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Massachusetts Department of Public Health  
 Minutes of the Drug Formulary Commission  
 Meeting of Thursday, March 15, 2018  
 239 Causeway Street, Room 417  
 Boston, MA 02114

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**Date of Meeting:** Thursday, March 15, 2018  
**Beginning Time:** 9:22 AM  
**Ending Time:** 11:22 AM

**Advisory Council Members Present:** The following (13) appointed members of the Drug Formulary Commission attended on March 15, 2018, establishing the required simple majority quorum (9) pursuant to Massachusetts Open Meeting Law (OML): DPH Bureau of Health Professions Licensure Director James Lavery (Chair); Dr. Shihab Ahmed, Cheryl Campbell; Dr. Daniel Carr; Dr. Joanne Doyle-Petrongolo; Dr. Kenneth Freedman, Dr. Paul Jeffrey, Logan Leslie; Tracey McMillan; Cindy Steinberg; Dr. Jeffrey Supko, Dr. Theoharis Theoharides, Dr. Alec Walker.

**1. Welcome and Introductions**

James Lavery called the meeting to order at 9:22AM.

Mr. Lavery thanked everyone for being here today, and reminded everyone that the meeting was being recorded. He then asked if anyone was recording, receiving no affirmative response.

Mr. Lavery provided a brief recap of the last meeting on February 5, 2018, where the commission received three presentations on the cost impact of abuse deterrent substitution from health economist Joshua Cohen, the Center for Health Information and Analysis (CHIA) and the Institute for Clinical and Economic Review (ICER); and the commission staff presented the timeline for promulgation of the proposed revision of 105 CMR 720, *The Drug Formulary Commission*, which includes the first draft formulary.

Mr. Lavery reminded the members that all currently approved drugs were included on the first draft formulary in the regulation, and no new drugs have been presented for approval in Component 2 for the second draft formulary yet.

Mr. Lavery stated the goal for today’s meeting: to hear from an expert with the Chapter 55 Study on statewide addiction and overdose data, and discuss how this data may help the commission determine the cost impact of the abuse deterrent substitutions.

Mr. Lavery called for approval of the minutes from the February 5, 2018 meeting.  
 Motion to Approve: Dr. Carr

Second: Ms. Steinberg  
All in favor: 12; Opposed: 0; Abstentions: Dr. Walker

## **2. Cost Impact Review**

Mr. Lavery noted that Pursuant to Chapter 258 of the Acts of 2014, the Commission is tasked with getting expert feedback to consider as part of its work to develop the formulary, and reminded members that, at our last meeting, the commission heard from three speaker panels about “cost impact”, one of the four criteria for determining whether a drug is a chemically equivalent substitution. Ultimately, we are looking to answer your question “what does it mean for an abuse deterrent substitute to be cost prohibitive?”

Mr. Lavery noted that, at the last meeting, we heard a health economics perspective that included the idea that patient stratification may provide a substitution rate that is a more realistic and more useful factor when comparing HPHR opioids and IAD substitutions. These speakers were invited based on recommendations from Commission members in December.

### **a. Speakers**

Mr. Lavery informed members that today, they would hear a presentation of addiction and overdose data, collected and analyzed as part of the Chapter 55 Study, that may provide perspective on the scope of the crisis and assist us in identifying populations at risk and determining an appropriate substitution rate to use in calculating cost impact.

He asked the members to introduce themselves to the speakers and the audience, and they did.

Mr. Lavery then introduced the speaker:

- Dana Bernson is an Epidemiologist and the Assistant Director of the Office of Special Analytic Projects at the MA department of Public Health. For the past several years, she has been involved in DPH’s response to the opioid overdose epidemic and has held key leadership and analytic roles on an interdisciplinary team tasked with analyzing linked data related to the epidemic. Additionally, she has extensive experience analyzing data in a wide range of perinatal issues. Previously, she worked in cardiology clinical research at Boston Children’s Hospital. She completed her Master of Public Health in Epidemiology and Bachelor of Arts in Political Science degrees at Boston University.

Ms. Bernson presented “Examining the opioid Epidemic using Linked Data: MA chapter 55”. See attached slides

Ms. Campbell asked Ms. Bernson to read numbers from slide 5 of presentation.

Ms. Bernson read the numbers, which were very small on the slide.

Dr. Theoharides asked why some counties were significantly worsening.

Ms. Benson responded that this question is part of what they are trying to explain with that data analysis.

Ms. Campbell asked if the death rates reported on slide 5 were only referring to illicit opioids abuse.

Ms. Bernson responded that the rates included all death related to opioids abuse regardless of whether they were illicit or not.

Ms. Steinberg asked about data separating the drug leading to death.

Ms. Bernson directed her to one of the slides with that data.

Dr. Carr asked if they differentiated in the studies between fentanyl lollipops and patches.  
Ms. Benson answered that they did not.

Dr. Freedman asked if methadone could be tracked.  
Ms. Benson directed him to data on the showing the difference between drug at death and drug prescribed.

Dr. Carr stated that alcohol and Benzodiazepines were risk factors in non-opioids death, and asked if their presence was tracked in this data.  
Ms. Benson stated that they are tracked in toxicology reports and prescription history.

Mr. Leslie questioned the validity of the time from initial prescription to overdose death data.  
The question remained pending and Ms. Benson agreed to come back to Mr. Leslie with a more satisfying answer.

Dr. Walker asked what prevented the Chapter 55 study from getting data after 2015.  
Ms. Benson responded that privacy and security were limitations.

Ms. Benson cited data showing a 4% prevalence of Substance Use Disorder among Massachusetts children ages 11 to 25.  
Dr. Carr asked if the “unknown” factor was estimated but not captured.  
Ms. Benson estimated that this was a 339% increase for this age group.

Dr. Walker asked if non-fatal overdose data linked in Narcan.  
Ms. Benson stated that the Bureau of Substance Addiction Services only has data on known reversals, although it is clear that fatal overdoses would be higher without Narcan, and a non-fatal overdose is the #1 indicator of a fatal overdose.

Dr. Carr asked about data indicating that prescriptions led to overdoses.  
Ms. Benson noted that 58% of fatal overdoses had an opioid prescription within one year prior to death, but that only 1% had a legal prescription at the time of death.  
Ms. Steinberg asked if that meant we should not be looking at doctors’ prescribing patterns as a contributor.  
Dr. Walker responded that the data may show that prescriptions may be the gateway to fatal overdose.  
Dr. Freedman supported that statement with an assertion that patients come to treatment always having started on prescriptions.  
Ms. Benson agreed, but noted that the prescriptions are not always their own, but are being diverted from a large initially legal market supply.

Ms. Benson reiterated the confirmed statistic that, in a study of opioid naïve only, there is an average of 36 months from the first opioid prescription to fatal overdose, and that non-fatal overdoses are generally not followed by treatment, but by more getting more prescriptions.

Dr. Walker asked if PMP data could show an inflection point at which the standard patient is likely to fall into addiction.

Ms. Steinberg asked what other factors could be included in that determination.  
Members discussed some of the possible factors listed on the slide relative to opioid naïve average time to death, claiming that the statistic would seem more valid if there were broader comparators.

Ms. Lauren Nelson agreed to include the Chapter 55 studies on the DFC website.

Mr. Lavery thanked the speaker for attending today's meeting and for her thoughtful remarks and engaging discussion.

Mr. Lavery called for a break at 10:40 pm, and called the commission back to order at 10:52 pm.

#### **b. Discussion**

Mr. Lavery opened up the discussion on Ms. Bernson's presentation and the three presentations from the February meeting, and gave the members an opportunity to discuss their thoughts and provide feedback with a goal of developing comprehensive criteria for determining whether an IAD's inclusion as a therapeutically equivalent substitute is cost prohibitive.

Dr. Doyle-Petrongolo noted that the CHIA data was based on an early draft formulary and may need to be updated to include additional drugs.

Mr. Leslie stated that information was needed on potential changes in drug prices over time and asked if a manufacturer could come in to talk about pharmacoeconomics.

Mr. Lavery asked if there is a cost that is considered too high to implement IAD.

Dr. Doyle-Petrongolo expressed the need to estimate the cost of switching to an IAD and present the results to the commission.

Dr. Freedman asserted that a deeper dive was needed on oxycodone overdoses.

Dr. Walker stated that prescribers should be given all the information and tools available and let them discuss the viability of substitution with the patient based on everything out there.

Ms. Steinberg asserted that clinicians would be more aligned to adjust their prescription patterns to control the opioid epidemic. For instance, they can weigh the amount to be spent with the lives saved.

Dr. Carr stated that the commission should be able to provide recommendation to physicians and let them decide with their patient.

Dr. Jeffrey suggested creating a decision tree to be used by prescribers. If X then X options.

Dr. Theoharides compared it to a public health decision to give the flu vaccine to everyone, when only two people die each year from flu.

Ms. Campbell noted that a publicly traded pharmaceutical company must file certain information with the SEC, which could include projections, so they should have this information already and it may be public. She suggested hiring a system dynamics expert or borrowing a model for the commission to use. She offered to send an example.

Mr. Lavery agreed that the commission should come with an algorithm or thought process on how the commission can make the decision if a drug is cost prohibitive or not. There is a need for a framework. He noted that the commission should come up with a template framework based on a system dynamics model. He agreed to put something together with Ms. Campbell to present at next meeting.

Mr. Lavery thanked the commission for engaging in this interesting and informative discussion. He noted that there will be more opportunities at future meetings to continue this discussion as part of an effort to memorialize the commission's and procedures in this policies in this area.

### **3. Draft Formulary and Regulation**

Mr. Lavery reminded members of the public review and promulgation process for 105 CMR 720, which was approved by the Public Health Council on August 9, 2017.

Mr. Lavery stated the regulation will take effect once it is filed with the Secretary of State, which will occur at least 30 days after the prescribing and dispensing guidance is distributed to begin the education and outreach process.

Mr. Lavery stated he will keep everyone informed if there is any movement on this process

Mr. Lavery announced that On March 1st, the Board of Registration in Pharmacy approved a policy clarifying that a pharmacist may add a "no substitution" notation on Schedule II-III prescriptions after consultation with the prescriber.

Mr. Lavery asked if there was any further discussion.

### **4. Drugs Products for Future Consideration**

Mr. Lavery reminded members that, at the last meeting, we discussed our plan to present a new drug for evaluation. However the drug does not yet qualify for DFC evaluation because the manufacturer of RoxyBond has not yet begun marketing the drug in the United States, which the commission established as a necessary criteria for evaluation on March 3, 2016, when it denied consideration of Targaniq.

Mr. Lavery introduced Dr. Karen Stevens to update the commission on the drug product pipeline.

Dr. Karen Stevens announced that a new Oxycodone ER NDA was submitted to the FDA, and the expected return date from the FDA is anticipated in August.

Dr. Stevens reminded members that Vantrela ER was FDA approved, but there is no information on when it will be released.

Dr. Stevens noted the same for Targiniq ER. She stated there is no information available on why these drugs are not being pursued by the developing company.

Mr. Lavery stated that as the FDA continues to review and approve drugs with ADP properties, and more of these drug products are brought to the US market, the Commission will need to determine how these drugs may interact on the Formulary.

Mr. Lavery also stated that if information comes to light at any time to potentially change the evaluation of an existing drug product on the formulary, the product can be added to the agenda for reconsideration.

Mr. Lavery asked if there were any questions or comments on these drug products or this process.

There were none.

### **5. Meeting Schedule**

Mr. Lavery thanked the members for their thoughtful comments and questions and thanked Ms. Bernson for providing important information. He will update the committee with any updates related to the effective date of the regulation and the distribution of the guidance.

Mr. Lavery noted that monthly meetings will continue to be held on the 3rd Thursday of each month, from 9:00-12:00PM in the PHC room at 250 Washington Street, with a few exceptions. As noted previously, the April 19th meeting is cancelled due to school Vacation Week and other staffing considerations. It will be necessary to meet prior to August 30<sup>th</sup> to update the Non-opioid Pain Management List, which must be approved and posted on-line by September 1, 2018.

The next meeting is anticipated for May 17th at 9AM at 250 Washington Street.

Commission staff hopes to continue discussion about "cost impact" and possibly finalize related protocols and also hopes to present RoxyBond for IAD evaluation and approval at that meeting, assuming the product is fully launched at that time.

### **6. Closing Remarks/Adjournments**

Mr. Lavery asked for any final discussion or questions, and hearing none, called for a motion to adjourn.

- Motion to Adjourn: Dr. Doyle-Petrongolo
- Second: Dr. Freedman
- All in favor: Unanimous

Meeting adjourned at 11:22AM