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![banner](Picture4.jpg)
Review of the Drug Formulary Commission

Bureau of Health Care Safety and Quality
Department of Public Health
October 15, 2015
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### Notes:

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# Opening Remarks

Draft Formulary
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 Presentation Agenda
Review of October 1 Meeting
Feedback from panelists
Discussion of Evaluation Criteria
Heightened Public Health Risk Criteria
Drug Groups
Therapeutically Equivalent Substitution Criteria
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### Notes:

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Review of October 1 Meeting:
Feedback from Panelists
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### Notes:

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# Feedback: October 1 Public Hearing
Expert Panels addressed key factors for consideration:
Efficacy
Effectiveness of Abuse Deterrent Formulations
Accessibility
Pharmacist / Pharmacy
Medical Association/Pain Management
Cost Effectiveness
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# Efficacy Panel
Implementation of the formulary may have an impact on the availability of opioids, leading to increased usage of riskier alternatives.
It is important to provide education on safe prescribing practices.
There are drug substitution concerns:
Patient Variability
Patient Monitoring
Alternative Therapies (adjunctive therapy)
Tricyclic Antidepressants
Non-Pharmaceutical Alternatives
The importance of data and evidence-based decision making.

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# Effectiveness of Abuse Deterrent Formulations Panel
The FDA’s Abuse Deterrent Formulations (ADF) labeling process is lengthy and rigorous.
Current ADFs with FDA approval are limited.
There are rigorous testing standards.
ADFs are one tool in a more comprehensive approach to the opioid crisis.
There is a robust innovation product pipeline.
Equi-analgesic ratios are not reliable.
There are many studies being done to determine the effectiveness of ADFs.

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# Accessibility Panel: Pharmacist / Pharmacy
It is important for the formulary to have exemptions.
ADFs are not abuse deterrent but are tamper resistant.
The formulary may result in an impact on the patient if there are communication breakdowns and delays in receiving prescriptions.
There is an opportunity to educate people in advance to help mitigate these issues.
The formulary should include one substitute for each drug and not be a list of options for substitution.

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# Accessibility Panel:Medical Association/Pain Management
The formulary should be comprised of chemically equivalent drugs.
Therapeutic equivalency is more complex.
Opioids are part of a multimodal approach to pain management.
Pharmacogenetics response could impact patient outcomes.
Education of the patient and prescriber is critical.

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# Cost Effectiveness Panel
Will need to constantly evaluate the formulary against what is available in the market.
The formulary must be a dynamic document.
Once more ADF drugs are available, they can be added.
Most national P&T committees prioritize safety and effectiveness over cost.
If there are two or more drugs that have the same effectiveness, cost is reviewed.
Formulary needs to be based off data and medical/clinical literature.
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Discussion of Evaluation Criteria
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Heightened Public Health Risk:
Drug Groups
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### Notes:

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# Heightened Public Health Risk:Considerations

The US Drug Enforcement Administration (DEA) classifies drugs into 5 distinct categories or schedules depending upon the drug’s acceptable medical use and the drug’s abuse or dependency potential.

All drugs in Schedule II and Schedule III are designated by the DEA as having a public health risk.

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# Heightened Public Health Risk: Considerations
Schedule II

“drugs, substances, or chemicals are defined as drugs with a high potential for abuse, less abuse potential than Schedule I drugs, with use potentially leading to severe psychological or physical dependence. These drugs are also considered dangerous.”

Source: US Drug Enforcement Administration, United States Department of Justice
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# Heightened Public Health Risk:Considerations
Schedule III

“drugs, substances, or chemicals are defined as drugs with a moderate to low potential for physical and psychological dependence. Schedule III drugs abuse potential is less than Schedule I and Schedule II drugs but more than Schedule IV.”

Source: US Drug Enforcement Administration, United States Department of Justice
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List of Schedule II and III Opioids

![](Picture2.jpg)
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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# Heightened Public Health Risk:Criteria

Does the Drug Formulary Commission want to place all Schedule II and III drug groups on the formulary as having a heightened public health risk?

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# Component 1: Drugs Of Heightened Public Health Risk
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Therapeutically Equivalent Substitutes
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### Notes:

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Therapeutically Equivalent Substitution: Process
To determine which opiates will be designated as therapeutically equivalent substitutes for other drugs,  we will follow a process consisting of three steps.

Step 1: Criteria:  The Commission will develop criteria for determining what constitutes a therapeutically equivalent substitute.
Per the statute, the Commission shall consider:
Efficacy/Effectiveness
Effectiveness of its Abuse-Deterrent Properties
Accessibility
Cost

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### Notes:

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Therapeutically Equivalent Substitution: Process
Step 2: Review: The Department will apply these criteria to all drugs that may potentially meet the Commission’s established set of criteria.
This will be completed through the use of a monograph, which will allow for a consistent and transparent review process.

Step 3: Vote: The results of this review will be presented to the Commission for evaluation and discussion.  Following the Commission’s review, there will be a vote on each drug that might be a therapeutically equivalent substitution.

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Therapeutically Equivalent Substitution: Process

Once the full evaluation and vote has taken place on all drugs for consideration, the Commission will have completed the second component of the Formulary.

This completed component may look like the following:
| Therapeutically Equivalent Substitutes (TES) |
| --- |
| TES Drug A |
| TES Drug B |
| TES Drug C |
| TES Drug D |
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### Notes:

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# Therapeutically Equivalent Substitution: Process
The process will be conducted for all of the individual drug products within each of the 28 drug groups of Schedule II and III opioids.

Example:  There are 32 individual Acetaminophen/Oxycodone Hydrochloride  drug products within that drug group.

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# Therapeutically Equivalent Substitution: Evidence-Based Decision Making

To facilitate the Commission’s efforts in making recommendations for the therapeutic substitution of opioid drug products, Commission should consider adoption of a process for developing a formulary based on Evidence-Based Decision Making.

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# Therapeutically Equivalent Substitution: Evidence-Based Decision Making
Inclusion of a medication on the formulary should reflect that an evidence based evaluation of the relative merits and risks of the medication has been performed.

It should also show that the Commission, through the review of approved therapeutic substitution criteria, has determined that the medication is appropriate for therapeutic substitution and routine use in the management of patients being treated for pain.

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# Therapeutically Equivalent Substitution: Criteria
Based on Evidence-Based Decision Making and the feedback received during recent meetings, the following should be included in the therapeutically equivalent substitute criteria:
Literature:

FDA abuse deterrent labeling or abuse deterrent property
Therapeutic class and mechanism of action
Dosage forms and storage
FDA approval information, including data and FDA rating
FDA approved indications for use
Potential non-FDA-approved indications for use
Comparisons of the drugs efficacy (equianalgesic ratios, morphine equivalents)
Pharmacokinetic considerations
Use in special populations (e.g., elderly, patients with renal or liver disease)
Safety Profile (adverse drug reactions, drug-drug and drug-food interactions)
Cost and access assessments
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# Therapeutically Equivalent Substitution: Criteria

Data:
Prescriptions written/dispensed
Solid dose quantity dispensed
Average days supply dispensed
High Prescriber Utilizers
Multiple Prescriber Episodes
Pharmacies with high number of MPE episodes

Source: PMP
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# Therapeutically Equivalent  Substitution: Monograph

The criteria will be applied to the review of each drug product through the use of a monograph.

The monograph will be completed for each drug product , ensuring consistency and transparency.

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Draft Formulary
Overview
Following completion of the review of each drug product to determine if it is a therapeutically equivalent substitute, the Commission will have an initial draft formulary.
The FDA labeled drugs will be noted separately, as shown in the example below:

| Heightened Public Health Risk
Groups of Drugs and
their Individual Drug Products | FDA Approved Labeled Individual Drugs
(ADF) | Therapeutically Equivalent Substitute Individual Drug Products
(TES) |
| --- | --- | --- |
| HPHR Group A – Drug Product 1
 Drug Product 2 | FDA Drug 1 | TES Drug A |
| HPHR Group B – Drug Product 1 | FDA Drug 2 | TES Drug B |
| HPHR Group C – Drug Product 1
 Drug Product 2
 Drug Product 3  | FDA Drug 3 | TES Drug C  |
| HPHR Group D – Drug Product 1 | FDA Drug 4 | TES Drug D |
| HPHR Group E – Drug Product 2 |  | TES Drug E |
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### Notes:

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# Meeting Summary
Meeting Recap

Review of takeaways

Next steps

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