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**Drug Formulary Commission**

Bureau of Health Care Safety and Quality

Department of Public Health

July 14, 2016

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**Presentation Agenda**

* Review of June 2nd meeting
* Non-Opioid Pain Management List
* Draft Formulary Guidance
* Next Steps

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**Non-Opioid Pain Management**

Section 4 of Chapter 52 of the Acts of 2016 amends Section 13 of Chapter 17 of the General Laws to require the Drug Formulary Commission, by September 1, 2016, to publish, distribute, and update annually a list of:

* + FDA approved, non-opioid drug products;
  + That are effective pain management alternatives; and
  + Have a lesser potential for abuse than Schedule II and III opioid drug products
  + By September 1, 2016.

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**Promulgation of Regulation and Formulary**

* Present to the Drug Formulary Commission.
* Propose the draft to Public Health Council as part of the proposal of a redrafted regulation, 105 CMR 720, *List of Interchangeable Drug Products.*
* Present the draft regulation, including the draft Formulary of Chemically Equivalent Substitutions, for public hearing and comment.
* Review comments and amend regulation as appropriate.
* Present final draft regulation and draft formulary to PHC again for promulgation.
* Review by Secretary of State.
* Regulation becomes effective.
* Issue guidance, including:
  + special substitution considerations as decided by the commission, and
  + the requirements and process of substitution.

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* **Formulary Background**This draft formulary is a tool for prescribers when continuing and initiating the treatment of pain.
* Guidance will be issued on the same day the regulation, including the draft formulary, becomes effective.
* “No Substitution”
* The following items on a Schedule II prescription may not be changed by a pharmacist, pursuant to applicable DEA rules:
  + Name of Patient
  + Name of the Drug
  + Name of the Prescriber
  + Date of the Prescription

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**Formulary Terminology**

* Formulary of Chemically Equivalent Substitutions for Opioids with a Heightened Public Health Risk
* The formulary consist of
  + Interchangeable Abuse Deterrent Drug Products

(IAD drug products)

* + Opioids with a Heightened Public Health Risk

(HPHR opioids)

* Chemically Equivalent Substitution = when an IAD drug product may appropriately substitute for an HPHR opioid.

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**Opioids with a Heightened Public Health Risk**

Table listing Schedule 2 and 3 opioid products

Source: BHCSQ, MA PMP. This list is derived from all prescriptions dispensed and reported to the Prescription Monitoring Program during CY 2014. This list represents 100% of all Schedule II and III opioids, and 68% of all of the Schedule II and III drug products (including opioids and non-opioids), dispensed and reported to the PMP.

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**Interchangeable Abuse Deterrent Drug Products: FDA Approved ADF Labeling**

**List of Medications with FDA-Approved ADF Labeling**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Product Name** | **Manufacturer** | **Ingredient(s)** | **Dose Form** | **Method of Abuse Deterrence** | **DFC Action** |
| Targiniq ER® | Purdue | Oxycodone ER and Naloxone | Tablet | Antagonist | Voted NOT to approve for Crosswalk consideration at  December 17, 2015 meeting |
| OxyContin® | Purdue | Oxycodone ER | Tablet | Crush-resistant Formulation | Voted to approve for Crosswalk consideration at  January 7, 2016 meeting |
| Hysingla ER® | Purdue | Hydrocodone ER | Tablet | Crush-resistant Formulation | Voted to approve for Crosswalk consideration at  December 17, 2015 meeting |
| Embeda® | Pfizer | Morphine ER and Naltrexone | Capsule | Antagonist | Voted to approve for Crosswalk consideration at  January 7, 2016 meeting |

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**Interchangeable Abuse Deterrent Drug Products: Abuse-Deterrent Claims no FDA-Approved Labeling**

**List of Medications with Abuse-Deterrent Claims**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Product Name** | **Manufacturer** | **Ingredient(s)** | **Dose Form** | **Method of Abuse Deterrence** | **DFC Action** |
| Opana ER® | Endo | Oxymorphone | Tablet | Crush-resistant formulation | Voted NOT to approve for Crosswalk consideration at  February 4, 2016  Meeting |
| Oxaydo® | Egalet | Oxycodone ER | Tablet | Aversion technology with assumed ADF properties | Voted to approve for Crosswalk consideration at  February 4, 2016  Meeting |
| Nucynta ER® | Jansen | Tapentadol | Tablet | Crush-resistant formulation | Voted to approve for Crosswalk consideration at  February 4, 2016  Meeting |
| Zohydro ER® | Pernix Therapeutics | Hydrocodone ER | Capsule | BeadTek Technology | Voted NOT to approve for Crosswalk consideration at  June 2, 2016  Meeting |

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**Chemically Equivalent Substitution**

“Chemically Equivalent Substitution”, for the purpose of creating a formulary of drugs with abuse deterrent properties that the commission has determined may be appropriately substituted for opioids that have been determined to have a heightened public health risk due to the drugs’ potential for abuse and misuse, shall mean drug products which contain the same active ingredients, and are equivalent in strength or concentration, dosage form, and route of administration, and produce a comparable biologic effect. Prodrugs or ingredients without analgesic effect that are used solely for abuse deterrent formulations need not be equivalent.

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**Draft Guidance Discussion**

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**Meeting Schedule**

* September 15, 2016
* October 20, 2016
* November 17, 2016
* December 15, 2016
* January 19, 2017
* February 16, 2017
* March 16, 2017
* April 20, 2017

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**Future Review Process**

* Two drug products with claims of ADP technology:
  + MorphaBond®
  + Xtampza ER®
* Three additional ADP drugs in FDA approval process:
  + Vantrela ER®
  + SequestOx®
  + Troxyca ER®
* The evaluation process for substitution of additional interchangeable abuse deterrent (IAD) drug products with opioids with a heightened public health risk (HPHR opioids):
  + Revisit Component 2 to evaluate the IAD drug products.
  + Present each IAD drug product with a completed monograph.
  + Vote to place the IAD drug product on the formulary for potential pairing as a chemically equivalent substitution for one or more HPHR opioid.
  + Crosswalk with identified HPHR opioids.
  + Vote on chemically equivalent substitutions.

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**Future Review Process**

Drug Formulary Commission Statutory Mission

Schedule II and III Opioids

Component 1: Drug Products with Heightened Public Health Risk

Component 2: Drug Products with Abuse Deterrent Properties

Component 3: “Cross Walk”

Draft Formulary

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**Meeting Summary**

* Meeting Recap
* Review of takeaways
* Next Steps
* Next Meeting – September 15, 2016
  + @ 250 Washington Street