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**Massachusetts Department of Public Health**

**Minutes of the Drug Formulary Commission**

**Meeting of Thursday, December 15, 2016**

Henry I. Bowditch Public Health Council Room, 2nd Floor

250 Washington Street

Boston, MA 02114

**Date of Meeting:** **Thursday, December 15, 2016**

**Beginning Time:** 9:08 AM

**Ending Time:** 10:41 AM

**Advisory Council Members Present:** The following (14) 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; Cheryl Campbell, Dr. Daniel Carr (9:13AM); Dr. Joanne Doyle-Petrongolo (9:15AM); Stephen Feldman, Dr. Kenneth Freeman, Dr. Paul Jeffrey; Neils Puetthoff, Dr. Jeffrey Supko, Cindy Steinberg, Dr. Theoharis Theoharides and Dr. Alexander Walker.

**1. Welcome and Introductions**

Eric Sheehan called the meeting to order at 9:08AM

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.

At the last meeting, it was announced that William de Groot resigned from the Commission when he accepted a new job out of state. Mr. Sheehan introduced Dr. Shihab Ahmed, who has been appointed in his place. Dr. Ahmed comes to Commission from Massachusetts General Hospital, Department of Anesthesia, Critical Care and Pain Management, where he conducts research, among other endeavors, on the Influence of Psycho-social variables on pain relief from Spinal Cord Stimulation therapy for chronic pain. Dr. Ahmed introduced himself to the Commission.

Mr. Sheehan next announced that Tammy Thomas, who represented the Division of Insurance, had left to pursue other opportunities in New York. Neils Puetthoff has represented the Division from time to time in the past, and will continue to do so in Tammy’s absence. Mr. Puetthoff introduced himself.

Mr. Sheehan noted that one vacancy remains on the Commission and we are actively working to fill this spot for a member representing members of the public. We welcome any assistance or recommendations you may provide.

Mr. Sheehan recapped the last meeting on September 15, 2016, noting the DFC’s approval of Xtampza ER as an interchangeable abuse deterrent drug product; reviewed the ADP efficacy of Xtampza ER for future consideration of potential pairings; and received a briefing on newly approved drug products and products in development for future consideration as IAD drug products to be placed on updated versions of the Formulary of Chemically Equivalent Substitutions.

By approving Xtampza ER as an IAD drug product in September, the Department was able to include it on the draft formulary that is currently being proposed for promulgation in 105 CMR 720, List of Interchangeable Drug Products (as proposed with a name change to Drug Formulary Commission)

The September 15th meeting, therefore, marked the completion of the work necessary for the first completed draft Formulary of Chemically Equivalent Substitutions, as was the Commission’s mission under Section 13 of Chapter 17 of the General Laws, as charged in Chapter 258 of the Acts of 2014.

Next, Mr. Sheehan called for approval of the minutes from the September 15, 2016 meeting. Minor typographical changes were offered by the members.

* Motion to Approve: Dr. Jeffrey
* Second: Mr. Feldman
* All in favor: 11; Opposed: 0; Abstentions: Ms.Steinberg; Not Present: Dr. Doyle

**2. Draft Formulary (105 CMR 720)**

Mr. Sheehan and Lauren Nelson, Policy Director, gave a presentation on the proposed amendments to 105 CMR 720 that was presented to the Public Health Council on November 9, 2016. The public hearing on the regulation will be held on January 19, 2017.

The proposed amended regulation is online under the title “List of Interchangeable Drug Products”, the public comment period is open, and public comments must be received by January 24, 2017. There was discussion of how the Commission may choose to provide public comment as individuals and/or as a group.

Mr. Freedman applauded Department leadership and the Commission for its great work. A lot of great minds have put together a stellar work product. Does the regulation allow for a connection to the MassHealth formulary? Mr. Sheehan responded stating that the Commissioner’s statutory authority is only related to the Commission’s list. The Public Health Council can’t change the list- it would need to be voted on by the Commission. Ms. Nelson noted that there is a public comment period for all proposed regulations and the Department considers all feedback before proposing a final regulation.

Mr. Sheehan stated that the Division of Insurance has its own regulatory process but it is similar to this one. We have been coordinating with the Division on this process. MassHealth is not required to comply with the same mandated coverage that other insurance companies are.

Dr. Jeffrey stated that MassHealth will comply with all statutory and regulatory requirements would need to determine if required to comply. MassHealth reports to the same Secretary as DPH.

Mr. Freedman suggested that the Commission may recommend to MassHealth to consider adoption of this formulary. Would that be something that is reasonable? Dr. Jeffrey noted that it would be and MassHealth is also obligated to consider public comment.

Mr. Feldman asked how the Formulary will be operationalized. Mr. Sheehan noted that this is DPH’s task with guidance from the Commission. One of our responsibilities is to consider the Commission’s feedback in the guidance that we put out and the Public Health Council asked a similar question. We need to get out in front of all stakeholders and what timing looks like. We will also work closely with our licensure boards as far as training and deliverables. This is what we own as part of final promulgation.

Mr. Feldman asked if it was possible for the regulation to get promulgated without the guidance being done. Ms. Nelson stated that it was our goal for guidance to go out on same day as promulgation. Comment review takes time and we need to consider if changes need to be made.

Dr. Doyle Petrongolo stated that people are confused about other requirements in effect and are concerned that patients won’t be able to get what they need.

Dr. Brandoff stated that clinicians are busy and they may not be aware that this is going out. The more we can be preemptive, the better we will be. On March 14, 2016, Governor Baker signed a new law and some parts went into effect immediately. One positive example of advanced outreach and communication was the implementation of MassPAT. Yes, there was an adjustment but we were prepared as we could be. I want this rollout to mirror MassPAT.

Mr. Sheehan noted that we envisioned using the MassPAT implementation model. How do we engage and become more visible? Our top priority is preserving health care for constituents. Any advice from the Commission will be helpful.

Ms. Campbell asked if there were plans to do outreach to pharmaceutical companies. Mr. Sheehan noted that we will collaborate with anyone to get the right information out there.

Ms. Nelson noted that we have had regular conversations with drug manufacturers that have come up for review or those with products on the horizon. We also have other projects that involve manufacturers that we are working on.

Dr. Carr stated that we need explicit guidance on cost. Although CDC guidelines don’t say to never treat with opioids, some providers think that is what it means and patients can’t continue to receive these drugs. There is an opportunity in roll out to make it clear that there is a role for opioids in some patients and there are tools to assess risk and compliance. Mr. Sheehan noted that we will talk about cost during discussion on CHIA report. During development, we provided analysis on cost but will discuss further.

Ms. Steinberg included that we want to make it clear to prescribers that this is not an excuse not to prescribe. We are seeing great confusion between guidelines and laws to the point that docs won’t prescribe. We have been inundated with clients that have not been able to get prescriptions. This is yet one more thing that may frighten prescribers to treat people with pain.

Mr. Sheehan noted that at the next meeting, if you want to discuss the proposed regulations as a group, we will put it on the agenda. There was interest in this from the members and discussion amongst the members on the best way to organize review understanding that the product also speaks for itself.

Dr. Supko wanted to discuss how this will work. What happens if there is an issue with supply at pharmacy with dispensing drugs on the formulary? Will the language in the regulation cover these situations so the patient isn’t held without anything?

Mr. Sheehan noted that for the January meeting agenda, we will ensure that we discuss group comments. DPH will work on it to divide up the minutes for review.

There was a suggestion to add language “and is available” to address potential issues with supply. Dr. Jeffrey noted that the DEA does have a limitation on pounds of morphine that can be produced and having an interchange doesn’t increase the amount of morphine in the market place. We will need make sure language is artfully written.

Dr. Doyle Petrongolo stated that we want to utilize technology that we have—this way when the physician sends a prescription, will have info right there.

**3. IAD Drug Product Evaluation**

Mr. Sheehan stated that as we did for the first Draft Formulary, we will begin the process of evaluating newly approved drug products with abuse deterrent claims or FDA approved abuse deterrent labelling as potential Interchangeable Abuse Deterrent (IAD) Drug Products to include as List A drugs for Formulary 2.0.

To do this, we will revisit Component 2 and evaluate newly approved drug products that have claims of ADP technology using the same monograph this commission approved for the first Draft Formulary.

The Commission will not need to revisit Component 1 again, as your 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 you.

The Commission does not have any drug products to evaluate today, but there are several newly approved drug products and products in development that we may consider in the future. Three newly approved drug products may be ready for presentation in the coming months:

* MorphaBond
* Troxyca ER®
* SequestOx®

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

There are also three drug products in development that we may be able to present to you before this evaluation period ends:

* Remoxy®
* Arymo ER®
* Vantrela ER®

Mr. Sheehan stated that we may also need to look at Oxaydo again based on new info available.

**4. CHIA Benefits Review**

Mr. Sheehan noted that at the January 7, 2016 meeting, the Commission voted to request a benefits review from the Center for Health Information and Analysis, as was your statutory prerogative. This review was meant to inform the commission in its evaluation of the cost impact of designating IAD drug products as chemically equivalent substitutions for heightened public health risk opioids.

CHIA completed its report, which is now ready for your review. The Department didn’t create it so in order for you to have sufficient time to review this document, we are providing it for you now, and will include it on the agenda for the January 19th meeting for discussion. We will see if CHIA can come to that meeting to present. This is for your information and discussion only. Members will not have the opportunity to edit the document.

**5. Next Steps**

As the Commission discussed, the 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. Ms. Nelson noted that this list is being used in lots of different situations across DPH as reference.

The Department will be in touch with updates related to promulgation schedule of the draft regulation and first 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: 14; Opposed: 0; Abstentions: 0