

# Department of Consumer Protection

## Drug Control Division

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Drug Control Division

Department of Consumer Protection

State of Connecticut

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# Department of Consumer Protection Drug Control Division

Drug Control Division:

Compliance, Investigations, Enforcement,  
Education.

- Agents (RPh).

Prescription Monitoring Program

Medical Marijuana Program

Board Administrator - Commission of Pharmacy



# Medical Marijuana





# What is Medical Marijuana

## Medical Marijuana

21a-240 (29) "Marijuana" means all parts of any plant, or species of the genus cannabis or any infra specific taxon thereof, whether growing or not; the seeds thereof; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin. It does not include the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture or preparation of such mature stalks, except the resin extracted therefrom, fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination. Included are cannabimon, cannabimol or cannabidiol and chemical compounds which are similar to cannabimon, cannabimol or cannabidiol in chemical structure or which are similar thereto in physiological effect, and which show a like potential for abuse, which are controlled substances under this chapter unless modified;

21a-408 (6) "Palliative use" means the acquisition and distribution, possession, cultivation, use or transportation of marijuana or paraphernalia relating to marijuana to alleviate a qualifying patient's symptoms or the effects of such symptoms, but does not include any such use of marijuana by any person other than the qualifying patient. For the purposes of this subdivision, "acquisition and distribution" means the transfer of marijuana and paraphernalia relating to marijuana from the primary caregiver to the qualifying patient;





# Medical Marijuana Program (MMP)

## Understanding the Law

- Connecticut General Statute, Chapter 420f, Section 21a-408, An Act Concerning the Palliative Use of Marijuana, signed into law on May 31, 2012.
- [http://www.cga.ct.gov/current/pub/chap\\_420f.htm](http://www.cga.ct.gov/current/pub/chap_420f.htm)
- Designed to enable truly sick patients to engage in the palliative use of marijuana while preventing marijuana from being misused or diverted from its medical purpose.
- Provides immunity from **state** criminal and civil penalties for physicians, patients, caregivers, dispensaries and producers who act responsibly in accordance with the law.





# Understanding the Law Designed to Prevent Misuse and Diversion

- Limited Group of Debilitating Medical Conditions Qualify
- Physicians are the Gatekeepers
- Patients and Caregivers Must Meet Strict Requirements and Act Responsibly
- Producers Will be Limited and Tightly Controlled
- Dispensaries Will Treat Marijuana as the Controlled Substance it is.
- Marijuana Cannot be Used in a Place or Manner that Puts Others at Risk





# Debilitating Medical Conditions Recognized by the Law

- Cancer
- Glaucoma
- Positive status for human immunodeficiency virus or acquired immune deficiency syndrome
- Parkinson's disease
- Multiple sclerosis
- Damage to the nervous tissue of the spinal cord with objective neurological indication of intractable spasticity
- Epilepsy
- Cachexia
- Wasting Syndrome
- Crohn's disease
- Post-traumatic stress disorder





# Scope of Immunity

- Those who comply with the law are protected from negative consequences, including:
  - Arrest;
  - Prosecution;
  - Civil Penalties; or
  - Any other penalties, including disciplinary action by the Connecticut Medical Examining Board or other professional licensing board.





## Patient & Caregiver Registration Fees

- All registration and license fees will be used to fund the Medical Marijuana Program.
- Non-refundable application fee for a qualifying patient is \$100.00.
- Non-refundable application fee for a primary caregiver is \$25.00.





## Dispensary, Dispensary Technician and Dispensary Facility Employee License/Registration Fees

- Non-refundable fee for a Dispensary is \$100.00.
- Non-refundable fee for a Dispensary Technician is \$50.00.
- Non-refundable fee for a Dispensary Facility Employee registration is \$50.00.





# Dispensary Facility, Dispensary Facility Backer, and Dispensary Facility Manager License/Registration Fees

- Non-refundable application fee for a Dispensary Facility is \$1,000.00.
  - Non-refundable license fee of \$5,000.00.
- Non-refundable fee for a Dispensary Facility Backer is \$100.00.
- Non-refundable fee for a Dispensary Facility Manager is \$50.00.





# Producer, Production Facility Employee and Producer Backer License/Registration Fees

- Non-refundable application fee for a Producer is \$25,000.00
  - Non-refundable license fee of \$75,000.00.
  - \$2,000,000 escrow account, letter of credit or surety bond.
- Non-refundable fee for a Production Facility Employee is \$100.00.
- Non-refundable fee for a Producer Backer is \$100.00.





# Medical Marijuana

- Where we are:

## Dispensary and Grower.

- The RFA (Request For Application) process is completed and applicants chosen.
- End Date was November 15 th, 2013
- 4 Producers
- At least 6 Dispensaries (one has zoning issues)





# The Producers

- Theraplant, LLC, Watertown, CT
- Connecticut Pharmaceutical Solutions, LLC ,  
Portland, CT
- Curaleaf, LLC, Simsbury, CT
- Advance Grow Labs, LLC, West Haven, CT





# Producers

- 4 Producers have been chosen.
- Plants are only allowed to be grown indoors.
- Plants are already growing.
- The Division has begun inspections.



# Movement of Product

- Distribution from Producer to Dispensary Facility.
- Responsibility of the producer.
  - Can be outsourced
  - Can be internal



# The Dispensary Facilities

- The Healing Corner Inc., Bristol, CT
- Arrow Alternative Care Inc., Hartford, CT
- Bluepoint Wellness of Connecticut, LLC, Branford, CT
- Thames Valley Alternative Relief, LLC, Montville, CT
- Prime Wellness of CT, South Windsor, CT
- DB Wellness, Bethel, CT





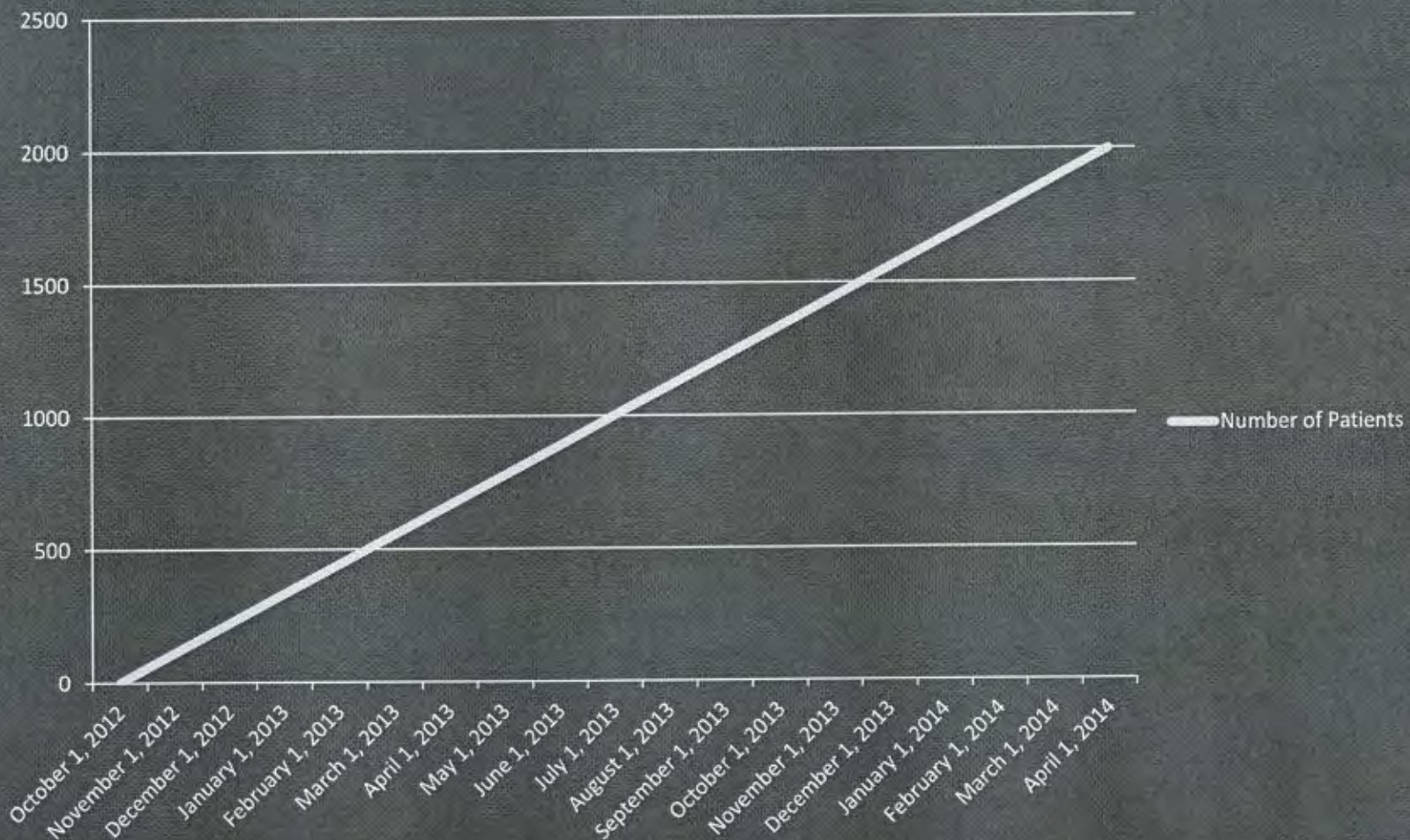
# Dispensaries

- Pharmacist = Dispensary
- Number of Dispensary Facilities determined by the number of patients. Currently the number is 6 with one in a zoning issue.



# Medical Marijuana




## Number of Patients





# Medical Marijuana

## A Growing Business | States with or considering laws on marijuana use

-  States that have legalized marijuana for both medicinal and recreational use
-  States that have legalized marijuana for medicinal use only
-  States that have bills pending that would legalize marijuana for medicinal and/or recreational use



Note: As of April 9

\*Have filed bills to legalize recreational marijuana

Source: Marijuana Policy Project





# Medical Marijuana Laws Get Tougher

June 19, 2013

## A Potpourri of Medical-Marijuana Laws

States have increased restrictions on medical-marijuana laws in recent years, making the drug more politically viable in some states but also sparking complaints that the new laws restrict access for some patients. Select column headers to sort.

State/district	Year initially enacted	Home cultivation	Allowed for general pain
California	1996	Allowed	Yes
Alaska	1998	Allowed	Yes
Oregon	1999	Allowed	Yes
Washington state	1998	Allowed	Yes, with restrictions
Maine	1999	Allowed	Yes
Hawaii	2000	Allowed	Yes
Nevada	2000	Limited*	Yes
Colorado	2000	Allowed	Yes
Montana	2004	Allowed	Yes
Vermont	2004	Allowed	Yes with restrictions
Rhode Island	2006	Allowed	Yes
New Mexico	2007	Allowed	Yes with restrictions
Michigan	2008	Allowed	Yes
Arizona	2010	Limited	Yes
New Jersey	2010	Not allowed	No
Washington D.C.	2010**	Not allowed	No
Delaware	2011	Not allowed	Yes with restrictions
Connecticut	2012	Not allowed	No
Massachusetts	2012	Limited	Yes
Illinois	expected 2013	Not allowed	No
New Hampshire	expected 2013	Not allowed	Yes with restrictions





# Medical Marijuana

## Federal Restrictions on Cannabis Research

### Schedule I Controlled Substance

- high potential for abuse
- no currently accepted medical use in treatment
- lack of accepted safety under medical supervision
- use and possession is a federal offense



# Federal versus State

- Exposure
  - Pharmacists
  - Physicians
  - Pharmacies

Example: Massachusetts



# Medical Marijuana

## National Institute of Drug Abuse (NIDA)

- NIDA does not stock purified (a.k.a., Good Manufacturing Practice grade)  $\Delta^9$ -THC or CBD in their drug supply inventory for use in clinical trials
  - not the case with other Schedule I drugs like heroin, LSD, and MDMA
    - » which are provided legally by “private U.S laboratories” or easily imported from abroad with federal permission, making marijuana the only Schedule I drug with a single federal provider





# Medical Marijuana Pharmacology

## ADMINISTRATION AND INTOXICATION

- 420 chemicals (30 to 60 “cannabinoids”– most potent, delta-9-tetrahydrocannabinol, or THC)
- ingested orally, intoxication effects in 30 minutes
  - smoking inhalation, intoxication effects within minutes
  - 59% of smoked THC absorbed; 3% THC when orally ingested
- smoked THC effects 3 – 4 hours; longer if ingested orally
- 1960’s “joint” had 1-3% THC; wide range now (4-15%)
  - one “joint” today equivalent to smoking 3-5 “joints” in the 1960s.



# Medical Marijuana Pharmacology

- marijuana is fat soluble
- effects may persist or reoccur for 12-24 hours
- the ability to drive a car or a plane, other motor performance tasks, alertness and the ability to concentrate may be affected for hours to days



# Next

- Patient (MMP) is admitted into a:
  - Acute Care facility,
  - Long Term Care facility,
  - Hospice,
    - The 'Institution of Hospice'
      - Institution,
      - Home.



# Factors to Consider

- Will your facility allow a marijuana product to be used in your facility?
  - Schedule 1 - Federal
  - Schedule 2 – CT
- Most facilities do not allow smoking on the premises.
- Many facilities do not allow personal medications to be used.
- No use of non formulary drugs.



# Factors to Consider

- Federal Courts have told the FDA that e-cigarettes should be seen as tobacco products.
  - Vaporization.
- Equivalency between dosage forms.
- Constant communication between patient, physicians, facility, dispensary (pharmacist).
  - Anticipatory actions.



# Factors to Consider

- How to get product to the patient (Legally).
  - Caregiver (If the patient has one).
  - Obtaining a caregiver if the patient does not have one at the time of admission.
  - Proper planning goes a long way.
- Develop the appropriate policies and procedures.



# Establishment of standards

- Expiration dates.
- Stability testing.
- Storage requirements,
  - Recent issue with botulism with non- refrigerated product.



# Questions