PART [X] – Cannabis distribution operations

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SUBPART A – GENERAL PROVISIONS

Section 1.1 Subject operations

(a) Except as provided by paragraph (b) of this section, any person, group of persons, or business entity that provides cannabis or cannabis-derived product to compliant individuals in the jurisdiction in which this part applies[1] is engaged in a cannabis distribution operation, and is subject to this part.

(b) A compliant individual who transfers or gives cannabis or cannabis-derived product to another compliant individual at no charge is not a cannabis distribution operation and is not subject to this part.

Section 1.2 Other statutory provisions and regulations

In addition to this part, distribution operations must comply with all other applicable statutory provisions and regulations related to providing cannabis or cannabis-derived product in the jurisdiction in which this part applies, and related to all other business activities undertaken in conducting the distribution operation.

Section 1.3 Definitions

The following definitions apply to this part:

Cannabis means any part of a plant in the genus *Cannabis* that is used by a compliant individual, or that is used as an ingredient in manufacturing a cannabis-derived product, and does not mean hemp.

Cannabis-derived product means a product, other than cannabis itself, that contains or is derived from cannabis, and does not mean a product that contains or is derived from hemp.

Compliant individual means a person who has met all legal requirements to obtain and use cannabis or cannabis-derived product in the jurisdiction where this part applies.

Co-owned operation means a cultivation, processing, or manufacturing operation that has the same ownership as a distribution operation.

Cultivate means to grow plants in the genus *Cannabis*. A person, group of persons, or business entity that cultivates is a *cultivator*, and a facility where cannabis plants are cultivated is a *cultivation operation*.

Delivery service means a distribution operation that delivers cannabis or cannabis-derived product to compliant individuals.

Direct-from-garden or *caregiver operation* means a distribution operation whereby compliant individuals obtain cannabis or cannabis-derived product directly from a cannabis cultivator.

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[1] This term "in the jurisdiction where this part applies" may be replaced throughout with the name of the specific jurisdiction.

Distribution operation means a person, group of persons, or business entity that provides cannabis or cannabis-derived product to compliant individuals, and includes *delivery services*, *direct-from-garden operations*, *growing co-ops*, and *storefront operations*.

Growing co-op means a distribution operation that consists of a group of compliant individuals who grow cannabis collectively on property belonging to, leased or rented by, or otherwise authorized for use by the entire group, or by a member of the group, or who cooperatively produce cannabis-derived product for use by members of the group.

Hemp means any part of a plant in the genus *Cannabis*, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 (three-tenths) percent on a dry weight basis.

Manufacture means to make or otherwise produce cannabis-derived product. A person, group of persons, or business entity that manufactures is a *manufacturer*, and a facility where manufacture occurs is a *manufacturing operation*.

May is used to indicate an action or activity that is permitted; *may not* is used to indicate an action or activity that is not permitted.

Must is used to state a requirement.

Oral cannabis or *edible* means cannabis or cannabis-derived product that is ingested through the mouth and into the digestive system.

Process means to inspect, grade, package, label, or otherwise prepare cannabis prior to providing to compliant individuals, and does not mean to manufacture. A person, group of persons, or business entity that processes is a *processor*, and the facility where the described processes occur is a *processing operation*.

Provide means to offer for sale or to sell, including by barter, cannabis or cannabis-derived product to compliant individuals.

Should is used to state recommended or advisory procedures.

Smoked cannabis means cannabis or cannabis-derived product that is burned and inhaled into the lungs.

Storefront operation means a distribution operation that provides cannabis or cannabis-derived product to compliant individuals at a physical location.

Topical cannabis or *topical* means a cannabis-derived product intended to be rubbed on the skin and not intended for oral consumption.

Vaporized cannabis means cannabis or a cannabis-derived product that is heated to a temperature at which the contained constituents are released into a vapor without combustion of the material.

Vendor means a person, group of persons, or business entity that supplies cannabis or cannabis-derived product to storefront or delivery service distribution operations, and may be either the direct representative of a cultivation, processing, or manufacturing operation, or may function independently of such operations by purchasing cannabis or cannabis-derived product from such operations and reselling it to distribution operations.

SUBPART B – DISTRIBUTION OPERATIONS

Section 2.1 Types of distribution operations

(a) Except as provided by paragraph (c) of this section, cannabis or cannabis-derived product may be provided by any of the following types of distribution operations, as defined in section 1.3, that are in compliance this part:
- (1) Storefront operations, which may also operate a delivery service operation from the same physical location;
- (2) Delivery service operations, which may operate either with or without a storefront operation; and
- (3) Direct-from-garden operations, which may:
  - (i) Operate either with or without a storefront operation; and
  - (ii) Be located either at the same location as cultivation occurs, or at another location.
- (4) Growing co-op operations.

(b) Distribution operations may provide:
- (1) Cannabis that is cultivated by:
  - (i) The distribution operation itself;
  - (ii) A co-owned cultivation operation; or
  - (iii) A cultivation operation that is not co-owned, which may be obtained by the distribution operation either:
    - (A) Directly from the cultivation operation; or
    - (B) From a vendor of the cannabis;
- (2) Cannabis-derived product that is manufactured by:
  - (i) The distribution operation itself;
  - (ii) A co-owned manufacturing operation; or
  - (iii) A manufacturing operation that is not co-owned, which may be obtained by the distribution operation either:
    - (A) Directly from the manufacturing operation; or
    - (B) From a vendor of the cannabis-derived product.

(c) Notwithstanding paragraph (a) of this section, distribution operations must be in compliance with all other legal requirements in the jurisdiction where this part applies.

Section 2.2 Ancillary operations

(a) In addition to providing cannabis or cannabis-derived product, a distribution operation described in section 2.1 may also engage in other operations, including:
- (1) Cultivation of cannabis;

(2) Processing, packaging and labeling of cannabis;
(3) Manufacturing, packaging, and labeling of cannabis-derived product;
(4) Laboratory operations; and
(5) Sale and marketing of products other than cannabis or cannabis-derived product.

(b) The ancillary operations identified in section 2.2(a) may be conducted:
(1) At the same location as providing cannabis or cannabis-derived product, so long as such operations are permitted at this location in the jurisdiction in which this part applies; or
(2) At another location at which such operations are permitted in the jurisdiction in which this part applies.

(c) The ancillary operations identified in section 2.2(a) must be conducted in compliance with all regulations relevant to such operations in the jurisdiction in which this part applies.

Section 2.3 Personnel

(a) All distribution operation employees must have the education, training, or experience to perform all assigned functions.

(b) Distribution operations must:
(1) Provide employees who have any assigned functions that involve providing compliant individuals with cannabis or cannabis-derived product with training that includes:
(i) Specific uses of cannabis or a specific cannabis-derived product;
(ii) Clinical application of the specific constituents of cannabis;
(iii) The laws, regulations, and policies relevant to providing cannabis or cannabis-derived product to compliant individuals in the jurisdiction where this part applies.
(2) Provide all employees with training on the U.S. federal laws, regulations, and policies relating to individuals employed in distribution operations, and the implications of these for employees and for compliant individuals; and

(c) Distribution operations should:
(1) Provide all employees with training that includes instructions regarding regulatory inspection preparedness and law-enforcement interactions; and
(2) Maintain a mechanism for communicating with all employees.

(d) Storefront operations should be prepared to administer cardiopulmonary resuscitation (CPR) at all times during which the operation is open for business. To do so, the operation should:
(1) Ensure that one or more employee has received adequate training to be capable of performing CPR;
(2) Schedule personnel to ensure that one such CPR-trained employee is on the premises at all times during which the operation is open for business.

Section 2.4 Physical facilities

(a) Physical facilities of distribution operations must:
(1) Be operated in adherence with any regulation in the jurisdiction in which this part applies that is relevant to its specific operations, including:

(i) Locations and zoning, which can vary depending upon the specific operation or operations undertaken at each facility.
(ii) Business hours;
(iii) Parking;
(iv) Drive-through services; and
(v) Signage;

(2) Be maintained in a clean and orderly condition;
(3) Be equipped with such utensils and equipment as are necessary to conduct all operations, including ancillary operations as described in section 2.2 of this part, that occur at the facility;
(4) Implement policies that ensure the privacy of financial transactions; and
(5) Have information available to compliant individuals regarding local and federal laws on cannabis possession.

(b) Physical facilities of distribution operations should:
(1) Provide and use adequate refrigeration if it stores cannabis-derived product, as needed to ensure the safety of products that require refrigeration and to reduce spoilage;
(2) Provide and use a secure area for storage of cannabis or cannabis-derived product in inventory; and
(3) Provide and use a secure area to keep money that is needed to be kept at the facility, and remove money from the facility on a regular basis.

(c) Storefront operations must:
(1) Maintain Americans with Disabilities Act (ADA) compliance;
(2) Establish a policy regarding on-site consumption of cannabis or cannabis-derived product, except that, if a statutory or regulatory requirement exists in the location of the operation with regard to this practice, the operations must comply with such requirement. Any voluntary on-site consumption policy should address:
(i) The type or types of consumption allowed (e.g., eating; smoking; vaporizing; or topical application);
(ii) A limit on the amount of time that can be spent in on-site consumption if such a time limit is advisable;
(iii) A ventilation plan, if needed;
(iv) A protocol to prevent and to address a compliant individual who is or becomes over-medicated;
(v) Additional issues as needed.

Section 2.5 Security

(a) Distribution operations must provide any security that is required by regulation[2] for the specific operation and each facility it operates.

(b) Distribution operations should:
(1) Provide additional security as needed and in a manner that reflects the community where it operates, and should include, as necessary:
(i) For storefront operations:

[2] It may be desirable to state any such regulation in this section.

(A) In-store security personnel in sufficient number to ensure the safety of staff and served compliant individuals;
(B) In-store security cameras; and
(C) Monitoring of dedicated parking, if any, either with security personnel or with security cameras.

(ii) For delivery service operations:
(A) Security personnel at the facility where product is acquired, stored, or processed in sufficient number to ensure the safety of staff and security of all cannabis and cannabis-derived product on site.
(B) Training for delivery staff to ensure awareness of how to maintain personal and product safety and to provide contact information to police or other emergency personnel.
(C) Restriction of deliveries only to a private address and never to a public location.
(D) Compliance with local regulations regarding delivery areas and hours of operation.

(iii) For direct-from-garden and growing co-op operations:
(A) Security practices at the growing facility, and at associated locations where cannabis or cannabis-derived product or money are kept or from which money or cannabis or cannabis-derived product is transferred, sufficient to ensure the safety of staff and security of cannabis on site.

(2) Refrain from arming security personnel, except as allowed and in full compliance with all relevant legal requirements in the jurisdiction in which this part applies; and
(3) Provide training to make all staff aware of the operation's security procedures, and each individual employee's security roles and responsibilities.

(c) Distribution operations that are also engaged in cultivation, processing, or manufacturing operations must also comply with all security measures required for such operations, and should also establish and implement any relevant security measures recommended for such operations.

SUBPART C – CANNABIS PRODUCT

Section 3.1 Subject cannabis products

(a) Distribution operations that are subject to this part may provide cannabis and cannabis-derived product that meet any of the following definitions, as stated in section 1.3, and that are intended to be consumed consistent with these definitions:
(1) Smoked cannabis;
(2) Vaporized cannabis;
(3) Oral cannabis (edibles); and
(4) Topical cannabis (topicals).

(b) Each distribution operation must keep an up-to-date record of the cannabis and cannabis-derived product it provides, including:

(1) Identification of the cannabis and cannabis-derived product it provides, as described in section 3.1 (a)(1)-(a)(4);
(2) Information to indicate whether each cannabis or cannabis-derived product it offers to compliant individuals is provided or produced by a co-owned operation, or from an operation that is not co-owned;
(3) For cannabis and cannabis-derived product obtained from an operation that is not co-owned:
    (i) If obtained directly from a cultivation, processing, or manufacturing operation, the identity of the operation; or
    (ii) If obtained from a vendor, the identity of the vendor;
(4) Restrictions, if any, on providing any specific cannabis or cannabis-derived product to compliant individuals, such as, for example:
    (i) Limitations as to employees who may, or who may not, provide the specific cannabis or cannabis-derived product to compliant individuals;
    (ii) Limitations as to compliant individuals who may, or who may not, obtain the specific cannabis or cannabis-derived product.

Section 3.2 Cannabis product acquisition

(a) Distribution operations that receive cannabis or cannabis-derived product from one or more cultivation, processing, or manufacturing operation, or from one or more vendor, should establish and implement policies for acquisition of such cannabis or cannabis-derived product, including policies on:
(1) Locations for receipt of cannabis or cannabis-derived product;
(2) Scheduling of deliveries, which may be made either:
    (i) By scheduling appointments with specific vendors; or
    (ii) By establishing open vending times, during which any vendor may make a delivery without a specific appointment.
(3) Any policies required of cultivation, processing, or manufacturing operations, or of vendors, if any, with regard to:
    (i) Cultivation practices;
    (ii) Processing or manufacturing;
    (iii) Packaging or labeling;
    (iv) Chemical analysis; or
    (v) Transport conditions, such as refrigeration.
(5) In establishing and implementing policies to comply with this section 3.2 (a) of this part, distribution operations must ensure that all such policies conform to all relevant legal requirements in the jurisdiction in which this part applies.

(b) Distribution operations that receive cannabis or cannabis-derived product from one or more cultivation, processing, or manufacturing operations, or from one or more vendor must:
(1) Record each receipt of cannabis and cannabis-derived product, such record to include:
    (i) The name of the cultivation, processing, or manufacturing operation, or of the vendor;
    (ii) A description of the cannabis or cannabis-derived product of sufficient specificity; and

(iii) A statement of the quantity of each cannabis or cannabis-derived product.

(2) If the operation is a storefront, minimize deliveries at times and in locations where compliant individuals are present, if space allows.

(3) Inform all cultivation, processing, and manufacturing operations and all vendors of the policies established in compliance with paragraph (a) of this section, and of the requirements set forth in paragraph (b) of this section.

Section 3.3 Cannabis product information

(a) Information provided by a distribution operation, whether written or verbal, about the identity, quality, and cultivation conditions of cannabis it provides must be accurate.

(b) A distribution operation must disclose the extent and type of testing it conducts, or causes to have conducted, on the cannabis it provides, including:

(1) The type of test or examination used, if any, to determine the particular strain or cultivar of each lot of cannabis provided;

(2) Whether or not the cannabis provided is tested to determined the quantitative levels of contained constituents, and if so, the type of testing used;

(3) Whether or not the cannabis provided is tested to determine the absence or presence of specific classes of potential contaminants, and if so, the type of testing used. The information required by this paragraph must be disclosed for each of the following:

(i) Pesticides;

(ii) Yeasts and molds; and

(iii) Other microbiological contaminants.

(4) The information required to be disclosed by this paragraph must be made available:

(i) At each physical facility maintained by a storefront distribution operation, either:

(A) With posted and readily visible signage; or

(B) With printed handouts that are provided to each compliant individual prior to purchase of any cannabis.

(ii) On any website at which cannabis or cannabis-derived products are available for ordering by or sale to compliant individuals, by posting the information so that compliant individuals will see the information prior to ordering and purchasing.

(c) Information provided by a distribution operation about cannabis-derived product it provides must:

(1) Be provided in whatever manner is required in the jurisdiction in which this part applies, whether with labeling or with other markings, or with other written or verbal information;

(2) Be accurately conveyed:

(i) If manufactured by a co-owned operation, through labeling or other accurate markings or communications, in a manner that complies with all relevant requirements; or

(ii) If manufactured by another person or business entity, by providing the information as provided by each product's manufacturer, such that the

distribution operation may not modify the labeling or other information provided by such product's manufacturer.

(3) In the event that a distribution operation has reason to believe that the information provided by the manufacturer of a cannabis-derived product is not accurate, the distribution operation must seek clarification or correction of any such information.

Section 3.4 Cannabis product recalls

(a) Each distribution operation must establish a policy for communicating a recall of a cannabis or cannabis-derived product that has been shown to present a reasonable or a remote probability that the use of or exposure to the product will cause serious adverse health consequences, or could cause temporary or medically reversible adverse health consequences. This policy should include:

(1) A mechanism to contact all customers who have, or could have, obtained the product from the distribution operation, which communication must include information on the policy for return or destruction of the recalled product;

(2) A mechanism to contact the cultivation, processing, or manufacturing operation, or the vendor which supplied the product to the distribution operation; and

(3) Communication and outreach via media, as necessary and appropriate.

(b) Any recalled cannabis or cannabis-derived product that is returned to a distribution operation must either:

(1) Be disposed of by the distribution operation in manner that ensures that it cannot be salvaged and will not be used by a compliant individual or by any other person; or

(2) Be returned to its cultivator, processor, or manufacturer for such disposal.

SUBPART D – COMPLIANT INDIVIDUALS

Section 4.1 Requirements for purchase

(a) Distribution operations may provide cannabis or cannabis-derived product only to compliant individuals and may not provide cannabis or cannabis-derived product to any other person.

(b) If any restrictions exist by statute or regulation in the jurisdiction in which this part applies on the health or medical conditions for which cannabis or cannabis-derived product can be recommended, distribution operations may not recommend use of any cannabis or cannabis-derived product for any other condition.

(c) Distribution operation employees who have any assigned functions that involve providing compliant individuals with cannabis or cannabis-derived product must be aware of the legal requirements for becoming a compliant individual.

(d) Distribution operations must make available information on the regulations that apply in the jurisdiction in which this part applies to obtaining and maintaining status as a compliant individual.

Section 4.2 Purchase limits

(a) Quantitative limitations on the amount of cannabis or cannabis-derived product obtained by a compliant individual in any given timeframe:

(1) Must be enforced by a distribution operation in conformity with any statutory or regulatory restriction, if any exists in the jurisdiction in which this part applies;

(2) May be established by a distribution operation in the absence of any statutory or regulatory limitation; and

(3) Should be clearly communicated to compliant individuals.

Section 4.3 Personal information

(a) Distribution operations should obtain identifying information for each compliant individual to whom cannabis or cannabis-derived product is provided, including:

(1) The individual's name;

(2) Contact information of sufficient specificity to serve as a means of contact, such as a phone number, email address, or mailing address;

(3) A physician of record identified by the compliant individual; and

(4) Health or medical conditions for which cannabis or cannabis-derived product is used.

(b) All identifying information obtained about any compliant individual must be obtained and stored in compliance the privacy and security rules of the Health Insurance Portability and Accountability Act (HIPPA).[3]

Section 4.4 Adverse event records

(a) Distribution operations should establish a policy for receiving and recording adverse event reports associated with use of the cannabis or cannabis-derived products it provides. Such policy should include:

(1) Identification of the minimum data elements to record for any adverse event report, which could include:

(i) An identifiable individual who is reported to have experienced the adverse event;

(ii) An initial reporter, who may be the same as the identifiable individual or another person;

(iii) The identity of the specific cannabis or cannabis-derived product used, if known; and

(iv) A description of the adverse event.

(2) A procedure for determining if an adverse event should:

(i) Be reported to any public health authority;

(ii) Be reported to the physician of record for the compliant individual reported to have experienced the adverse event, if known;

(iii) Require a product recall.

(3) Procedures for communicating the policy to:

(i) Employees of the distribution operation with task assignments that require knowledge of the policy; and

[3] These can be found at http://www.hhs.gov/ocr/privacy.

(ii) Compliant individuals who are provided with cannabis or cannabis-derived products by the distribution operation.

(b) For purposes of this section, an adverse event is a health-related event associated with use of cannabis or a cannabis-derived product that is adverse, and that is unexpected or unusual.

(c) For purposes of this section, an adverse event report recorded under a policy established by a distribution operation may not be construed as an admission or as evidence that the cannabis or cannabis-derived product involved caused or contributed to the adverse event.

Section 4.5 Rights and responsibilities of compliant individuals

(a) Each distribution operation should establish a policy that describes the rights and responsibilities of compliant individuals who obtain cannabis or cannabis-derived products from the distribution operation. Such policy should include:

(1) How compliant individuals can expect to be treated by employees of the distribution operation;

(2) Information that each compliant individual will be required or requested to provide to the distribution operation;

(3) A procedure for providing feedback and suggestions, including procedures for communicating commendations and complaints;

(4) Contact information for the distribution operation, and for specific employees for a compliant individual to contact;

(4) Hours of operation; and

(5) The distribution operation's policies related to:

(i) Payment for cannabis and cannabis-derived products;

(ii) Use of cannabis and cannabis-derived product on the premises;

(c) Any other applicable policies.