

Ohio Medical Marijuana Control Program

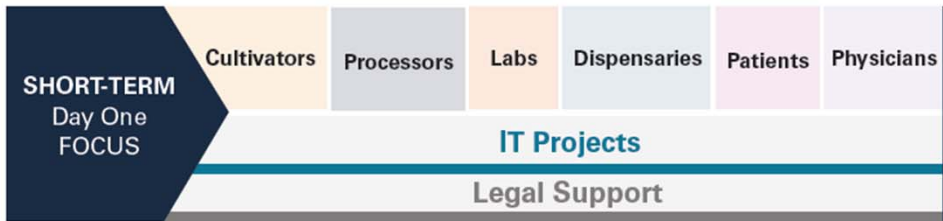


Guiding Principles

- ▶ Patient-centered and safe
- ▶ Responsive, data-driven, and transparent
- ▶ Flexible, scalable, and sustainable
- ▶ Characterized by consistency, integrity, and collaboration across one program



Strategy



Cultivators

- ▶ Certificates of Operation
 - ▶ First Level I: Buckeye Relief, Eastlake (Lake County)
 - ▶ 3 Total (1 Level I, 2 Level II)
- ▶ Cultivator inspection status
 - ▶ August: (3 Level I, 2 Level II)



Cultivators

- ▶ Requests for extension
 - ▶ Level II: 9 requests, 7 granted
 - ▶ Reasons: construction delays (weather, real estate, vendors), local permitting
 - ▶ Range: 21 days to 180 days
 - ▶ 2 still under review
 - ▶ Level I critical dates: August 16/August 30



Processors

▶ Criteria

- ▶ Experience (manufacture of related products, using extraction equipment, business operations, etc.)
- ▶ Proposed products/compliance with rules
- ▶ Production capacity/construction timelines
- ▶ Facility layout - operational and security
- ▶ Understanding of packaging, labeling, & ingredient sourcing/handling requirements
- ▶ Understanding/commitment to inventory control
- ▶ Security requirements (surveillance, transportation, recordkeeping)



Processors

- ▶ Rollout Plan - two cycles
 1. 13 applicants who meet minimum scoring criteria
 - Seven initial announcements
 - Six additional - tax compliance & background checks
 2. Clarification request - rescore and award to top-ranked remaining applicants



Processors



Company Name	City	County	Score
Ohio Grown Therapies, LLC	Johnstown	Licking	185.48
Fire Rock Processing Ltd.	Columbus	Franklin	182.00
Ohio Green Grow LLC	Toledo	Lucas	177.28
Greenleaf Therapeutics, LLC	Middlefield	Geauga	176.72
Greenleaf Therapeutics, LLC	Willoughby	Lake	176.72
Grow Ohio Pharmaceuticals, LLC	Newton Twp.	Muskingum	172.20
Standard Farms Ohio LLC	Garfield Heights	Cuyahoga	156.52
Corsa Verde, LLC	Columbus	Franklin	155.32

Processors

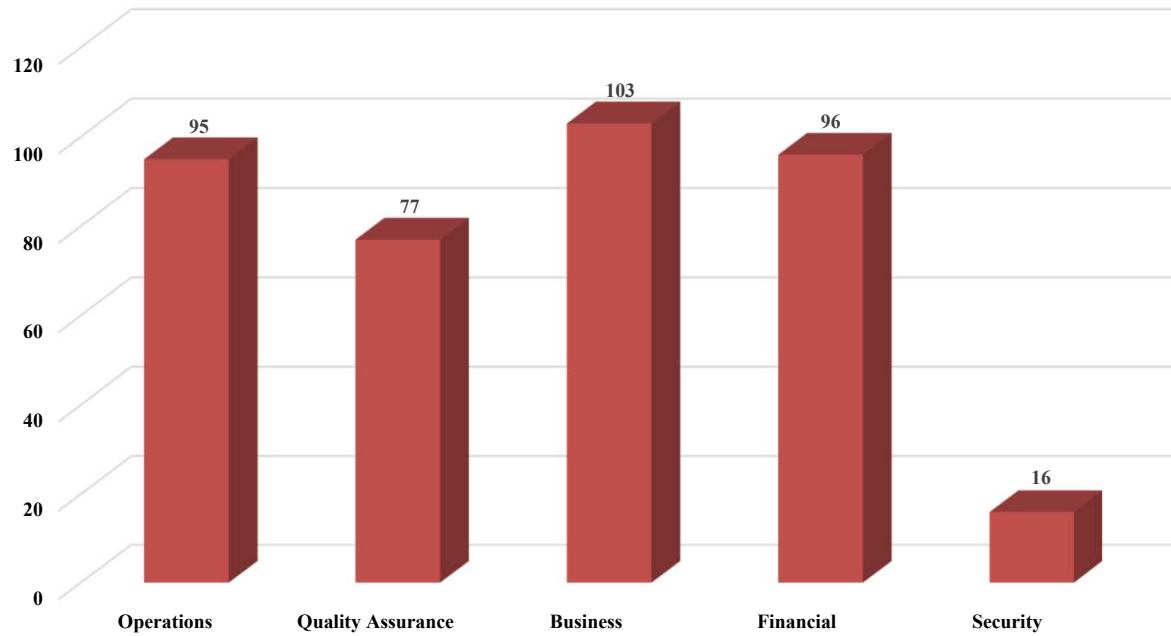


▶ Round 1

- 5 sections (business, operations, quality assurance, financial, security)
- Application must achieve minimum score (60%) on each section, and across the application
 - Must also demonstrate compliance with Section 1 requirements (local regulations, tax compliance, background checks, etc.)
- Up to 13 provisional licenses
- Security plan - most commonly missed
 - Rules very specific - opportunities for clarification

Processors

Applicants Meeting Minimum Qualifications



Processors

- ▶ Round 2
- ▶ Up to 27 licenses
- ▶ Clarification request
 - ▶ Apply across entire application
 - ▶ Specific requests - not requesting new application
 - ▶ Elements driven by rules - compliance is not optional
 - ▶ Quantitative (yes or no), not qualitative (how)
- ▶ Timing





Medical Marijuana Dispensaries



Provisional Dispensary License (PDL)

PDL Engagement

- Email communication and meetings
- Site visits
- Developing newsletter

Progress Toward Operation

- Advertising approvals commenced
- Approval of continuing education materials
- Compliance checklists refined
- Variance approval process continues

119 Requests for Hearings

- 27 applicants have requested 58 hearings



Patient Rules Review

3796:7-2-01 Procedure for patient registration



Physician examines patient and determines that patient has a qualifying condition



Physician or delegate uses OARRS credentials to log into registry and begin registration process

Makes requisite attestations

Specifies number of 90-day refills authorized

Notes instruction for use, if any



Recommendation is generated in the patient registry



Patient and/or caregiver emailed link to access registry

Patients will be able to modify home address, email address, and payment information



Patient access to the patient registry

Patient or caregiver receives email containing link and accesses link



Webpage contains patient information including recommendation

Patient or caregiver has ability to modify only certain fields

Patient or caregiver establishes password



Patient card is generated and electronically available to patient

Valid for 1 year

Can be accessed by patient at anytime



3796:7-2-05 Patients and caregivers -- generally

- Patients and caregivers may not cultivate or extract medical marijuana
- Samples may not be accepted
- Medical marijuana must be securely stored to prevent theft and unauthorized access and be kept in a dispensary container with original label
- Caregivers may not receive payment exclusively for serving as a caregiver
- Must dispossess selves of marijuana within 7 days of expiration, suspension, or revocation of registration



3796:7-2-07 Duty to report

- Fraudulent use of registration identification cards and known unauthorized access to the medical marijuana registry
- Patients or caregivers must report to the board within 7 days if the patient no longer is diagnosed with a qualifying condition
- Caregivers must report any arrest, charges pending, or conviction for any felony or misdemeanor except non-DUI-related traffic misdemeanors
- Affords 7 days or more to report in many cases where licensed professionals must report immediately



Expansion of Authorized Forms of Medical Marijuana



House Bill 523-Approved Forms

Oils

Tinctures

Plant
material

Edibles

Patches

House Bill 523 Prohibitions on Form and Method of Administration



Forms and methods considered attractive to children

Forms that require smoking or combustion



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
- Currently contains only those forms established by the General Assembly



3796:8-2-02 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:
 - Reproducible scientific evidence
 - Expert opinion
 - Extent to which the prospective form or method of administration is generally accepted by the medical community
 - Information known to petitioner of any benefits or adverse effects
 - Benefits to approving the form or method of administration
 - The Board is authorized to gather its own evidence as well



Review Process

- Petition for nasal spray received
- Bifurcated review process
 - Petition presented to Board for approval to invest in 90-day supply research
 - Board vote regarding 90-day supply for new form
- Start with maximum THC content in Tier I and Tier II – approximately equivalent
 - Maximum 90-day supply of THC content in plant material is approximately 52 g
 - This number is calculated based upon the maximum 90-day supply of plant material

Certificates to Recommend



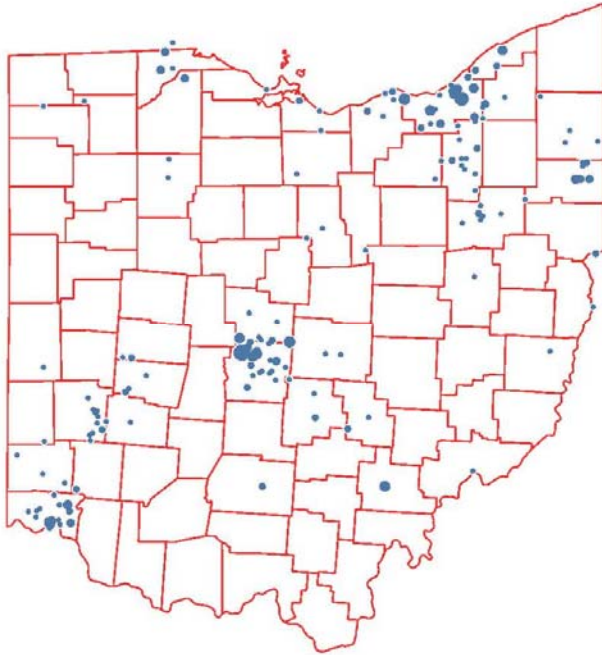
Certificates to Recommend

- ▶ March 19, 2018: Began accepting CTR applications
- ▶ Currently: 222 approved CTRs
 - ▶ Including 38 approved during August board meeting
- ▶ Licensees with CTR can be found at med.ohio.gov
 - ▶ MedicalMarijuana.ohio.gov -> Physicians
 - ▶ Med.ohio.gov -> Publications -> Rosters





Certificates to Recommend



Full License		CTR Endorsement	
Total MDs	42,265	MDs with CTR	161
Total DOs	6,676	DOs with CTR	61
Total Physicians	48,941	Physicians with CTR	222
Ratio	7:1	Ratio	3:1

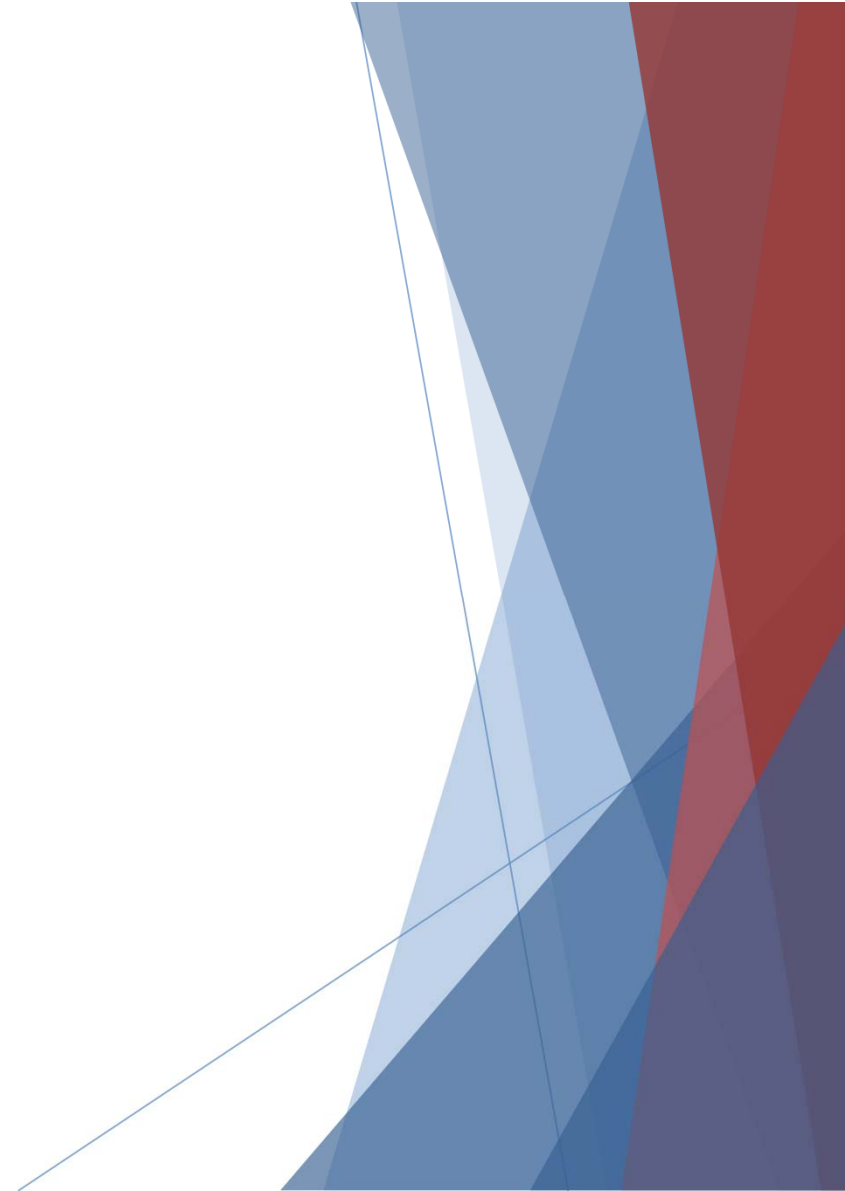
► *Note: Physicians may enter the address to which they wish to receive SMBO correspondence. This may differ from their practice address(es)*

Certificates to Recommend

- ▶ Physician Outreach
 - ▶ Monthly reminder in eNews
 - ▶ Presentations to physician groups, associations
- ▶ CTR Physician Education
 - ▶ How-to video for patient portal
 - ▶ Program overview: what to do once you have a CTR



Qualifying Conditions



Qualifying Conditions

- ▶ First submission period: Nov. 1, 2018 – Dec. 31, 2018
- ▶ Petitions **NOT** accepted before Nov. 1, 2018
- ▶ A petition needs to include:
 - ▶ The name and contact information
 - ▶ Specific disease or condition requested to be added
 - ▶ Information from experts who specialize in the study of the disease or condition
 - ▶ Relevant medical or scientific evidence
 - ▶ Consideration of whether conventional medical therapies are insufficient to treat or alleviate the disease or condition
 - ▶ Evidence supporting the use of medical marijuana to treat or alleviate the disease or condition and other types of medical or scientific documentation
 - ▶ Letters of support provided by physicians



Qualifying Conditions

- ▶ Web form created, tested and ready to publish Nov. 1



CONDITION

Petition to Request Approval of Condition or disease to be Designated as a Qualifying Medical Condition for Treatment with Medical Marijuana

Acceptance Period Dates: _____

Please note: Any petition received after _____, 201, will not be accepted or considered. Any petition seeking to add a broad category of diseases or conditions will not be considered. Any petition for a condition that has been previously reviewed by the Board and rejected, will not be considered by the Board unless accompanied by new scientific research that supports the request offered.

CONDITION

Name _____

Address _____

City _____ State _____

Email _____

Phone _____

Specific Disease or Condition _____

Please provide information from experts who specialize in _____

Please provide information regarding whether conventional or alternative the disease or condition.

Please provide evidence supporting the use of medical disease or condition, including but not limited to journal articles, peer-reviewed studies and other types of medical or scientific documentation

[Choose File](#) No file chosen

Please provide letters of support provided by physician or condition

[Choose File](#) No file chosen

SUBMIT

THE STATE OF OHIO BOARD OF PHARMACY

60 E. Spring St
Columbus OH 43215

jen@ohb.com
(614) 644-8557

Cancer

Contrary to popular belief, Lorem Ipsum is not simply random text. It has roots in a piece of classical Latin literature from 45 BC, making it over 2000 years old. Richard McClintock, a Latin professor at Hampden-Sydney College in Virginia, looked up one of the more obscure Latin words, consectetur, from a Lorem Ipsum passage, and going through the cites of the word in classical literature, discovered the undoubtable source. Lorem Ipsum comes from sections 1.10.32 and 1.10.33 of "de Finibus Bonorum et Malorum" (The Extremes of Good and Evil) by Cicero, written in 44 BC. This book is a treatise on the virtues of citizenship for Romans.

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Please provide evidence supporting the use of medical marijuana to treat or alleviate the disease or condition, including but not limited to journal articles, peer-reviewed studies and other types of medical or scientific documentation.

[Choose File](#) No file chosen

Please provide letters of support provided by physicians with knowledge of the disease or condition

[Choose File](#) No file chosen

SUBMIT

Please provide evidence supporting the use of medical marijuana to treat or alleviate the disease or condition, including but not limited to journal articles, peer-reviewed studies and other types of medical or scientific documentation.

- [Choose File](#) PHONE LIST.03.23.17.pdf
- [Choose File](#) 021212400.pdf
- [Choose File](#) PHONE LIST.03.23.17.pdf
- [Choose File](#) NotPDF.pdf
- [Choose File](#) PHONE LIST.03.23.17.pdf

Please provide letters of support provided by physicians with knowledge of the disease or condition

- [Choose File](#) No file chosen

SUBMIT



CONDITION

HOME ABOUT PROGRAMS TIMELINE & RULES ABUSE PREVENTION NEWS CONTACT

CONDITION

Your form has been submitted successfully!

The Board will issue its written decision no later than 180 days after the end of the acceptance period. The Board will notify the petitioner of the decision and publish the decision on the medical marijuana control program website.

Qualifying Conditions

- ▶ Medical Marijuana Expert Review Committee
 - ▶ A committee of 4 board members will help identify experts
 - ▶ Experts will review petitions to add a qualifying condition and make a recommendation to the board
- ▶ Full board will vote to add a qualifying condition

