

Recommendations for Regulators – Cannabis Operations

Developed by:
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This document includes the following Recommendations for Regulators:

- Dispensing Operations

Introduction

The legal status of products derived from *Cannabis* spp. is in a transitional phase in many states in the United States. Where products that contain marijuana and its derivatives were formally illegal throughout the U.S., many state laws now allow adult use of these either for medical purposes only or for any adult personal use.

The American Herbal Products Association (AHPA) chartered a Cannabis Committee in 2010 with an express purpose to address issues related to the safe use and responsible commerce of legally-marketed products derived from *Cannabis* species.

To meet its purpose the AHPA Cannabis Committee has developed recommendations to regulators for best practice rules to address four operational stages of *Cannabis* production and distribution: cultivation; manufacturing and related operations; laboratory practice; and dispensing.

This document is specific to the area of Cannabis Dispensing Operations, and is presented in the form of a draft regulation. These recommendations establish a basis for oversight of entities that provide marijuana products directly to compliant consumers. These recommendations focus on personnel, security, product acquisition, record keeping, customer policies, and other matters that can contribute to best practice in the dispensary setting.

This Revision 4 of the document incorporates minor editorial changes to definitions and clarifies the definition of hemp. It incorporates new recommendations for the establishment of quality control systems. Other minor revisions and clarifications have been added throughout the document.

The AHPA Cannabis Committee offers this document to states and local municipalities where use of marijuana is allowed under local law such that regulatory authorities can consider the adoption of these recommendations, in whole or in part, as the basis for development of jurisdiction-specific regulations.

Please contact AHPA for further information or to discuss this document further.

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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, non-profit entity, or business entity that provides cannabis or cannabis-derived product to compliant individuals in the jurisdiction in which this part applies¹ is engaged in a cannabis dispensing operation², 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 dispensing operation and is not subject to this part.

Section 1.2 Other statutory provisions and regulations

In addition to this part, dispensing 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 dispensing operation.

Section 1.3 Definitions

The following definitions apply to this part:

Adverse event means a health-related event associated with use of cannabis or a cannabis-derived product that is adverse, and that is unexpected or unusual.

Cannabis means any of the aerial parts of a plant in the genus *Cannabis*, and does not mean hemp.

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

Compliant individual means an individual 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 or manufacturing operation that has the same ownership as a dispensing operation.

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

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

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

¹ This term “in the jurisdiction where this part applies” may be replaced throughout with the name of the specific jurisdiction.

² It is noted that different jurisdictions may have other terminology for the type of operation that is defined as a dispensing operation in this document.

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Dispense means to provide cannabis or cannabis-derived product to compliant individuals.

Dispensing operation means a person, group of persons, non-profit entity, 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 operations².

Growing co-op means a dispensing 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 an effective yield of not more than 0.3 (three-tenths) percent delta-9 tetrahydrocannabinol on a dry weight basis³.

Manufacture means to compound, blend, grind, extract, or otherwise make or prepare cannabis-derived product. A person, group of persons, non-profit entity, 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.

Process (verb) means to trim, inspect, grade, or pack cannabis. A person, group of persons, non-profit entity, or business entity that processes is a *processor*, and a facility where cannabis is processed 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 dispensing 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.

³ The term "hemp" is intended to be consistent with the exclusions provided in the Controlled Substances Act definition of "marijuana", specifically the following: Such term does not include the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination.

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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.

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

SUBPART B – DISPENSING OPERATIONS

Section 2.1 Types of dispensing 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 dispensing operations, as defined in section 1.3, that are in compliance with 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) Dispensing operations may provide:
- (1) Cannabis that is cultivated by:
 - (i) The dispensing operation itself;
 - (ii) A co-owned cultivation operation; or
 - (iii) A cultivation operation that is not co-owned, which may be obtained by the dispensing 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 dispensing operation itself;
 - (ii) A co-owned manufacturing operation; or
 - (iii) A manufacturing operation that is not co-owned, which may be obtained by the dispensing 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, dispensing operations must be in compliance with all other legal requirements in the jurisdiction where this part applies.

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Section 2.2 Ancillary operations

- (a) In addition to providing cannabis or cannabis-derived product, a dispensing operation described in section 2.1 may also engage in other operations, including:
 - (1) Cultivation of cannabis;
 - (2) Manufacturing, packaging, holding, and labeling of cannabis-derived product;
 - (3) Laboratory operations; and
 - (4) 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 dispensing operation employees must have the education, training, or experience to perform all assigned functions.
- (b) Dispensing operations must provide employees who have any assigned functions that involve providing compliant individuals with cannabis or cannabis-derived product with training that includes:
 - (1) Appropriate consumption guidelines for products containing multiple doses or servings;
 - (2) The laws, regulations, and policies relevant to providing cannabis or cannabis-derived product to compliant individuals in the jurisdiction where this part applies.
- (c) Dispensing operations should provide all employees with training that includes:
 - (1) Responsible use guidelines, such as storage around children and pets;
 - (2) Instructions regarding regulatory inspection preparedness and law-enforcement interactions; and
 - (3) Information on applicable local, state, and U.S. federal laws, regulations, and policies relating to individuals employed in dispensing operations, and the implications of these for employees and for compliant individuals.
- (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.
- (e) Dispensing operations should assign one or more qualified personnel to oversee quality control procedures. Each of these personnel must be qualified by education, training, or experience to develop and implement quality control procedures.

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Section 2.4 Physical facilities

- (a) Physical facilities of dispensing 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 dispensing operations should:
- (1) Provide and use appropriate storage conditions to protect the physical and chemical integrity of cannabis and cannabis-derived product, as needed;
 - (2) Establish policies or procedures to document facility cleaning practices;
 - (3) Design operational areas to minimize the risk of contamination or adulteration.
 - (4) Provide and use a secure area for storage of cannabis or cannabis-derived product in inventory; and
 - (5) Provide and use a secure area to manage financial transactions.
- (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) Dispensing operations must establish and adhere to such security procedures as are provided by applicable regulation in the jurisdiction in which this part applies.

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- (b) Dispensing operations should:
 - (1) Provide additional security as needed and in a manner appropriate for the community where it operates, and should include, as necessary:
 - (i) For storefront operations:
 - (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 at the facility where product is acquired, stored, or processed 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) Dispensing operations that are also engaged in cultivation 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.

Section 2.6 Quality systems

- (a) Dispensing operations must establish a quality system sufficient to ensure that all cannabis and cannabis-derived products supplied by the operation comply with established specifications.
- (b) The quality system must include a process for the creation and maintenance of product specifications.
- (c) A system for reporting any non-conformance to quality control personnel should be established.

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SUBPART C – CANNABIS PRODUCT

Section 3.1 Subject cannabis products

- (a) Dispensing operations that are subject to this part may provide cannabis and cannabis-derived product including, but not limited to the following:
 - (1) Smoked cannabis;
 - (2) Vaporized cannabis;
 - (3) Oral cannabis (edibles); and
 - (4) Topical cannabis (topicals).
- (b) Each dispensing 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);
 - (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 is 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 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 inventory control

- (a) Dispensing operations that receive cannabis or cannabis-derived product from one or more cultivation, processing, or manufacturing operations, or from one or more vendors, 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) Manufacturing;
 - (iii) Packaging or labeling;
 - (iv) Chemical analysis; or
 - (v) Transport conditions, such as environmental control;

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- (4) Quality control procedures for the acceptance of cannabis and cannabis-derived products.
- (b) Dispensing operations must establish intake procedures for cannabis and cannabis-derived products.
 - (1) A process for reviewing relevant documentation and test results prior to dispensing to compliant individuals should be established.
 - (2) Cannabis and cannabis-derived products meeting specifications and requirements may be released for dispensing.
 - (3) Cannabis and cannabis-derived products not meeting specifications and requirements may not be released for dispensing. An indication of rejection should be placed on the cannabis.
- (c) Dispensing operations that receive cannabis or cannabis-derived product from one or more cultivation or manufacturing operations, or from one or more vendors must:
 - (1) Record each receipt of cannabis and cannabis-derived product, such record to include:
 - (i) The name or other unique identifier (if required) of the cultivation or manufacturing operation, or of the vendor;
 - (ii) An appropriately complete and specific description of the cannabis or cannabis-derived product;
 - (iii) Quality control procedures performed on the cannabis or cannabis-derived product to ensure it meets product specifications prior to its release for use; and
 - (iv) 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 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.
 - (4) Record the amount of cannabis or cannabis-derived product provided to compliant individuals.
 - (5) Record the amount of cannabis or cannabis-derived product that is disposed of by the dispensing operation for any reason.
 - (6) Any other information required by the jurisdiction in which the dispensing operation is located.

Section 3.3 Cannabis product information

- (a) Information provided by a dispensing operation, whether written or verbal, about the identity, quality, and cultivation conditions of cannabis it provides must accurately reflect information provided by the cultivation operation.
- (b) A dispensing operation must disclose the extent and type of testing it conducts, or causes to have conducted, on the cannabis it provides, including, but not limited to:
 - (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 determine the quantitative levels of contained constituents, such as individual cannabinoids and terpenes, and if so, the type of testing used;

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- (3) Any tests to determine the absence or presence of specific classes of potential contaminants, and if so, the type of testing used. This information must be disclosed for each of the following:
 - (i) Common or known pesticides;
 - (ii) Yeasts and molds;
 - (iii) Other microbiological contaminants; and
 - (iv) Heavy metals.
- (c) Information provided by a dispensing 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 dispensing operation may not modify the labeling or other information provided by such product's manufacturer.
 - (3) In the event that a dispensing operation has reason to believe that the information provided by the manufacturer of a cannabis-derived product is not accurate, the dispensing operation must seek clarification or correction of any such information.
- (d) A dispensing operation must disclose the extent and type of testing it conducts, or causes to have conducted, on the cannabis-derived product it provides, including, but not limited to the quantitative levels of contained constituents, and if so, the type of testing used.
- (e) The information required to be disclosed by this paragraph must be made available:
 - (1) At each physical facility maintained by a storefront dispensing operation, either:
 - (i) With posted and readily visible signage; or
 - (ii) With printed handouts that are provided to each compliant individual prior to purchase of any cannabis.
 - (2) 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.
- (f) A dispensing operation should provide information or guidance on responsible use of cannabis and cannabis-derived products through signage or other appropriate means.

Section 3.4 Cannabis product recalls

- (a) Each dispensing operation must establish a policy for communicating a recall of a cannabis or cannabis-derived product that has been shown to present a probability that the use of or exposure to the product will cause serious adverse health

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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 dispensing operation, which communication must include information on the policy for return or proper disposal of the recalled product;
 - (2) A mechanism to contact the cultivation or manufacturing operation, or the vendor which supplied the product to the dispensing 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 dispensing operation must either:
- (1) Be disposed of by the dispensing 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 or manufacturer for such disposal.
- (c) Dispensing operations should periodically conduct a mock recall to assess the effectiveness of the recall plan.

SUBPART D – COMPLIANT INDIVIDUALS

Section 4.1 Requirements for purchase

- (a) Dispensing 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) Dispensing 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.
- (c) Dispensing 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 dispensing 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 dispensing 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) Dispensing operations should obtain identifying information for each compliant individual to whom cannabis or cannabis-derived product is provided, including:
 - (1) The individual's name;

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- (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 with the privacy and security rules of the Health Insurance Portability and Accountability Act (HIPAA).⁴

Section 4.4 Adverse event records

- (a) Dispensing operations must 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 dispensing operation with task assignments that require knowledge of the policy; and
 - (ii) Compliant individuals who are provided with cannabis or cannabis-derived products by the dispensing operation.
- (b) For purposes of this section, an adverse event report recorded under a policy established by a dispensing 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 dispensing operation should establish a policy that describes the rights and responsibilities of compliant individuals who obtain cannabis or cannabis-derived products from the dispensing operation. Such policy should include:
- (1) How compliant individuals can expect to be treated by employees of the dispensing operation;
 - (2) Information that each compliant individual will be required or requested to provide to the dispensing operation;

⁴ These can be found at <http://www.hhs.gov/ocr/privacy>.

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- (3) A procedure for providing feedback and suggestions, including procedures for communicating commendations and complaints;
- (4) Contact information for the dispensing operation, and for specific employees for a compliant individual to contact;
- (5) Hours of operation; and
- (6) The dispensing operation's policies related to:
 - (i) Payment for cannabis and cannabis-derived products;
 - (ii) Use of cannabis and cannabis-derived product on the premises;
 - (iii) Return of cannabis or cannabis-derived products;
 - (iv) Any other applicable policies.