**Slide 1**

 **Drug Formulary Commission**

**Bureau of Health Care Safety and Quality**

**Department of Public Health**

**April 7, 2016**

* Drug Formulary Commission Statutory Mission

**Opening Remarks**

* Schedule II and III Opioid Universe
* Component 1: Drugs Of Heightened Public Health Risk
* Component 2: Drug Formulary Therapeutic Substitutes With Abuse Deterrent Properties
* Component 3: “Cross Walk”

**Slide 2**

Draft Formulary

* Review of March 17th meeting
	+ Voted on a DFC definition of “Chemically Equivalent Substitution”
	+ Voted on form to evaluate Abuse Deterrent Property efficacy
* Opioid Bill Presentation
	+ Drug Formulary Commission Provision
* Crosswalk
	+ Chemically Equivalent Substitution - Definition
	+ Embeda
* Next Steps

**Slide 3**

 Presentation Agenda

**Slide 4**

**Opioid Bill**

**AN ACT RELATIVE TO SUBSTANCE USE, TREATMENT, EDUCATION AND PREVENTION – Chapter 52 of the Acts of 2016**

Section 4 amends section 13 of chapter 17 of the General Laws as follows:

(e)  The commission shall also identify and publish a list of non-opioid drug products that have been approved by the United States Food and Drug Administration that are effective pain management alternatives and have a lesser potential for abuse than an opioid drug product contained in Schedules II and III of section 3 of chapter 94C.
     The commission shall provide for distribution, including electronic distribution, of copies of the list and revisions to the list among all prescribers and dispensers licensed to practice in the commonwealth and to other appropriate individuals and shall supply a copy to any person on request and upon payment of the cost of printing.
     The list shall be revised not less frequently than annually to include new pertinent information on non-opioid drug products approved for inclusion or non-opioid drug products to be deleted and to reflect current information as to the therapeutic efficacy of drugs and pharmaceuticals.

Section 72 makes this section effective on September 1, 2016.

**Opioid Bill**

**Slide 5**

**Opioid Bill**

**AN ACT RELATIVE TO SUBSTANCE USE, TREATMENT, EDUCATION AND PREVENTION – Chapter 52 of the Acts of 2016**

Section 19 Adds definition of “Extended-release long-acting opioid in a non-abuse deterrent form” in the Controlled Substance Act as a drug that is:

* + (i) subject to the United States Food and Drug Administration’s extended release and long-acting opioid analgesics risk evaluation and mitigation strategy;
	+ (ii) an opioid approved for medical use that does not meet the requirements for listing as a drug with abuse deterrent properties pursuant to section 13 of chapter 17; and
	+ (iii) identified by the drug formulary commission pursuant to said section 13 of said chapter 17 as posing a heightened level of public health risk.

**Slide 6**

**Opioid Bill**

Other notable provisions of the bill include:

* Voluntary non-opioid directive
* Partial Fill
* 7-day prescribing limit
* PMP check for all Schedule II and III opioid prescriptions
* Health Policy Commission Dual-Diagnosis Study
* PMP Gabapentin Monitoring

**Slide 7**

**Slide 8**

**Crosswalk**

“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 ~~opiates~~ 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.

**Slide 9**

 Chemically Equivalent Substitution



**Slide 10**

**List A: Generic Drug Products with a Heightened Public Health Risk**

LIST A - Generic



**Slide 11**

List B: Drug Products

Advanced to Component 3

as Potential Substitutes

LIST B

… In considering whether a drug is a **chemically equivalent substitution** the commission shall consider:

* the **accessibility** of the drug and its proposed substitute;
* whether the drug's substitute is **cost** prohibitive;
* the **effectiveness** of the substitution (FDA approved for pain); and
* whether, based upon the current patterns of abuse and misuse, the drug's substitute incorporates abuse deterrent technology that will be an **effective deterrent** to such abuse and misuse.

**Slide 12**

 Drug Product Criteria

**Embeda**

**Slide 13**

\*Wholesale acquisition cost per Online Red Book as of 3/15/2016

ADP=abuse-deterrent property, Q12H=every 12 hours, Q24H=every 24 hours

Cost of Substitution: $85,924

Cost of substitution assumes every 24 hour dosing for Embeda® and morphine extended-release 24 hour capsules.

**Embeda® and Morphine Extended-Release 24 Hour Capsule**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Medication** | **Active Ingredient** | **Strengths** | **Dosage Form** | **Route of Administration** | **Dosing Schedule** | **Cost/unit\*** | **Units Dispensed 2015** | **Approximate Cost 2015** | **ADP Efficacy** |
| Embeda® | morphine sulfate and naltrexone | 30 mg | extended-release capsule | Oral | Q12H or Q24H | $8.93 | 5,601 | $50,017 | Category II |
| 60 mg | $14.08 | 2,354 | $33,144 |
| Morphine extended-release 24 hour | morphine sulfate | 30 mg | extended-release capsule | Oral | Q24H | $4.58 | 8,103 | $37,112 | N/A |
| 60 mg | $8.90 | 9,783 | $87,069 |

**Embeda**

**Slide 14**

Cost of Substitution: $114,967

\*Wholesale acquisition cost per Online Red Book as of 3/15/2016

ADP=abuse-deterrent property, Q24H=every 24 hours

**Embeda® and Morphine Extended-Release 24 Hour Capsule**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Medication** | **Active Ingredient** | **Strength** | **Dosage Form** | **Route of Administration** | **Dosing Schedule** | **Cost/day\*** | **Units Dispensed 2015** | **Approximate Cost 2015** | **ADP Efficacy** |
| Embeda® | morphine sulfate/ naltrexone hydrochloride | 60 mg/ 2.4 mg | extended-release capsule | Oral | 2 capsules Q24H | $28.16 | 2,354 | $33,144 | Category II |
| Morphine extended-release 24 hour | morphine sulfate | 120 mg | extended-release capsule | Oral | 1 capsule Q24H | $15.79 | 9,294 | $146,752 | N/A |

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Medication** | **Active Ingredient** | **Strengths** | **Dosage Form** | **Route of Administration** | **Dosing Schedule** | **Cost/unit\*** | **Units Dispensed 2015** | **Approximate Cost 2015** | **ADP Efficacy** |
| Embeda® | morphine sulfate and naltrexone | 20 mg/0.8 mg | extended-release capsule | Oral | Q12H or Q24H | $5.95 | 6,248 | $37,176  | Category II |
| 30 mg/1.2 mg | $8.93 | 5,601 | $50,017  |
| 50 mg/2 mg | $11.74 | 2,675 | $31,405  |
| 60 mg/2.4 mg | $14.08 | 2,354 | $33,144  |
| 80 mg/3.2 mg | $18.78 | 598 | $11,230  |
| 100 mg/4 mg | $23.48 | 742 | $17,422  |
| Kadian® | morphine sulfate | 20 mg | extended-release capsule | Oral | Q12H or Q24H | $8.15 | 6,034 | $49,177  | N/A |
| 30 mg | $8.87 | 2,378 | $21,093  |
| 50 mg | $14.83 | 1,596 | $23,669  |
| 60 mg | $17.74 | 19,490 | $345,753  |
| 80 mg | $23.63 | 1,046 | $24,717  |
| 100 mg | $29.16 | 10,010 | $291,892  |

Cost of Substitution: -$151,327 (Cost Avoidance)

\*Wholesale acquisition cost per Online Red Book as of 3/15/2016

ADP=abuse-deterrent property, Q12H=every 12 hours, Q24H=every 24 hours

**Embeda**

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**Embeda® and Kadian®**

**Embeda® and Kadian®**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Medication** | **Active Ingredient** | **Strength** | **Dosage Form** | **Route of Administration** | **Dosing Schedule** | **Cost/day\*** | **Units Dispensed 2015** | **Approximate Cost 2015** | **ADP Efficacy** |
| Embeda® | morphine sulfate/ naltrexone hydrochloride | 20 mg/ 0.8 mg | extended-release capsule | Oral | 2 capsules Q12H or Q24H | $11.90 to $23.80 | 6,248 | $37,176  | Category II |
| Kadian® | morphine sulfate | 40 mg | extended-release capsule | Oral | 1 capsule Q12H or Q24H | $11.83 to $23.66 | 2,964 | $35,064 | N/A |

**Embeda**

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Cost of Substitution: $208

\*Wholesale acquisition cost per Online Red Book as of 3/15/2016

ADP=abuse-deterrent property, Q12H=every 12 hours, Q24H=every 24 hours

**Embeda® and Kadian®**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Medication** | **Active Ingredient** | **Strength** | **Dosage Form** | **Route of Administration** | **Dosing Schedule** | **Cost/day\*** | **Units Dispensed 2015** | **Approximate Cost 2015** | **ADP Efficacy** |
| Embeda® | morphine sulfate/ naltrexone hydrochloride | 100 mg/4 mg | extended-release capsule | Oral | 2 capsules Q12H or Q24H | $46.96 to $93.92 | 742 | $17,422  | Category II |
| Kadian® | morphine sulfate | 200 mg | extended-release capsule | Oral | 1 capsule Q12H or Q24H | $59.91 to $119.82 | 434 | $26,001 | N/A |

**Embeda**

**Slide 17**

Cost of Substitution: -$5,620 (Cost Avoidance)

\*Wholesale acquisition cost per Online Red Book as of 3/15/2016

ADP=abuse-deterrent property, Q12H=every 12 hours, Q24H=every 24 hours

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Medication** | **Active Ingredient** | **Strengths** | **Dosage Form** | **Route of Administration** | **Dosing Schedule** | **Cost/unit\*** | **Units Dispensed 2015** | **Approximate Cost 2015** | **ADP Efficacy** |
| Embeda® | morphine sulfate and naltrexone | 20 mg/0.8 mg | extended-release capsule | Oral | Q12H or Q24H | $5.95 | 6,248 | $37,176  | Category II |
| 30 mg/1.2 mg | $8.93 | 5,601 | $50,017  |
| 50 mg/2 mg | $11.74 | 2,675 | $31,405  |
| 60 mg/2.4 mg | $14.08 | 2,354 | $33,144  |
| 80 mg/3.2 mg | $18.78 | 598 | $11,230  |
| 100 mg/4 mg | $23.48 | 742 | $17,422  |
| Morphine extended-release 12 or 24 hour | morphine sulfate | 20 mg | extended-release capsule | Oral | Q12H or Q24H | $4.18 | 48,677 | $203,470  | N/A |
| 30 mg | $4.55 | 40,811 | $185,690  |
| 50 mg | $7.60 | 27,077 | $205,785  |
| 60 mg | $9.10 | 22,246 | $202,439  |
| 80 mg | $12.12 | 8,318 | $100,814  |
| 100 mg | $15.21 | 28,226 | $429,317  |

\*Wholesale acquisition cost per Online Red Book as of 3/15/2016

ADP=abuse-deterrent property, Q12H=every 12 hours, Q24H=every 24 hours

Cost of Substitution: $776,621

**Embeda**

**Slide 18**

**Embeda® and Morphine Extended-Release 12 or 24 Hour Capsule**

**Embeda® and MS Contin®**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Medication** | **Active Ingredient** | **Strengths** | **Dosage Form** | **Route of Administration** | **Dosing Schedule** | **Cost/unit\*** | **Units Dispensed 2015** | **Approximate Cost 2015** | **ADP Efficacy** |
| Embeda® | morphine sulfate and naltrexone | 30 mg/1.2 mg | extended-release capsule | Oral | Q12H or Q24H | $8.93 | 5,601 | $50,017  | Category II |
| 60 mg/2.4 mg | $14.08 | 2,354 | $33,144  |
| 100 mg/4 mg | $23.48 | 742 | $17,422  |
| MS Contin®  | morphine sulfate | 30 mg | extended-release tablet | Oral | Q12H or Q8H | $5.77 | 11,153 | $64,353  | N/A |
| 60 mg | $11.27 | 18,616 | $209,802  |
| 100 mg | $16.68 | 16,650 | $277,722  |

**Embeda**

**Slide 19**

\*Wholesale acquisition cost per Online Red Book as of 3/15/2016

ADP=abuse-deterrent property, Q8H=every 8 hours, Q12H=every 12 hours, Q24H=every 24 hours

Cost of Substitution: $200,774

Cost of substitution assumes every 12 hour dosing for Embeda® and MS Contin®.

**Embeda® and MS Contin®**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Medication** | **Active Ingredient** | **Strength** | **Dosage Form** | **Route of Administration** | **Dosing Schedule** | **Cost/day\*** | **Units Dispensed 2015** | **Approximate Cost 2015** | **ADP Efficacy** |
| Embeda® | morphine sulfate/ naltrexone hydrochloride | 30 mg/ 1.2 mg | extended-release capsule | Oral | 1 capsule Q24H | $8.93 | 5,601 | $50,016.93 | Category II |
| MS Contin® | morphine sulfate | 15 mg | extended-release tablet | Oral | 1 tablet Q12H | $6.08 | 10,875 | $33,060.00 | N/A |

**Embeda**

**Slide 20**

\*Wholesale acquisition cost per Online Red Book as of 3/15/2016

ADP=abuse-deterrent property, Q12H=every 12 hours, Q24H=every 24 hours

Cost of Substitution: $85.50 per 30 day prescription

**Embeda® and MS Contin®**

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Medication** | **Active Ingredient** | **Strength** | **Dosage Form** | **Route of Administration** | **Dosing Schedule** | **Cost/day\*** | **Units Dispensed 2015** | **Approximate Cost 2015** | **ADP Efficacy** |
| Embeda® | morphine sulfate/ naltrexone hydrochloride | 60 mg/ 2.4 mg | extended-release capsule | Oral | 1 capsule Q24H | $14.08 | 2,354 | $33,144 | Category II |
| MS Contin® | morphine sulfate | 30 mg | extended-release tablet | Oral | 1 tablet Q12H | $11.54 | 11,153 | $64,353 | N/A |

**Embeda**

**Slide 21**

\*Wholesale acquisition cost per Online Red Book as of 3/15/2016

ADP=abuse-deterrent property, Q12H=every 12 hours, Q24H=every 24 hours

Cost of Substitution: $76.20 per 30 day prescription

**Embeda® and MS Contin®**

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Medication** | **Active Ingredient** | **Strength** | **Dosage Form** | **Route of Administration** | **Dosing Schedule** | **Cost/day\*** | **Units Dispensed 2015** | **Approximate Cost 2015** | **ADP Efficacy** |
| Embeda® | morphine sulfate/ naltrexone hydrochloride | 100 mg/ 4 mg | extended-release capsule | Oral | 4 capsules Q24H | $93.92 | 742 | $17,422 | Category II |
| MS Contin® | morphine sulfate | 200 mg | extended-release tablet | Oral | 1 tablet Q12H | $61.10 | 100 | $3,055 | N/A |

**Embeda**

**Slide 22**

\*Wholesale acquisition cost per Online Red Book as of 3/15/2016

ADP=abuse-deterrent property, Q12H=every 12 hours, Q24H=every 24 hours

Cost of Substitution: $984.60 per 30 day prescription

**Embeda® and MS Contin®**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Medication** | **Active Ingredient** | **Strength** | **Dosage Form** | **Route of Administration** | **Dosing Schedule** | **Cost/day\*** | **Units Dispensed 2015** | **Approximate Cost 2015** | **ADP Efficacy** |
| Embeda® | morphine sulfate/ naltrexone hydrochloride | 100 mg/ 4 mg | extended-release capsule | Oral | 6 capsules Q24H | $140.88 | 742 | $17,422 | Category II |
| MS Contin® | morphine sulfate | 200 mg | extended-release tablet | Oral | 1 tablet Q8H | $91.65 | 100 | $3,055 | N/A |

**Embeda**

**Slide 23**

\*Wholesale acquisition cost per Online Red Book as of 3/15/2016

ADP=abuse-deterrent property, Q8H=every 8 hours, Q24H=every 24 hours

Cost of Substitution: $1,476.90 per 30 day prescription

**Embeda® and Morphine Extended-Release Tablet**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Medication** | **Active Ingredient** | **Strengths** | **Dosage Form** | **Route of Administration** | **Dosing Schedule** | **Cost/unit\*** | **Units Dispensed 2015** | **Approximate Cost 2015** | **ADP Efficacy** |
| Embeda® | morphine sulfate and naltrexone | 30 mg/1.2 mg | extended-r elease capsule**Embeda****Slide 24**\*Wholesale acquisition cost per Online Red Book as of 3/15/2016ADP=abuse-deterrent property, Q8H=every 8 hours, Q12H=every 12 hours, Q24H=every 24 hoursCost of Substitution: $51,983,893Cost of substitution assumes every 12 hour dosing for Embeda® and morphine extended-release tablet. | Oral | Q12H or Q24H | $8.93 | 5,601 | $50,017  | Category II |
| 60 mg/2.4 mg | $14.08 | 2,354 | $33,144  |
| 100 mg/4 mg | $23.48 | 742 | $17,422  |
| Morphine extended-release  | morphine sulfate | 30 mg | extended-release tablet | Oral | Q12H or Q8H | $1.14 | 2,955,878 | $3,369,701  | N/A |
| 60 mg | $2.23 | 1,469,363 | $3,276,679  |
| 100 mg | $3.29 | 571,850 | $1,881,387  |

**Embeda® and Morphine Extended-Release Tablet**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Medication** | **Active Ingredient** | **Strength** | **Dosage Form** | **Route of Administration** | **Dosing Schedule** | **Cost/day\*** | **Units Dispensed 2015** | **Approximate Cost 2015** | **ADP Efficacy** |
| Embeda® | morphine sulfate/ naltrexone hydrochloride | 30 mg/ 1.2 mg | extended-release capsule | Oral | 1 capsule Q24H | $8.93 | 5,601 | $50,016.93 | Category II |
| Morphine extended-release | morphine sulfate | 15 mg | extended-release tablet | Oral | 1 tablet Q12H | $1.20 | 3,161,026 | $1,896,616 | N/A |

**Embeda**

**Slide 25**

\*Wholesale acquisition cost per Online Red Book as of 3/15/2016

ADP=abuse-deterrent property, Q12H=every 12 hours, Q24H=every 24 hours

Cost of Substitution: $231.90 per 30 day prescription

**Embeda® and Morphine Extended-Release Tablet**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Medication** | **Active Ingredient** | **Strength** | **Dosage Form** | **Route of Administration** | **Dosing Schedule** | **Cost/day\*** | **Units Dispensed 2015** | **Approximate Cost 2015** | **ADP Efficacy** |
| Embeda® | morphine sulfate/ naltrexone hydrochloride | 60 mg/ 2.4 mg | extended-release capsule | Oral | 1 capsule Q24H | $14.08 | 2,354 | $33,144 | Category II |
| Morphine extended-release | morphine sulfate | 30 mg | extended-release tablet | Oral | 1 tablet Q12H | $1.14 | 2,955,878 | $3,369,701 | N/A |

**Embeda**

**Slide 26**

\*Wholesale acquisition cost per Online Red Book as of 3/15/2016

ADP=abuse-deterrent property, Q12H=every 12 hours, Q24H=every 24 hours

Cost of Substitution: $388.20 per 30 day prescription

**Embeda® and Morphine Extended-Release Tablet**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Medication** | **Active Ingredient** | **Strength** | **Dosage Form** | **Route of Administration** | **Dosing Schedule** | **Cost/day\*** | **Units Dispensed 2015** | **Approximate Cost 2015** | **ADP Efficacy** |
| Embeda® | morphine sulfate/ naltrexone hydrochloride | 100 mg/4 mg | extended-release capsule | Oral | 4 capsules Q24H | $93.92 | 742 | $17,422 | Category II |
| Morphine extended-release | morphine sulfate | 200 mg | extended-release tablet | Oral | 1 tablet Q12H | $12.00 | 52,738 | $316,428 | N/A |

**Embeda**

**Slide 27**

\*Wholesale acquisition cost per Online Red Book as of 3/15/2016

ADP=abuse-deterrent property, Q12H=every 12 hours, Q24H=every 24 hours

Cost of Substitution: $2,457.60 per 30 day prescription

**Embeda® and Morphine Extended-Release Tablet**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Medication** | **Active Ingredient** | **Strength** | **Dosage Form** | **Route of Administration** | **Dosing Schedule** | **Cost/day\*** | **Units Dispensed 2015** | **Approximate Cost 2015** | **ADP Efficacy** |
| Embeda® | morphine sulfate/ naltrexone hydrochloride | 100 mg/4 mg | extended-release capsule | Oral | 6 capsules Q24H | $140.88 | 742 | $17,422 | Category II |
| Morphine extended-release | morphine sulfate | 200 mg | extended-release tablet | Oral | 1 tablet Q8H | $18.00 | 52,738 | $316,428 | N/A |

**Embeda**

**Slide 28**

\*Wholesale acquisition cost per Online Red Book as of 3/15/2016

ADP=abuse-deterrent property, Q8H=every 8 hours, Q24H=every 24 hours

Cost of Substitution: $3,686.40 per 30 day prescription

* Review of Oxaydo
* Continuing Review of New Drugs with ADP
	+ Tracking of Medications in Pipeline
	+ Process for Review
	+ Regular Meetings
* Regulatory Review

**Slide 29**

 Next Steps

**Meeting Schedule**

* April 21, 2016 9:00AM-12:00PM
	+ April School Vacation
* May 5, 2016 2:00PM-5:00PM
* May 19, 2016 9:00AM-12:00PM

**Slide 30**

**Meeting Summary**

* Meeting Recap
* Review of takeaways
* Next Meeting
	+ April 21, 2016 9:00AM-12:00PM

 250 Washington Street

**Slide 31**