patient Advocate, Louisville, Kentucky; Matt Holder, MD, Founding Director, Lee Specialty Clinic; Jeff Allen, Kentucky Board of Dentistry; Julie Brooks, Policy Specialist, Department for Public Health, Cabinet for Health and Family Services; Jonathan Scott, Executive Advisor, Department for Medicaid Services, Cabinet for Health and Family Services; and Maria Lewis, Assistant Director, Department for Income Support, Cabinet for Health and Family Services.

LRC Staff: DeeAnn Wenk, Ben Payne, Logan Bush, Chris Joffrion, Samir Nasir, Becky Lancaster, D. J. Burns, and Eric Rodenberg.

Approval of Minutes

A motion to approve the minutes of the September 28, 2022, meeting was made by Senator Berg, seconded by Senator Alvarado, and approved by voice vote.

Consideration of Referred Administrative Regulations

The following referred administrative regulations were placed on the agenda for consideration: **201 KAR 008:550 Proposed** - Anesthesia and sedation related to dentistry; **202 KAR 007:701 Emergency** - Scope of practice matters; **902 KAR 008:120 Proposed** - Leave provisions applicable to employees of local health departments; **907 KAR 001:065 Emergency** - Payments for price-based nursing facility services; **907 KAR 023:020 Proposed** - Reimbursement for outpatient drugs; and **921 KAR 001:380 Proposed** - Child Support Enforcement Program application and intergovernmental process. The listed administrative regulations were reviewed by the committee.

Update on the Kentucky Center for Cannabis - 2022 Regular Session House Bill 604

Shanna Babalonis, PhD, Director, Kentucky Cannabis Center, gave a brief history of establishing the Kentucky Center for Cannabis and discussed the executive committee members and the advisory committee members. She discussed the center's initial progress with studies regarding opioid use disorder, cancer, driving under the influence of CBD quality, a pilot growing project, and a collaboration with the Pennsylvania medical cannabis program. She gave an example of a general timeline of a trial, listed areas the executive committee is exploring, and discussed faculty grant programs and funding decisions.

In response to questions and concerns from Representative Moser, Dr. Babalonis stated that the vetoes on 2022 Regular Session House Bill 604 did not change what the center is working on structurally. Bart Hardin, Director of Government Relations, University of Kentucky (UK), stated that the veto had no impact on research, the boards are now determined by the president of the university, and funding was set on a biennial basis.

In response to questions and comments from Senator Alvarado, Dr. Babalonis stated that the amount of Tetrahydrocannabinol (THC) in the cannabis is controlled in the edible doses that are used in the cancer trial. She stated that all plant material is highly regulated by the United States Drug Enforcement Administration (DEA) and Food and Drug Administration (FDA).

In response to questions and concerns from Representative Willner, Dr. Babalonis stated that the Kentucky Center for Cannabis is one of several research laboratories in the country but UK is one of the only places in the world that can do an inpatient, placebo-controlled, cannabis trial.

In response to questions and concerns from Representative Bentley, Dr. Babalonis stated that there are many unregulated products that are available for anyone to purchase online with many derivatives of THC and the center has not analyzed any of those products.

In response to questions and concerns from Representative Sheldon, Dr. Babalonis stated that the center was required to have only UK faculty on the boards but all studies go through FDA and DEA review before a trial is launched.

In response to questions and comments from Senator Carroll, Dr. Babalonis stated that the center focused on the components in HB 604, but is starting a program to determine if the UK College of Agriculture can grow cannabis that matches federal and international standards.

In response to questions and concerns from Representative Moser, Dr. Babalonis stated that it would be helpful to reschedule marijuana to a Schedule II drug so that researchers could start testing and using marijuana in the research studies.

The Importance of Biomarker Testing in Health Care

Tim Mullett, MD, Medical Director, Markey Cancer Center Network, Development Markey Cancer Center, University of Kentucky HealthCare, discussed the leading types of cancer, risk factors, and health inequities. He discussed the rates of cancer and mortality, decline in lung cancer death rates, success of lung cancer screenings, reduction of late-stage lung cancer diagnoses, genetic discoveries to control cancer cell growth, causes of cancer-related genetic changes, progression of biomarkers with drug targets, biomarker guidelines, and policy changes to decrease barriers to obtaining biomarker testing.

Jill Kolesar, PharmD, Professor, College of Pharmacy, University of Kentucky, discussed somatic versus inherited germline biomarker testing, sequencing for non-small cell lung cancer (NSCLC) patients, survival rates of NSCLC patients after genomics, current drug treatments for different mutations, cancer mutation testing, implementation and strategy of the Molecular Tumor Board, and the design and outcomes of the control study of NSCLC cases.

Michael Gieske, MD, Director, Lung Cancer Screening, St. Elizabeth Healthcare, discussed the different terminology relating to biomarkers, the Integrative Analysis of Lung Cancer Etiology and Risk U19 Program, Multi-Cancer Early Detection (MCED) tests for early detection and lower mortality rates, targeted therapy with nine genes with driver mutations, immunotherapy drugs, ongoing research and therapeutic trials, and the need for a better risk prediction model.

Matt Holder, MD, Founding Director, Lee Specialty Clinic, discussed the range of diagnoses of the clinic's Intellectual and Developmental Disabilities (IDD) patients,

diagnostic overshadowing for IDD patients, and the use of pharmacogenetics testing with IDD patients to streamline prescription drug care for a better quality of health.

Leah Phillips, Lung Cancer Patient Advocate, Louisville, Kentucky, shared her personal experience with biomarker testing when diagnosed with lung cancer. She discussed the cost and the progression of biomarker testing.

Tony Remington, MBA, Chief Executive Officer, Gravity Diagnostics, discussed the capabilities of Gravity Diagnostics to do pharmacogenetic testing, the benefits and evidence to support pharmacogenetic tests, and reviewed an example of a testing report given to patients.

In response to questions and comments from Representative Moser, Mr. Remington stated that the pharmacogenetic test is usually a one-time test.

In response to questions and comments from Senator Berg, Mr. Remington stated that utilizing pharmacogenetics testing may be possible to predict an addiction to alcohol. Gravity Diagnostics is working on algorithms with patient demographics and zip codes to determine if pharmacogenetic testing may one day lead to information regarding addiction to alcohol. Mr. Remington stated that the cost of testing is going down from previous years with the hope that testing becomes more affordable for patients.

In response to questions and comments from Senator Kerr, Dr. Mullett stated that there are genetic drivers present for many tumors and Kentucky has a high population with lynch syndrome. This is a genetic driver of colon cancer. The new recommended age for colon cancer screening is 45 years old, and there are risks associated with moving that screening to an earlier age. He stated genetic testing was not done 20 years ago because it took far too long to get the results back from the genetic testing.

In response to questions and comments from Representative Bentley, Dr. Kolesar stated that the advertised testing turn-around time is two weeks but can take longer depending on pathology. Several commercial providers offer standard care and are paid for by Medicare. The number of genes vary with each test but ranges from 350 on the Foundation Medicine test and up to 500 on a Caris test, and the trend is to test every gene available and report on the ones with mutations.

In response to questions and comments from Representative Burch, Dr. Mullet stated that all the tests that can be done for patients, do not make up for a lack of care by a physician for his or her patients. Dr. Gieske stated that listening to patients is key to their health and getting a second opinion is never unreasonable.

Hospital Price Transparency

Nancy Galvagni, President, Kentucky Hospital Association (KHA), discussed the determinants of patients out-of-pocket (OOP) costs, hospitals' support to help patients anticipate and pay for OOP costs, the federal hospital price transparency tool to post standard charges, the machine-readable files, federally required shoppable services, estimates of expected charges, eligibility for a federal dispute resolution, new processes for providers to generate estimates, and the different factors in hospital pricing.

In response to questions and comments from Representative Moser, Ms. Galvagni stated that machine-readable files were not designed for consumers, but KHA believes shopping tools will be created from those files and will be helpful for patients to figure out the costs of treatment.

In response to questions and comments from Representative Raymond, Ms. Galvagni stated that the advance explanation of benefits (EOB) for insured patients will consolidate the charges by the hospital and providers for the services rendered.

Eligibility Criteria and Requirements Relating to Prior Authorization – 2022 Regular Session House Bill 343

Monalisa Tailor, MD, President, Kentucky Medical Association (KMA), discussed the background of prior authorizations, the 2021 American Medical Association annual survey results regarding prior authorizations causing care delays, abandonment of treatment, adverse clinical outcomes, federal and state reform efforts to improve timely access to care, and the 2023 Regular Session legislative priority for KMA to reduce the administrative burden and ensure patients have timely access to care.

In response to questions and comments from Representative Fleming, Dr. Tailor stated that KMA is waiting on information from Texas to provide a cost savings analysis.

Adjournment

There being no further business, the meeting was adjourned at 1:29 PM.