



# North Dakota Compassionate Care Act

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# Disclaimer

This presentation is not intended as legal advice. Please consult your legal counsel when needed.

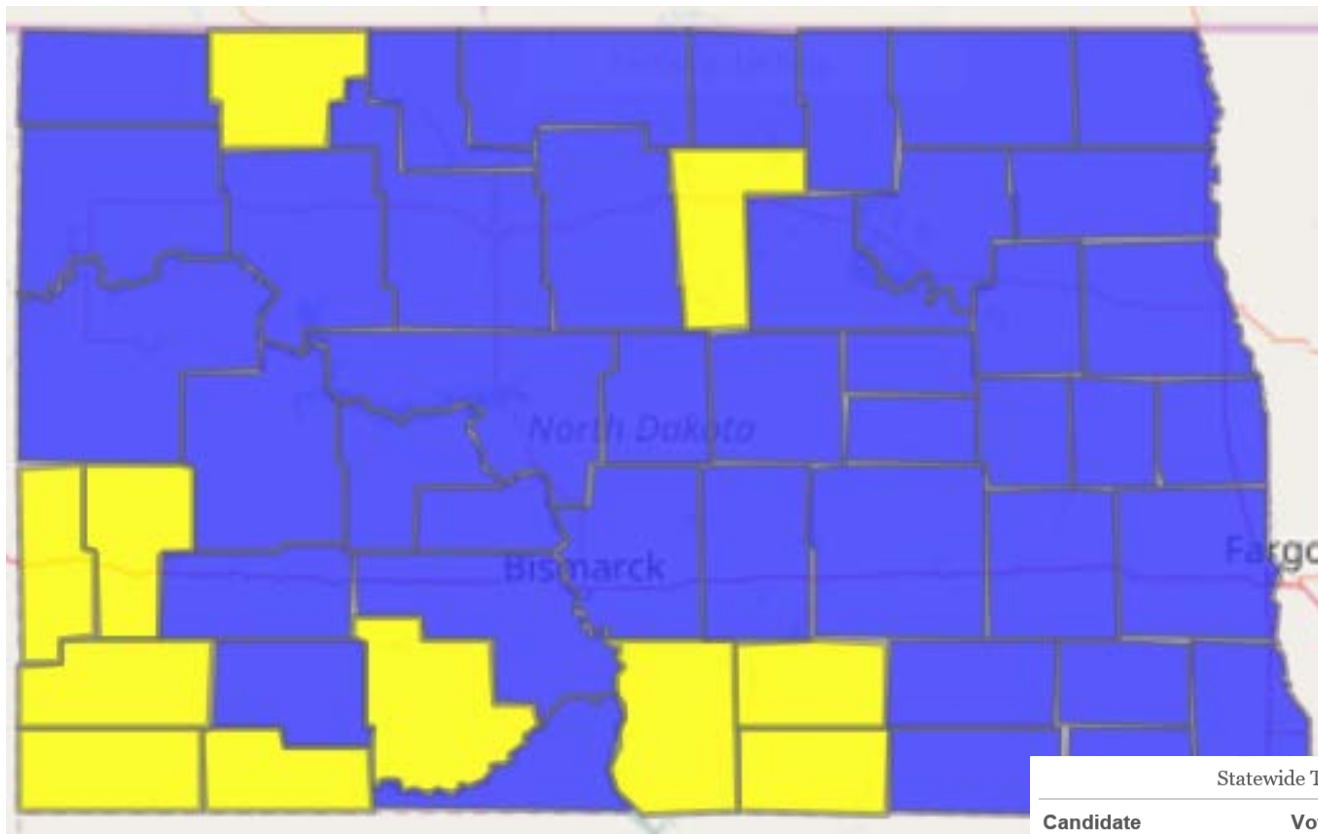
# Compassionate Care Act


- History of the Compassionate Care Act
- The Cole Memo
- Process Overview
- Statutory Details – N.D.C.C. 19-24.1
- PDMP and Current Prescriptions
- Program Implementation
- Employment Law Issues

# History of the Compassionate Care Act

- November 8, 2016
  - Initiated Measure 5, legalizing the use of medical marijuana for patients with qualifying medical conditions, was approved by North Dakota voters.

# History of the Compassionate Care Act



Statewide Totals		
Candidate	Votes	Percent of Vote
No	122,615	36.2%
Yes	216,042	63.8% 

# History of the Compassionate Care Act

## ***N.D. Constitution – Article 3, Section 8***

If a majority of votes cast upon an initiated or a referred measure are affirmative, it shall be deemed enacted. ***An initiated or referred measure which is approved shall become law thirty days after the election***, and a referred measure which is rejected shall be void immediately. If conflicting measures are approved, the one receiving the highest number of affirmative votes shall be law. ***A measure approved by the electors may not be repealed or amended by the legislative assembly for seven years from its effective date, except by a two-thirds vote of the members elected to each house.***

# History of the Compassionate Care Act

- Implementation of the Original Measure
  - Analysis raised significant concerns
- Legislative Amendment – SB 2344
  - Incorporate priorities in the Cole Memo issued by the U.S. Dept. of Justice
  - [US DOJ Cole Memo](#)
- Signed by the Governor on April 17, 2017

# The Cole Memo

“Congress has determined that marijuana is a dangerous drug and that the illegal distribution and sale of marijuana is a serious crime that ***provides a significant source of revenue to large-scale criminal enterprises, gangs, and cartels.*** The Department of Justice is committed to enforcement of the CSA consistent with those determinations.”



# The Cole Memo

“The Department is also committed to using its ***limited investigative and prosecutorial resources*** to address the ***most significant threats*** in the ***most effective, consistent, and rational way***. In furtherance of those objectives, as several states enact laws relating to the use of marijuana for medical purposes, the Department in recent years has ***focused its efforts on certain enforcement priorities*** that are particularly important to the federal government.”

# The Cole Memo

- Preventing the distribution of marijuana to minors;
- Preventing revenue from the sale of marijuana from going to criminal enterprises, gangs, and cartels;
- Preventing the diversion of marijuana from states where it is legal under state law in some form to other states;
- Preventing state-authorized marijuana activity from being used as a cover or pretext for the trafficking of other illegal drugs or other illegal activity;

# The Cole Memo

- Preventing violence and the use of firearms in the cultivation and distribution of marijuana;
- Preventing drugged driving and the exacerbation of other adverse public health consequences associated with marijuana use;
- Preventing the growing of marijuana on public lands and the attendant public safety and environmental dangers posed by marijuana production on public lands; and
- Preventing marijuana possession and use on federal property.

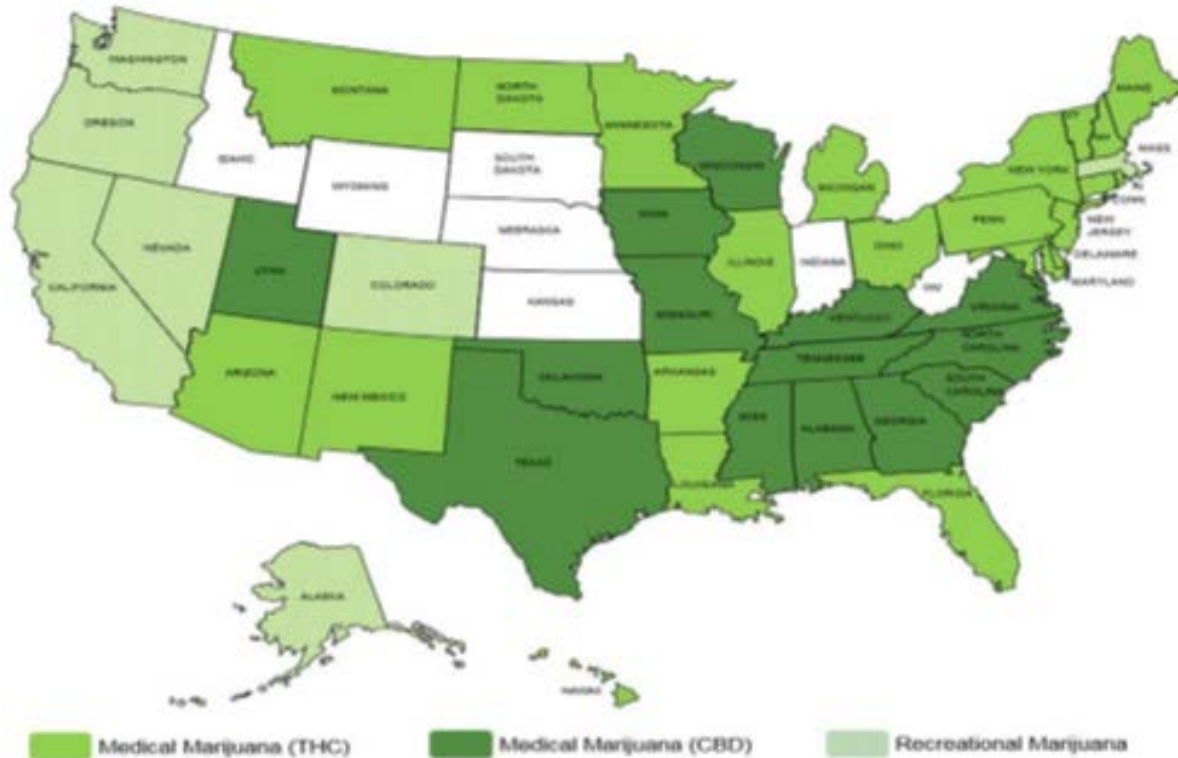
# Marijuana Defined

" All parts of the plant of the genus cannabis; the seeds of the plant; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture, or preparation of the plant.

*Patients possess usable marijuana.*



# Across the Country



# Across the Country - THC



# Across the Country - CBD





# Process Overview

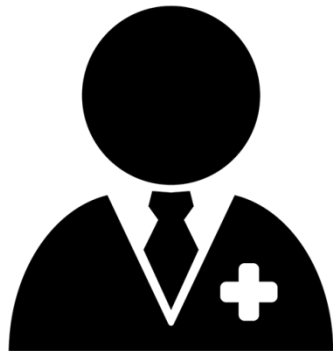
Patient has a debilitating medical condition

Health Care Provider executes a written certification

Patient applies for a registry identification card with DoH

Approved patient receives a registry identification card

Patient can purchase usable marijuana at registered compassion centers



# Qualifying Patient

An individual who has been diagnosed by a health care provider as having a debilitating medical condition.

# Debilitating Medical Conditions

- Cancer
- Positive status for HIV
- Decompensated cirrhosis caused by HCV
- Amyotrophic lateral sclerosis
- PTSD
- Agitation of Alzheimer's disease or related dementia
- Crohn's disease
- Fibromyalgia
- Spinal stenosis or chronic back pain
- Glaucoma
- Epilepsy
- A terminal illness

# Debilitating Medical Conditions

## Terminal Illness

- A disease, illness, or condition of a patient:
  - For which there is not a reasonable medical expectation of recovery;
  - Which as a medical probability, will result in death of the patient, regardless of the discontinuance of medical treatment implemented for the purpose of sustaining life or the life processes; and
  - As a result of which, the patient's health care provider would not be surprised if death were to occur within six months.

# Debilitating Medical Conditions

## Chronic Conditions

- A chronic or debilitating disease or medical condition or treatment for such disease or medical condition that produces one or more of the following:
  - Cachexia or wasting syndrome;
  - Severe debilitating pain that has not responded to previously prescribed medication or surgical measures for more than three months or for which other treatment options produced serious side effects;
  - Intractable nausea;
  - Seizures; or
  - Severe and persistent muscle spasms, including those characteristics of multiple sclerosis

# Written Certification

## Health Care Providers

- Includes:
  - Physicians
  - Advanced Practice Registered Nurse
- Must be licensed to practice in North Dakota.

# Written Certification

## Requirements

- Executed by a health care provider stating that *"in the health care provider's professional opinion the patient is likely to receive therapeutic or palliative benefits from the medical use of marijuana to treat or alleviate the patient's debilitating medical condition."*
- Can only be executed in the course of a bona fide provider-patient relationship

**Health care providers do NOT prescribe medical marijuana.**

# Written Certification

## Bona Fide Provider-Patient Relationship

- A treatment or counseling relationship between a health care provider and a patient where all of the following are present:
  - Review of relevant medical records and full assessment of patient's medical history and current medical condition. Must be in-person.
  - Health care provider maintains adequate medical records related to the condition
  - Patient is under the providers continued care for the condition
  - The provider has a reasonable expectation they will continue to monitor and treat the patient
  - The relationship is NOT for the sole purpose of providing a written certification



# Qualifying Patient Registration

## Patient Application

- Application fee: \$50
- An original written certification
- An executed application
  - Name, Address and DOB
  - Social Security Number
  - Designated Caregiver Information
- A consent for the release of medical information
- A recent 2x2 photograph
- Any other information required by rule

# Qualifying Patient Registration

## Patient Application - MINOR

- Additional Requirements Include:
  - Documentation indicating the health care provider has explained the potential risks and benefits to the parent or legal guardian
  - Parent or legal guardian must consent in writing to the following:
    - Allow the minor's use of medical marijuana
    - Serve as the minor's designated caregiver
    - Control acquisition and dosage
    - Prevent the access to the minor
- Application fees may be waived for minors

# Designated Caregiver

An individual who agrees to manage the well-being of a registered qualifying patient with respect to the qualifying patient's medical use of marijuana

# Designated Caregiver Registration

## Designated Caregiver Application

- Application fee: \$50
- An executed application
  - Name, Address and DOB
  - Social Security Number
  - Qualifying Patient Information
- Authorization form executed by a qualifying patient
- A recent 2x2 photograph

# Designated Caregiver Registration

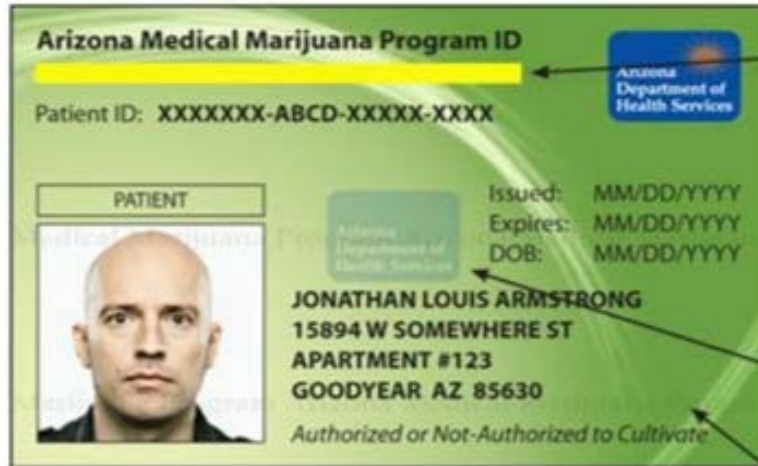
## Designated Caregiver Application

- Criminal History Record Check
  - Drug related misdemeanor within five years of application
  - Felony conviction
- A separate application is required for each qualifying patient
- Minor patients must have a designated caregiver

# Registry Identification Card

A document issued by the department which identifies an individual as a registered qualifying patient, registered designated caregiver, or registered compassion center agent.

## Patient ID Card and Security Features



### Color Bar Identifier

As of May 8, 2013, ADHS began printing ID cards with colored bar identifiers as follows:

Qualifying Patient – Yellow  
Designated Caregiver – Red  
Dispensary Agent – Blue

*NOTE: Cards issued prior to May 8, 2013 will not have the color bar identifier.*

### Ultraviolet Security Image

Under a black light, the ADHS logo (*without* the copper sunburst) is revealed in the center of the card.

### Clear Laminate Hologram

The words "Arizona Medical Marijuana Program" are printed across the card on three separate lines within the clear laminate—once across the top, middle, and bottom of the card.

### WARNING:

Possessing marijuana may be in violation of local, state or federal laws. Possession of this card does not provide legal protection. Marijuana use can be addictive and can impair an individual's ability to drive a motor vehicle or operate heavy machinery. Marijuana smoke contains carcinogens and can lead to an increased risk of severe health problems. **KEEP MARIJUANA OUT OF REACH OF CHILDREN AND ANY UNAUTHORIZED INDIVIDUAL.**

Call the Poison Control Hotline at 1-800-222-1222 if you have concerns.



Arizona Department of Health Services | Will Humble, Director  
www.azdhs.gov

# Registry Identification Cards

- Name of the cardholder
- Purpose of participation
- Date of issuance
- Additional designations
  - Minor patient
  - Authorized to use dried leaves and flowers
- Photograph
- Random alphanumeric identification number
  - Patient
  - Designated Caregiver
- Verification information



# Registry Identification Cards

## Notification of Changes

- Changes in name or address
- Changes related to participant eligibility
  - Patients
  - Designated Caregivers
  - Health Care Providers
- Loss of registry identification card

# Verification System

## Verification System Contents

- Confidential list of all cardholders
- Secure verification system for law enforcement, health care providers, pharmacists, and compassion centers
- Provides the following:
  - If the card is valid
  - The name of the cardholder
  - Cardholder designation
  - Minor status
  - Registry identification number of a qualifying patient or designated caregiver

[Arizona Verification System for Medical Marijuana](#)

# Compassion Center

A manufacturing facility or a dispensary.



# Compassion Centers

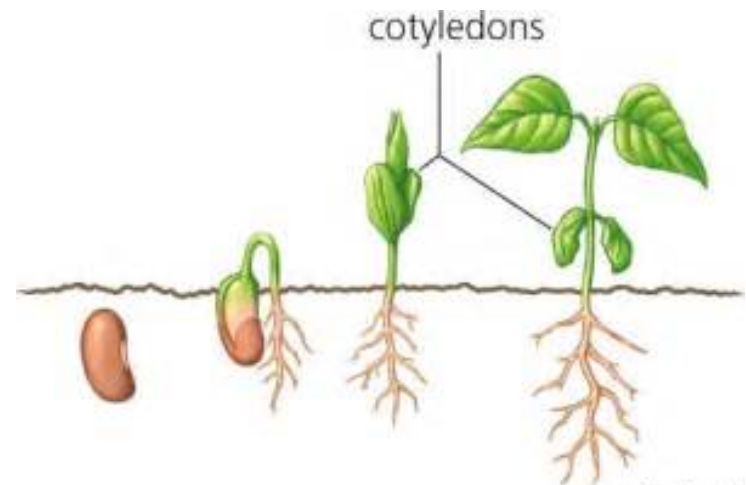
## Manufacturing Facility

- An entity registered by the department as a compassion center authorized to produce and process and to sell usable marijuana to a dispensary
- Two facilities in North Dakota
  - Up to 1,000 marijuana plants (regardless of the stage of growth)
  - Additional 50 plants for R&D

# Compassion Centers

## Marijuana Plant

A marijuana plant that has produced cotyledons or a cutting of a marijuana plant that has produced cotyledons.



# Compassion Centers

## Dispensary

- An entity registered by the department as a compassion center authorized to dispense usable marijuana to a registered qualifying patient and a registered designated caregiver
- Eight facilities in North Dakota
  - Up to 3500 ounces of usable marijuana
  - Point in time possession



2

- **Manufacturing Facility**

8

- **Dispensary**

- **Qualifying Patient**
- **Designated Caregiver**

# Compassion Center Agents

A principal officer, board member, member, manager, governor, employee, volunteer, or agent of a compassion center.



# Compassion Center Agents

## Compassion Center Agent Applications

- Application fee: \$200
- An executed application
  - Name, Address and DOB
  - Social Security Number
- Statement executed by compassion center executive validating association
- A recent 2x2 photograph

# Compassion Center Agents

## Compassion Center Agent Applications

- Criminal History Record Check
  - Drug related misdemeanor within five years of application
  - Felony conviction
- A separate application is required for compassion center agent
- Each compassion center agent must possess a valid registry identification card.

# Compassion Center Application

## Application Period

- The Dept. of Health to establish an open application period for submission of applications

# Compassion Center Application

## Fees

- Application Fee
  - \$5,000
- Registration Fee
  - Manufacturing Facility \$110,000
  - Dispensary \$90,000

# Compassion Center Application

## Application Requirements

- Application Fee
- Business Filings
  - Evidence of registration and good standing with ND SOS
- Physical address
  - Evidence of approval from local officials as to compliance with local zoning laws
  - 1,000 feet from a pre-existing school
- Description of the facility used for production and processing. Activities cannot be in public view

# Compassion Center Application

## Application Requirements Continued

- Compassion center agent application completion
- Relevant experience of principal officers and board members
- A description of security and safety features
- An example of usable marijuana containers
- A complete operations manual
- Description of the plan for making usable marijuana available on an affordable basis to registered patients with limited resources

# Compassion Center Application

## Application Requirements Continued

- A list of all individuals and business entities:
  - Having direct or indirect authority over the management of the compassion center
  - An ownership interest
  - The identity of any creditors

# Compassion Center Registration

## Registration Certificates

- Dept. of Health will review applications and select applicants to register
- Not transferrable

## Renewal

- Compassion center registration certificates must be renewed every two years
- The Dept. of Health will review the actions of the center and determine whether to reissue the registration certificate



# Compassion Center Registration

## Registration Revocation

- The Dept. of Health may suspend or revoke a cardholders registry identification card or a compassion center's registration certificate for **any violation** of this chapter or rules adopted under this chapter.
- Plan of Correction

# Compassion Center Operations

## **Inspections**

- Compassion centers are subject to random inspection

## **Quality Testing**

- Quality sampling conducted by the Dept.
- Pesticide testing

## **Safety and Security Requirements**

- Limited access to production and processing
- Fully operational security system with backup system

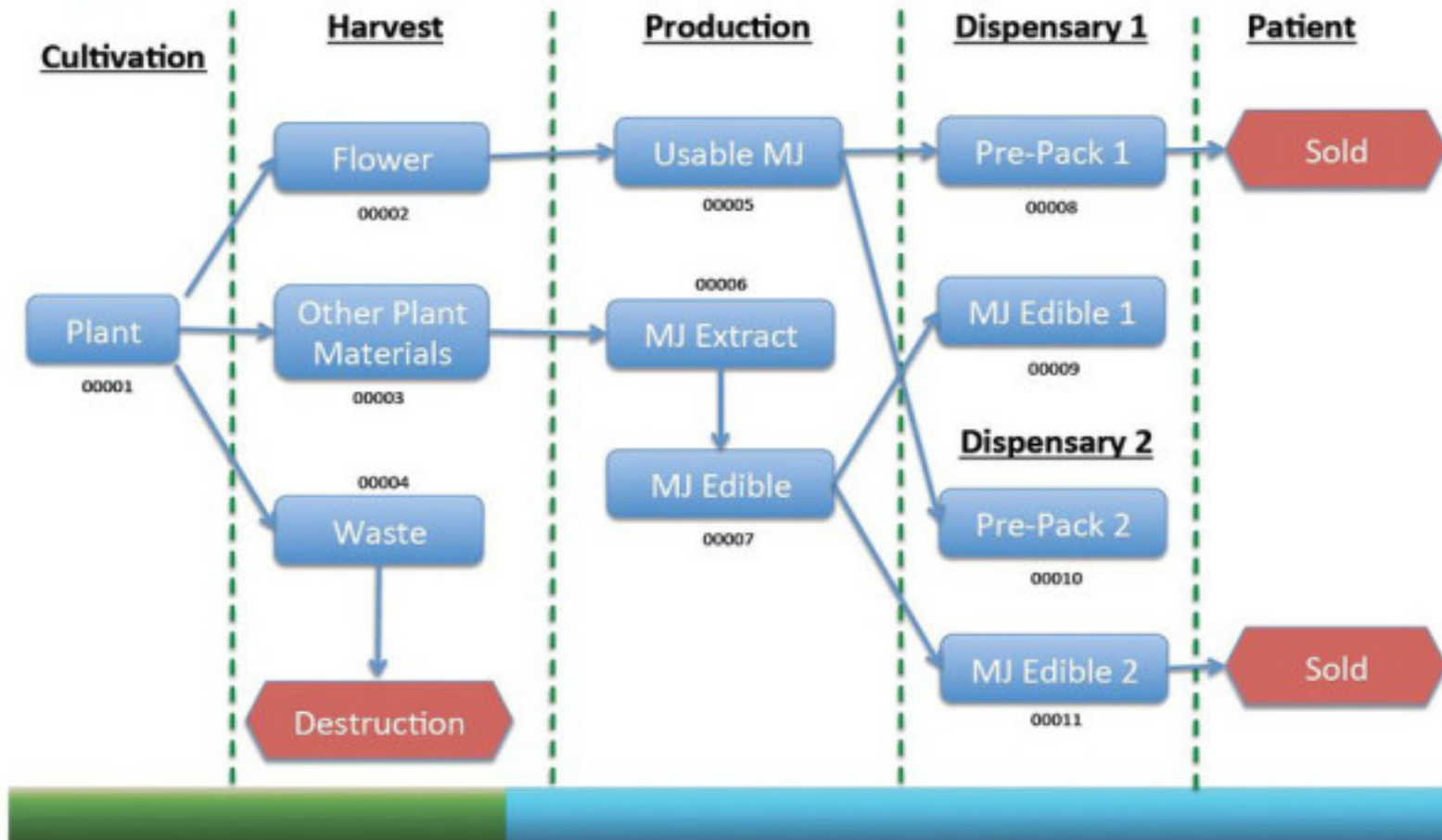
# Compassion Center Operations

## Inventory Controls

- Seed to sale barcoding

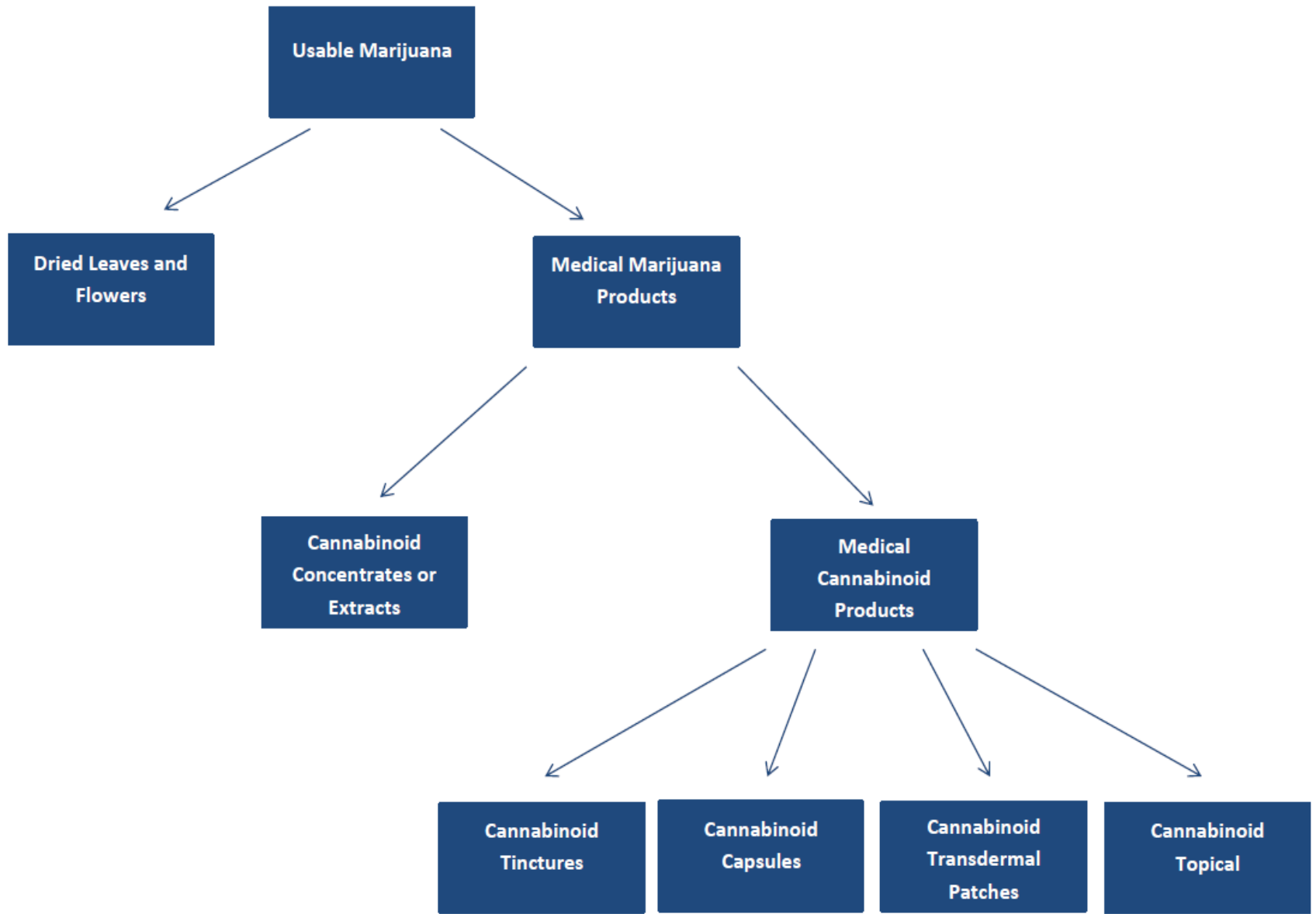


# Seed to Sale Barcoding



# Usable Marijuana

- Dried Leaves and Flowers
  - *Physician Authorization Required*
- Concentrates or Extracts
- Tinctures
- Capsules
- Transdermal Patches
- Topicals



# Methods of Ingestion

*The effects of usable marijuana vary depending on the method of ingestion.*

# Cannabinoid Edible Products

Means a food or potable liquid into which a cannabinoid concentrate or the dried leaves or flowers of the plant of the genus cannabis is incorporated.

***CANNABINOID EDIBLE PRODUCTS ARE  
PROHIBITED UNDER NORTH DAKOTA LAW***



# Pediatric Medical Marijuana

A **medical marijuana product** containing cannabidiol which may not contain ***a maximum concentration*** or amount of tetrahydrocannabinol of more than ***six percent***.

Why the limitation for children?

# Usable Marijuana Production and Processing



# Allowable Amounts of Usable Marijuana

## NORTH DAKOTA MEDICAL MARIJUANA PURCHASE AND POSSESSION LIMITS

Product	Maximum Purchase Amount in 30 day period	Maximum Possession Amount
Dried Leaves and Flowers (Written Certification)	2.5 ounces	3 ounces

# Allowable Amounts of Usable Marijuana

## NORTH DAKOTA MEDICAL MARIJUANA CONCENTRATION AND SERVING LIMITS

Types of Medical Marijuana Products	Maximum Concentration or Amount of THC Per Serving	Maximum Concentration or Amount of THC every 30 days
Cannabinoid Topicals	6%	2,000 mg
Pediatric Marijuana Oil	6%	
Cannabinoid Tinctures	N/A	
Cannabinoid Capsules	50 mg	
Cannabinoid Transdermal Patches	50 mg	
Cannabinoid Concentrates or Extracts	N/A	

# Limitations on Protections

## Does NOT authorize the following:

- Undertaking an activity under the influence if it would constitute negligence or malpractice
- Possessing or consuming:
  - School van or bus
  - School grounds
  - Any grounds while a school sanctioned event is occurring
  - Correctional facility
  - Grounds of a child care facility or licensed home day care
- Violating the smoke free laws
- Operating, navigating or being in actual physical control of a motor vehicle, aircraft, train or motorboat while under the influence.

# Acts not Required

## Does NOT require:

- Insurance to reimburse costs
  - This includes Medicaid and Medicare
- A person to allow a guest, client or other customer to possess or consumer marijuana on their property
- A landlord to allow production or processing on their property
- A healthcare provider to provider a written authorization for a patient

## Does NOT prohibit:

- Employers from disciplining employees for possessing or consuming marijuana in the work place or for working while under the influence

**Facilities are able to adopt reasonable restrictions on usage**

# Confidentiality

## Cardholder and Compassion Center Data

- All data is confidential

### **Disclosure allows for the following:**

- Verification of registration status
- Submission to annual report
- Submission to the PDMP
- Notification to law enforcement
- Notification to Board of Medicine and Board of Nursing

**Data submitted to a local government to demonstrate compliance with security requirements by local zoning ordinances is confidential**

# Violations and Penalties

- Violations may result in the following:
  - Criminal Charges
  - Disqualification from participating in the program.



# Prescription Drug Monitoring Program

- A place where electronic data related to prescribing and dispensing of ***controlled substances*** is collected.
- ***Controlled Substances*** defined.
- Who submits information to the PDMP?
- Who has access to the PDMP?

# Prescription Drug Monitoring Program

## Information provided by the PDMP

- Patient name, DOB, and address
- Prescriber Name
- Dispenser name, city, state, and phone number
- Drug name and strength, prescription number, days' supply, quantity dispensed and dispensing date

# Prescription Drug Monitoring Program

Medicine misuse and abuse is one of the fastest growing health concerns in the county. The NDPDMP *helps protect you and your loved ones, increases the quality of your care, decreases health care costs, decreases crime, and protects your future.*

# Prescription's Containing Marijuana Chemical Components

- Sativex
- Marinol and Cesamet
- Epidiolex

# Implementation

- Dept. of Health
  - Medical Marijuana Division
    - Kenan Bullinger
    - Medical Marijuana Division Director
    - [kbullinger@nd.gov](mailto:kbullinger@nd.gov)
  - Administrative Rules
  - Information Technology System Procurement
  - Appointed Advisory Committee Members
- Implementation Goal: Between 12 and 18 months.

# Employment Law Issues

- The Americans with Disability Act (ADA)  
Requires employers to provide a reasonable accommodation to qualified individuals with a disability.
  - Marijuana is illegal under federal law
  - Marijuana use is not a required accommodation
- Federal Contractors

# Employment Law Issues

- No Tolerance policy
- DOT policy
- Relaxed policy



# Questions



# Contact Information

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