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Massachusetts Department of Public Health
Minutes of the Drug Formulary Commission
Meeting of Thursday, March 20, 2017
Henry I. Bowditch Public Health Council Room, 2nd Floor
250 Washington Street
Boston, MA 02114

Date of Meeting: **Thursday, March 20, 2017**
Beginning Time: 9:05 AM
Ending Time: 10:35 AM

Advisory Council Members Present: The following (11) appointed members of the Drug Formulary Commission attended on December 15, 2016, establishing the required simple majority quorum (9) pursuant to Massachusetts Open Meeting Law (OML): DPH Bureau of Health Care Safety and Quality Director Eric Sheehan (Chair); Dr. Shihab Ahmed, Dr. Douglas Brandoff; Dr. Daniel Carr (9:16AM); Dr. Joanne Doyle-Petrongolo (9:13AM); Stephen Feldman; Dr. Paul Jeffrey; Logan Leslie; Tracey McMillan; Dr. Jeffrey Supko; and Dr. Alexander Walker.

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1. Welcome and Introductions

Eric Sheehan called the meeting to order at 9:05AM

Mr. Sheehan 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. Sheehan made two membership announcements. Tracey McMillan, the Director of the Bureau of Managed Care at the Division of Insurance (DOI) will serve as the Commission's representative from the Division. In addition, Logan Leslie has been appointed to the Commission as a representative of the public. Mr. Leslie's interest in the DFC stems from his experience as a Veteran, having served 8 years in active duty, and a total of 13 years. He is particularly focused on issues related to Opioid use and PTSD. Mr. Leslie is currently a student at Harvard Law School, where he is engaged in the study of health care law.

Mr. Sheehan recapped the last meeting on December 15, 2016, in which the Commission discussed two important documents:

- The DFC regulation, 105 CMR 720, including the process remaining before promulgation; and
- The CHIA benefits review.

At the last meeting, Commission presented the timeline for continued review of the proposed amendments to 105 CMR 720, including the first draft formulary. A public hearing was held on January 19, 2017, and staff hope to complete review of the comments and present the regulation for promulgation in the next couple months. Commission staff also presented the final benefits review completed by the Center for Health Information Analysis (CHIA).

Next, Mr. Sheehan called for approval of the minutes from the December 15, 2016, meeting.

- Motion to Approve: Mr. Feldman
- Second: Dr. Jeffrey
- All in favor: 7; Opposed: 0; Abstentions: Mr. Leslie and Ms. McMillan; Not Present: Dr. Carr and Dr. Doyle

2. IAD Drug Product Evaluations

Mr. Sheehan introduced the next agenda item. In September 2016, the Commission began the task of evaluating more drug products for the second abuse deterrent formulary by approving Xtampza ER as an Interchangeable Abuse Deterrent. Today, we will continue this process for Troxyca ER.

To do this, the Commission will revisit Component 2 to evaluate its claims of ADP technology using the approved monograph. The Commission does not need to revisit Component 1 again, as its vote on October 15, 2015, to include all Schedule II and III opioids on the Heightened Public Health Risk (HPHR) list, allows all new opioids to automatically be placed on the HPHR opioid list upon FDA approval, until approved as IAD drug products by the Commission.

Dr. Tyson Thompson gave a presentation on Troxyca ER®. Following the presentation, there was discussion by the members.

Mr. Ahmed stated that there seems to be potential for abuse and asked about the GI absorption. Dr. Thompson noted that there is some risk of getting a high but when naltrexone is introduced, can minimize the high. Naltrexone is orally active as a product; crushing and release would cause an effect.

Dr. Carr asked about the use of the word “significantly” and if it meant statistically or clinically significant in relation to its use on slide 6. Dr. Thompson stated that statistically significant is

the meaning on that slide. Dr. Carr stated that it may not be clinically significant and Mr. Thompson replied that it may be still liked but less so.

Dr. Jeffrey asked if the FDA provided an explanation of why they didn't accept recommendation of their committee. Mr. Thompson stated that from reading labeling, it seems like the FDA felt like they couldn't go off of a simulated product. If you can't see it, it may not get abuse deterrent labeling.

Dr. Doyle-Petrongolo asked if there should be a red flag related to the information on page 1 of the monograph. Dr. Thompson stated that the information is from the package insert. If an individual can crush and administer, it's possible you may have a fatal overdose. The other side is that the naltrexone may restrict that from happening.

Dr. Ahmed replied that he's not sure naltrexone is used to prevent overdoses. Dr. Thompson agreed that it is not a rescue drug but used to blunt a high from manipulating the product.

Mr. Leslie asked if there many products that have taluc in them. Dr. Thompson responded that it was mentioned because there can be issues with it.

Dr. Carr indicated that there appears to be a substantial reduction in liking. Mr. Sheehan stated that for this component, the Commission is considering if this drug has enough of an ADP to make the list. The Commission will do another comparison if there is.

Mr. Feldman stated that after looking at all the data, if this is a product that we agree is abuse deterrent. If no, then that's the end of it. If yes, we will look at the drug in comparison to those that are abuse deterrent where an interchange is recommended.

Dr. Jeffrey noted that injectable abuse deterrent properties weren't evaluated for them to consider. How would there be no formation of a gel? Dr. Thompson noted that you can crush but there was no mention of a gel in the materials. Dr. Supko stated that the Commission approved Embeda and this is the same technology. Dr. Thompson stated that Embeda is essentially the same product- just a different opioid.

Mr. Sheehan requested a motion to approve Troxyca ER® as an IAD Drug Product.

- Motion to Approve: Mr. Feldman
- Second: Dr. Walker
- All in favor: 11; Opposed: 0; Abstentions: 0

While Troxyca ER® is the only newly approved drug product to be presented today, there are several others that may be ready for presentation in the coming months:

- MorphaBond®
- Arymo ER®
- Vantrela ER®

- Opana ER® – Given recent news from the FDA, confirming the DFC's determination on February 4, 2016, that the dangers of Opana ER® outweighed its abuse deterrent benefits, it is unlikely that this drug product will be reevaluated in the near future.

On December 17, 2015, in consideration of Targaniq ER, the Commission voted unanimously not to consider Targiniq ER or other drugs that are not marketed in the United States for inclusion as potential substitutes.

3. Chemically Equivalent Substitutions

Next, the Commission reviewed the ADP Efficacy evidence for evaluation and categorization; however, there were no appropriate pairings to present for the Commission for approval.

There is no non-abuse deterrent Oxycodone ER for which to substitute Troxyca ER®. OxyContin tablet and its authorized generic, Oxycodone ER tablet, are already on the Formulary, with no equivalent HPHR opioid identified.

Dr. Thompson reviewed the ADP Efficacy form including an explanation of the evidence and categories. Mr. Sheehan reviewed the statutory requirements for reviewing drugs and noted that the Commission defined chemically equivalent in a previous meeting.

Mr. Feldman noted that if you look on the ADP Efficacy form, it includes the abuse deterrent proof provided to FDA. The FDA came up with requirements to get abuse deterrent labelling. It is understood that evidence wouldn't be available right away but the criteria was developed. The Commission followed the same definitions to avoid confusion.

Dr. Ahmed asked what the recommendation of category 2 based on. Dr. Thompson responded that all data available in monograph and published literature of the product goes into the determination.

Mr. Sheehan stated that the Commission had a similar conversation last year and wanted to benchmark its decision at a point in time as more information and studies become available. The goal is to make a snapshot of the category determined based on info available at that time.

Dr. Jeffrey stated that it may be best to not refer to these as categories. Mr. Sheehan noted that since the DFC already voted on the Form, it will need a recommendation to reconsider and would need to be put on agenda for vote at a future meeting. Dr. Carr added that the Commission may want to reconsider the use of certain words.

4. Draft Formulary

The Commission reviewed the process for promulgation of the regulation. DPH will coordinate the issuance of guidance to prescribers and pharmacists with promulgation of the regulation to assure a smooth implementation and appropriate compliance.

While the Department believes this guidance will provide reasonably clear instructions to comply with the regulation, it is apparent that additional education will be necessary to adequately respond to uncertainty, especially on the part of prescribers seeking to avoid inconvenience to patients receiving opioid prescriptions.

DFC staff investigated several potential methods and a variety of materials to provide this information and arrived at a potential recommendation that we'd like to present to you.

Section 19A of Chapter 94C of the General Laws now includes a universal requirement for prescribers to receive training and education on safe opioid prescribing prior to initial and renewal licensing. DFC staff suspect some of you may have already participated in this training and education as part of your license to practice.

DPH may seek to supplement this mandatory training curriculum with a brief, but detailed tutorial on the effects of this new regulation on opioid prescribing practices. By adding this topic to the training curriculum, we would strive to engrain in prescribers the habitual practice of consulting the formulary prior to prescribing a Schedule II or III opioid drug product to determine if the drug has an associated abuse deterrent substitute, in order to prevent patients from having to return for a new prescription.

DFC staff would recommend the training also include an advisory about noting "no substitution" on the prescription. While this may be a useful tool to allow a patient to receive a non-abuse deterrent opioid in many circumstances, prescribers should consider the potential cost impact on patients.

Dr. Doyle-Petrongolo asked if this will still go into effect in July. If so, if we are looking at doing this before license renewal, does that timing make sense? How often do they renew? Mr. Sheehan responded by asking that once it is promulgated and is final regulation to enforce, what does a good transition period look like? What is a reasonable timeframe for a provider to take this training? Would it take 60 or 90 days to get the training done?

Dr. Doyle-Petrongolo stated that 90 days may not be enough. You need 6 months or a year depending on how quickly you can get the technology in place. It is important to think about innovative technology options that may enable faster access to this information. We find that sometimes email is not up to date so sending out the requirement via email may result in bounce backs.

Ms. Lauren Nelson stated that we are primarily discussing prescriber education but dispenser information will be in guidance that will go out the same day that we promulgate.

Mr. Feldman suggested having a conversation with DEA to identify any available technology.

Mr. Brandoff stated that it is helpful to have a sense of what degree of frameshift are we thinking about—what is the 10,000 foot view of what this will entail? The Commission has been in the details and that will help to figure out what elements need to be in place. Having to do partial fill was challenging and this is a bigger endeavor. We need to do advanced planning and education

to be successful. It is problematic to start on July 1 for residents. It also has the potential to further stress patients that are under duress so we want to make sure outreach is done to patients.

Dr. Ahmed replied that education can start sooner than an exact date. Doing it at registration is good idea but in our experience, when we apply for hospital privileges, there are requirements to go through so maybe the hospitals can put the education in the module.

Ms. Nelson stated that it can be hard to start education before the law goes into effect because it doesn't technically exist. It is also possible that changes may be made during the process requiring education and outreach to take place twice.

Dr. Jeffrey asked what would be the process to engage stakeholders. Mr. Sheehan stated that it would be similar to the rollout of MassPAT and how boards engage their stakeholders. We will engage associations to engage their members, along with our expert stakeholders. We know that the rollout will not be successful if these individuals are not engaged.

Dr. Jeffrey asked about outreach to general public--How does that happen? Would this reach the level of expending funds to do PSAs? Mr. Sheehan stated that PSAs are a good recommendation.

Ms. Nelson stated asked that given challenges of educating prescribers, how do you educate consumers that may not be as well versed? Dr. Doyle-Petrongolo responded stating that we are living in a fearful society and if patients think that their medications are at risk, they will get more scared. It will also create more stress for providers trying to help them. If there are more frequent prescribers of those that may be impacted, maybe do targeted outreach.

Dr. Carr noted that we should look at in comparable way to rollout of PMP and use insurers and health care associations to help. Blue Cross Blue Shield has put standards in place to help with implementation of certain requirements.

Mr. Feldman asked if it was possible to utilize the MassPAT system. Can a provider run a report to see which of their patients are impacted? Mr. Sheehan responded that we may have technology challenges with vendor but will take another look at this suggestion. MassPAT is intended to be an awareness tool so have to be careful about what you incorporate in. There are dashboard reports and we will be turning alerts on in the future but it is important to note that MassPAT is only a snapshot for the last 12 months.

Dr. Doyle-Petrongolo stated that the education piece needs to include what the patient needs to do to have a conversation with their prescriber on writing no substitution.

Mr. Feldman asked if is there a way to determine how effective the formulary is. It would be nice to see if it is measureable. Mr. Sheehan stated that DPH is always looking at how we view our benchmarks. Chapter 55 reporting is a key example of this work.

5. CHIA Benefits Review

Mr. Sheehan opened discussion on the CHIA benefits review that was provided to the Commission members in December 2016. While this report is complete and final, it is the Department's hope that you found it informative of many of the issues, particularly those related to cost, that we discussed during our evaluation and crosswalk of abuse deterrent products in the first year of formulary.

There were no questions on the report.

6. Next Steps

Today, the Commission approved Troxyca ER® as an IAD Drug Product and categorized its Abuse Deterrent Efficacy for future consideration of potential pairings.

The second draft Formulary will be an evolving document. 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.

Additionally, the review of the non-opioid pain management list is an annual task for the Commission, with an updated list due to be published by September 1 of each year. We may also see more tasks assigned to the Commission by the Legislature that we will need to be prepared to respond to in a timely manner.

We have scheduled monthly meetings through June. Please expect to receive Doodle polls from Suzanne to confirm quorum as these meetings approach.

As always, please stay tuned for meeting news, including doodle polls. We will confirm that we will have quorum as far in advance as possible, and if a scheduled meeting must be cancelled for lack of information to present or any other reason, we expect to notify you at the previous month's meeting, if at all possible.

As we stated earlier, we will also be in touch with updates related to the presentation of the draft regulation to the Public Health Council if any of you wish to attend as audience members for the presentation of the amended regulation and draft formulary.

Mr. Sheehan asked for any final discussion or questions, then called for a motion to adjourn.

- Motion to Adjourn: Dr. Jeffrey
- Second: Dr. Doyle-Petrongolo
- All in favor: 11; Opposed: 0; Abstentions: 0