Form and Method of Administration Rules

State of Ohio Board of Pharmacy
90-Day Supply

Physicians

Pharmacists

Clinical Director

Front Line Dispensary Employees

- No Disqualifying Offenses
- Over the Age of 21
- HS Diploma / GED
- Training prerequisites
THC Level

- Responsible for most of the psychoactive effects of cannabis

- Best available clinical data is for less than 23% THC
  - Data focuses on efficacy based on THC content
  - Does not take into account the “Ensemble Effect” (also known as the Entourage Effect)
  - Limited studies demonstrate this effect at this time

- Encouraging stakeholders to provide us with additional studies
Form & Method of Administration Per HB 523

**Form**
- Plant
- Edibles
- Tinctures
- Patches
- Oils

**Method of Administration**
- Inhalation / Vaporize
- Transdermal
- Oral
90-Day Supply

• Determining a 90-day supply of plant material
  
  o Benchmark with other states
  o Expert clinical review of efficacy and adverse event data

• After determining a 90-day supply of plant material, the maximum 90-day supply is converted for non-plant forms (oil, patches, etc.)
Expert Panel

• An expert panel composed of pharmacists (Pharm. D.) conducted a thorough review of the best clinical data available

• Reviewed maximum 90-day supply of plant material by THC content

• Expert panel recommended a tiered 90-day supply based upon THC content

• The recommendation was based on a review of studies demonstrating medical efficacy (based on THC only) and adverse events
Committee Recommendation

<table>
<thead>
<tr>
<th>Tier</th>
<th>THC Content</th>
<th>THC Medical Efficacy</th>
<th>Adverse Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tier 1</td>
<td>0 – 10%</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Tier 2</td>
<td>10.1 – 23%</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Tier 3</td>
<td>23.1 – 35%</td>
<td></td>
<td>+</td>
</tr>
</tbody>
</table>
# 90-Day Supply

<table>
<thead>
<tr>
<th>State</th>
<th>90-Day Equivalent of Plant Material (Ounces)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arizona</td>
<td>16</td>
</tr>
<tr>
<td>Connecticut</td>
<td>7.5</td>
</tr>
<tr>
<td>Delaware</td>
<td>19</td>
</tr>
<tr>
<td>District of Columbia</td>
<td>6</td>
</tr>
<tr>
<td>Hawaii</td>
<td>24</td>
</tr>
<tr>
<td>Illinois</td>
<td>16</td>
</tr>
<tr>
<td>Maine</td>
<td>15</td>
</tr>
<tr>
<td>Maryland</td>
<td>12.7</td>
</tr>
<tr>
<td>Massachusetts</td>
<td>15</td>
</tr>
<tr>
<td>Nevada</td>
<td>16</td>
</tr>
<tr>
<td>New Jersey</td>
<td>6</td>
</tr>
<tr>
<td>New Mexico</td>
<td>8</td>
</tr>
<tr>
<td>Vermont</td>
<td>7.5</td>
</tr>
</tbody>
</table>
90-Day Supply

1 oz. of plant material
Draft Rule

- Consolidation of tiers based on THC medical efficacy

<table>
<thead>
<tr>
<th>Tier</th>
<th>THC Content</th>
<th>Maximum 90-Day Supply</th>
<th>THC Medical Efficacy</th>
<th>Adverse Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tier 1</td>
<td>0 – 23%</td>
<td>6 oz.</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Tier 2</td>
<td>23.1 – 35%</td>
<td>4 oz.</td>
<td>+</td>
<td>+</td>
</tr>
</tbody>
</table>
From Plant Material to Non-plant Forms

• Most states use a definition of “usable marijuana” to apply the limit across products, but not a common definition of “usable marijuana”

• In Illinois, for example, the purchase amount varies from product to product (oil to oil, edible to edible) based on how much plant material was used to make the extract

• The application of “usable marijuana” does not take THC content into account
From Plant Material to Non-plant Forms

• At least two other states—Maryland and New Mexico—differentiate between plant material and extracts using THC content

• No other state differentiates between each medical marijuana form based on THC content
Conversion Factor Overview

• Statutory THC limitations
  o Extracts can have up to 70% THC content
  o Plant materials is limited to 35% THC content

• The body absorbs medicine differently based on the method of administration

• Start with the maximum THC content in both Tier I and Tier II – approximately equivalent
Conversion Factor Overview

- Conversion is used to provide some consistency in allowable THC content across forms.

- This is done for other medications, such as morphine.

- An IV dose and an oral dose differ in the amount of medicine that is required to obtain roughly the same level of pain relief.

<table>
<thead>
<tr>
<th></th>
<th>IV Dose</th>
<th>Oral Dose</th>
<th>Duration of Action, h</th>
</tr>
</thead>
<tbody>
<tr>
<td>Morphine</td>
<td>10 mg</td>
<td>30 mg</td>
<td>3-4h</td>
</tr>
</tbody>
</table>

Conversion Factor

- Proposed conversion is based on several recent scientific studies, including a Colorado equivalency study that has been applied to its recreational market.

- Application has also been made to transdermal patches for buprenorphine and fentanyl.

- Over 30 studies were considered when researching 90-day supply.
Conversion Factor

THC in Plant Material:

• The maximum 90-day supply of THC content in plant material is approximately 40.5 g

• This number is calculated based upon the maximum 90-day supply of plant material (4 oz. & 6 oz.)

• REMEMBER: The tiered system allows approx. the same max amount of a 90-day supply THC across plant material.
Conversion Factor

Oils for Vaporizing:

• Subset of expert panel found that currently available data suggest that delivery via smoking and via vaporizer are approximately equivalent in amount of THC generated from plant material. This conclusion is also validated by the CO study

• Therefore, the conversion of plant material to oils for vaporizing is 1 to 1

• This translates to a maximum 90-day supply of 40.5 g of THC for oils for vaporizing. This number is rounded up to ensure a rounded max 90-day supply
Conversion Factor

Patches:

• Subset of expert panel reviewed the approximate proportion of THC from inhalation that enters circulation when introduced into the body (i.e. bioavailability)

• Also reviewed the bioavailability of other drugs administered via patch form (such as fentanyl and buprenorphine)

• Recommends the following conversion factor: 1 mg THC in plant material to 2 mg THC in patch form

• This translates to a maximum 90-day supply of 19.8 g of THC for patches
Conversion Factor

Edibles:

• Subset of expert panel recommends the use of the Colorado study which has developed a conversion factor for edibles

• Recommended conversion factor in CO study: 5.71 mg THC in plant material to 1 mg THC in edible form

• This translates to a maximum 90-day supply of 9 g of THC for edibles. This number is rounded up to ensure a rounded max 90-day supply
# Conversion Factors in Draft Rules

<table>
<thead>
<tr>
<th>Form</th>
<th>Conversion from Plant Material</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oils for vaporizing</td>
<td>1:1</td>
</tr>
<tr>
<td>Patches for transdermal administration</td>
<td>1:2</td>
</tr>
<tr>
<td>Edibles, oils, and tinctures for oral administration</td>
<td>1:5.71</td>
</tr>
</tbody>
</table>
Conversion Factor

Conversion based on a two tier system:

<table>
<thead>
<tr>
<th>Form</th>
<th>THC content proposed conversion</th>
<th>THC Equivalency in MD</th>
<th>THC Equivalency in NM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patches</td>
<td>19.8 g</td>
<td>108 g</td>
<td>46 g</td>
</tr>
<tr>
<td>Edibles</td>
<td>9 g</td>
<td>108 g</td>
<td>46 g</td>
</tr>
<tr>
<td>Oils for Oral Administration</td>
<td>9 g</td>
<td>108 g</td>
<td>46 g</td>
</tr>
<tr>
<td>Oils for Vaporizing</td>
<td>40.5 g</td>
<td>108 g</td>
<td>46 g</td>
</tr>
</tbody>
</table>
Doses in a 90-day Supply for Oral Administration

<table>
<thead>
<tr>
<th>Total Doses</th>
<th>10 MG</th>
<th>20 MG</th>
<th>30 MG</th>
<th>40 MG</th>
<th>50 MG</th>
</tr>
</thead>
<tbody>
<tr>
<td>900</td>
<td>450</td>
<td>300</td>
<td>225</td>
<td>180</td>
<td></td>
</tr>
</tbody>
</table>
3796:8-1-01 Definitions

• Defines terms specific to forms and methods of administration
3796:8-2-01 Authorized medical marijuana forms and methods of administration

• Sets forth authorized forms and methods of administration

• Couples form with method of administration; and places the following limitations on vaporizing devices:
  
  o Cannot place medical marijuana in direct contact with the heating element
  o Cannot heat to a temperature at which plant material will burn
Establishment of additional forms or methods of administration

• Establishes a petition process through which new forms and methods of administration may be approved by the State Board of Pharmacy

• Requires petitions to include:
  o Reproducible scientific evidence
  o Expert opinion
  o Extent to which the prospective form or method of administration is generally accepted by the medical community
  o Information known to petitioner of any benefits or adverse effects
  o Benefits to approving the form or method of administration
  o The Board is authorized to gather its own evidence as well
3796:8-2-03 Forms and form variations considered attractive to children

- Outlines the products that will be considered attractive to children

  - Requires all medical marijuana to be packaged in child-resistant containers
  - Bars the use of many items including cartoon characters, resemblance to commercially available candy, and fruit shapes
  - With respect to vaporizing, characterizing flavors other than menthol and those intended to mimic strain flavors are prohibited
  - Vaporizing is prohibited for patients under 18 as attractive to children
3796:8-2-05 Assignment of a product identifier

- Product identifier is akin to a national drug code used to help track standard pharmaceuticals and necessary to report to OARRS

- The assignment of a product identifier will serve as evidence that a product conforms with the rules related to authorized forms of medical marijuana

- Sets forth procedure for the assignment of a product identifier, established in collaboration with Commerce

- Processors and cultivators will be required to register products with Commerce and provide information on form, dose, and ingredients
3796:8-3-01 Product identifier fee

- Establishes the fee for the assignment of a product identifier

- $100 fee for each dose of each strain and product. No additional fee for the assignment of a product identifier for additional packaged quantities