# New Jersey Department of Health Division of Medicinal Marijuana

**Selection Committee Training** 



September 18+23, 2019

# Agenda for Today's Training

- Required Signatures
- Introduction: Medical Cannabis in NJ
- Overview of RFA
- Scoring Process Overview
- Additional Important Points





# Required Signatures

- Confidentiality Agreement
- Business Disclosure Form
- Non-conflict of interest certification



#### Introduction

- This RFA represents the ongoing commitment of the Department of Health to expand access to medical cannabis.
- Thanks to reforms implemented over the course of the last 19 months, enrollment under the Division of Medicinal Marijuana has reached 55,000 patients – or triple the enrollment from January 2018.
  - 6 new conditions, fees cut in half, streamlined enrollment for patients, caregivers and physicians, promulgated new rules and expanded the industry.
- Jake Honig's Law will only expand on those reforms, and continue to grow the program.



# **Executive Order #6: Expanding Access to Medicinal Marijuana**



#### **Executive Order #6**

- Directed the NJ Department of Health to review the Medicinal Marijuana Program to improve access to patients, reduce regulatory burdens, and increase physician participation
- 60 day timeline
- After internal review, issued Executive Order #6 Report to Governor on March 23, 2018



#### **Executive Order #6**

- Report included three sets of recommended actions:
  - ✓ Immediate (through executive action)
  - ✓ Regulatory (through rule-making process)
  - ✓ Statutory (through legislation)



Issued by Acting Commissioner Shereef Elnahal, M.D., M.B.A.

March 23, 2018



#### **E06: Immediate Action**

- Expanded conditions
- Reduced fees
- Physician name publication optional
- Mobile Access
- Allow ATC satellites
- Allow 2 caregiver per patient





#### **New Conditions**

#### **Qualifying Conditions**

#### **Debilitating:**

- Chronic pain related to musculoskeletal disorders
- Migraine
- **Anxiety**
- Chronic pain of visceral origin
- Tourette's Syndrome
- Opioid Use Disorder
- Amyotrophic lateral sclerosis
- Multiple sclerosis
- Terminal cancer
- Muscular dystrophy
- Inflammatory bowel disease (IBD), including Crohn's disease
- Forminal illness, if the physician has determined a prognosis of less than 12 months of life.

#### Resistance, or intolerance, to conventional therapy:

- Seizure disorder, including epilepsy
- Intractable skeletal muscular spasticity
- Glaucoma
- Post-Traumatic Stress Disorder (PTSD)

#### Severe or chronic pain, severe nausea or vomiting, cachexia or wasting syndrome resulting from the condition or treatment of:

- Positive status for human immunodeficiency virus (HIV)
- Acquired immune deficiency syndrome (AIDS)
- Cancer





#### E06: Regulatory Action

- Streamline process for the addition of new conditions for treatment with medicinal marijuana
- Create separate endorsements in permitting process: dispensary, processor, cultivator
- Eliminate 10% THC limit
- Eliminate psychiatrist evaluation for minors



## **E06: Statutory Action**

- Allow edible forms for all patients, not only minors
- Allow patients to go to more than one ATC at a time
- Allow marijuana as a first-line treatment for all approved conditions
- Eliminate 2 ounce per month limit for terminal patients
- Raise limit for all others over time
- Remove non-profit requirement for original ATCs



## **E06: Statutory Action**

- **✓** Allow edible forms for all patients, not only minors
- **✓** Allow patients to go to more than one ATC at a time
- ✓ Allow marijuana as a first-line treatment for all approved conditions
- Eliminate 2 ounce per month limit for terminal patients
- **✓** Raise limit for all others over time
- **✓** Remove non-profit requirement for original ATCs

All enacted with Jake Honig's Law



#### **E06: Future Considerations**

- Redesigning patient/physician portal
- Home delivery
- Using external labs for quality control
- Elimination of sales tax
- Review of ATC permitting and background check process



#### **E06: Future Considerations**

- Redesigning patient/physician portal in progress
- **✓** Home delivery
- **✓** Using external labs for quality control
- **✓** Elimination of sales tax
- **✓** Review of ATC permitting and background check process



# Division of Medicinal Marijuana Biennial Report



## **Findings**

- Prices are not excessive, but are high and are artificially suppressing demand among patients.
- 2 ounce per month limit should be raised for all patients, removed for terminal patients.
- More ATCs are needed. Between 25-50 cultivation sites and 50-90 dispensaries.



### **Prices at ATCs**

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Alternative Treatment Center	Avg Ounce with Discount	% of Illegal Price
Greenleaf Compassion Center	\$413.24	120%
Garden State Dispensary	\$387.69	113%
Breakwater Dispensary	\$322.11	94%
Compassionate Care Foundation	\$332.00	97%
Curaleaf	\$307.32	89%

#### 2018

Avg Ounce with Discount	
\$409.52	119%
\$401.87	117%
\$392.30	114%
\$310.87	90%
\$321.22	94%
\$316.51	92%
	\$409.52 \$401.87 \$392.30 \$310.87 \$321.22

Source: ATC Inventory Management systems, compared against crowd-sourced price of illegal market on PriceOfWeed.com.

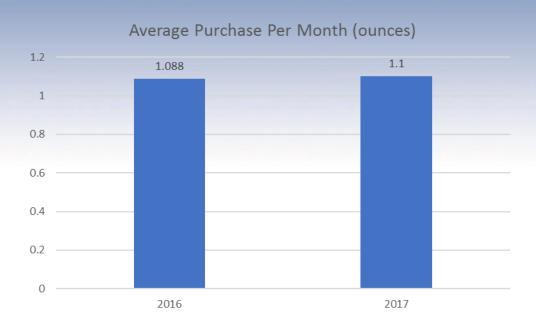
### **Prices at ATCs**

	1/8 Ounce Whole Flower	1/4 Ounce Whole Flower	Whole Ounce
ATC	Price	Price	
			\$460.00
Breakwater ATC (Cranbury)	\$58.00	\$115.00	
			\$472.00
Compassionate Care Foundation (Egg Harbor Twp)	\$59.00	\$118.00	
			\$360.00
Curaleaf (Bellmawr)	\$50.00	\$90.00	
			\$500.00
Garden State Dispensary (Woodbridge)	\$64.50	\$125.00	
			\$500.00
Greenleaf Compassion Center (Montclair)	\$65.00	\$125.00	
			\$480.00
Harmony Foundation (Secaucus)	\$60.00	\$120.00	

Source: ATC Menus, Sales Tax included



# **Monthly Purchase Limit**



Source: Patient Registry – Average purchase amount among patients making a purchase in a given month.



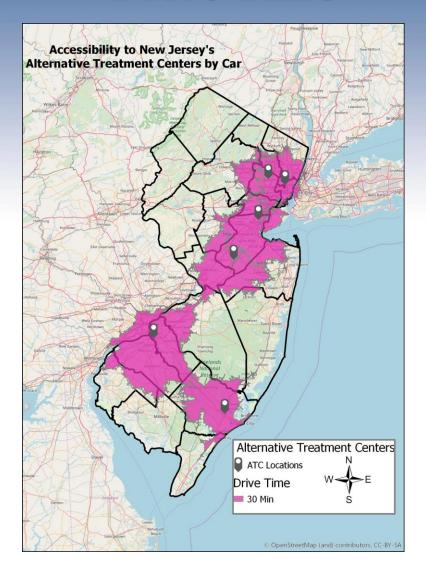
# **Monthly Purchase Limit**

Year	% of Patients Purchasing Up to Limit	# Number of Months
2016		6 of 12 months
2016	24.24%	1 of 12 months
2017	8.62%	6 of 12 months
2017	27.71%	1 of 12 moths

Source: Patient Registry – Percentage of patients purchasing up to the limit in a specified time period.

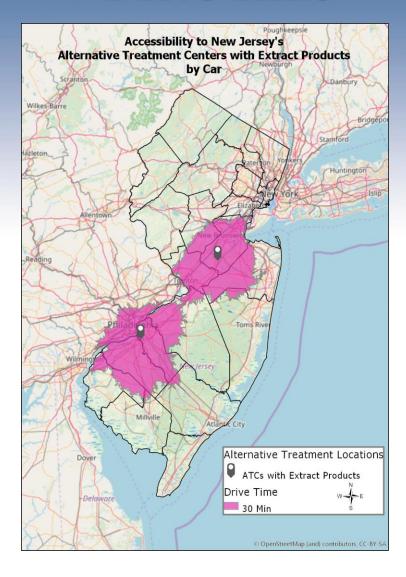


# ATC Needs Analysis – Drive Time



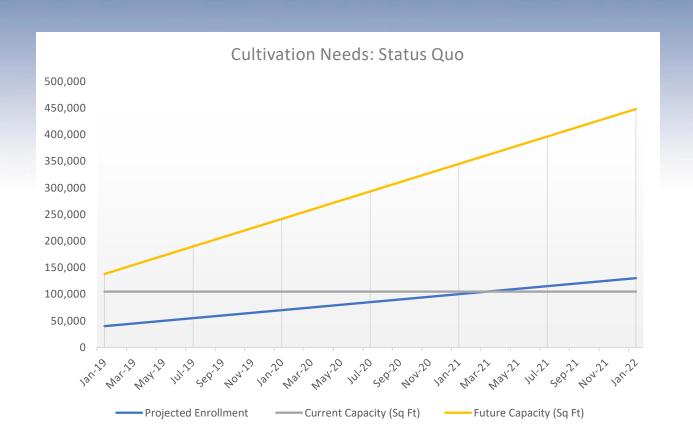


## ATC Needs Analysis – Drive Time



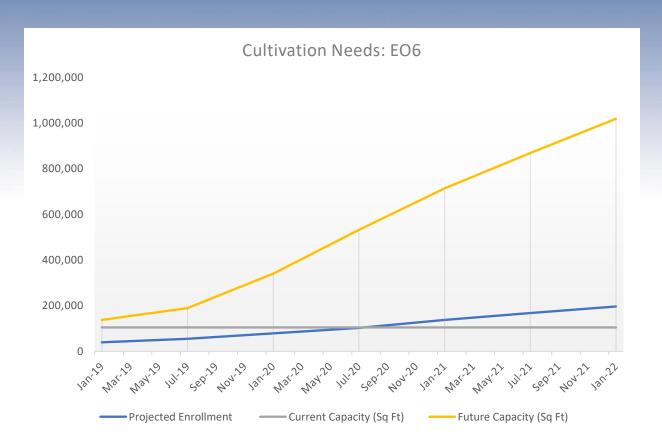


# ATC Needs Analysis – Cultivation Capacity





# ATC Needs Analysis – Cultivation Capacity





#### Call to Action

- We need lower prices, and better value for patients.
- We need more accessible locations, especially for extracted products.
- More ATCs are needed specifically those committed to operating in more competitive market.





#### Current forms of medicinal marijuana in NJ

- Oral primarily lozenges that dissolve in the mouth
- Topical—oils, ointments, and other formulations that are meant to be absorbed through the skin
- Flower the "buds" that can be smoked, vaporized, or baked.
- Oil oils that contains extracted THC and CBD that can be vaporized.
- Edibles tablets, capsules, drops or syrups that are ingested
- Any other form approved by the Department/Commission



#### Plant Types:

- Cannabis Indica
- Cannabis Sativa
- Hybrid

#### Chemotypes:

- 1: High THC/Low CBD
- 2: THC/CBD ratio between .5 and 3.0
- 3: High CBD/Low THC



#### Lozenges/Edibles

- High-CBD
- High-THC
- CBD/THC

Pictured: three types of lozenges, all with 10:1 THC:CBD ratio.
Lozenges come in full dose (10 mg THC, 1 mg CBD), half (5 mg THC, .5 mg CBD) or quarter (2.5 mg THC, .25 mg CBD)





#### Oils









#### Not in NJ yet, but in other markets:

- Tinctures
- Suppositories
- Concentrates
- Transdermal patches



It has been and continues to be an explicit goal of the Department of Health to emphasize non-smokable/non-vapable forms for patients.



# **RFA Overview**



## **RFA** Overview

The Department of Health is seeking new applicants to operate <u>up</u> to <u>24</u> Alternative Treatment Centers (ATCs):

#### Northern Region – UP TO 8

Cultivation Endorsements: 2

Dispensary Endorsements: 5

Vertically Integrated Permits\*: 1

#### <u>Central Region – UP TO 8</u>

Cultivation Endorsements: 2

Dispensary Endorsements: 5

Vertically Integrated Permits\*: 1

#### <u>Southern Region – UP TO 7</u>

Cultivation Endorsements: 1

Dispensary Endorsements: 5

Vertically Integrated Permits\*: 1



The Department will also award up to 1 "at-large" vertically integrated permit.

\* Each vertically integrated permit includes <u>3 endorsements</u>: 1 cultivation endorsement, 1 manufacturing endorsement and 1 dispensing endorsement.



# RFA Process Timeline

DATE	ACTION
Monday, July 1, 2019	Notice of Request for Applications (RFA)
Monday, July 15, 2019	RFA Forms Posted
Friday, August 2, 2019	Pre-Application Webinar Posted
Wednesday, August 21, 2019 at <b>3:00 PM EST</b>	Submission Deadline for <b>DISPENSARY APPLICATIONS</b>
Thursday, August 22, 2019 at <b>3:00 PM EST</b>	Submission Deadline for <b>CULTIVATION AND VERTICALLY INTEGRATED APPLICATIONS</b>

Responses to frequently asked applicant questions will be posted on the Department's website after this webinar.

The review and award schedule shall be determined based on the volume of applications received.





### RFA Overview - Cultivation

The Department has established the following tiers of cultivation canopy size to provide opportunities for businesses of all sizes to participate in this RFA:

- Up to 5,000 Square Feet: up to 1 cultivation endorsement
- 5,001 square feet to 20,000 Square Feet: up to 2 cultivation endorsements
- 20,001 square feet to 30,000 Square Feet: up to 2 cultivation endorsements.

The maximum initial canopy size shall not exceed 30,000 square feet.

Vertically integrated applicants may choose any of the canopy tiers.



# RFA Overview – Vertically Integrated Permits

- The Department will seek to issue at least 1 vertically integrated permit in each region and 1 vertically integrated permit to be determined at the time of award based on overall score and patient need.
- Applicants seeking a vertically integrated permit shall maintain all operations under a single ATC Entity, and seek to operate in accordance with the provisions of N.J.A.C. 8:64-7.9.
- Applicants for a vertically integrated permit shall submit 1 Part A as part of its application.
- Vertically integrated applicants shall submit 3 Part Bs as part of its application.



#### RFA Part A

- Each applicant shall submit one Part A for each region being sought.
- Part A requires applicants to supply the Department with mandatory information, <u>including but not limited to</u>, the following topics:
  - Legal name, status, and owners of business entity
  - Proposed location, evidence of site control and local approval, including evidence of compliance with applicable local codes and ordinances
  - Proposed ATC employees, principal officers, directors, owners, and board members
  - Investors and creditors of the ATC
  - Entities or persons with direct or indirect authority or interest over ATC, including through management services agreements
  - Floor plans, exterior renderings



#### RFA Part B

- For Part B, applicants shall file a single .pdf for each endorsement being sought that includes a full and truthful response to the following criteria and measures.
- The page limit for Part B is 100 pages for each endorsement, with no exceptions/exemptions.
- For Criterion 6, applicants shall only respond to the measure that is applicable to the endorsement being pursued.
- Vertically integrated applicants shall submit 3 Part Bs as part of their application.



# Part B: Exemptions from 100 Page Limit

None.



#### **Evaluation Process**

DATE	ACTION
Thursday, August 22, 2019	End of Open Application Period
August 23 – Sept 23	Completeness Review
September 24, 2019*	Beginning of Application Review
TBD**	Target date to wrap up scoring.
TBD**	Target date to issue awards and denials

<sup>\*</sup>Concurrently with the start of the application period, the first round of denials will be issued for those applications that fail the completeness review.

<sup>\*\*</sup>Review period determined based on number of applications and time to review.





Scored Criteria: The information in the scored sections will be judged by the selection committee according to weights on a 300-point scale per permit endorsement.



#### Three teams:

- General measures
- Endorsement specific
- Diversity and labor



#### Three teams:

- General measures
  - Composite score.
- Endorsement specific
  - Composite score.
- Diversity and labor
  - Measures split, based on expertise.



# Team 1



Ability to meet overall health and safety needs of qualified patients and safety of the public.

- Security Plan 10 pts
- Environmental Impact Plan 10 pts
- Quality Control and Quality Assurance Plan 10 pts

History of compliance with policies and regulations governing government-regulated marijuana programs

Background of principals, board members and owners

 experience in cannabis industry OR other highly
 regulated industry – 20 pts



Ability and experience of applicant in ensuring an adequate supply of marijuana

Financing plan (20 pts)

Community support and participation

Ties to the local community (20 pts)

Ability to provide appropriate research data

Research contributions (10 pts)



# Team 2



Experience in cultivating, manufacturing, or dispensing marijuana in compliance with government-regulated marijuana programs. 100 pts.

- Cultivation Plan (cultivators and vertically integrated)
- Manufacturing Plan (vertically integrated only)
- Dispensary Plan (dispensaries and vertically integrated)

Applicants shall only respond to the applicable measure(s).



#### **Cultivation plan:**

- Overall practices, policies and procedures
- Experience/education in botany, horticulture and phytochemistry and the application of those sciences in the cultivation of medical cannabis.
- Methods to control insects and pests that do not include the application of pesticides.
- Methods to prevent, minimize and test for plant disease and other contamination.
- Methods and practices related to odor mitigation, sanitation and airflow, and employee safety in cultivation environments.

20 pts each = 100 pts



#### Manufacturing plan:

- Overall practices, policies and procedures
- Experience/education in biochemistry, laboratory science, engineering and cannabinoid extraction methods.
- Description of products that the applicant intends to manufacture, including information on ingredients (both active and inactive), methods of production, and relevant patient information like dosing and administration method.
- Methods to prevent and test for contamination in extracted products.
- Health and safety standards for lab employees.



#### Dispensary plan:

- Overall practices, policies and procedures (20 pts)
- Experience/education in the treatment of patients with qualifying health conditions. (20 pts)
- Patient education and counseling methods. (15 pts)
- Employee education procedures for patient-facing staff members. (15 pts)
- Plans to recruit and educate health care professionals regarding the dispensing of medical cannabis to qualified patients. (15 pts)
- Explanation of how the proposed dispensary location expands access to patients and caregivers (15 pts)





# Team 3



#### Workforce and job creation plan

- Labor Peace Agreement 30 pts
- Labor Compliance Plan 20 pts
- Minority-owned, women-owned or veteran-owned business certification – 30 pts
- Workforce and job creation plan 20 pts



#### Labor peace agreement

Applicants shall provide a signed labor peace agreement that includes provisions to ensure the cultivation, manufacturing and dispensing of medical cannabis will not be disrupted by labor-related disputes.

Failure to provide a signed agreement will result in a score of 0 for this measure.



Minority-owned, women-owned or veteran owned business certification:

Applicants shall provide a copy of certification(s) issued by the Department of the Treasury, Division of Revenue which verifies MBE/WBE certification or VOB certification, or evidence that the applicant would otherwise meet the MBE/WBE certification or VOB certification requirements once generating revenue. Applicants with a certification will receive the full 30 pts.

Applicants that provide evidence of meeting the criteria in the future shall receive partial credit, based on the strength of the evidence. The selection committee shall take into account related entities for this measure.



# Accessing the Applications

Applications will be distributed to the selection committee via SharePoint.

Selection committee members will have access to a person-specific SharePoint folder with all the electronic copies of the application.

This will be provided on or before 9/24.

Applications and all materials are to be treated as highly confidential.



#### Order of Review

- 1: Cultivation Only
- 2: Dispensaries
- 3: Vertically Integrated

2+3 subject to change based on market conditions.



### Weekly Check-In Calls

Department will organize weekly, team-specific check-in calls.

#### Structured opportunity to:

- Discuss process and ask technical questions.
- Assess progress.

<u>Specific scores will not be discussed</u>, and should not be shared/discussed between selection committee members under any circumstance.



# **Additional Important Points**



#### Part A: Question 20

Owners/investors with an interest of less than 5% do not need to be listed, nor do they need to fill out a Personal History Disclosure as part of the application process.

If there is an investment fund or company in which no owner/investor has an interest of more than 5% (including publicly traded companies), but in total has more than a 5% stake in an applicant, then the primary decision makers for that fund/company should be included and fill out the Personal History Disclosure.



# **Applicant Eligibility**

<u>Current ATC permit holders (including awardees from December 2018) are not eligible to participate in this RFA.</u>

By "NOT ELIGIBLE" we mean "NOT ELIGIBLE" – which includes management services agreements, funding that represents over 5% equity, intellectual property, any/all board representation, and any other significant involvement.



#### **Public Disclosure**

- Items submitted and created pursuant to the RFA are generally subject to public release pursuant to the N.J. Open Public Records Act (OPRA) and/or the common law.
- Proprietary and other types of information may be exempt from public disclosure, including but not limited to:
  - Personally identifiable information
  - Confidential information
  - Information that would provide a competitive advantage or disadvantage





### Canopy

"Canopy" means the total area in square feet in which an ATC is authorized by the Department to cultivate medicinal marijuana in accordance with N.J.A.C. 8:64-1 et seq. For the purposes of this RFA, "canopy" shall not include areas used exclusively for harvesting, labeling or storing of medicinal marijuana.



### Medical Advisory Board

Pursuant to statutory changes enacted on July 2<sup>nd</sup>, 2019, an ATC <u>may</u> have a Medical Advisory Board.

Therefore, for this RFA, Medical Advisory Boards are optional – but if included as part of the application, must be disclosed on Part A.



# Residency

There is <u>no requirement</u> in the Request for Applications that applicants (or those involved in applicant entities) be New Jersey residents.

Ties to the local community, through a history of residency, will be scored as part of Criterion 4, Measure 1.



# **Proof of Residency**

A driver's license may be accepted as one proof of residency. Applicants are instructed to use their best judgment in the preparation of applications.

Please refer to N.J.A.C. 8:64-1.1 for some other types of documents that the Department routinely accepts as proof of residency.



#### "Silent Partners"

Not permissible in this RFA.

All individuals and entities, as outlined in the RFA, must be disclosed.

Failure to disclose may result in disqualification.

The Department expects a high degree of transparency and disclosure from applicants.



#### Application Rejection – Section IX

Section IX of the RFA enumerates reasons that RFA applications may be rejected by the Department:

- Late/incomplete delivery of application (all aspects of application are due by the submission deadline – <u>NO EXCEPTIONS</u>)
- Failure to follow RFA instructions/format requirements (including 100 page limit for Part B)
- Failure/inability to demonstrate applicant's ability to satisfy all mandatory requirements of the RFA without material change
- Provision of misleading or inaccurate responses
- Failure to include any signature, certification, etc. as required by the RFA
- Failure to disclose all contracts and term sheets
- Initiation of unauthorized contact regarding the RFA with a State employee/official



# Q+A and Next Steps

