



Efficacy of Statutes and Rules to Protect Patient Safety

South Dakota Medical Marijuana Oversight Committee

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Overview

- Limited to patient safety, not public safety
- Assessment of
 - Statute – Chapter 34-20G – Medical Cannabis
 - Administrative Rule – Article 44:90 – Medical Cannabis
- Focus on responsibilities of cultivators/manufacturers, testing laboratories and DOH in the context of product quality
- Assessment of action limits for contaminants
- A quick cannabis science refresher and some chemistry
- Assessment of cannabis available outside of the regulatory framework
 - Statute – Chapter 34-20B-118 – Industrial Hemp – Chemical modification or conversion – Sale or Distribution - Penalty

Medicinal Cannabis Program Controls

Prevention-focused: The system of planned and systematic actions that ensure cannabis is produced, handled, and sold under conditions that consistently protect patient health and product integrity.

Detection-focused: The activities used to verify that requirements are fulfilled — primarily through testing, inspection, and corrective action.

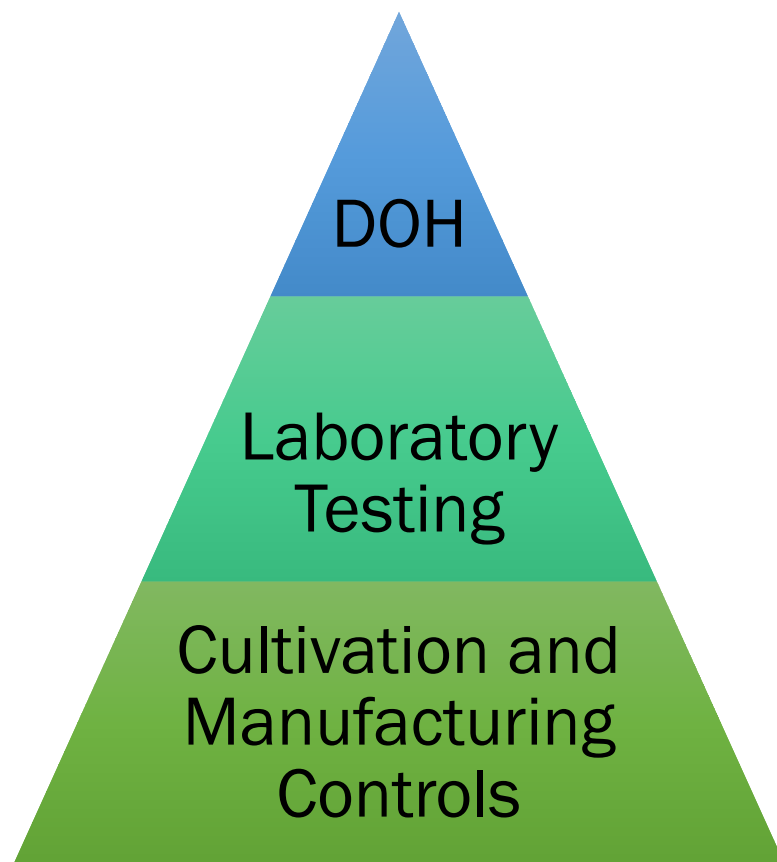
Quality Assurance (QA)

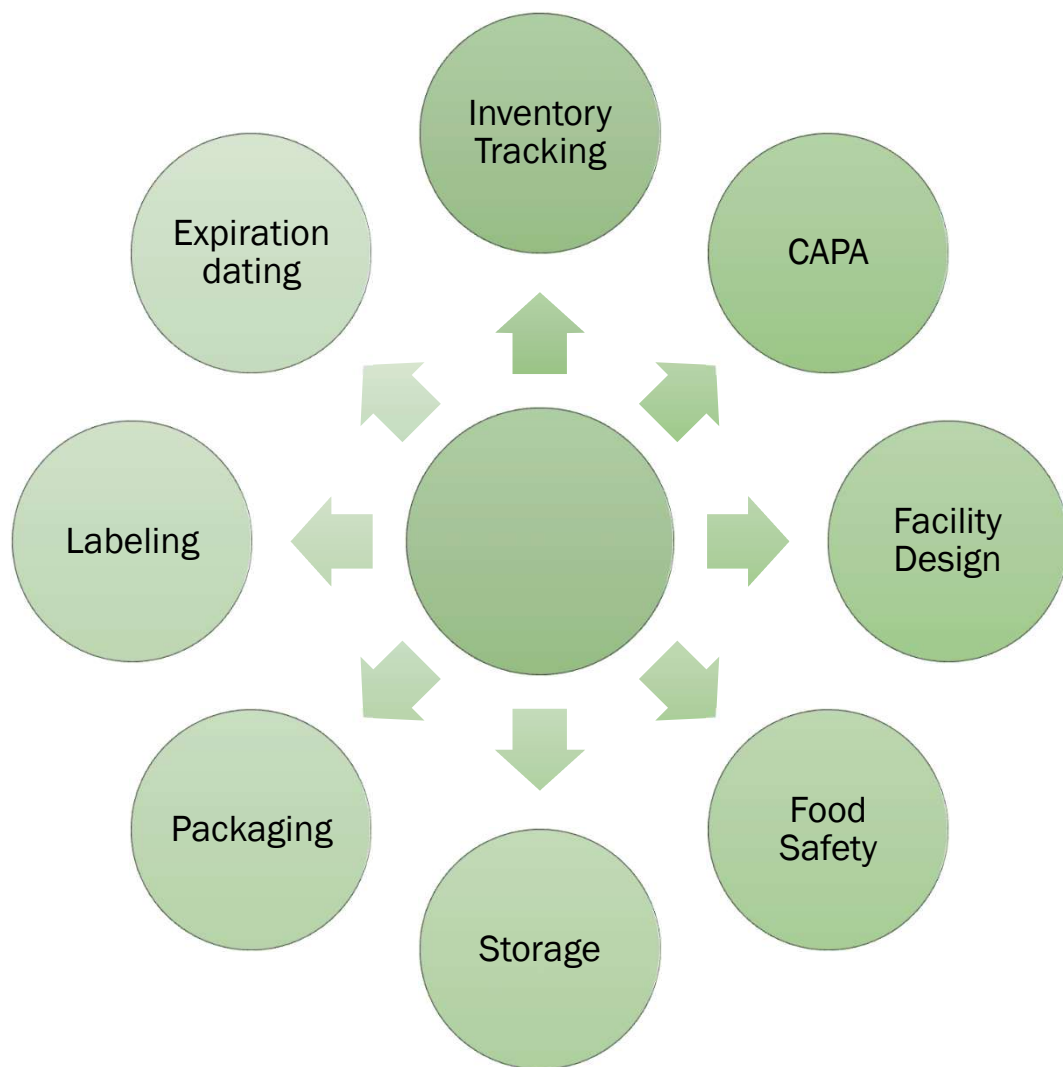


Quality Control (QC)



**Safe
Medicine
for
Patients**



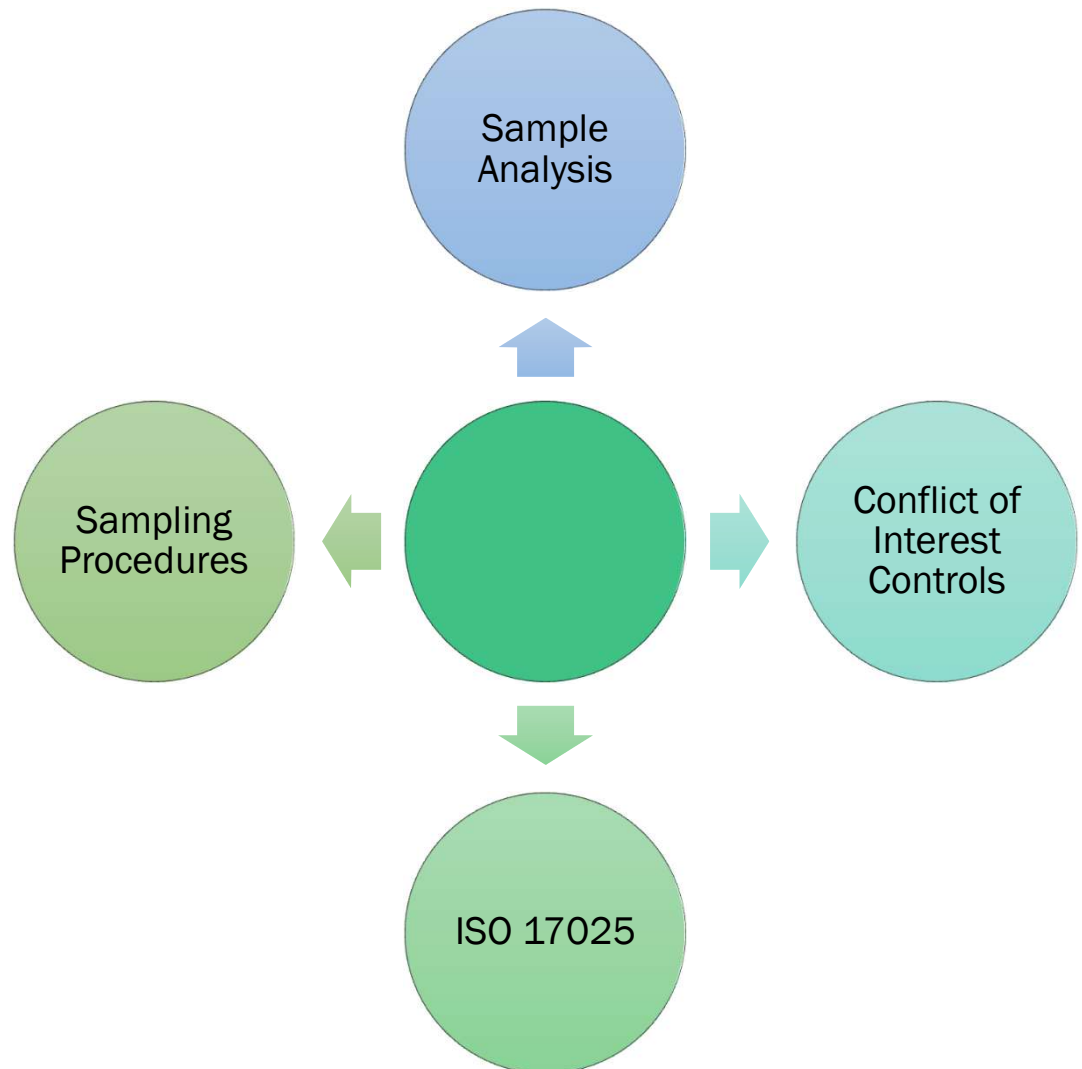


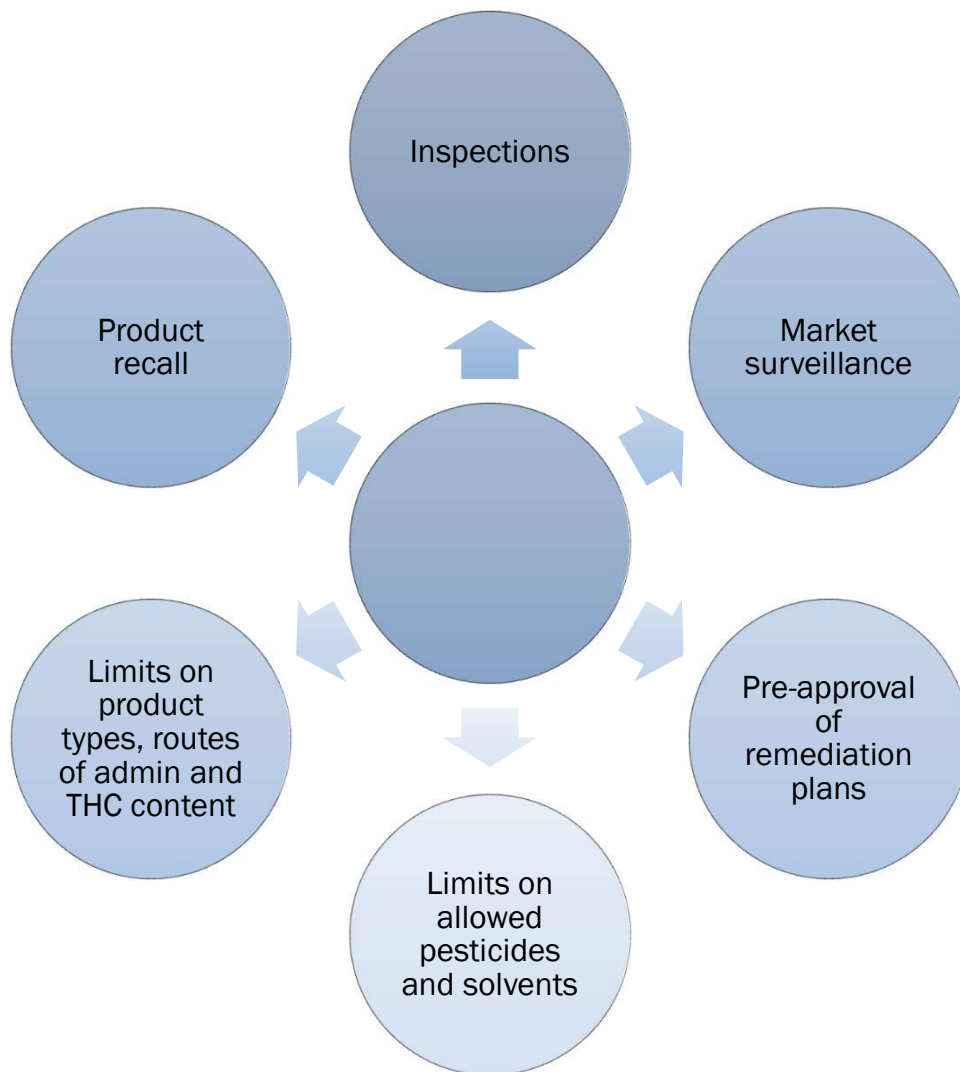
Cultivation and Manufacture

Ensures that every medical cannabis product is produced under conditions that protect patient safety and maintain consistent quality.

Laboratories

Provide independent verification that medical cannabis products meet established safety, purity and potency standards before they reach patients.





Department of Health

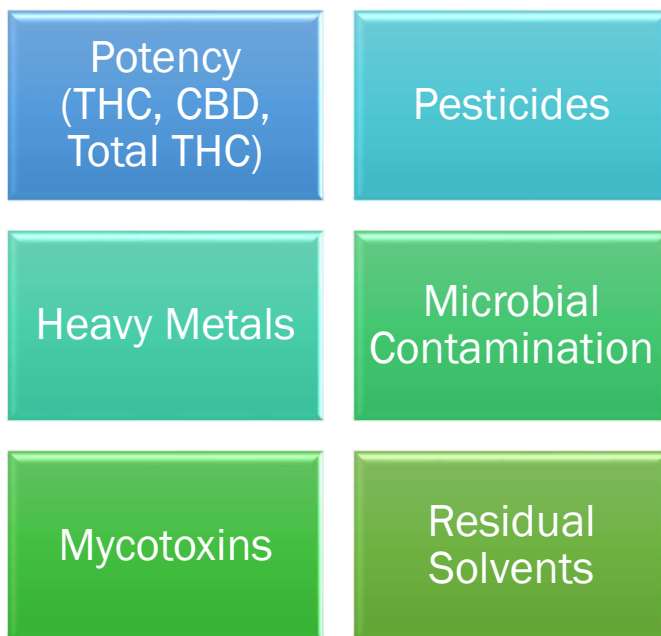
Provides regulatory oversight through inspections, testing and enforcement – ensuring that products and facilities meet all health and safety standards established by rule.

Testing Requirements



Testing Overview

Required by Rules:



Required for Metro Submission:



Not Currently Required:



Potency Testing Requirements

Analyte	Requirement
Δ^9 -THC, THCA	Analyzed to obtain Total THC
Total THC	Δ^9 -THC + (THCA \times 0.877)
CBD	Test if labeled

Potency testing ensures accurate labeling which supports patient dosing.

Metrc requires Δ^9 -THC, THCA, CBD, CBDA, Total THC, Total CBD

Products must be \pm 10% of labeled amount

Pesticides

Analyte	Action Level ug/g (ppm)
Abamectin	0.5
Azoxystrobin	0.2
Bifenazate	0.2
Etoxazole	0.2
Imazalil	0.2
Imidacloprid	0.4
Malathion	0.2
Myclobutanil	0.2
Permethrins	0.2
Spinosad	0.2
Spiromesifen	0.2
Spirotetramat	0.2
Tebuconazole	0.4
Any other prohibited synthetic pesticide	0.5

Limits are based on toxicological data and aligned with national and state cannabis programs.

Remediation of pesticide failures prohibited.

Heavy Metals

Analyte	Inhalation Limit (ppm)	Other product limit (ppm)
Arsenic (As)	0.2	0.4
Cadmium (Cd)	0.2	0.4
Lead (Pb)	0.5	1.0
Mercury (Hg)	0.1	0.2

Cannabis accumulates and concentrates heavy metals from the soil.

Remediation of heavy metal failures prohibited.

Limits equal to or tighter than 90% of limits in other states.

Equivalent or tighter than USP/ICH Q3D limits.

Microbial Contamination

Total Aerobic Bacteria
$\leq 1 \times 10^5$ cfu/g
Indicates general sanitation

Total Yeast & Mold
$\leq 1 \times 10^4$ cfu/g
Prevents respiratory irritation or infection

Bile-Tolerant Gram-Negative
$\leq 1 \times 10^3$ cfu/g
Detects spoilage bacteria

Failure requires destruction or DOH approved remediation.

STEC (E. coli)
Absence
Pathogenic strains unsafe for consumption.

Salmonella spp.
Absence
Major foodborne pathogen

Aspergillus spp.
Absence
Infectious mold risk via inhalation.

Mycotoxins

Analyte	Action Limit (ppb)
Aflatoxins B ₁ , B ₂ , G ₁ , G ₂	20
Ochratoxin A	20

Mycotoxins are toxic secondary metabolites produced by fungi, remaining potent even after sterilization.

Action limits are consistent with USP and action limits in other states.

Residual Solvents

Analyte	Inhalation Action Level (ppm)	Infused Product Action Level (ppm)
Acetone	750	5000
Butanes	800	5000
Heptanes	500	5000
Pentanes	750	5000
Propane	2100	5000
Ethanol	1000	NA
Benzene	1	2
Toluene	150	890
Hexane	50	290
Total Xylenes	150	2170
Isopropyl alcohol	500	5000
Methanol	250	3000
Ethyl acetate	400	5000
Any other prohibited solvent	50	290

Based on USP <467> and ICH Q3C limits.

Remediation of prohibited solvents not allowed.

Water Activity

- Water activity is the measure of the available water for microbial growth.
- Not required by rules but recommend to be added for edible products.

R&D Testing

- Not allowed per mandate from DOH except for potency and terpene testing.
- Prevents cultivators and manufacturers from generating CAPA data needed to solve product quality issues.


A Quick Refresher and Some Chemistry



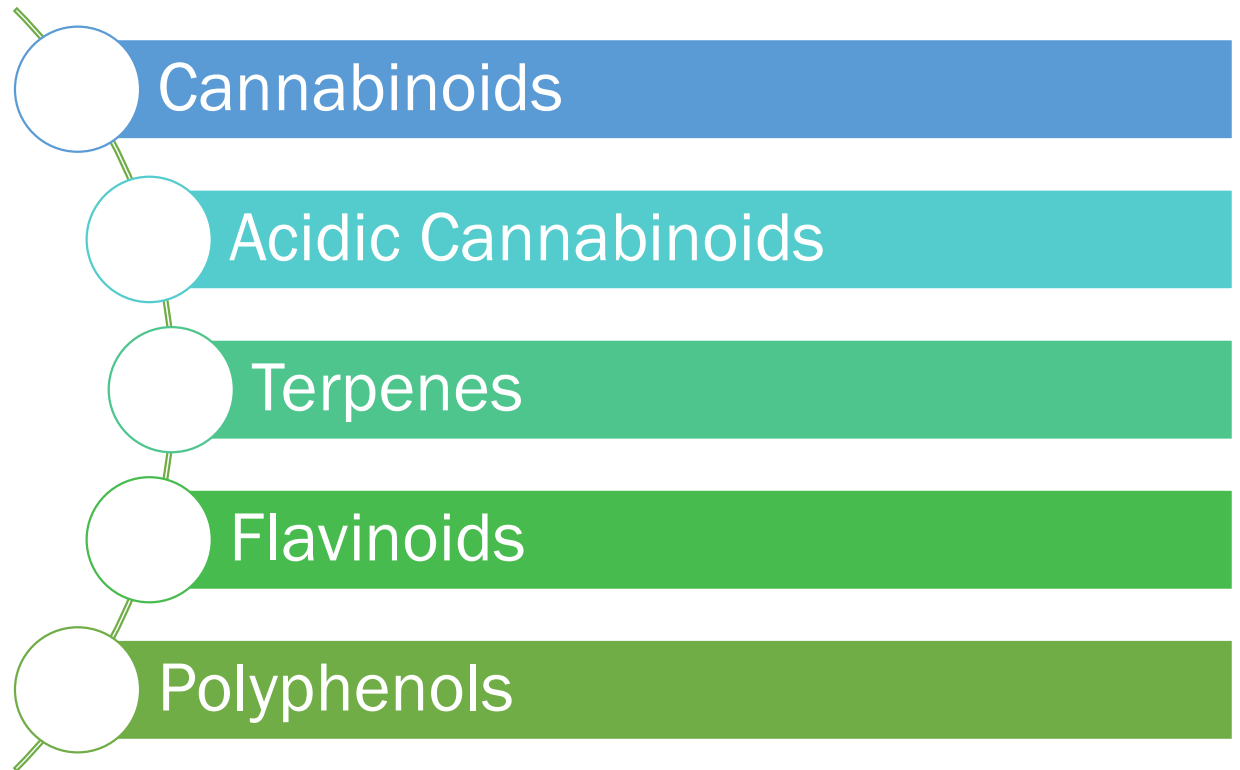
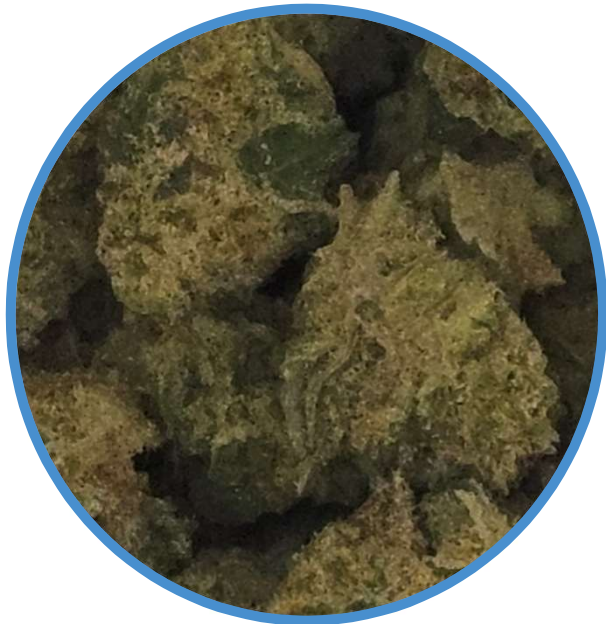
Cannabis

Hemp
 $\leq 0.3\%$ Total THC

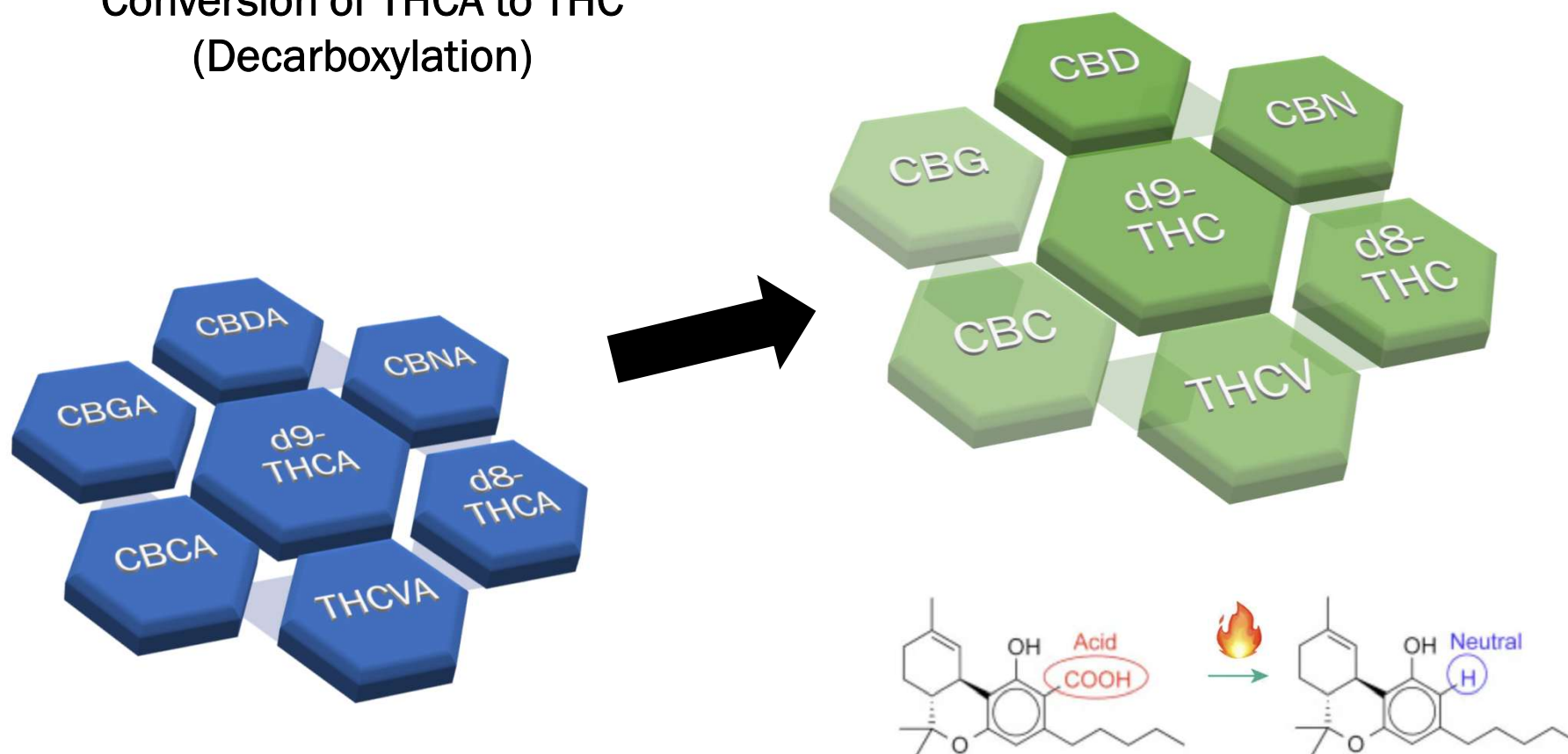
Marijuana
 $\geq 0.3\%$ Total THC



Chemical Constituents of Cannabis



Conversion of THCA to THC (Decarboxylation)

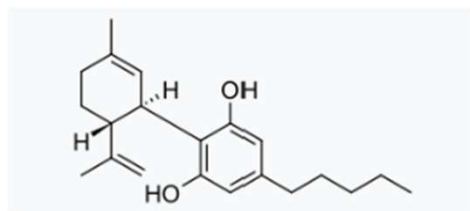




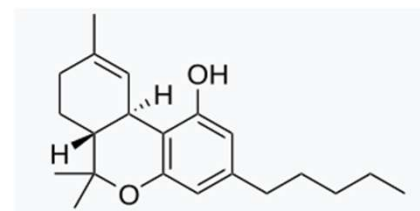
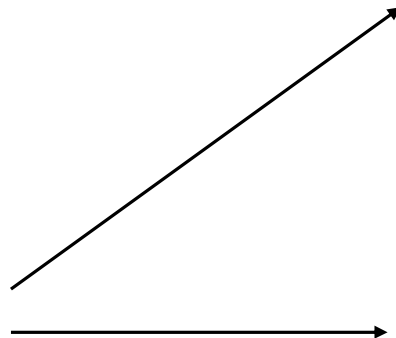
For every 1 mg of
THCA there is only
0.877 mg of THC

Total THC calculates the maximum potential THC a product could yield after heating (decarboxylation)

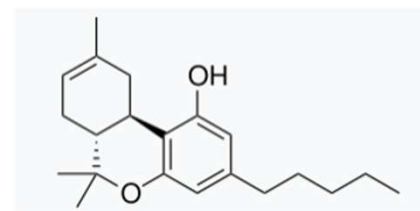
Conversion of CBD to THC



CBD



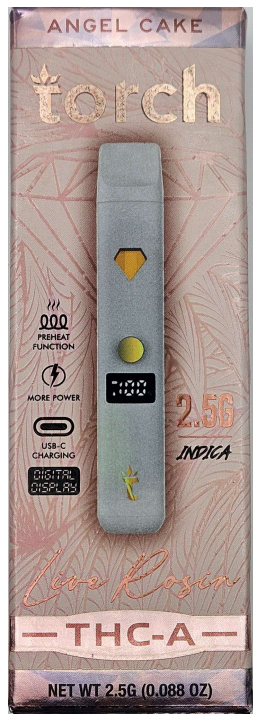
d9-THC



d8-THC

Assessment of Cannabis Available Outside of Regulated Market





Products
Purchased in
Rapid City

Tested at
Triverity
Analytical

Tested for
potency, HM,
Pesticides,
Y&M



d9-THC - 6.9%
d8-THC - 54.5%

Pesticide, Heavy Metals and
Total Yeast/Mold met action
limits.



d9-THC – 1.8%

d8-THC – 7.8%

Heavy Metals and Total
Yeast/Mold met action limits.

*Live bug found in packaging



d9-THC – 0.6%

d8-THC – 10.2%

Heavy Metals and Total
Yeast/Mold met action limits.



d9-THC – 9.4%

THCA – 8.2%

Total THC – 16.7%

Heavy Metals and Total
Yeast/Mold met action limits.

Conclusion

South Dakota's medical cannabis statutes and rules establish a comprehensive framework that effectively safeguards patient safety and ensures the quality, consistency, and integrity of regulated products.

Thank you for your time