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**Massachusetts Department of Public Health
 Minutes of the Drug Formulary Commission
 Meeting of Thursday, October 19, 2017**
 Henry I. Bowditch Public Health Council Room, 2nd Floor
 250 Washington Street
 Boston, MA 02114

Date of Meeting: Thursday, October 19, 2017
Beginning Time: 9:43 AM
Ending Time: 11:41 AM

Advisory Council Members Present: The following (9) appointed members of the Drug Formulary Commission attended on October 19, 2017, 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. Douglas Brandoff; Cheryl Campbell; Dr. Daniel Carr; Dr. Joanne Doyle-Petrongolo; Stephen Feldman, Logan Leslie; Tracey McMillan; and Dr. Jeffrey Supko.

1. Welcome and Introductions

James Lavery called the meeting to order at 9:43AM.

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 called for approval of the minutes from the August 17, 2017 meeting.

- Motion to Approve: Mr. Feldman
- Second: Ms. Campbell
- All in favor: 7; Opposed: 0; Abstentions: Dr. Supko, Mr. Leslie

3. Drug Formulary Commission

Mr. Lavery stated that the regulation was currently in its final discussion stages

Mr. Lavery stated that the formulary guidance has had several incantations. The formulary is complex but DPH is hopeful that it will be finalized shortly.

Ms. McMillan stated that the Division of Insurance will issue a bulletin for carriers of insured business despite the guidance not yet being finalized. Carriers say that they will be ready for implementation by December 1 of this year.

4. Prescriber Education Program

Mr. Lavery opened up discussion for the content necessary for prescriber education. Ms. Lauren Nelson will take live notes.

Dr. Doyle-Petrongolo stated that education for pharmacists is needed as a parallel to prescriber education.

Mr. Lavery agreed as the implementation will be a game-changer that will be challenging for the pharmacists.

Dr. Doyle-Petrongolo stated that the draft formulary may lead a pharmacist to turn a patient away due to insufficient education on the process.

Dr. Carr stated that, in the shoes of the everyday overworked clinician, there is a role for a one-page document, pocket card, or pamphlet with important information on contributory factors to the crisis and how the state has altered laws, rules, and regulations to address the issue. The pocket card should include information on abuse deterrents' role in therapy. There is a career program for mid-level practitioners at Tufts that he is happy to share information about.

Dr. Brandoff stated that the program needs patient education as well. For the prescriber, the following questions should be answered in educational materials: What are the formulary and its context? What is an abuse deterrent formulation? How does it work? Is it mandatory or optional?

Ms. Nelson clarified whether Dr. Brandoff was referring to the formulary being mandatory or optional.

Dr. Brandoff confirmed. Finally, in situations of no substitutions, how can the prescriber opt out? He stated that the education needs explicit commentary on prior authorization needs and insurance company payments. The education should include a comment on naloxone ("Are we reversing the analgesic?"). Does the formulary apply in the inpatient setting (will hospitals need to carry abuse-deterrent formulations in their formulary?) Will frequency of provider notification letters increase? Is someone keeping track at the Board level? How often is someone writing no substitution?

Mr. Feldman stated that we should first discuss "learner objectives" prior to discussing content.

Mr. Lavery stated that the education should include the distinction between therapeutic and chemical equivalence.

Dr. Carr stated that he would like to see a reiteration that none of the above is to interfere with the appropriate treatment and management of pain. They are not trying to end pain as a complaint or symptom, or opioids completely as a therapy.

Mr. Lavery stated that he will advocate for patient education as well.

Ms. Nelson stated that she reached out to Ms. Cindy Steinberg for her comments as well.

Ms. Campbell stated that people are confusing the following: we are not trying to prevent opioid deaths, but to stop addiction from starting in the first place. This should be included in the problem statement.

Mr. Leslie stated that we should describe what abuse deterrents are. He noted the concerns in the public comment that the formulary will imply that abuse deterrents are safe. Furthermore, in reality, they will not totally fix abuse.

Mr. Lavery stated that overall education will be important.

Ms. Campbell asked what the actual process is for prescribing. Is there education to the patient or a contract?

Dr. Carr stated that the process depends on the office. Possibly the process involves pamphlets. In a medical home, there may be nurse and pharmacist education due to the increased resources. He noted that they should refer to white papers about safe, effective use of pain medications.

Mr. Feldman stated that the committee has built a tool such that new products will be considered by the committee as they are developed. There should be a mention in the education about what the committee has achieved and is prepared to do.

Mr. Lavery suggested a step-by-step guide or flow chart for prescribing.

Dr. Doyle-Petrongolo stated that she likes the idea of a simple pocket card for prescribers and pharmacists.

Mr. Lavery stated that time will be an issue in this process. We do not want people to become frustrated and default to no substitution.

Ms. Campbell stated that we should discuss how the materials will be sent out, for example through Mass Mail or PMP?

Dr. Carr suggested a bank of phone operators. He also stated that a QR code might be an easy way to prevent the prescriber from having to type the link.

Dr. Doyle-Petrongolo stated that, thinking proactively, prescribers should review their patient populations to see for example how many are taking MS Contin, so that they are able to anticipate and caution of what is coming.

Mr. Feldman stated that the committee should conduct a literature search on how often no substitution is written and reasons to designate no substitution, to better understand the motivations.

Dr. Tyson stated that there is nothing jumping out in the research about the reasons, but a common reason to designate no substitution on opioid prescriptions is due to better street recognizability with certain tablet appearances.

Mr. Feldman stated that there must at least be some research in Medicare.

Dr. Tyson stated that no substitution is likely most common with antiepileptic agents.

Mr. Feldman stated that he thinks it would be worthwhile to conduct a literature search.

Mr. Lavery stated that they will check on this.

Dr. Brandoff asked if pharmacies are going to have these products in stock, and what if they do not.

Dr. Doyle-Petrongolo stated that, in reference to her previous point, pharmacies should be speaking with patients if they are on applicable opioids to let them know what is coming.

Mr. Leslie stated that we need a website where people can access answers, rather than giving people packets.

Mr. Lavery stated that we must be judicious about what is sent out, as there is a large group that must be reached.

Dr. Young stated he did not see severe inventory issues, as inventory in retail pharmacies adjust based on prescribing practices.

Dr. Brandoff stated that stores are consciously choosing not to stock for security reasons.

Ms. Campbell stated that we must address how the information is going to fit into the flow of an office visit, which is already limited in time.

Dr. Carr seconded Ms. Campbell's comment and also stated that partial filling should be mentioned in a "Then versus Now" statement.

Mr. Lavery stated that the challenge is learning new ways to do things.

Ms. Nelson stated that another barrier is that we may change qualifications for payment, such that copays will be higher.

Mr. Lavery asked Ms. McMillan to speak on insurance issues.

Ms. McMillan stated that as for education between companies, prescribers, and pharmacists, the question is if the prescription does not say no substitution and the member goes to the pharmacy, can the pharmacist suggest the formulary crosswalk? Who has the authority to make the change? Many consumers complain about this.

Dr. Doyle-Petrongolo stated that the pharmacist does not have this authority. If not required to go to brand, would a tier "... " letter be accepted?

Ms. McMillan stated that this is between the provider, patient, and insurance. What I have seen is that it is ad hoc.

Mr. Lavery stated that to be clear, IAP is going to have to be dispensed as written and insurance companies will not be able to make a determination about that.

Ms. McMillan agreed.

Mr. Brandoff stated that prescribers need to know what insurance partners will and will not cover. We must all be notifying one another in a combined effort.

Dr. Doyle-Petrongolo stated that we are not accounting for Medicare Part D, who must be considered in terms of what will happen if a patient goes into the donut hole for example.

Dr. Carr stated that we must make sure that a diverse group of representatives from insurance and pharmacies is consulted, after Draft I is created, to conduct a stress test of the educational documents. A focus group would help if that is possible.

Dr. Thompson stated that, referring to a few comments ago, IADs cannot be disadvantaged so the tiering issue does not come up beyond part D.

Dr. Brandoff wondered how this would refer to out-of-state patients, or MA resident patients who receive a prescription from out of state.

Ms. Nelson stated that an out-of-state pharmacy is not required to substitute.

Dr. Brandoff asked what the proposed timetable is for this roll out.

Mr. Lavery stated that we need to get the guidance out before we know the roll out date.

Ms. Nelson stated that the guidance will at least answer a lot of the process questions.

Dr. Carr stated that they should be mindful of the established pathway and should model the roll-out after Mass PAT.

Dr. Doyle-Petrongolo agreed that Mass PAT went well, but there was more time involved, at least 6 months. However, this formulary only has until November or December.

Mr. Lavery agreed that this is a real and important challenge. We have a good basis for the educational component of the program. He would like to now open the discussion for how the information will be sent out like professional associations, webinars, and material distribution.

Dr. Carr stated that he wants to defer to Mr. Feldman about roll outs. He would like to explore literature on health communications and relevance to curricular changes and framework.

Mr. Lavery asked where do prescribers and pharmacists get their information? What is the best resource that will collectively grab enough attention for each health care provider?

Ms. Campbell stated that this is a marketing problem. We need brand ambassadors to help people understand in a field that is already so used to their practice.

Mr. Leslie stated that the audience is motivated to find information if they know that this is coming down the path. He would like a direct website possibly for a secondary source to provide ease of access to information. We can have a blog or forum where people are answering each other's questions.

Dr. Brandoff stated that he thinks many people will need motivation, since they are sieged with demands. There is a negative affect associated with the Board. DPH would be listened to and for our leaners to have an optimal, positive mindset. We could also incentivize meetings with CME credits counting toward pain management. There must be flexibility with time for online webinars, such as 1 AM, and possibly availability on demand for respect to providers convenience.

Mr. Lavery stated that with respect to the PMP, the driving force was the stakeholder engagement.

Mr. Feldman stated that on the state and federal level, live webinars should be held that people can call into, which should then be recorded and placed on the website so people can hear the exchange.

Dr. Carr stated that there must be internal resources as education is a big part of DPH. What resources orchestrate the public health campaigns?

Mr. Lavery stated that the Bureau of Substance Abuse Services has done a great job.

Dr. Carr asked if they used a consultant in their campaign.

Mr. Lavery stated that he will look into it.

Ms. Campbell stated that there was a general grant process. At a counseling level, we can have a pamphlet that a prescriber can provide to the patient during encounters.

Dr. Doyle-Petrongolo stated that in the media, patients may interpret this as not being able to get their medications. There is a need to frame this as a positive change for the commission.

Mr. Feldman suggested a press release.

Mr. Lavery agreed.

Dr. Doyle-Petrongolo stated that the media has already come through the public relations department at her hospital.

Mr. Leslie stated that talking points for the meeting members would help everyone be on the same page.

Dr. Carr stated that he would be comfortable referring all media questions to Ms. Nelson or Mr. Lavery.

Mr. Lavery stated that that would be fine.

Mr. Leslie stated his concern about the public comment regarding e-prescribing not being formatted for this formulary.

Ms. Nelson stated that e-prescribing would actually make this process easier and that there are current bills in legislation to mandate so that it could be a potential non-issue eventually.

Mr. Leslie clarified that he was referring to the format of the e-prescribing, regarding “1 line” for space on the prescription.

Ms. Nelson stated that this is based on the electronic health record of the facility.

Dr. Brandoff stated that there is a Notes to Pharmacy section on his e-prescriptions with ample amount of characters available to input information.

Ms. Nelson stated that this would be in a different regulation about e-prescribing which is why that public comment was not addressed.

Mr. Lavery stated that he will consolidate all comments and will go over them with the committee in emails in the interim or at the next meeting.

5. Next Steps

Mr. Lavery asked Dr. Thompson for an update on IADs.

Dr. Thompson stated that he is still watching 2 products, Vantrela ER (hydrocodone ER) and Roxybond (oxycodone IR). The pipeline is very full. NKATR-181 is interesting; the chemical entity crosses the blood-brain barrier more slowly so that the molecule is less euphoric. He will watch closely.

Dr. Carr asked if this was a novel molecule.

Dr. Thompson confirmed.

Mr. Lavery thanked the Commission members for their thoughtful comments and questions. He will update the committee as he learns about the roll out date. Ms. Nelson stated that they will resend an email to get a quorum call for the next meeting.

Mr. Lavery asked for any final discussion or questions, and hearing no, then called for a motion to adjourn.

- Motion to Adjourn: Mr. Feldman
- Second: Ms. Campbell
- All in favor: Unanimous