

Medical Cannabidiol Program Update

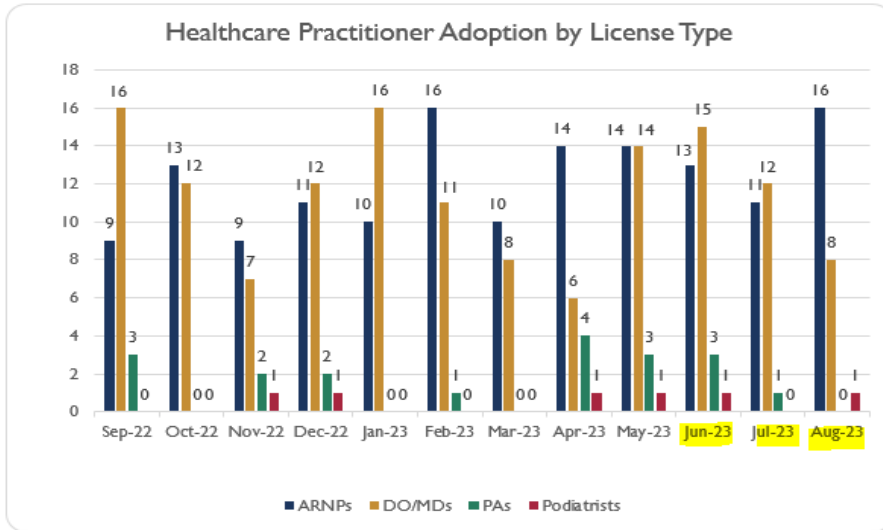
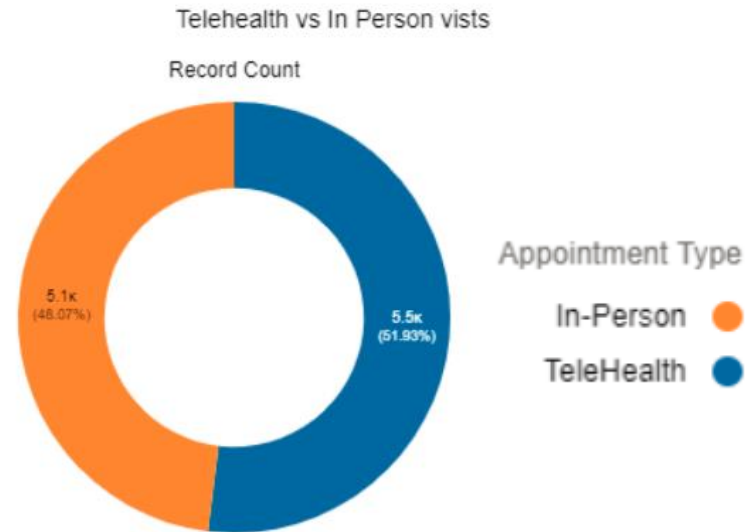
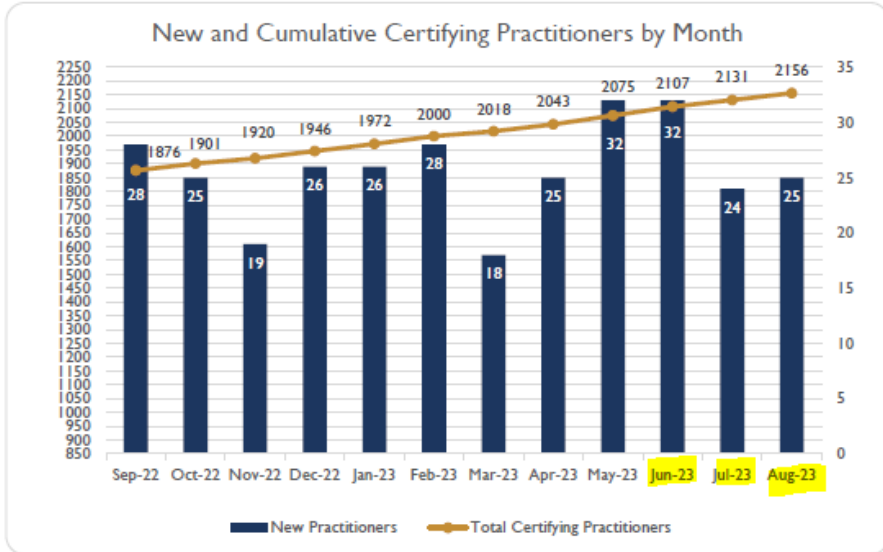
September 15, 2023

Owen Parker, MPH
Chief, Bureau of Medical Cannabidiol

What We'll Cover

- Data Update
- Red Tape Review Update
- Consumable Hemp Alignment Update
 - “Bureau of Cannabis Regulation”
 - Consumable Hemp Landscape
- Housekeeping, Other
 - Board Alignment Panel
 - Board vacancies
 - 2nd Manufacturer Update
 - National Updates

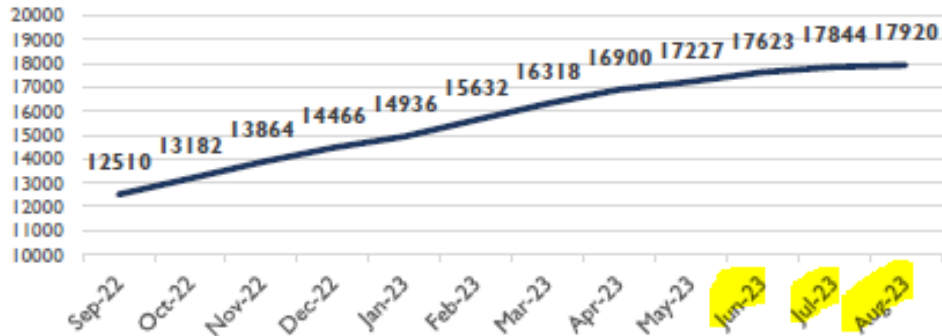
Data Update: Practitioners



■ Specific reporting on telehealth visits began 3/1/23

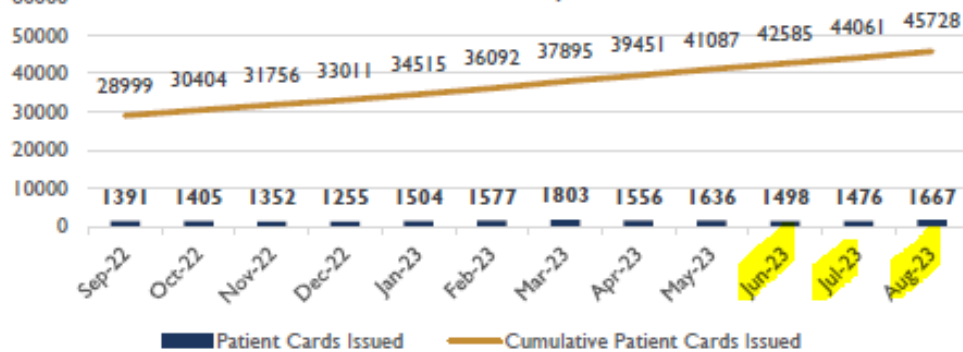
Data Update: Patients

Total Patient Cardholders



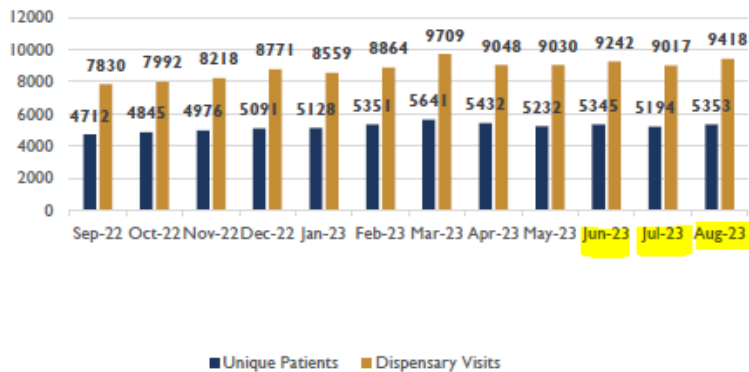
- Over the last three months, although the program has approved 4,641 new patients, we have only seen a net gain of 297 active patients in that same time frame

Patient cards issued monthly and cumulative



Data Update: Dispensary Visits & Sales

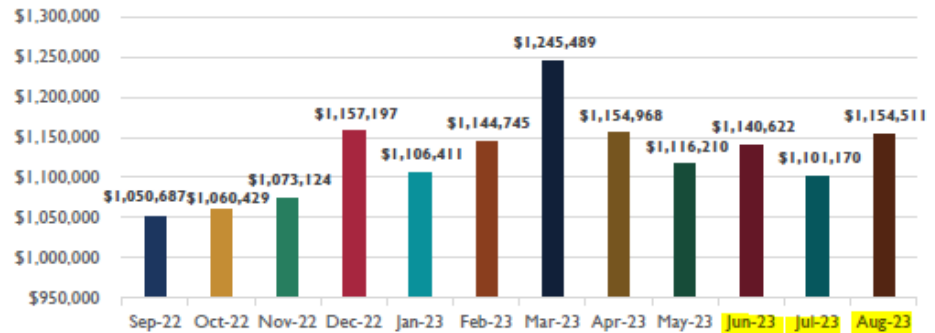
Dispensary Visits and Unique Patients by Month



Average Transaction Price

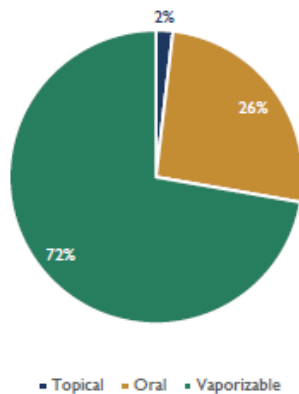


Dispensary Sales - Previous 12 Months



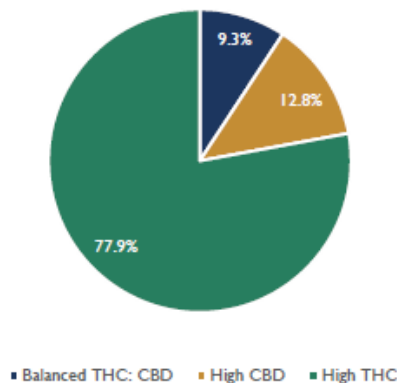
Data Update: Dispensary Visits & Sales

Sales by Product Type-Previous 12 months



- Vaporizable products, and High-THC products, make up nearly $\frac{3}{4}$ of sales by product type and formulation.
- With the availability of un-tracked Consumable Hemp products in physical and online retailers, we should be objective about the suppression of actual use of medical cannabis program products and through what channel patients are acquiring cannabinoid products.

Sales by Formulation- Previous 12 Months



Red Tape Review Update

- This project is in response to January 10, 2022, Executive Order issued by Governor Reynolds
 - Red Tape Review - Reduce redundancies, red tape, etc.
 - Opportunity for updates and additional clarity

- The BCR submitted proposed rules and analysis reports in late July. Next steps:
 1. Public hearing dates will be set, with additional analysis
 2. NOIAs prepared with repealed and promulgated rules
 3. Set public hearings on new rule making
 4. Then proceeds along normal rulemaking path

- Focus of updates:
 - Compliance and Enforcement
 - Marketing and advertising, packaging and labeling, seed-to-sale data
 - Make rules easier to follow for both the agency and stakeholders

Consumable Hemp Alignment Update

- On July 1, legacy IDPH merged with DHS to create the Iowa Department of Health and Human Services (HHS). In this alignment, the Consumable Hemp program, formerly with DIA, transferred to HHS
- HHS formed a new Bureau regulating cannabis products for human consumption (Medical Cannabis and Consumable Hemp) in Iowa
 - “Bureau of Cannabis Regulation”
 - Similar strategy of many more evolved programs
- This implementation was managed by the previous Bureau of Medical Cannabidiol, and successfully made the alignment deadline
- Registration and product submission processes have been built into the Bureau’s single-sign-on regulatory tool using Salesforce. We have been processing registrations since July 5.
- Shared service model, where registration and compliance personnel and resources will be shared between both programs

What is Consumable Hemp in Iowa?

- A noncombustible (or inhalable) form of hemp that may be digested, such as food; internally absorbed, such as chew or snuff; or absorbed through the skin, such as topical application (oils and lotions)
 - Allows for “edible” and “drinkable” products
- Cannot contain a total THC (inclusive of any isomers, derivatives, and analogs, whether naturally occurring or synthesized) >0.3% by weight
 - Total THC calculation takes THCA into account
 - Iowa’s use of total THC in the definition of a hemp product, as well as inclusion of derivatives in the total THC calculation, allows for prohibition of many proposed flower products, and those containing THC derivatives
- There are > 1000 active registrants in Iowa, including many bars and restaurants.
 - Many are selling intoxicating THC products.
- Inhalable (combustible, vaporizable. etc.) consumable hemp products are prohibited
 - Flower marketed as combustible, vapes, etc.

Consumable Hemp – Heavy Edibles

- **Common misconception:** Hemp is not intoxicating
- **Reality:** The federal definition of hemp has loopholes that allow for a wide variety of intoxicating hemp products with little to no regulation
- **Loophole:** The 0.3% THC limit applies by weight to *all products*, not just flower
- **Result:** Edibles with large doses of THC that scale with the product weight

What does 0.3% look like?	
	Hemp Potency Limit
A single 5 g gummy	15 mg Δ^9 -THC
20 g pack of gummies	60 mg Δ^9 -THC
50 g bar of chocolate	255 mg Δ^9 -THC
20 oz package of cookies	1,700 mg Δ^9 -THC



- A bottle of hemp gummies containing 15 mg THC per serving, and 450 mg THC per container
- Standard Adult-Use THC limits are 5-10 mg/serving, and 100 mg/container*

Consumable Hemp - Drinkables

- **Common misconception:** Hemp is not intoxicating
- **Reality:** The federal definition of hemp has loopholes that allow for a wide variety of intoxicating hemp products with little to no regulation
- **Loophole:** The 0.3% THC limit applies by weight to *all products*, not just flower
- **Result:** Drinkable products with large doses of THC that scale with the product weight



What does 0.3% look like?		
	Hemp Potency Limit	Adult-Use Marijuana Limit
12 oz beverage	>1,000 mg Δ ⁹ -THC	100 mg Δ ⁹ -THC

Cannabinoids Date Tested: 06/15/2023

Analytes	%	mg/g	mg/ml	mg/serving	LOQ
CBC	<LOQ	<LOQ	<LOQ	<LOQ	0.001
CBD	0.001	0.013	0.013	4.484	0.001
CBDa	<LOQ	<LOQ	<LOQ	<LOQ	0.001
CBDV	<LOQ	<LOQ	<LOQ	<LOQ	0.001
CBG	<LOQ	<LOQ	<LOQ	<LOQ	0.001
CBGa	<LOQ	<LOQ	<LOQ	<LOQ	0.001
CBL	<LOQ	<LOQ	<LOQ	<LOQ	0.001
CBN	<LOQ	<LOQ	<LOQ	<LOQ	0.001
Δ ⁸ -THC	<LOQ	<LOQ	<LOQ	<LOQ	0.001
Δ ⁹ -THC	0.001	0.007	0.007	2.342	0.001
THCa	<LOQ	<LOQ	<LOQ	<LOQ	0.001
THCVa	<LOQ	<LOQ	<LOQ	<LOQ	0.001

Method: HPLC
 Total THC = THCa * 0.877 + Δ⁹-THC
 Total CBD = CBDa * 0.877 + CBDV

Total Cannabinoids represents the sum of all cannabinoids in the table above.
 Results are reported on a dry weight basis. Cannabinoid % / (1.0 - moisture content % / 100) = Dry weight cannabinoids %
 LOQ = Limit of Quantitation

- 12fl oz = 340 g
 - 0.3% of 340 g = 1.02 g
 - 1.02 g = **1,020 mg THC (legal limit)**
- 2.3, or 5, or 10 mg THC/serving is intoxicating, and well below allowable limit

Primary Public Health and Safety Issues

- **No Age Restriction**

- Currently, any Iowan can legally purchase Consumable Hemp products
- Many Registrants are known to have implemented their own age restrictions

- **No limits on “THC” potency per Serving or Container**

- With 0.3% total THC being very intoxicating for some products, consideration for potency-based limits (like those in adult use cannabis programs)
- Restrictions on synthetic or semi-synthetic THC derivatives

- **Enforcement Authority**

- Improved authority for compliance and enforcement

Housekeeping & Miscellaneous

■ Board Alignment Panel

- As part of alignment, a state panel made recommendations for maintenance, change, or removal of the various boards
- This Board will be maintained as-is

■ Board vacancies

- Pediatrics, Neurology, Pain Medicine, Pharmacy
- Outreach update

■ 2nd Manufacturer Update

- Local permitting and HHS inspection complete, facility operational

■ National Updates

- August 18 - CANNRA report on Cannabinoid Hemp
- HHS rescheduling recommendation

Questions?

Owen Parker, MPH
Chief, Bureau of Cannabis Regulation