DEPARTMENT OF HEALTH

Sale of Certain Cannabinoid Products Workgroup

REPORT TO THE LEGISLATURE

1/13/2020

Sale of Certain Cannabinoid Products Workgroup Report to the Legislature

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Background and Approach

Legislation Creating the Workgroup

In 2019 Minnesota established the Sale of Certain Cannabinoid Products Workgroup (SCCPW). Laws of Minnesota 2019, 1st Spec. Sess. Chapter 9, Article 11, section 110 established the workgroup, which charges the commissioner of health, in consultation with the commissioners of commerce, agriculture, and public safety, and the executive director of the Board of Pharmacy, to convene a workgroup to advise the legislature on how to regulate products that contain cannabinoids extracted from hemp and to develop a regulatory framework, as laid out in the language below:

Sec. 110. SALE OF CERTAIN CANNABINOID PRODUCTS WORKGROUP.

a. **The commissioner of health, in consultation with the commissioners of commerce, agriculture, and public safety, and the executive director of the Board of Pharmacy, shall convene a workgroup to advise the legislature on how to regulate products that contain cannabinoids extracted from hemp.** For purposes of this section, "hemp" has the meaning given to "industrial hemp" in Minnesota Statutes, section 18K.02, subdivision 3.

b. The commissioner shall assess the public health and consumer safety impact on the sale of cannabinoids derived from hemp and shall develop a regulatory framework of what the legislature would need to consider, including, but not limited to:

(1) cultivation standards for industrial hemp if the hemp is used for any product intended for human or animal consumption;

(2) labeling requirements for products containing cannabidiol extracted from hemp, including the amount and percentage of cannabidiol in the product, the name of the manufacturer of the product, and the ingredients contained in the product;

(3) possible restrictions of advertising and marketing of the cannabidiol product;

(4) restrictions of false, misleading, or unsubstantiated health claims;

(5) requirements for the independent testing of cannabidiol products, including quality control and chemical identification;

(6) safety standards for edible products containing cannabinoids extracted from hemp, including container and packaging requirements; and

(7) any other requirement or procedure the commissioner deems necessary.

c. **By January 15, 2020, the commissioner of health shall submit the results of the workgroup to the chairs and ranking minority members of the legislative committees with jurisdiction over public health, consumer protection, public safety, and agriculture.**

Workgroup Members

The legislation required that a representative from the departments of health, commerce, agriculture, and public safety and the Board of Pharmacy be involved in the workgroup. These entities are represented by the following members:

Chris Tholkes, Acting Director, Office of Medical Cannabis—Minnesota Department of Health

Anthony Cortilet, Supervisor, Noxious Weed and Industrial Hemp Programs—Minnesota Department of Agriculture

Brian Marquart, Statewide Gang & Drug Coordinator—Minnesota Department of Public Safety

Cody Wiberg, Executive Director—Minnesota Board of Pharmacy

Greg VanderPlaats, Director, Weights and Measures Division—Minnesota Department of Commerce

Karen Gaides and Jessica Burke, Senior Management Consultants from Minnesota Management and Budget's Management Analysis and Development (MAD), aided the workgroup with project planning, meeting facilitation, documentation, and writing.

Workgroup Process

SCCPW assessed the public health and consumer safety impact of the sale of cannabinoids derived from hemp. SCCPW was working under a compressed timeline and had four working sessions to develop a regulatory framework for cultivation standards for industrial hemp, labeling requirements for products containing cannabidiol, possible restrictions on advertising and marketing of cannabidiol products, restrictions of false, misleading or unsubstantiated health claims, testing requirements, and safety standards for edible products. SCCPW's approach was to highlight issues for the legislature as they continue to consider legislation related to cannabinoid products. The workgroup provided a draft copy of the report to stakeholders and also made it available on the Minnesota Department of Health (MDH) website for input. The workgroup reviewed and considered the comments, which appear in Appendix B.

The Minnesota Department of Health Office of Medical Cannabis (OMC) engaged with MAD to design, facilitate, and document the SCCPW process. In consultation with key OMC staff, MAD consultants designed, facilitated, and documented SCCPW meetings. MAD prepared materials to support SCCPW discussions and provide guidance to assigned SCCPW members in preparing information for SCCPW meetings and report input.

Legal Context

In the 2019 session, the Minnesota Legislature passed a law allowing for the sale of certain cannabinoid products (see MINN. STAT. 151.72 and Appendix A). While the sale of certain cannabinoid products meeting the requirements laid out in the 2019 law will become legal in Minnesota on January 1, 2020, these products will still be illegal under federal law.

The SCCPW notes there is much conflicting legislation at the state and federal level on the sale of anything related to the cannabis plant, including products containing cannabinoids, medical cannabis, and recreational marijuana. The regulatory landscape will be in flux in the coming years as states and the federal government, as well as the courts, try to understand this nascent industry and how to manage it while protecting consumers.

SCCPW provides the table below as an overview of many of the various laws regarding cannabis in the US and in Minnesota. Federal and state laws differ based on the intended use of cannabis and regulations regarding possession, production, processing, sale, and marketing. The Minnesota Legislature should be aware of these differences among the various laws and take

into consideration any intended or unintended consequences of future policy decisions regarding the cannabis plant and any cannabis-derived products.

The impacts of these decisions for state regulatory agencies and law enforcement could be—and have been—challenging to effectively deal with. For example, the passage of the 2014 Farm Bill, and subsequently the Minnesota Industrial Hemp Development Act (MINN. STAT. 2015, Chapter 18), both provided a federal and state definition of hemp. These laws were initially intended to support industrial hemp development in the US through fiber and grain production. The marijuana industry in states where recreational use was legalized at the state level (e.g., Colorado, Oregon) saw an opportunity to also operate in states that allowed industrial hemp, by producing non-tetrahydrocannabinol (THC) cannabinoid-infused products using cannabis varieties bred to meet the 0.3 percent d-9 THC requirement defining hemp. This has created many issues for state hemp regulators and state and local law enforcement where the laws governing industrial hemp production are not designed to deal with cannabinoid extraction and products.

Furthermore, there are no stable cannabinoid s or cannabinoid-use hemp varieties guaranteed to stay below the 0.3 percent d-9 THC threshold, causing additional issues for state regulators, law enforcement, and farmers hoping to take advantage of the high demand for cannabinoid products. As the SCCPW points out in this report, these products are considered druglike by the Food and Drug Administration (FDA), and there is currently no regulatory structure or consumer protection for the thousands of retail outlets in Minnesota and throughout the country that are selling them. The cannabinoid industry has well outpaced state and federal regulatory structures and this needs to change if the state wants to protect consumers and ensure safety.

Table 1. Cannabis Laws 2019

MN/Federal	Statute/Rule/Law	Brief Description	Agency Lead	Legal Status
Federal	Controlled Substance Act - 21 U.S. Code 802(16)	Regulation of listed controlled substance throughout the US	Department of Justice - Drug Enforcement Administration	Cannabis is a Schedule 1 Narcotic unless defined as hemp under the Agricultural Marketing Act of 1946 (7 U.S. Code 1621 et. seq.)
Minnesota	Drugs; Controlled Substances – MINN. STAT. Chapter 152	Minnesota Controlled Substances Laws	Department of Public Safety for criminal safety sections; Board of Pharmacy for non-criminal sections	Schedules and list controlled substances; establishes requirements for prescribing; defines crimes and establishes penalties

MN/Federal	Statute/Rule/Law	Brief Description	Agency Lead	Legal Status
Federal	Agricultural Marketing Act of 1946 - 7 U.S. Code 1621 et. seq. – Interim Rules - 7 CFR Part 990 (Published 10/31/2019)	Regulation of hemp production in the US	US Department of Agriculture (USDA) - Agriculture Marketing Service (AMS)	Hemp as defined is legal to produce and sell throughout the US. States must submit a plan to have jurisdiction over regulation in their regions. Interstate commerce is protected. USDA-AMS draft rules released (10/29/2019)
Minnesota	Industrial Hemp Development Act - MINN. STAT. Chapter 18K - Expedited Rulemaking in progress (2019/2020)	Regulation of industrial hemp (hemp) production in Minnesota	Minnesota Department of Agriculture (MDA)	Hemp as defined (in state and federal law) is legal to produce as an agricultural commodity in Minnesota. MDA must submit a plan to the Secretary of Agriculture approving jurisdictional authority to regulate
Federal	Food, Drug and Cosmetic Act - 21 U.S. Code 301 et seq. (FD&C Act)	Regulation oversight for the safety of food, drugs, medical devices, and cosmetics	FDA	Products derived from hemp grain and hemp grain-derived ingredients—hulled hemp seed, hemp seed protein powder, and hemp seed oil—are considered Generally Recognized As Safe (GRAS) and can be used in food products. Cannabinoids are considered drugs under this act and are prohibited for use in dietary substances and foods. This includes cannabinoids.
Minnesota	MINN. STAT. Chapter 151; Pharmacy Practice and Wholesale Drug Distribution Act	Regulation of the practice of pharmacy *and* the manufacturer and distribution of drugs and biologic products	Board of Pharmacy	Board is required to regulate the manufacture and distribution of drugs pursuant to the FD&C Act. Chapter prohibits sale of misbranded and adulterated drugs

MN/Federal	Statute/Rule/Law	Brief Description	Agency Lead	Legal Status
State	MINN. STAT. Chapters 31 (Food) and 34 (Non-alcoholic beverages)	State regulation and oversight for laws relating to food and non-alcoholic beverages	Minnesota Department of Agriculture	MDA provides local enforcement authority for foods and non-alcoholic beverages—"The rules when applicable must conform, insofar as practicable and consistent with state law, with those promulgated under the federal law"
Federal	Section 351; Public Health Service Act - 42 U.S. Code 262	Regulates Biological Products	Health and Human Services (HHS) with Authority for Section 351 also given to the FDA	Gives the HHS and FDA authority to regulate products containing cannabis or cannabis-derived compounds as biological products
Minnesota	MINN. STAT. 152.21–152.37; Therapeutic Research Act; Medical Cannabis and Minnesota – Rules Chapter 4770	Regulates Medical Cannabis production, manufacturing, sale, testing, etc.	Minnesota Department of Health	Medical cannabis can be grown, manufactured, and distributed within Minnesota through the regulations of this law and corresponding rules. It is considered illegal to produce any cannabis not defined as hemp under Federal Law, thus medical cannabis cannot be imported or exported
Minnesota	Various medical cannabis statutes – MINN. STAT. 13.3806, subdivision 22; MINN. STAT. 144G.70, subdivision 6; MINN. STAT. 256B.0625, subdivision 13d. (b)(7); MINN. STAT. 290.0132, subdivision 29; MINN. STAT. 290.0134, subdivision 19	Various medical cannabis statutes	Minnesota Department of Health	Statutes applying to regulation and responsibilities for medical cannabis

MN/Federal	Statute/Rule/Law	Brief Description	Agency Lead	Legal Status
Minnesota	MINN. STAT. 151.72	Sale of non-intoxicating cannabinoid products derived from hemp	Board of Pharmacy	Allows for the sale of cannabinoid products extracted from hemp if they follow the testing, labeling, and marketing requirements

Workgroup Goals

The legislature gave the SCCPW the charge to advise the legislature on how to regulate products that contain cannabinoids extracted from hemp. Ultimately, the workgroup is recommending the legislature consider clarifying existing regulations and consider additional regulations. SCCPW developed this report with public safety being the primary concern. Cannabidiol (CBD), the cannabinoid that is currently the most commonly extracted from hemp and sold for human or animal consumption, is a pharmacologically active drug. However, there are other non-psychoactive cannabinoids produced by the cannabis plant that manufacturers are using to formulate new products for sale, including cannabinol (CBN) and cannabigerol (CBG). Consequently, it is very important that cannabinoid-containing products be appropriately regulated to prevent members of the public from being harmed by them. SCCPW believes the state must act in a meticulous way—from cultivation and extraction to the creation of products—much as it did with the process for legalization of medical cannabis. SCCPW also believes the industry as a whole would benefit from a tightly regulated marketplace that would eliminate bad actors.

Producers of cannabinoid products must follow existing rules and laws beyond those noted above. For example, all other businesses making a product for human or animal consumption must follow these rules governing labeling, packaging, advertising, and many other aspects of producing and selling products for use by humans or animals. However, the SCCPW is also aware of the potential for hemp to be the basis of a new industry that may be financially beneficial to farmers and business owners. The SCCPW believes that its recommendations are a reasonable approach to regulation that would protect the public without being onerous to farmers and businesses.

Key Recommendations

In the report below, the workgroup discusses a number of recommendations the legislature should consider in regard to the sale of certain cannabinoid products. In addition to expanding on existing regulations in several areas, SPCCW has some key recommendations, discussed below. However, each section of the report contains additional regulatory recommendations the legislatures should consider.

- Create an office of cannabis management that would oversee industrial hemp, medical cannabis, and cannabinoid products, either on its own or as a part of another agency.
- Create a statewide database that allows law enforcement 24-hour access to all MDA hemp license data.

- Develop a coordinated plan between the Minnesota Public Safety and Agriculture agencies to address crop sampling, testing, licensing and crop destruction for plants testing above 0.3 percent total d-9 THC.
- For labeling, for better public safety, consider implementing the recommended approaches, detailed in the Labeling section of the report, above and beyond the requirements passed during the 2019 Session.
- Restrict any marketing that would be attractive to youth or young children.
- Restrict the sale of cannabinoid-containing products to individuals who are 21 years of age or older, and require this restriction be stated on labeling.
- Consider whether to allow food products to contain cannabinoids.
- Designate Minnesota Environmental Laboratory Accreditation Program (MNELAP) as the accreditation provider for Minnesota's cannabis testing laboratories. Set up MDH's Public Health Lab Environmental Laboratory Section to perform reference testing as an oversight for commercial laboratory testing of any cannabis products intended for human consumption.
- Require all cannabis products to fit into a blockchain scheme that will allow public health and law enforcement to track products.
- Clarify and address issues about cannabinoid use in schools, hospitals, nursing homes, and other long-term care facilities.
- License retailers, in a manner similar to the process for tobacco licensing.

Regulatory Framework Areas—Background and Recommendations by Area

This section of the report discusses background and recommendations for the seven areas described in the legislation that created the SCCPW: cultivation standards for industrial hemp; labeling requirements for products containing cannabidiol extracted from hemp; possible restrictions of advertising and marketing of the cannabidiol product; restrictions of false, misleading, or unsubstantiated health claims; testing requirements; safety standards; and other requirement or procedures.

1. Cultivation Standards

Background Information

Hemp is an old-world crop that has been cultivated by human societies for centuries. Prior to prohibition in the US, hemp was an important fiber crop used in a variety of homespun applications (such as clothing), paper materials, and ropes of various sizes and qualities. However, prohibition of hemp led to the displacement of cultivation and processing infrastructure throughout the US. More than half a century after prohibition, the US Congress passed the 2014 Farm Bill defining hemp in federal law and establishing provisions allowing states to develop pilot programs to study the growth, cultivation, and marketing of hemp as an agronomic crop. Soon after, many states, including Minnesota, passed hemp production laws

and developed pilot programs. Most recently, the passage of the 2018 Farm Bill amended the US Agricultural Marketing Act of 1946 (7 U.S.C. 1621 et. seq.) to include the first national hemp production laws since prohibition and removal of the definition of hemp from the Controlled Substances Act (21 U.S.C. 802(16)).

In addition to fiber and grain production, cannabinoid extraction from female hemp flowers has become a burgeoning industry over the last several years. Fiber and grain cultivation practices are very similar to corn, soybean, and small grain production, whereas varieties grown for cannabinoid extraction can be cultivated on a large scale (similar to corn or soybeans) or on a smaller scale that resembles vegetable production and requires a higher degree of manual labor. Since hemp is now considered an agronomic crop in the US, all laws established for grain and vegetable crops in the US apply to all three types of cultivation. This includes all state and federal laws for food safety, pesticides, fertilizers, and processing standards.

Therefore, cultivating hemp for cannabinoid extraction is now subject to the same processes and regulations as any other crop intended for ingestion by humans or animals. In addition to the regulatory aspects already established for food safety of crops in the US, hemp is further subject to state and federal laws for licensing, field registration, THC concentration, and storage.

Basic Requirements to Legally Cultivate Hemp for Sale

Note: On October 31, 2019, the USDA posted interim federal rules (IFR) for industrial hemp production in the US (7 CFR Part 990). These rules apply to states seeking to submit state plans to the Secretary of Agriculture for approval to continue regulating hemp in their jurisdictions. The IFR also establishes a federal plan for USDA regulation in states that do not submit or receive approval for state plans. Because of the timing of USDA's interim rules being posted, and the extent the MDA would need to change to implement the new program, MDA will continue operating under a pilot program for the 2020 growing season while it works with USDA's Domestic Hemp Production Program leadership to develop an acceptable state plan for implementation in 2021. Under Section 7605 of the 2018 Federal Farm Bill, states are allowed to operate under the hemp pilot program provision of Section 7606 of the 2014 Farm Bill for "one year after the date on which the Secretary establishes a plan under section 297C of the Agricultural Marketing Act of 1946." Therefore, states can continue to operate under pilot programs until October 31, 2020. MDA has also requested that USDA extend the time permitted to operate under the pilot program until the end of the calendar year (December 31, 2020) to prevent disruption and confusion with its currently established annual licensing period. Anyone with questions about the status of Minnesota's state hemp plan or the most current rules and regulations for production of hemp in the state are encouraged to visit the MDA (https://www.mda.state.mn.us/plants/hemp) or USDA (https://www.ams.usda.gov/rules-regulations/hemp) Hemp Programs websites for the most current information.

A. While there are no specific standards on cultivating a hemp crop from seed to harvest, to legally grow and process hemp in Minnesota a person must meet all of the following requirements under the Minnesota Industrial Hemp Development Act (MINN. STAT. Chapter 18K), the Agricultural Marketing Act of 1946 (7 U.S.C. 1621 et. seq.), and the

interim federal rules (7 CFR Part 990) for establishment of a domestic hemp production program.

a. **Obtain a license from MDA.** MDA is required to license all persons wanting to cultivate hemp in Minnesota under the authority of both state (MINN. STAT. 18K.04) and federal law (7 U.S.C. 1621 et. seq.), and the interim federal rules (7 CFR Part 990). Growers are required to pay fees for licensure and must register all growing locations with MDA.
    i. No person can obtain a license to grow hemp if they have been convicted of a drug-related felony in the US within 10 years of application. MDA conducts national criminal background checks of all first-time applicants through the Minnesota Bureau of Criminal Apprehension and the Federal Bureau of Investigation and may require returning applicants to submit to background checks if the department has probable cause to believe a potential drug-related crime has been committed by the licensee after the initial background check was approved.
    ii. All persons growing or processing hemp must have the license readily available for law enforcement officers to review when requested.
    iii. The license number should accompany any hemp for sale and/or processing.
    iv. If the landowner of the growing or processing location is different from the licensee, the landowner should have a copy of the license readily available for review at the location.
b. **Provide accurate addresses of all growing and processing locations to MDA.** All hemp growing and processing locations must be registered with MDA. MDA shares a list of all growing and processing locations with state and local law enforcement officials so that they are aware of where legal cannabis activities are occurring within their jurisdictions.
    i. The license should contain all current and accurate locations.
        1. Any change or addition of growing locations must be reported to MDA immediately.
    ii. Locations that are not registered with MDA are considered illegal and could be subject to fines and/or seizure/destruction by MDA and law enforcement.
c. **Produce *Cannabis sativa* L. plants or products with 0.3 percent Total Delta-9 THC or less (total d-9 = Decarboxylated test analysis [d-9THC + (THC-A X 0.877)]).** Cannabis plants, plant materials, and products that are tested to be 0.3 percent total d-9 THC or less by dry weight are considered hemp under state and federal law. Any cannabis exceeding the 0.3 percent total d-9 tolerance meets the definition of marijuana under both Federal and Minnesota Controlled Substance Laws and must be destroyed.
    i. MDA will conduct a second test for a failed crop if the grower requests. If the second test fails, the crop must be destroyed by approved means.

ii. There is no criminal violation for producing a crop that tests above the 0.3 percent total d-9 THC threshold if the grower submits a corrective action report and complies with MDA's order to destroy the crop in an approved and timely matter.
    1. Federal law considers this a negligible offense. If a grower has three negligible offenses in a five-year period, they are banned from growing hemp in the US for a five-year period beginning at the date of the last offense.

d. **Only sell or process hemp materials that were issued an MDA Fit For Commerce certificate or a USDA/other state's similar document.** Any crop that passes the THC test requirement is considered hemp and can move into the stream of commerce. MDA issues a Fit For Commerce certificate that must accompany the harvested hemp material through the processing stage. The Fit For Commerce certificate shows the licensee's contact information, state license number, and the test results for the raw harvested hemp in question.
    i. Any raw hemp material without an MDA Fit For Commerce certificate (or similar document if the raw material was harvested in another state) is not considered legal hemp for transportation, processing, or product development and sale in Minnesota.

e. **Must follow all rules and guidelines in both MINN. STAT. Chapter 18K and Agricultural Marketing Act of 1946 (7 U.S.C. 1621 et. seq.), and USDA Interim Rules (7 CFR Part 990).** In addition to MDA and UDSA hemp regulations, cultivation and processing of hemp is subject to other state and federal laws that apply to a variety of agricultural crops. Hemp crops are cultivated both indoors and outdoors and there are state and federal regulations that apply to both situations.
    i. Pesticide and fertilizer laws are common regulations to which agricultural producers must adhere.
    ii. Processors of hemp for consumable products must adhere to food and drug licensing standards in order to develop legal and safe end products.
    iii. Growers who wish to become certified under the National Organic Program must be aware of the federal requirements established for certification—including but not limited to cultivation and processing requirements.

Recommendations—Cultivation Standards

Given the existing legal requirements outlined above, SCCPW recommends the following cultivation practices be considered for any hemp being grown for cannabinoid extraction:

A. Cultivation standards must incorporate all federal rules as developed throughout 2020 and 2021 (7 CFR Part 990).
B. Adherence to all federal and state pesticide and fertilizer laws.

Currently, there are no pesticides labeled or approved for cannabis. However, through the passage of the 2018 Farm Bill, hemp is now considered an agricultural commodity and pesticide manufacturers can begin applying to the Environmental Protection Agency (EPA) for product registration. Upon EPA approval of products, all hemp growers will be required to follow the label instructions and restrictions. Any misuse of pesticides or fertilizers should be immediately disclosed and reported to the MDA Pesticide and Fertilizer Management Division (PFMD).

a. Periodic inspection of crops for pesticide drift and disease throughout the field season.
b. Any drift shall be reported to the PFMD for investigation and compliance.
    i. Hemp intended for human or animal consumption cannot be processed or sold if pesticide levels exceed EPA (or MDA) tolerances.
c. Test harvested materials and final products to ensure total d-9 level, and also run tests for heavy metals, pesticides, and other contaminants if the crop is intended for consumption (grain or cannabinoid extraction).
    i. Sampling protocols must be developed, and testing must be done by an accredited laboratory for cannabis.[1]
d. If marketing the product as organic, a grower must adhere to all National Organic Program certification standards and be certified and inspected periodically by an accredited agency.
e. Growers should use certified varieties when at all possible.
f. Cannabinoid products should reflect the cultivated origin of the hemp used for extraction (state and hemp producer license number).
g. Manufacturers of the products should be able to produce records of all testing results in order to determine that the material extracted is free of harmful substances and total d-9 THC concentrations are not greater than 0.3 percent by dry weight.

C. A statewide database should be created that allows law enforcement access to all MDA hemp license data. The database should be accessible 24 hours a day so that law enforcement officers encountering individuals with raw cannabis in their possession and are claiming to be licensed under the program can be verified. The database would also be extremely useful to law enforcement officers receiving tips on marijuana grows to quickly determine whether the locations are registered hemp cultivation or processing sites.[2]
D. MINN. STAT. Chapter 18K noted above in the cultivation standards should be amended, or a rule should be created, to prohibit growers from using a residential dwelling as a growing or processing location.

[1] Refer to suggested cannabis testing standards outlined later in this report.

[2] Refer also to recommendations under safety standards later in this report.

   a. Residential location should be defined (for example, does it include detached buildings, garages, gardens?)
      i. There would need to be a phase-out period for 2020 growers who had initially invested in residential dwellings in previous years to give them an opportunity to re-invest in commercially zoned properties and move their production operations.
   b. MINN. STAT. 151.72 should be amended to prohibit the manufacturing and wholesaling of cannabinoid products within a residential dwelling.

E. The Commissioners for Public Safety and Agriculture should develop a coordinated plan to address crop sampling, testing, licensing and crop destruction for plants testing above 0.3 percent total d-9 THC.
   a. A coordinated plan between MDA hemp regulators and Minnesota law enforcement is needed to establish clear areas of operations for both agencies. Such a plan will also allow the state to combine resources and expertise from each agency to determine standard operating procedures for determining civil/administrative vs. criminal responses to violations when they occur. For example, the state Violent Gang and Drug Task Force already has expertise in handling destruction of controlled substances. MDA could partner with law enforcement personnel to destroy hemp crops that test above the THC threshold.

2. Labeling Requirements for Products Containing Cannabidiol Extracted From Hemp

Background Information

The federal Fair Packaging and Labeling Act, enacted in 1967, directs the Federal Trade Commission and the FDA to issue regulations requiring all “consumer commodities” be labeled to disclose net contents, identity of commodity, and name and place of business of the product’s manufacturer, packer, or distributor. MINN. STAT. 293.093 requires similar information be labeled on all consumer packages.

The FDA has promulgated rules and issued guidance related to the labeling of packages containing legally allowed foods, drugs, dietary supplements, and cosmetics. However, products containing cannabinoids for human consumption are not legal under federal law. Therefore, some of the FDA labeling requirements found for drugs and dietary supplements are not appropriate for products containing cannabinoids. For example, FDA-approved nonprescription drugs must include the intended uses of the drug (for example, pain relief and fever reduction for acetaminophen, one brand name of which is Tylenol). Cannabinoid products derived from hemp have not been approved for any medical purpose and therefore should not be allowed to make unsubstantiated treatment claims. Similarly, dietary supplements must contain nutritional information, but cannabinoid products that are sold as if they were drugs or dietary supplements often have no nutritional value.

The Minnesota Department of Health, Office of Medical Cannabis, has adopted rules for the packaging and labeling of the products under its jurisdiction (MINN. R. 4770.0850), which contain non-patient-related requirements such as:

A. Packaging must be tamper-evident and child-resistant.

B. Packaging must not bear a reasonable resemblance to an existing commercial product.

C. Packaging must be designed to minimize its appeal to children.

D. Trade names can't be identical, or confusingly similar to, the name of an existing non-cannabis product. Nor can they be identical to, or confusingly similar to, the name of an unlawful product or substance.

E. A list of all ingredients of the product shown with common or usual names, including any colors, artificial flavors, and preservatives, listed in descending order by predominance of weight.

F. A notice with the statement, including capitalization: "This product has not been analyzed or approved by the United States Food and Drug Administration. There is limited information on the side effects of using this product, and there may be associated health risks. Do not drive or operate heavy machinery when under the influence of this product. KEEP THIS PRODUCT OUT OF REACH OF CHILDREN."

During the 2019 Session, the legislature adopted the following language for the labeling of "druglike" products under the jurisdiction of the Board of Pharmacy. This language does not apply to the labeling of food products (see MINN. STAT. b151.72):

> Subdivision 5. **Labeling requirements.** (a) A product regulated under this section must bear a label that contains, at a minimum:
>
> > (1) the name, location, contact phone number, and website of the manufacturer of the product;
> >
> > (2) the name and address of the independent, accredited laboratory used by the manufacturer to test the product;
> >
> > (3) an accurate statement of the amount or percentage of cannabinoids found in each unit of the product meant to be consumed; and
> >
> > (4) a statement stating that this product does not claim to diagnose, treat, cure, or prevent any disease and has not been evaluated or approved by the FDA unless the product has been so approved.
>
> (b) The information required to be on the label must be prominently and conspicuously placed and in terms that can be easily read and understood by the consumer.
>
> (c) The label must not contain any claim that the product may be used or is effective for the prevention, treatment, or cure of a disease or that it may be used to alter the structure or function of human or animal bodies, unless the claim has been approved by the FDA.

Recommendations—Labeling Requirements

SCCPW notes that all manufacturers and packagers of consumer products are already required to provide certain information for consumers on their packages. This helps ensure consumers have access to information they need to make value comparisons between products. In the case of nonprescription drugs, federal regulations require labeling to include additional information concerning appropriate use and safety considerations. Additional information may also be required on labeling to help protect consumers from fraudulent marketing. Cannabinoids are pharmacologically active drugs and manufacturers of products that contain cannabinoids for human or animal consumption should not be exempt from the packaging, labeling, and marketing requirements that the manufacturers of other consumer products must follow. Appropriate packaging, labeling, and marketing requirements and restrictions are necessary to protect public health and safety.

In addition to the requirements passed during the 2019 Session, the legislature should consider:

A. Clarify the requirements of MINN. STAT. 151.72 paragraph (c) also apply to any other labeling documents distributed by the manufacturer. (The term "labeling" includes any written materials that accompany the product, not just the label affixed to the immediate container that holds the products: e.g., outer wrappings, boxes, package inserts).

B. Restrict the sale of cannabinoid-containing products to individuals who are 21 years of age or older and require that this restriction be stated on labeling. Although cannabinoids not cause intoxication, it does cause sedation and is a pharmacologically active drug that affects the central nervous system.[3]

C. Require the following warning on these products: "This product, taken alone or with alcohol, may cause drowsiness and may affect the ability to drive or operate heavy machinery." This is consistent with rules of the Board of Pharmacy that require pharmacists to include that statement on the label of certain prescription drugs dispensed to patients. It is also consistent with federal labeling requirements for nonprescription drugs that can cause sedation.

D. Restrict any products or packaging that would be attractive to youth or children (e.g., no flavors that target youth, cartoonish ads, photographs of the product on the label) and require consumables to be in opaque packaging.

E. Require packaging to be tamper-evident and child-resistant.

F. Allow the labeling of small containers to be accomplished in alternative ways, e.g., use QR codes or a supplemental label—hang-tags, peel-back labels, inserts, or the use of labeled outer containers such as boxes—to include some of the required information.

G. Require hemp producer's license number (or some other identifier), lot or batch numbers, expiration dates, information about allergens, nutritional information, and storage requirements on labels (as applicable).

[3] Also required under Advertising and Marketing Restrictions.

H. Require a list of all ingredients of the product—shown with common or usual names—including any colors, artificial flavors, and preservatives, listed in descending order by predominance of weight.

I. Unless the legislature changes the law to permit the legal recreational use of marijuana, consider requiring that the purchasers of products containing cannabinoids derived from *Cannabis sativa* plants, particularly products that contain unprocessed plants or plant parts, keep the products in their original packaging after purchase. It is impossible to visually inspect some of these products and determine if they are derived from hemp plants or from marijuana plants. That puts law enforcement officers in the position of having to decide whether to arrest someone who is in possession of what appears to be marijuana or a marijuana derivative but could actually be hemp or a hemp derivative.

J. Consider whether to allow food products to contain cannabinoids. If allowed, consider establishing labeling, packaging, and marketing requirements similar to those noted in legislation and in this report for nonfood cannabinoid products as well as any other required label elements for a food product that are in existing statutes and rules, administered by the Minnesota Departments of Agriculture and Commerce. (Note that the recently enacted MINN. STAT. 151.72 does *not* apply to food products to which cannabinoids have been added. The sale of such products remains illegal under both federal and state law), yet they remain widely available for sale in Minnesota.

K. Regarding nonfood products, clarify that the packaging and labeling requirements apply to:

    a. Products made by extracting cannabinoids from hemp and adding it to the products

    b. Oils derived from hemp that contain cannabinoids

    c. The sale of parts of the hemp plant, for human consumption, that contain cannabinoids[4]

L. Consider as a possible model the work of other states that have set standard for the labeling of products derived from *Cannabis sativa* plants. In addition to the requirements listed above, the legislature should consider labeling standards set by other states. For example, California has requirements similar to those enacted by the Minnesota Legislature in 2019, and has the following additional labeling and packaging requirements:

    a. A division of the label into a primary and information panels, with certain information being required on each panel.

    b. Allowances for the labeling of small containers that are difficult to label. For example, the use of a supplemental label to include some of the required information. Examples include hang-tags, peel-back labels, and inserts. (The Minnesota Board of Pharmacy will be issuing a guidance allowing these sorts of

[4] Consider also under Advertising and Marketing Restrictions.

supplemental labels to meet the requirements of the provisions passed by the legislature in 2019.)

c. Inclusion on the label of a batch or lot number.

d. Date of manufacturing of the lot and, when applicable, an expiration date.

e. A list of allergens, if applicable.

f. A statement such as "REFRIGERATE" or "KEEP REFRIGERATED" for products that require refrigeration.

g. Sodium, sugar, carbohydrates, and total fat per serving for products sold as foods.

3. Advertising and Marketing Restrictions

Background Information

There is considerable overlap in the areas of labeling, advertising and marketing restrictions, and restrictions of false and misleading claims. Advertising and marketing materials cannot make false or misleading claims, and labeling requirements apply under some advertising and marketing restrictions. SCCPW has attempted to note where recommendations could fall under more than one area.

Recommendations—Advertising and Marketing Restrictions

In addition to the requirements passed during the 2019 Session, the legislature should consider the following:

A. Additional information may also be required on labeling to help protect consumers from fraudulent marketing. Cannabinoids are pharmacologically active drugs, and manufacturers of products that contain cannabinoids for human or animal consumption should not be exempt from the marketing requirements manufacturers of other consumer products must follow. Appropriate marketing requirements and restrictions are necessary to protect public health and safety.[5]

B. Restrict any marketing that would be attractive to youth or children (e.g., no flavors that target youth, cartoonish ads, photographs of the product on the label) and require edibles to be in opaque packaging. Marketing restrictions will need to be within the confines of the First Amendment and could be modeled after existing tobacco restrictions.[6]

[5] Would also apply under Labeling Requirements.
[6] Similar to requirements discussed under Labeling.

4. Restrictions of False or Misleading Claims

Background Information

Unless already approved by the FDA as a drug or medicine, manufacturers of cannabinoid products derived from hemp should not be allowed to make unsubstantiated treatment claims.

Recommendations—Restrictions of False or Misleading Claims

In addition to the requirements passed during the 2019 Session, the legislature should consider the following:

A. Prohibit claims that a product is "natural" or "organic" unless the product has been appropriately certified.

B. The legislature should consider further clarification that marketing efforts of any type should not be allowed to make any claims that the product is effective for the prevention, treatment, or cure of a disease or that it may be used to alter the structure or function of human or animal bodies, unless the claim has been approved by the FDA, or the cannabinoid is being sold as part of the MN Medical Cannabis Program.[7]

5. Testing Requirements

Background Information

Outside of medical cannabis, there are not laboratory testing standards for cannabinoid products. SCCPW notes the following issues and concerns regarding product safety and laboratory testing to the legislature:

A. Product Safety

   a. Use of unapproved and potentially harmful pesticides and other adulterants that may end up in finished products.

   b. Cannabis has the potential to be added to a wide variety of products and in a variety of forms, making it difficult to identify jurisdiction and to develop test methods for these different matrices.

B. Laboratory Testing

   a. Other states have experienced problems with third-party laboratories providing inaccurate or fraudulent data in support of manufacturer claims. In some cases, laboratory licenses have been suspended.

   b. There are no established standards for contaminant limits or mandated test methods for cannabis. In other states, laboratories utilize very different test methodology, making it difficult to compare test results from one laboratory with another.

[7] Would apply under Advertising and Marketing Restrictions.

c. Ensuring that the plant or product to be tested is sampled appropriately is a critical step for any cannabis testing lab. Samples should be representative of the entire harvest or batch.

d. Current laboratory quality standards (methods, method validation protocols, and performance criteria) are insufficient to support a robust, science-based cannabis laboratory accreditation program. Revisions are needed for analytical methods, method validation protocols, performance criteria, proficiency testing, and homogenization procedures.

e. Widely accepted laboratory quality standards for testing cannabis and cannabis products do not yet exist.

Recommendations—Testing Requirements

In addition to the requirements passed during the 2019 Session, the legislature should consider the following:

A. User safety should be addressed by testing to ensure the product is free of harmful substances including, but not limited to, microbial contamination, pesticides, residual solvents, and heavy metals (for chemically extracted/processed products). Additional testing may include potency (e.g., THC, cannabinoids), homogeneity for multi-use products, and stability and shelf life.

B. Requirements should be as stringent as is necessary to protect consumers. The addition of testing components after the fact has been problematic in other states, with pushback from manufacturers who do not want increased testing costs to reduce their profits.

C. Designate Minnesota Environmental Laboratory Accreditation Program (MNELAP) as the accreditation provider for Minnesota's cannabis testing laboratories. Based on experience, skills, and expertise, MNELAP is uniquely equipped to establish, manage, and uphold accreditation of cannabis-testing laboratories. In addition to lab accreditation by MNELAP, it is recommended that MDH's Public Health Lab Environmental Laboratory Section (ENV) be set up and perform reference testing as an oversight for commercial laboratory testing of any cannabis products intended for human consumption. This testing would be directed at ensuring commercial cannabis-testing labs are performing required testing with the appropriate quality and ethics to ensure that the end users of cannabinoid products are reasonably protected from public health threats. This testing would be complementary to any testing the MDA laboratory would conduct on plant material and agricultural or food-related products. ENV could also be prepared to support cannabis-related adverse event investigations. The testing ENV would offer could align with the current safety testing paradigm used by the MDH Office of Medical Cannabis (OMC). With this capability, in the event of the loss of capacity at a lab supporting OMC, ENV could serve as a stopgap until commercial laboratory testing could be resumed, thus preventing a significant loss of consumer access to cannabinoid products.

D. One possible model is for MDA to be responsible for standards, regulatory and reference testing related to cultivation and plant material and food, and while Minnesota Department of Health Public Health Laboratory (MDH-PHL) would be responsible for extracted products, investigation of adverse reactions, and related standards and reference testing. MNELAP

would be responsible for working with MDH-PHL and MDA to establish laboratory standards and providing accreditation and oversight and enforcement.

E. Whether the grower or manufacturer, testing laboratory, or a third-party organization is performing the sampling, accreditation to ISO/IEC 17025[8] helps ensure proper sampling is performed. The current version of ISO/IEC 17025, which was published in 2017, expands upon the sampling requirements in previous versions, allowing organizations to be accredited for sampling only or to include sampling activities on their testing scope of accreditation. The requirements include the need for a sampling plan and method with appropriate statistical methods applied in a reasonable manner.

F. Laboratory standards over and above ISO 17025 accreditation (i.e., Minnesota cannabis laboratory requirements) need to be defined. Private laboratories may be accredited and licensed to provide product testing, assuming they meet the standards defined by MNELAP. Government labs (MDH/MDA) could provide reference testing to ensure that the data produced by private laboratories is accurate.

G. The testing and lab accreditation conducted by MDH/MDA for cannabis should be a completely separate enterprise from non-cannabis activities.

H. Funding (e.g., licensing fees) should be established to cover fixed costs of setting standards, regulatory and reference testing, and laboratory accreditation.

I. Enforcement authority should be provided in statute.

J. There are some general principles that should be followed to ensure that proper sampling is performed. Sampling should always be performed at the closest point to consumer consumption. Flowers should be tested right after being harvested, prior to packaging in containers; edibles and nonedibles should be tested as a finished and packaged product; and concentrates should be sampled prior to being added to a product. Packaging, especially when not done properly, affects the testing results through degradation and exposure to improper lighting, meaning that the label on the final product will not be representative of the final product unless these factors are accounted for.

6. Safety Standards

Background Information

SCCPW does not believe it can comment on safety standards for edible products. In the group's opinion, the definition of "edible" for these types of products is not sufficient because it elicits the idea of a food. The legislature used the word "edible" in the new law, but MINN. STAT. 151.72, subdivision 2(a) specifically states… "other than food," so SCCPW thinks the focus was on druglike products or dietary supplements. This means that as of January 1, 2020, products

[8] ISO/IEC 17025 enables laboratories to demonstrate that they operate competently and generate valid results, thereby promoting confidence in their work both nationally and around the world. It also helps facilitate cooperation between laboratories and other bodies by generating wider acceptance of results between countries. Test reports and certificates can be accepted from one country to another without the need for further testing, which, in turn, improves international trade.

that are clearly food with cannabinoids in them will be considered adulterated and will remain illegal under state and federal law.

New laws would be necessary to allow food products to contain cannabinoids. That legislation would need safety standards, similar to those noted in the current legislation for druglike products, as well as testing standards and regulatory testing for declared cannabinoids and adulterants of concern.

Recommendations—Safety Standards

The SCCPW recommends the legislature require all cannabis products to fit into a blockchain scheme for tracking. Such a system would address safety in several ways. First, the system would allow for efficient tracking of a product back to the source, should a public health problem arise at any time in the product's lifecycle. A statewide database would also allow law enforcement access to all MDA hemp license data. The database should be accessible 24 hours a day so law enforcement officers can verify whether individuals with raw cannabis in their possession are licensed under the program. The database would also be useful to law enforcement officers receiving tips on marijuana grows to quickly determine whether the locations are registered hemp cultivation or processing sites.

Consumers with a cannabinoid or cannabis product would be required to have the barcode that is part of the blockchain identifier on each product. Essentially, the SCCPW recommends a state-centralized seed-to-sale system be instituted. Currently, law enforcement must investigate backward from the street level to determine whether a person found to be in possession of something that looks like cannabis is licensed and allowed to have it. There is no 24-hour availability of information for law enforcement to determine license status.

7. Other Requirements

Please see the items discussed below.

Other Advice and Considerations for the Legislature

SCCPW would like to provide additional advice and considerations for the legislature in the following areas, which were not specifically noted in the legislation creating SCCPW.

Establishment of an Office of Cannabis Management

The legislature should consider creating an office of cannabis management that would oversee industrial hemp, medical cannabis, and cannabinoid products, either on its own or as a part of another agency. The legislature should seek input from agencies on funding and logistics for the office of cannabis management. This office would need rulemaking and enforcement authority. For example, there is currently no clear procedure regarding when MDA should intervene when there is a problem with a grower versus when law enforcement should be involved [see Recommendations—Cultivation Standards; Section E.; a. (pg. 10)]. In addition to a lack of understanding about where responsibility lies for enforcement, none of the relevant agencies have enough staff to adequately enforce regulations as they stand. There are also conflicts among federal policies relating to recreational use that need consideration, for example, the federal government considers marijuana a Schedule 1 drug, as a result, most financial

institutions generally refuse to provide services to cannabis-related businesses. An office of cannabis management would allow for a multifaceted regulatory structure, responsible for licensing, compliance, product safety, research, taxation, and addressing violations via civil or administrative action up to criminal charges, if necessary. This office could be responsible for enforcement, with staff dedicated to enforcement, or an agency to which law enforcement can charge their time while serving in an enforcement role.

SCCPW would also recommend establishing a commission to advise the Office of Cannabis Management, made up of appointees from the following agencies:

- Minnesota Department of Health
- Minnesota Department of Agriculture
- Minnesota Department of Revenue
- Minnesota Department of Commerce
- Minnesota Department of Public Safety
- Board of Pharmacy

Food

As noted above in the section on safety standards, SCCPW's opinion is that while the legislation uses the term "edible," it does not apply to food products. SCCPW believes food needs to be addressed separately.

SCCPW consulted with MDA's food division to determine that current federal and state laws say cannabinoids cannot be added to food. Allowing cannabinoids in food would require a change in state law. Even if legalized by the legislature, cannabinoids in food products would remain illegal under federal law.

Many of the same labeling requirements noted above and in current legislation would have to be established for food. Food products containing cannabinoids would also be subject to existing regulations under MDA and the Department of Commerce. Therefore, food safety standards established for other foods would also have to apply to any cannabinoid food products. Foods containing cannabinoids would also be subject to most, if not all, of the regulations in other areas (e.g., cultivation, marketing and advertising, false claims) noted in current legislation and under the items discussed above under the regulatory framework.

Use in Institutional Settings and Who Can Administer

With cannabinoid products becoming legal on January 1, 2020, issues have arisen on use in institutional settings and about who can administer cannabinoid products (for example, a school nurse). The regulations for medical cannabis are clear on whether medical cannabis products can be used in schools and who can administer it. SCCPW recommends the legislature address issues about cannabinoid use in schools, hospitals, nursing homes, and other long-term care facilities.

Local Licensing

Cannabinoids are psychoactive substances that currently are not regulated at the retail level. Cannabinoid products are being sold as hemp flower, cannabinoid oils, tinctures, and infused products. The legislature should consider licensing retailers, similar to the process for tobacco licensing.

Related Work

In addition to national and local discussions on industrial hemp, cannabinoids, medical marijuana, and adult recreational use of marijuana, there are agencies working on issues potentially relevant to the discussion on cannabinoid products, as noted below.

Expedited Rulemaking—MDA

The commissioner of agriculture has created a hemp advisory committee of stakeholders in the hemp industry to assist MDA with developing rules for MINN. STAT. Chapter 18K as part of their expedited rulemaking approved by the 2019 legislature (see language below). The committee and MDA staff have developed proposed rules they are currently discussing and editing. The goal is to complete the rulemaking process before the 2020 field season. Rules will help set clearer guidelines and expectations of growers for licensing, handling, and processing of cultivated hemp under both state and federal law.

> ***2019 Legislative Session; 19-5229; Article 2; Sec.19. INDUSTRIAL HEMP; RULEMAKING.***
>
> *After consulting with stakeholders, the commissioner of agriculture may use the expedited rulemaking process in Minnesota Statutes, section 14.389, to adopt the rules required under Minnesota Statutes, section 18K.06, to conform to the Agriculture Improvement Act of 2018, Public Law 115-334, and federal rules authorized under that act. The commissioner of agriculture's authority to adopt rules under this section expires June 30, 2020.*

Production, Processing, and Transport of Cannabinoid Products

The 2019 legislature requested that the commissioner of agriculture consult with the commissioners of public safety and health to develop a potential framework for regulation of THC concentrated above the 0.3 percent d-9 threshold during the extraction process (see language below). MDA is currently assembling members from the departments of health and public safety for early winter meetings to discuss and develop a framework for a legislative report.

> ***2019 Legislative Session; 19-5229; Article 2; Sec.20. INDUSTRIAL HEMP; PLAN AND REPORT.***
>
> *(a) The commissioner of agriculture must submit a plan to the secretary of the United States Department of Agriculture and request primary regulatory authority over the production of industrial hemp in this state, as provided under section 10113 of the Agriculture Improvement Act of 2018.*

(b) The commissioner of agriculture, in consultation with the commissioners of public safety and health, must develop a framework for regulating the possession and use of tetrahydrocannabinol resulting from industrial hemp processing, including but not limited to the extraction of cannabidiol or other components. No later than February 15, 2020, the commissioner of agriculture must submit the proposed framework to the chairs and ranking minority members of the legislative committees and divisions with jurisdiction over agriculture, public safety, and health.

Appendices

Appendix A—Legislation on Cannabinoid Products

The following is an excerpt from Laws of Minnesota 2019, 1st Spec. Sess. Chapter 9, Article 11.

Sec. 76. **[151.72] SALE OF CERTAIN CANNABINOID PRODUCTS.**

Subdivision 1. **Definitions.** (a) For the purposes of this section, the following terms have the meanings given.

(b) "Hemp" has the meaning given to "industrial hemp" in section 18K.02, subdivision 581.21 3.

(c) "Labeling" means all labels and other written, printed, or graphic matter that are:

(1) affixed to the immediate container in which a product regulated under this section is sold; or

(2) provided, in any manner, with the immediate container, including but not limited to outer containers, wrappers, package inserts, brochures, or pamphlets.

Subdivision 2. **Scope.** (a) This section applies to the sale of any product that contains nonintoxicating cannabinoids extracted from hemp other than food that is intended for human or animal consumption by any route of administration.

(b) This section does not apply to any product dispensed by a registered medical cannabis manufacturer pursuant to sections 152.22 to 152.37.

Article 11 Sec. 76.

Subdivision 3. **Sale of cannabinoids derived from hemp.** Notwithstanding any other section of this chapter, a product containing nonintoxicating cannabinoids may be sold for human or animal consumption if all of the requirements of this section are met.

Subdivision 4. **Testing requirements.** (a) A manufacturer of a product regulated under this section must submit representative samples of the product to an independent, accredited laboratory in order to certify that the product complies with the standards adopted by the board. Testing must be consistent with generally accepted industry standards for herbal and botanical substances and, at a minimum, the testing must confirm that the product:

(1) contains the amount or percentage of cannabinoids that is stated on the label of the product;

(2) does not contain more than trace amounts of any pesticides, fertilizers, or heavy metals; and

(3) does not contain a delta-9 tetrahydrocannabinol concentration that exceeds the concentration permitted for industrial hemp as defined in section 18K.02, subdivision 3.

(b) Upon the request of the board, the manufacturer of the product must provide the board with the results of the testing required in this section.

Subdivision 5. **Labeling requirements.** (a) A product regulated under this section must bear a label that contains, at a minimum:

(1) the name, location, contact phone number, and website of the manufacturer of the product;

(2) the name and address of the independent, accredited laboratory used by the manufacturer to test the product;

(3) an accurate statement of the amount or percentage of cannabinoids found in each unit of the product meant to be consumed; and

(4) a statement stating that this product does not claim to diagnose, treat, cure, or prevent any disease and has not been evaluated or approved by the United States Food and Drug Administration (FDA) unless the product has been so approved.

(b) The information required to be on the label must be prominently and conspicuously placed and in terms that can be easily read and understood by the consumer.

(c) The label must not contain any claim that the product may be used or is effective for the prevention, treatment, or cure of a disease or that it may be used to alter the structure or function of human or animal bodies, unless the claim has been approved by the FDA.

Article 11, section 76.

Subdivision 6. **Enforcement.** (a) A product sold under this section shall be considered an adulterated drug if:

(1) it consists, in whole or in part, of any filthy, putrid, or decomposed substance;

(2) it has been produced, prepared, packed, or held under unsanitary conditions where it may have been rendered injurious to health, or where it may have been contaminated with filth;

(3) its container is composed, in whole or in part, of any poisonous or deleterious substance that may render the contents injurious to health;

(4) it contains any color additives or excipients that have been found by the FDA to be unsafe for human or animal consumption; or

(5) it contains an amount or percentage of cannabinoids that is different than the amount or percentage stated on the label.

(b) A product sold under this section shall be considered a misbranded drug if the product's labeling is false or misleading in any manner or in violation of the requirements of this section.

(c) The board's authority to issue cease and desist orders under section 151.06; to embargo adulterated and misbranded drugs under section 151.38; and to seek injunctive relief under section 214.11, extends to any violation of this section.

EFFECTIVE DATE. This section is effective January 1, 2020, and applies to any product sold in Minnesota on or after that date.

Appendix B—Public Comments

A draft of the SCCPW report to the legislature was made available for stakeholder and public input from November 22, 2019, through December 3, 2019, on the MDH website. Workgroup members also sent the draft report to stakeholders. Interested parties were directed to an online form to submit their written input on the main sections of the report (sections 1 through 6). A total of 10 individuals submitted comments on the report; the MDH page where the report was hosted had 187 views during the comment period, and the report was opened 87 times. SCCPW reviewed and considered the comments as they finalized the report. The public input received from the respondents is organized below by these sections (1 through 6) of the report.

Note: Word choice and spellings have been retained as written by respondents to avoid inadvertent mischaracterization of intent.

Cultivation standards

Dan Guida, Aitkin County Sheriff's Office

The MN Dept of Ag needs to gain some Law Enforcement authority (legislatively) to allow them to establish and enforce standards related to the cultivation of hemp

Warren Batzlaff

Why kind of morons does it take to propose this? The money you could possibly get out of this will never pay for the harm and damage to society! Politicians can not even perform their basic functions to society! What could possibly go wrong with this? It has been clearly demonstrated everything, death, extreme health problems. Politicians cannot even deal with narcotics, alcohol, amphetamines, cocaine, crack, heroin, underage drinking. Multiple DUI's, murder, gangs, vaping, nicotine addiction, What in the hell are they thinking?

Geir Friisoe

I am not sure "cultivation standards" is the proper title to this section as cultivation, typically refers to basic agronomic practices utilized to produce a crop. I do not support government dictating crop production methods. That said, I understand that the intent of this section is to meet standards dictated by the Federal Govt. under the Farm bill and also as a result of the CSA (Controlled Substances Act). This report does a good job meeting those requirements.

Luke Hennen, Scott County Sheriff

Limits to the amount of locations that can grow crops. Too many locations and it will be hard for Law Enforcement to know who is legal and who is black market. Any confusion leads to an increase of crimes. We are already seeing in increase of thefts happening at legal Hemp grow sites. We are under the impression that drug dealers are stealing hemp as a way to increase profit by cutting it into their MJ product for sale. Local Law Enforcement is already short on resources and can not be pulled away from our community to deal with this specific issue - there needs to be security protocols in place to reduce crime at these locations.

Labeling requirements

Dan Guida, Aitkin County Sheriff's Office

I believe the labels need to accurately describe amounts of product and testing certificates (provided by MN Dept of Ag) as well as location of manufacture and harvest dates.

Alida Casey

3rd party testing with a qr code for each batch

William Spitzer

There should be restrictions on any "appeal" to young people. A standard generic label should be created that would explain what the product is. Who produced the product. What the THC level is in product. Warning label that includes the health risks using the product.

Geir Friisoe

I am very pleased to read this well written and thorough section. As someone afflicted with MS I have long sought remedies for my muscle spasticity, muscle spams and chronic pain. I have consulted with my neurologist and other medical physicians and received recommendations for the amount of CBD that I should utilize for my condition. Unfortunately, as the report points out there are no uniform standards making it virtually impossible for me to determine what I should buy and what I am getting. I support this section strongly!

Advertising and marketing restrictions

Steve Branby, Otter Tail County Sheriff's Office

Continue to monitor the packaging and restrict the bright colors/appealing designs to young children.

Dan Guida, Aitkin County Sheriff's Office

These should match the labeling requirements above (labels need to accurately describe amounts of product and testing certificates as well as location of manufacture and harvest dates)

Wayne Jeffrey

The policies and restrictions must be applicable to ALL manufacturers AND retailers of cannabinoid products with specified penalties for noncompliance or you are wasting time

William Spitzer

Without a doubt, NO ads on TV, social media (especially twitter, Instagram, YouTube, snapchat or Facebook) Billboards MUST not be located within 1000 feet of any school or early childhood facility.

Geir Friisoe

As indicated in my response to Section #2 it is the Wild West for people like me trying to purchase CBD based on the recommendations of my neurologist. I strongly advertising restrictions to ensure the public and consumers such as myself seeking medical relief are provided clear, straightforward and SIMPLE to understand messaging.

Restrictions of false or misleading claims

Dan Guida, Aitkin County Sheriff's Office

Provide a law for the enforcement of these false or misleading claims.

Alida Casey

Cannot label for any health condition

William Spitzer

No promotion of health benefits should be allowed on any cannabis related products including CBD unless they have been proven with credible evidence from the FDA or CDC or other Federal or State government agency.

Geir Friisoe

Same comment as to #3 - As indicated in my response to Section #2 it is the Wild West for people like me trying to purchase CBD based on the recommendations of my neurologist. I strongly advertising restrictions to ensure the public and consumers such as myself seeking medical relief are provided clear, straightforward and SIMPLE to understand messaging.

Testing requirements

Dan Guida, Aitkin County Sheriff's Office

The testing requirements must be routinely done from seed to harvest. They must be standard to all growers, to include those on tribal lands outside regulatory authority, and must provide for immediate witnessed destruction of plants testing above .3% THC. If this is not accomplished these plants will likely be used illegally to produce concentrates and create a huge risk to public safety.

Alida Casey

3rd party or validated testing with qr code for each lot/batch

William Spitzer

A State testing agency should be created to test ALL marijuana, CBD and Hemp products. This agency would also be responsible for certifying the THC levels in each of those products. This agency will be funded by the TAX revenue from legalization. An official TAX stamp should be created similar to tobacco that would certify that the product was tested in Minnesota. This would also help LE locate illegal product.

Geir Friisoe

Again, I was very pleased to see that the authors of this report have outlined some of the challenges of utilizing independent laboratories and also some of the technical difficulties associated with this type of testing. I will acknowledge that the majority of private labs can and will do a great job of testing. However, as a crop consultant for 10 years and as a regulator for 30 years I have seen first hand that there are labs that either do a poor job analytically or will generate results that benefit the client. I would strongly advocate for a state lab testing model or ensure that the state provides vigorous private lab oversight through a fee supported certification process.

Safety standards

Dan Guida, Aitkin County Sheriff's Office

Standard OSHA rules and inspections should suffice.

Alida Casey

CBD products are fairly new. We should require vendors to take a rigorous course and/or passa rigorous test to be licensed to sell and advise. Only health care professionals should be allowed to advise on use, dosing, health effects, side effects, etc.

Geir Friisoe

Much needed. Well done.

Cannabinoids in food

Dan Guida, Aitkin County Sheriff's Office

I have concerns with labeling for CBD in foods.

William Spitzer

There should be restrictions on any "appeal" to young people. A standard generic label should be created that would explain what the product is. Who produced the product. What the THC level is in product. Warning label that includes the health risks using the product.

State oversight of cannabis

Steve Branby, Otter Tail County Sheriff's Office

Allow law enforcement better transparency to all issues. Allow easier access to state forms, grow/process locations and testing procedures.

Dan Guida, Aitkin County Sheriff's Office

I feel the state should be heavily involved in testing procedures.

Alida Casey

Should be treated as a medicine. Should not be sold by untrained vendors, MLM companies, etc. Should require a license to sell.

William Spitzer

The State of MN needs to develop a 3-tier system of marijuana distribution modelled after alcohol. This system could be monitored just as the alcohol system is monitored by state agencies. This is a proven system and has been in operation for many years.

Geir Friisoe

In the absence of the Federal Govt. fixing the hemp/CSA conflict and with little likelihood that the FDA is going to do anything soon (within years) of developing standards for CBD and THC the states have no choice but to provide oversight to ensure that all of us in Minnesota can benefit from hemp products and Cannabis derivatives.

Luke Hennen, Scott County Sheriff

appropriate staffing and budgets at the state to handle oversight. This program should not increase the burden on local law enforcement to manage. Other states have seen huge increases to crime because of black markets dealers moving into the area that can sell for less then the taxed legal products. Black market can operate in the shadows of the legal market. Due to the federal banking issues around MJ, these operations become a cash businesses that are ripe for robbery and home invasions. These person crimes are taxing on law enforcement resources and we will need support from the state to offset costs and resources. The state will need to provide significant resources to remove the black market.

Use of cannabinoid products in institutional settings

Dan Guida, Aitkin County Sheriff's Office

I do not feel we should be using cannabinoid products in institutional settings unless the MN Dept of Health has done extensive testing.

William Spitzer

This should only be allowed under strict medical supervision and only on conditions that have statistically proven results.

Production, processing and transportation

Steve Branby, Otter Tail County Sheriff's Office

Continue to provide clarification on the transportation issues with CBD and Hemp from grow operations to processing locations. Products being label more clearly.

Dan Guida, Aitkin County Sheriff's Office

I support the labeling measures to assist with these concerns.

William Spitzer

The State of MN needs to develop a 3-tier system of marijuana distribution modelled after alcohol. This system could be monitored just as the alcohol system is monitored by state agencies. This is a proven system and has been in operation for many years.

Geir Friisoe

The state should only be involved with production, processing or transportation of hemp to satisfy Federal mandates and nothing more. The state should however assist in the development of markets for hemp products. With regards CBD and THC I think the state needs far more robust involvement and I strongly support sections 2-6 in this regard, with additional caveat that the state should do the actual testing or have a vigorous oversight role.

Luke Hennen, Scott County Sheriff

very clear legislation on the these topics that leave no grey area for regulation and enforcement.

Any other comments

DeAnne Malterer, Waseca County Commissioner

It appears that due diligence was given to establish these standards. As noted all of these standards will be in flux as national laws and standards and those of many states continue to conflict and further develop. My questions continue to be of a broader scope and particularly have to do with funding. How much will this regulation cost? Unfunded mandates that roll downhill to the county level are a burden on local taxpayers! Monitoring and enforcement end up to be local issues that take resources. It is vital that we have conversations and planning that will address the costs. I'm all for innovation and the possibility of growth in our agricultural sector. This continues to lead us down the path of legalized recreational use without a field test further straining law enforcement.

Dan Guida, Aitkin County Sheriff's Office

We should not rush into this venture until the public safety concerns are addressed.

Alida Casey

We should not have another item that any home-based, MLM company can sell just to make money. Should only be sold by health carr professionals whose scope of practice can reasonably be thought to include advising of benefits, dosages, and risks.

Theodore Beatty, Pharmacy

My only comment is that I opposed legalization of any product containing THC. Look at Colorado and the impaired drivers on those roads.

William Spitzer

I want to serve on the State of MN committee that will introduce Marijuana to our State.

Geir Friisoe

I want to commend the authors of this well written report on a broad and complicated subject. I was very pleased to see that my former colleague Tony Cortilet is one of the work group members as I well respect his expertise and insights with regards hemp and cannabis products. I look forward to the legislature utilizing this report to take appropriate action to implement many of the report's recommendations.

Luke Hennen, Scott County Sheriff

guidance to hiring practices for public safety employers - 911 dispatchers, corrections officers and police officers provide vital services that can not be compromised by impairment. Law enforcement needs a proper way to measure impairment on the roadside for drug impairment.