

- (c) The designated employees transporting marijuana and manufactured marijuana products shall not stop at a location not listed on the manifest.
- (d) The dispensary licensee shall transport marijuana and manufactured marijuana products using routes that reduce the possibility of theft or diversion.
- (e) A dispensary licensee shall not transport marijuana or manufactured marijuana products:
  - (1) Off site to qualifying patients or to primary caregivers;
  - (2) To another county or another island within the same county; or
- (3) To, from, or within any federal fort or arsenal, national park or forest, any other federal enclave, or any other property possessed or occupied by the federal government.

BioTrackTHC provides functionality for Cultivators, Processors and Dispensary Licensees to create transfer manifest documents. Transfer manifests will be stored and tracked by the System. Input data may include, but is not limited to, the following fields: ship from name, license number and route description. For each item include destination address, destination name, license number, address, product description, product ID and lot number, quantity and units of measure. Transfer manifests will be used as shipping documents for transfers between locations within an organization or sales between Licensees.

(b) A dispensary licensee shall give the department access to all parts of the dispensary property, equipment, records, documents, and any other substance, material, or information relevant to ensure the dispensary licensee's compliance with this chapter, upon request.

BioTrackTHC™ enables the business to collect, store, and retrieve all data and activity -- with respect to inventory transfers, inventory-tracking records, supplier records, patient records, client-records, employee records, recall reports, quarantine and waste reporting, sales/transaction records, disposal records, and all scanned documents -- at any time, in real time, either in-system or through the report creation tool.

§11-850-38 Reports.

(a) A dispensary licensee shall submit quarterly reports on January 15, April 15, July 15, and October 15.

If the due date for submitting a quarterly report falls on a Saturday, Sunday, or State holiday, the report will be on time if it is submitted on the next day that is not a Saturday, Sunday, or State holiday. Reports shall be submitted on a form and in a manner prescribed by the department.

- (b) Reports shall include but not be limited to:
  - 1. Records of entry and exit for all individuals who entered a dispensary facility;



- 2. Amounts by category of marijuana produced and manufactured marijuana products manufactured and offered for sale;
- 3. Amounts by category of marijuana and manufactured marijuana products sold;
- 4. A list of all marijuana, manufactured marijuana products, or unusable marijuana materials that have been destroyed or will be destroyed;
- 5. A summary financial statement;
- 6. Laboratory results of all tests conducted;
- 7. Description of any breach or halt in its security system and tracking system; and
- 8. Any other information requested by the department.

BioTrackTHC™ enables the business to collect, store, and retrieve all data and activity -- with respect to inventory transfers, inventory-tracking records, supplier records, patient records, client-records, employee records, recall reports, quarantine and waste reporting, sales/transaction records, disposal records, and all scanned documents -- at any time, in real time, either in-system or through the report creation tool.

§11-850-39 Audits

- (a) A dispensary licensee shall obtain an independent financial audit annually, at the dispensary licensee's expense, and shall provide a copy of the audit's findings to the department.
- (b) The report shall be completed and submitted to the department no later than sixty days prior to the end of the license expiration date, or at another time as the department may direct.
- (c) When a license is revoked, suspended, surrendered, or expires, a dispensary licensee shall file a final report thirty days following revocation, suspension, surrender, or expiration.

In the course of doing business, a user can perform inventory audits to confirm or adjust what's showing in your inventory and what the user actually has on hand. After clicking on the Inventory Audit Icon a list will populate showing all of the items for inventory in the current inventory room. If the user wishes to run a "Blind Audit" this will prevent the employee from seeing the original weights or any differences. The Inventory Shrinkage report allows you to total loss across various products for a given time period with a threshold to ignore adjustments outside of a certain increment (mistakes).

## §11-850-41 Record retention.

- (a) A dispensary licensee shall retain for a minimum of six years business operation records including but not limited to:
  - (1) Inventory tracking including transport of marijuana and manufactured marijuana products;



- (2) Sales and compliance with dispensing limitations for each qualifying patient and primary caregiver;
- (3) Financial records including income, expenses, bank deposits and withdrawals, and audit reports;
  - (4) Logs of entry and exit for dispensary facilities; and
  - (5) Employee records.
- (b) A dispensary licensee shall retain for a minimum of one year all security recordings.

BioTrackTHC™ enables the business to collect, store, and retrieve all data and activity. All inventory records, patient records, recall reports, sales/transaction records, product disposal records, and all scanned documents can be accessed at any time (real time), either in-system or through the report creation tool. Though system actions can be adjusted or voided, at no time is any data ever fully deleted as BioTrackTHC™ maintains a log of every action, including adjustments and voids, so that the entire history of the system may be reconstructed. The availability and report ability of the system data enables the said entity to produce any information necessary for the Department during an inspection or at the Department's request.

## §11-850-42 Allowed quantities for dispensing.

- (a) A dispensary licensee may dispense to a qualifying patient or primary caregiver any combination of marijuana or manufactured marijuana products that shall not exceed four ounces of marijuana during a period of fifteen consecutive days, and shall not exceed eight ounces of marijuana during a period of thirty consecutive days.
- (b) Consistent with section 11-850-61, a dispensary licensee shall determine the quantity of marijuana or manufactured marijuana products purchased by a qualifying patient or primary caregiver from any other licensed dispensary within the state and shall not sell any amount of marijuana or manufactured marijuana products to that qualifying patient or primary caregiver of a qualifying patient that exceeds the limits identified in this chapter.

Within "Sales Limits" a user can regulate the permissible quantities allotted to a patient or caregiver.

# §11-850-43 <u>Disposal or destruction.</u>

(a) A dispensary licensee or laboratory certified by the department to test marijuana and manufactured marijuana products shall dispose of or destroy unused, unsold, contaminated, or expired marijuana or manufactured marijuana products, or waste products resulting from the



cultivating or manufacturing process, including any inventory existing at the time of revocation or surrender of a license, in a way that assures that the marijuana or manufactured marijuana product does not become available to unauthorized persons and is documented as subtracted from inventory.

- (b) A dispensary licensee shall destroy or dispose of unused, unsold, contaminated, or expired marijuana or manufactured marijuana products by a means prescribed by the department or the department of public safety narcotics enforcement division administrator.
- (c) A dispensary licensee shall establish written policies and procedures to be followed by all of its employees for the disposal or destruction of unused, unsold, contaminated, or expired marijuana and manufactured marijuana products.

During or after a Harvest or Cure, a user would create a batch for the "green waste" which would include broad leaf trim, and stems that weren't going to be converted into a concentrated format. All waste would be weighed, given it's own 16-digit barcode, which is permanently stored in the system prior to it being destroyed. When a BioTrackTHC user sends a sample for Quality Assurance testing and the sample does not meet minimum standards, a user may; 1) Place the product into quarantine for destruction, or, 2) Convert the product into a different format. If the user converts the non-conforming sample and originating lot, the new converted product must be retested.

# §11-850-61 Tracking requirements

- (a) A dispensary licensee shall track electronically the dispensary's inventory of marijuana and manufactured marijuana products through each stage of processing, from propagation to point of sale, disposal, or destruction, and maintain a record of clear and unbroken chain of custody at all stages, including during transport of the inventory between dispensary facilities and between a dispensary facility and a laboratory.
- (b) A dispensary licensee shall track electronically all sales of marijuana and manufactured marijuana products to qualified patients and primary caregivers from all dispensaries in the State, to ensure that no sales are authorized in excess of legal limits, as set out in section 3290-7, HRS, and shall have a sales system that automatically prohibits sales in excess of the legal limits and that cannot be overridden manually.
- (c) A dispensary licensee shall acquire, operate, and maintain a secure computer software tracking system that interfaces with the department's computer software tracking system to allow the department real time, twenty-four hour access to the dispensary licensee's tracking system and inventory records. The dispensary licensee's tracking system shall capture and report all the data required by the department's tracking system.



(d) In the event of a breach or failure of its tracking system, a dispensary licensee shall suspend operations dependent on the tracking system until the tracking system is fully operable. The dispensary licensee shall notify the department immediately upon the breach or failure, and again when it resumes operations.

BioTrackTHC™ enables the business to collect, store, and retrieve all data and activity -- with respect to inventory records, quality assurance/laboratory testing, supplier records, patient records, client-records, employee records, recall reports, quarantine and waste reporting, sales/transaction records, disposal records, and all scanned documents -- at any time, in real time, either in-system or through the report generation tool. The System is able to record transfers of small amounts of marijuana product to a laboratory for testing. Input may include fields including but not limited to: date of transfer, transferred by, order number, source license number, laboratory name, laboratory license number, and list of transferred products including product ID, product name, lot and/or batch number, and quantity. BioTrackTHC creates a 16 digit non-repeatable identifier for each plant. This identifier is printed onto a barcode that is affixed to the plant and will remain associated with this given plant throughout its lifecycle. A user can trace the lineage of any product all the way back to the plant from which it derived. Any action performed by an employee is stored within the system indefinitely and is searchable.

## PRODUCTS AND PRODUCT STANDARDS

# §11-850-71 <u>Marijuana.</u>

(a) A dispensary licensee may dispense marijuana only in the form of dried matured processed flowers of female cannabis plants.

## §11-850-72 Manufactured marijuana products.

(a) A dispensary licensee may manufacture marijuana products limited to capsules, lozenges, pills, oils and oil extracts, tinctures, ointments, and skin lotions.

# §11-850-74 Equivalent weights for manufactured marijuana products.

- (a) A dispensary licensee that produces manufactured marijuana products shall calculate the equivalent physical weight of the marijuana that is used to manufacture the product, and shall make available to the department and to consumers of the manufactured marijuana product the equivalency calculations and the formulas used.
- (b) A dispensary licensee shall include the equivalent physical weight of marijuana on the label of the products offered for sale.



BioTrackTHC is a complete inventory control system that also creates a searchable, secure, tamperevident record of each and every action performed within the system. The name and address of the recipient, the quantity delivered, and the product name, potency, batch number, and lot number of the product can all be recorded for each distribution.

## LABORATORY CERTIFICATION, TESTING, AND STANDARDS

# §11-850-81 Laboratory testing required.

A dispensary licensee shall not 'dispense marijuana or manufactured marijuana products unless a laboratory certified by the department pursuant to this chapter has tested the marijuana and manufactured marijuana products and they meet the requirements set out in this chapter.

# §11-850-85 Laboratory standards and testing

- (a) A certified laboratory shall test a statistically representative sample from each batch of marijuana or manufactured marijuana products. The dispensary licensee shall maintain in a secure tamper-proof manner a similar sample from the same batch, for verification testing as directed by the department.
- (a) A certified laboratory shall issue to the dispensary licensee and the department a certificate of analysis for each batch of marijuana and manufactured marijuana products tested for that dispensary; provided that a certified laboratory may only test and report on those things for which it is certified. The certificate of analysis shall include the results with supporting data for the following:
  - (1) The chemical profile of the batch for the following compounds:
    - (A) 9 (delta 9) Tetrahydrocannabinol (THC)
    - (B) Tetrahydrocannabinol Acid (THCA)
    - (C) Cannabidiol (CBD)
    - (D) Cannabidiolic Acid (CBDA)
    - (E) Cannabigerol (CBG)
    - (F) Cannabinol (CBN)
  - (2) The presence of the following contaminants, which shall not exceed the following levels:
  - (A) Heavy metals:
    - (i) Arsenic 10.0 ppm
    - (ii) Lead 6.0 ppm
    - (iii) Cadmium 4.0 ppm (iv) Mercury 2.0 ppm



- (B) Pesticides regulated by the U.S. Environmental
- Protection Agency: 1.0 ppm
- (C) Solvents:
  - (i) Butanes 800 ppm
  - (ii) Heptanes 500 ppm (iii) Benzene\*\* 1 ppm
  - (iv) Toluene\*\* 1 ppm (v) Hexane\*\* 10 ppm
  - (vi) Total Xylenes

(m,o,p-xylene) 1 ppm

- \*\* Contaminants in solvents
- (D) Any visible foreign or extraneous material, that is not intended to be part of the product being produced, including but not limited to mold, hair, insects, metal, or plastic;
  - (E) Moisture content of plant material <15%
  - (F) Microbiological impurities, including but not limited to:
    - 1. Total Viable Aerobic Bacteria:
      - a. Unprocessed and Processed Materials: 105 Colony Forming Unit (CFU)/g
      - b. C02 and Solvent Based Extracts: 104 CFU/g
    - 2. Total Yeast and Mold:
    - (a) Unprocessed and Processed Materials: 104 CFU/g
    - (b) C02 and Solvent Based Extracts: 103 CFU/g
- (iii) Total Coliforms:
  - (a) Unprocessed and Processed Materials: 103 CFU/g
  - (b) C02 and Solvent Based Extracts: 102 CFU/g
- (iv) Bile-tolerant Gram Negative Bacteria:
  - (a) Unprocessed and Processed Materials: 103 CFU/g
  - b) C02 and Solvent Based Extracts: 102 CFU/g
- (v) E. coli (pathogenic strains) and

Salmonella spp.: Not detected in

1 g

- (vi) Aspergillus fumigatus, Aspergillus flavus, Aspergillus niger : <1 CFU/g;
- (vii) Mycotoxins: <20 μg (micrograms) of any mycotoxin per kg of material; and
- (3) Additional testing requested at the discretion of the department.



The above information can all be generated within BioTrackTHC and reflected on the label for each product.

- (d) The certified laboratory may retest or reanalyze, the sample or a different sample from the same batch by following its standard operating procedure to confirm or refute the original result, upon request by the dispensary licensee or upon request by the department at the dispensary licensee's expense.
- (e) The certified laboratory shall return to the dispensary licensee or destroy in a manner approved by the department any samples or portions of samples of marijuana or manufactured marijuana products that remain after testing and analysis are completed.
- (f) A certified laboratory shall create, and maintain for a period of at least five years, records of testing it conducts on marijuana and manufactured marijuana products, including but not limited to:
  - 1. The time and date the sample was obtained;
  - 2. A description of the sample, including the amount;
  - 3. What tests were conducted on each sample;
  - 4. The results of the tests including the certificate of analysis; and
  - 5. Evidence of the time, date, and method of disposal or destruction of a sample after testing is completed, and the amount of sample disposed of or destroyed, or the time and date a sample was returned to a dispensary with a description including the amount;
  - 6. and shall make all the records available to the department upon request.
- (g) A dispensary licensee shall ensure that each sample is tested and analyzed for each of the items set out in subsection (c), and may obtain results from different laboratories for different items if a laboratory cannot perform all the tests.
- (h) A dispensary licensee shall maintain records of all laboratory testing results including the certificate of analysis.
- (i) The level of contaminants in marijuana and manufactured marijuana products shall not exceed the standards provided in subsection (c), and if any of the standards are exceeded, the dispensary licensee shall not dispense any portion of the batch of marijuana or manufactured marijuana product that does not conform to the standards.
- (j) A dispensary licensee shall destroy a batch that does not conform to the testing standards set out in subsection (c) as indicated by the certificate of analysis; provided that a dispensary licensee shall quarantine a non-conforming batch until any retesting pursuant to subsection (d) is completed, after which the dispensary licensee shall dispose of or destroy the batch if the results of retesting confirm that the batch is non-conforming. For purposes of this section, quarantine means that the batch shall be separated from all other inventory and the quarantine status shall be indicated in the tracking system. The quarantine shall be lifted only by the department, and only upon



receipt by the department of a certificate of analysis indicating that the batch conforms to the testing standards set out in subsection (c).

BioTrackTHC automatically syncs testing data upon receipt from a certified testing location. Testing will ensure the product is free of contaminants with consistent THC and/or CBD levels. Furthermore, every plant interaction is recorded, including but certainly not limited to what additives are used and when, allowing cultivators to replicate results or make applicable changes to increase plant quality and consistency. BioTrackTHC syncs testing data to the applicable plant batch or barcode for easy display and retrieval. To simplify the process that information can be directly ported onto the associated product labels.

All aspects of the marijuana plants, byproduct wastes, weights, ID numbers and associated data is stored in the system indefinitely. Destruction event information and explanations are also documented and stored within the BioTrackTHC system. This data cannot be modified or deleted by the cultivation center employees or even by BioTrackTHC.

BioTrackTHC records manual inventory adjustments through a detailed notes section. The reason for disposal and, if applicable, disposal company are recorded and archived to the 16 digit barcode associated with the disposed cannabis. As with all transactions in the BioTrackTHC system, the employee responsible for the transaction is required to enter a PIN number or biometric fingerprint recording the date, time, and reason for the transaction.

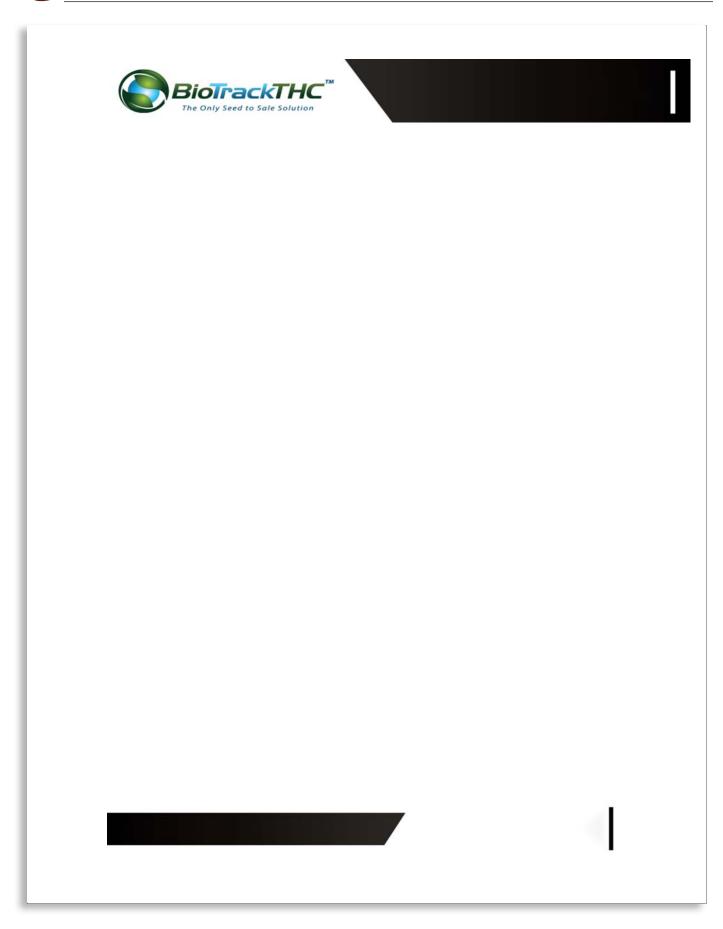
# §11-850-92 <u>Packaging and labeling for retail sale.</u>

- (b) Each package shall be labeled using only black lettering on a white background with no pictures or graphics and shall include:
  - (1) Information about the contents and potency of the marijuana and manufactured marijuana product, including but not limited to:
    - (A) Net weight in ounces and grams or volume; and for manufactured marijuana products, also the equivalent physical weight of the marijuana used to produce the manufactured marijuana product;
    - (B) The concentration of tetrahydrocannabinol or 9 tetrahydrocannabinol, total tetrahydrocannabinol and activated tetrahydrocannabinol-A, and cannabidiol;
  - (2) The dispensary licensee's license number and the name of the production center where marijuana in the product was produced;
  - (3) The batch number and date of packaging;



- (4) Includes a computer tracking inventory identification number barcode generated by tracking software;
- (5) Date of harvest or manufacture and "Use by date";
- (6) Instructions for use;
- (7) The phrases "For medical use only" and "Not for resale or transfer to another person";
- (8) The following warnings:
  - (A) "This product may be unlawful outside of the State of Hawaii and is unlawful to possess or use under federal law";
  - (B) "This product has intoxicating effects and may be habit forming";
  - (C) "Smoking is hazardous to your health";
  - (D) "There may be health risks associated with consumption of this product";
  - (E) "This product is not reconunended for use by women who are pregnant or breast feeding";
  - (F) "Marijuana can impair concentration, coordination, and judgment. Do not operate a vehicle or machinery under the influence of this drug"; and "When eaten or swallowed, the effects of this drug may be delayed by two or more hours";
    - (6) A disclosure of the type of extraction method, including any solvents, gases, or other chemicals or compounds used to produce the manufactured marijuana product; and
- (9) The name of the laboratory that performed the testing; provided that the information in paragraphs (1) through (7) shall appear on the package, and the remainder may appear on a package insert or on the package.
  - (c) A dispensary licensee shall not label as organic any marijuana or manufactured marijuana product unless permitted by the United States Department of Agriculture in accordance with the Organic Foods Production Act.

BioTrackTHC<sup>™</sup>'s label creation tool enables licensed producers to create custom container-client labels with any fields necessary to comply with applicable law. All aforementioned required fields can be added as variables. In addition to this a user can add custom disclaimers and warnings. The system will automatically print the container-client specific label upon completion of the sale.





# Hawaii Medical Marijuana Dispensary License Application Support Document

The format of the application asks for one's education, knowledge and experience with the sections outlined below, among others. The information contained within this document is to be used to assist an applicant with answering the questions that fall within the scope of the capabilities of BioTrackTHC; i.e. inventory tracking, sales limits, labeling, etc.

# No guarantees or warranties, either expressed or implied, are associated with this document.

I) Secure inventory tracking and control

All authentication is encrypted via industry standard SSL and hardware is managed and maintained internally. As with any system involving patient data, security is a top priority at BioTrackTHC. Each BioTrackTHC client utilizes the latest Secure Socket Layer (SSL) encryption technology to ensure a secure operating experience. All technology supporting remote access to the BioTrackTHC based solution can be described as fully secure and founded on current industry standards of strong authentication, encryption and HIPAA Compliance. Regardless of network connection type being wired/wireless or commercial/government ISP, the connection state is always encrypted end-to-end from browser to web server using Secure Socket Layer (SSL). Database connections are also encrypted via standard authentication + SSL. At no point in the network path will data be unencrypted.

- (4) Ability to comply with the security requirements of Chapter 11-850 and Section 329D-7, HRS;
  - (1) A protocol for admitting qualifying patients or primary caregivers with valid government issued photo identification and medical marijuana registration cards issued pursuant to chapter 329, HRS, prior to allowing them access to the secured room for sales;

This is the responsibility of the licensee.

(7) Ability to comply with the requirements in Chapter 11-850 and Sections 329 and 329D, HRS, for inventory tracking, security, and dispensing limits for qualifying patients;



# SUBCHAPTER 5 TRACKING REQUIREMENTS

# §11-850-61 <u>Tracking requirements.</u>

(a) A dispensary licensee shall track electronically the dispensary's inventory of marijuana and manufactured marijuana products through each stage of processing, from propagation to point of sale, disposal, or destruction, and maintain a record of clear and unbroken chain of custody at all stages, including during transport of the inventory between dispensary facilities and between a dispensary facility and a laboratory.

The BioTrackTHC system is comprised of several components; all of which are designed to seamlessly integrate with one another. Recognized as the industry leader in seed-to-sale tracking, the BioTrackTHC producer, processor and retail tracking components are completely interoperable with one another. Whether the tracking requirements include plants, trimmings, waste, conversion, dispensing or anything in between; the BioTrackTHC system, in concert with its unique inventory typing system, can currently track anything the industry allows by law.

The BioTrackTHC System issues a globally unique, non-repeating 16-digit identification number to each plant. At every stage in the product lifecycle where something needs to be differentiated, the System issues a new "child" identifier (e.g., separating flower from stems during the harvest process, separating edible batches that are going to different dispensaries, the creation of new clones or seeds from a mother plant, etc...). The System issues the identifier to prevent accidental or intentional identifier duplication by the user, and the 16-digit identifier ensure scalability and longevity—the System could generate 1,000,000 identification numbers per second and it would not run out of unique identifiers for over 317 years.

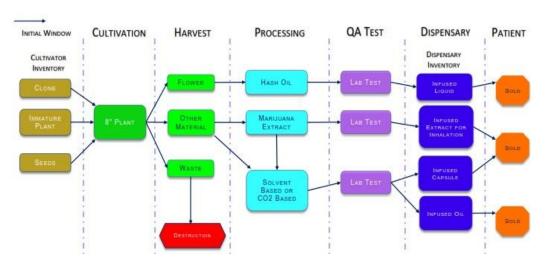
Every identifier is associated with a quantity that is measured in either discrete units or a weight depending on the item's classification; for example, plants, seeds, and infused edibles are measured in discrete units, whereas, bulk flower and stems are measured in continuous weight. This creates an unbroken audit chain. Select any identification number and both the State and the registered organization can backwards-trace the medical cannabis product's lineage all the way



back to the plant from which it came, and also forwards-trace every gram to where it is still in inventory, where it has been dispensed, to whom it was dispensed, and where it was destroyed.

As an example, if 100 grams were harvested from plant 98765: in this case, 2 grams were consumed by the testing laboratory, 8 grams were dispensed to patient Smith, 15 grams were dispensed to patient Jones, 55 grams are still in inventory, and 20 grams have been destroyed.

Laboratory testing is built-in and tied directly into the inventory typing system. This allows for very complex or very simple rules on what needs to be tested, what the testing requirements are, the pass/fail limits, etc. This testing paradigm provides a model for ensuring that only properly tested product may be sold to a patient. The system's integrated features can be setup to prevent the sale or transfer of product that has not passed state mandated laboratory tests, if necessary.



(b) A dispensary licensee shall track electronically all sales of marijuana and manufactured marijuana products to qualified patients and primary caregivers from all dispensaries in the State, to ensure that no sales are authorized in excess of legal limits, as set out in section 3290-7, HRS, and shall have a sales system that automatically prohibits sales in excess of the legal limits and that cannot be overridden manually.

Within "Sales Limits" a BioTrackTHC user can regulate the permissible quantities allotted to a patient or caregiver. The system stores patient purchases and cross-references with any Department defined limits. As the system will be recording every transaction, this data can be





parsed, filtered and reported against at any time. The system can also issue stop purchase alerts if a patient attempts to exceed said defined limits and disallow the completion of such a sale.

In the event that a patient has exceeded their purchasing limit; the retail dispensing location will be notified within the Tracking System that the patient has exceeded their sales limit; in response, the System will issue a stop purchase alert. The System does not allow for a retail dispensing location to transact with a patient that has exceeded their pre-defined sales limit.



(c) A dispensary licensee shall acquire, operate, and maintain a secure computer software tracking system that interfaces with the department's computer software tracking system to allow the department real time, twenty-four hour access to the dispensary licensee's tracking system and inventory records. The dispensary licensee's tracking system shall capture and report all the data required by the department's tracking system.

BioTrackTHC is the winner apparent to the state contract for Hawaii's computer software tracking system for the medical marijuana dispensary system based on and in compliance with Chapter 329D HRS. BioTrackTHC's commercial software provides seamless data exchange integration between a licensee and the state's marijuana tracking system. There will be integration via the application program interface (API) between the registered organization's BioTrackTHC enterprise system and the state interface utilized by the Hawaii DOH. This will



allow data to be sent in real time, not only from the registered organization to the state, but it will allow the registered organization to retrieve transferred data by Hawaii DOH.

(d) In the event of a breach or failure of its tracking system, a dispensary licensee shall suspend operations dependent on the tracking system until the tracking system is fully operable. The dispensary licensee shall notify the department immediately upon the breach or failure, and again when it resumes operations.

In the event of a loss of internet access, BioTrackTHC has the ability to operate in Offline mode. While operating in Offline mode a facility may continue to process sales with an on-site server, even if the internet connectivity goes down. When service is restored, all changes made in Offline mode will be updated and synced within the system.

(8) Ability to maintain confidentiality of a qualifying patient's medical condition, health status, and purchases of marijuana or manufactured marijuana products;

BioTrackTHC provides record retention of patient data including purchases and medical information that is voluntarily offered by the patient. Confidentiality of a patient's medical information is the responsibility of the licensee and their staff.

(10) Ability to comply with requirements for packaging, labeling, and chain of custody of products

Labels for medical marijuana and medical marijuana products will be labeled using only black lettering on a white background with no pictures or graphics[i] and will include:

- a) Net weight in ounces and equivalent physical weight of the marijuana used to produce the product.
- b) The concentration of tetrahydrocannabinol or tetrahydrocannabinol, total tetrahydrocannabinol and activated tetrahydrocannabinol-A, and cannabidiol; as well as the name of the laboratory that performed the testing
- c) The dispensary licensee's license number and the name of the production center
- d) The batch number and date of packaging
- e) A computer tracking inventory identification number barcode generated by tracking software.
- f) Date of harvest or manufacture and Use By Date
- g) Instructions for use
- h) The phrases: "For medical use only"; "Not for resale or transfer to another person"; "This product may be unlawful outside of the State of Hawaii and is unlawful to possess or use under federal law", "This product has intoxicating effects and may be habit forming"; "Smoking is hazardous to your health"; "There may be health risks associated



with consumption of this product"; "This product is not recommended for use by women who are pregnant or breast feeding"; "Marijuana can impair concentration, coordination, and judgment. Do not operate a vehicle or machinery under the influence of this drug"; "When eaten or swallowed, the effects of this drug may be delayed by two or more hours"; and a disclosure of the type of extraction method including any solvents, gases, or other chemicals used (if applicable)

BioTrackTHC's label creation tool enables licensees to create custom container-client labels with any fields necessary to comply with applicable law. All aforementioned required fields can be added as variables. In addition to this a user can add custom disclaimers and warnings. The system will automatically print the container-client specific label upon completion of the sale. The name and address of the recipient, the quantity delivered, and the product name, potency, batch number, and lot number of the product can all be recorded for each distribution.

The following list contains the fields already integrated into BioTrackTHC. Should the State desire additional fields, BioTrackTHC will create and implement those fields per request.

- Custom Text Fields
- Images
- Lines
- Additives
- Barcode
- Batch #
- Custom Batch #
- Customer MMJ #
- Customer Name
- Date
- Date and time
- Employee Name
- Employee License #
- Grow License #
- Harvest Date
- Inventory Grade
- License #
- MITS ID
- Package Date
- Package Weight
- Plant Birthdate
- Product Expiration
- Product Ingredients
- Product Name



- Strain
- Strain Type
- Testing Date
- Testing Lab
- Usable Weight
- Weight
- Test Results
  - All Available
  - CBC
  - CBD
  - CBD-A
  - CBG
  - CBN
  - D8-THC
  - D9-THC
  - D9-THC-A
  - H2O
  - Heavy Metals
  - Mold
  - Mildew
  - Total THC
  - Total Cannabinoids

# (11) A plan for secure disposal of marijuana and manufactured marijuana products;

The BioTrackTHC MMJ Tracking System tracks and reports on all disposal of marijuana and marijuana products within a licensed facility. The System allows for the adjustment of inventory quantities as the result of both non-sales operational activities (such as disposal, wastage, moisture loss, mistakes, and inventory audits) and external factors (such as theft and seizure by law enforcement). Data related to disposal information may include, but is not limited to: the amount disposed, reasons for disposal, day/time, identity of the employee(s) conducting the disposal, and manner of disposal in addition to all product-related data such as inventory classification, etc.

(12) Ability to ensure product safety, in accordance with Chapter 11-850 and Sections 329D-8, 329D-10, 329D-11, HRS.

After a testing laboratory has entered sample test results into the System, the licensee retrieves the testing laboratory results and the System applies those results to the original lot from which



the sample came. Only if the inventory item has a status of "Passed QA" can it be placed on a manifest. A registered organization user cannot, under any circumstance, place an item on transportation manifest if that item requires testing and does not have a "Passed QA" status (e.g. not yet tested or failed testing).

sionals and patients to set industry standards Safe Access (ASA). ASA has been fighting for the with regulators, industry, healthcare profeso medical cannabis for over decade. As an ights of patients and for safe and legal access cannabis industry offered by Americans for profit, third-party certification for the medical Patient Focused Certification (PFC) is a nonndependent organization, we are able to work

& services while giving patients, caregivers, es ensure the production of quality products can Herbal Pharmacopoeia. The program was quality standards for medical cannabis prod nealthcare providers, and regulators a way to established to help medical cannabis business acts and businesses issued by the American PFC is the only certification based on the nev Herbal Products Association and the Ameri-

# Where Do I Find PFC Certified Companies & Products?

Visit: patientfocusedcertification.org/companies

can be found on our website above. If there is Companies participating in the PFC program not a company near you, take this brochure to our local provider and ask them to enroll!



**PATIENT FOCUSED CERTIFICATION** a project of Americans for Safe Access Foundation

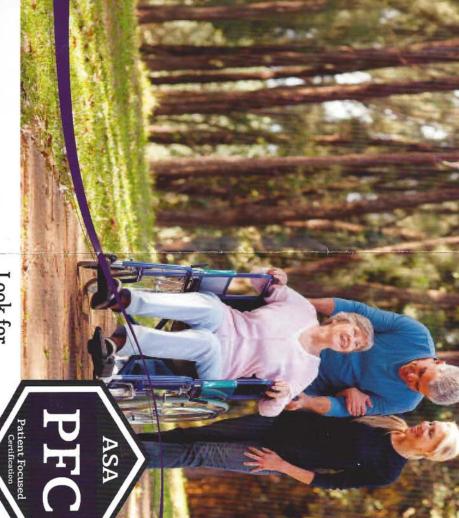
with Confidence

Medicine

Choose Your

1806 Vernon St. NW - Washington, DC 20009 202.857.4272 - pfc@safeaccessnow.org www.patientfocusedcertification.org

> Look for the PFC Seal







# PFC Seal tell you?

Focused Certification Program. been verified through the rigorous Patient the quality of products and services has center or on a product label, it tells you that When you see the PFC seal at a distribution

# **Patient Focused Certification means:**

Company staff are well trained

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Only allow the PFC seal to be used or

products that meet the PFC criteria

- Products and services have been tested for contaminates
- Products and services meet legal requirements as well as AHPA and AHP standards
- Companies have recall protocols in place



# How does PFC provide Certification?

evaluation process. fy their companies through a comprehensive to local laws, AHPA and AHP standards. We veriparticipate in the program and agree to adhere PFC works with companies who voluntarily

# Our auditors:

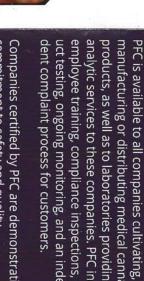
- Perform thorough audits of the facilities
- Test products in PFC certified laboratories.
- ensure PFC standards are upheld. Conduct at least one surprise audit a year to

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Maintain a consumer complaint database and

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corrective action. follow up with the company for any needed



# employee training, compliance inspections, pro analytic services to these companies. PFC inclu commitment to safety and quality. Companies certified by PFC are demonstrating uct testing, ongoing monitoring, and an indepe products, as well as to laboratories providing

# Quality Assurance

in states with medical cannabis laws, & over on cannabis under the care of a physician. million Americans are legally using medical More than one-third of the US population lives

of these businesses , they do not, for the most regulations to govern the location, size, & taxat ucts being sold. While many states and localities have created part, address the quality and safety of the proc

they are receiving has been handled with the cine has been produced, that is free of contam-Patients have the right to know how their medi ucts to purchase. the PFC seal to help them determine which pro highest quality standards. They can now look fo inates & should be confident that the medicine



# STATE OF HAWAI'I

DEPARTMENT OF HEALTH, OFFICE OF HEALTH CARE ASSURANCE (OHCA)

Medical Marijuana Dispensary License Application - Maui County

# Response to Criterion 13

"Business License Revocation"



# Launiupoko Farm

From Julie Okada, Individual Applicant, and Launiupoko Farm, LLC, Entity Applicant with the technical assistance of James Anthony Technical Assistance Consulting (JATAC), consultant.

# **CONTENTS**

# **ATTACHMENTS**

13-A: Alika Atay's signed statement

13-B: Julie Okada's signed statement

13-C: Masahiro Uchida's signed statement

13-D: Yashuhito Ogasawara's signed statement

# STATE OF HAWAI'I

DEPARTMENT OF HEALTH, OFFICE OF HEALTH CARE ASSURANCE (OHCA)

Medical Marijuana Dispensary License Application - Maui County

# Criterion 13 Language







