June 2018 Dispensary Training Plan, User Manual and Materials

Dispensary Training Plan

Dispensary training is expected to take place in October/November 2018.Following is a training plan, user manual and other materials to support that training.

The overall training approach is to educate the dispensary on all transactions (events) that the state is tracking and why that is important. For example, inventory reconciliation, recall procedures and patient verification are important processes supported by our system. We will use a train-the-trainer approach so that ongoing training can occur at the dispensary. Our initial training will be conducted both virtually (BioMauris and distant dispensaries) and on site at IDPH (local dispensaries) for the most efficient use of resources.

Intended audience -

This training material is intended for all dispensary employees that have accountability for tracking patient and caregiver verification, sales and inventory for medical cannabidiol products. The majority of data entry happens in the dispensary point of sale system and this training is NOT intended to duplicate the training for those systems. The Iowa Department of Public Health (IDPH or Department) has a seed to sale tracking system that receives significant amounts of data and information from the dispensary systems, and the department system is used to ensure compliance with all state regulations that apply to dispensaries of mCBD in Iowa. It is critical that dispensary employees understand how this system is used by the state for regulation as it is only as good as the data it is sent.

Key personnel -

There should be multiple dispensary trainers responsible for ongoing training at the dispensary so new employees receive orientation to this system. These may be the same trainers used for other dispensary systems.These materials will be updated as needed and can be reused for new employee training. Employees that receive transport deliveries will need special training on how to receive inventory from the dispensary. Managers that update employee information will also need some training on entry and updating of employee information in this system.

Initial training schedule -

Since new product is expected to go to market by December 1, 2018 the initial training of dispensaries will be conducted in the October/November 2018 timeframe. Specific dates are tentatively set at Thursday November 15, 2018 1-3 PM at IDPH 6th floor Lucas Building. Additional training sessions will be scheduled as needed.

Training approach -

We will cover a variety of “case studies” that demonstrate how the department will use the system to regulate dispensaries. Through understanding these cases and the alerts, notifications, views and reports the department receives, the dispensary employee will understand the importance of proper data entry and logging of events.

Training Agenda - Session 1 (All DISP Employees Required)

Thursday November 15, 2018 1-3 PM at IDPH 6th Floor Lucas Building

Time allotted	Item Covered	Item Description
10 minutes	Introductions	Allow all students to describe their role at the DISP
20 minutes	Definitions and Events that Trigger System Updates	Define and explain all events that cause data to be sent from DISP system to IDPH system
30 minutes	Case Studies	Review the case studies that describe how the state uses DISP data for regulation
20 minutes	Review Mobile Transfer App	Walk through all screens and fields that drivers use and how to receive a delivery
20 minutes	Enter employee info	Show the web page and all entry fields, and review employee data entry diagram
20 minutes	Q&A	Planted questions and answers plus any that students have from training

Dispensary User Manual - Definitions:

1. **Employee Records** – The State collects name, date of birth, contact information, date of an approved background check, date of hire and last date of employment. It is incumbent upon the dispensary to update employee contact information if/when it changes. All dispensary activities resulting in data being passed to the state are logged, indicating the employee who completed the activity (i.e. sales, inventory reconciliation, transfer acceptance).

2. **Account Records-** Each dispensary will have access to a state database of registered patients and caregivers which display the necessary information to verify their status in the program and help determine how to best the patient's needs. The information on a patient or caregiver's government-issued ID will be matched against that in the system, and a caregiver may only purchase medical CBD products for an active patient. Medical conditions and purchase history at the dispensary is visible to allow the staff to recommend products, as appropriate. In the event that a patient or caregiver's contact information has changed, the dispensary will pass these changes on to the State to inform the patient or caregiver of the necessary steps required to take with the DOT and IDPH.

3. Process Lot Records –The **Process Lot** begins with the input of biomass (ground, cured plant material) which goes through several stages of extraction and purification, resulting in the output of medicinal cannabidiol (CBD). This is the basic "active ingredient" of all products

sold at dispensaries. The Process Lot ID is assigned by the manufacturer and provided to the State, and every unit of product can be traced back to the process lot it was derived from.

4. Product Lot Records – A **Product Lot** is the formulated, finished product in its bulk state, not yet packaged for sale. The Product Lot Record links this product to the Process Lot(s) that it contains and is the ID on which all Product Recalls are based. The Product Lot ID is assigned by the manufacturer and provided to the State.

5. Package Lot Records – The **Package Lot** is the packaged, labelled, saleable form of the product. A single Product Lot may become multiple package lots to account for different unit sizes and distribution procedures. The Package Lot record is linked to the Product Lot and is a required item on the Transfer Record (see number 6). The Package Lot ID is assigned by the manufacturer and provided to the state.

6. Transfer Records – Any time medical CBD products are moved between two facilities, a Transfer Record is required. Manufacturers are the only entity that can transport medical CBD products. The **Transfer** contains origin, destination, driver, vehicle, estimated trip duration and arrival time, product information and quantity as well as the Transport Manifest (PDF). The Transport Manifest is required for law enforcement verification while in transit as well as audit purposes. The Transfer ID, which is provided to the State, is generated at the time the Transport Manifest is created. Transfers adjust inventory at the origin when leaving the facility and at the destination when accepted, which is tracked across the supply chain.

7. Return Transfer Records – **Return Transfer** Records perform the same function as Transfer Records, however the product is being transferred back from dispensaries or labs due to returns, recalls, excess sample material sent to labs, etc. As manufacturers are the only authorized transporter, they will drive to the lab or dispensary to pick up the material. Pickups will be mutually arranged between the two parties.

8. Recalls– **Product Recall** may be initiated by the manufacturer or State and is instituted on the Product Lot. When a Product Lot is recalled, notification is sent to the State and dispensaries to initiate the process of recovering the recalled product for destruction. The dispensaries will contact patients and caregivers who have purchased the product. A report will be provided to the dispensary to identify these consumers, with notification attempts and results logged.

9. Inventory Reconciliation – State requirements dictate weekly physical inventory reconciliation reporting for all dispensaries. **Inventory Reconciliation** is a reporting of the physical quantity by count of each product. Any time the physical count recorded on the reconciliation differs from the system count, notification will be sent to both the dispensary and the State. If the discrepancy is not mitigated within 24 hours, law enforcement may be notified if the discrepancy appears to be diversion of inventory. Inventory will be comprised of active (saleable) and inactive (items to be returned to the manufacturer) products.

Case Studies:

1. Inventory reconciliation -

The dispensary is required to conduct a physical inventory of all products that exist in the facility every week. This is a mechanism to identify potential diversion of products and possible issues with the dispensary or states' tracking procedures. The department receives a report of product inventory from the dispensary and the system will alert the department if the physical inventory does not match the system inventory records. For example, if the physical count of lotion available for sale at the dispensary is logged in physical inventory as 100 count and the system shows it is 105 count (based upon accepted transfers, recorded sales, returns and waste), an alert will be sent to the dispensary and the department that records don't match and a reconciliation action will need to be taken. The state will use the reconciliation reports to identify why a discrepancy exists. Inaccurate inventory counts could be due to a system data transfer error, an employee's failure to follow proper procedures (e.g. did not register a sale), or potential theft. To avoid auditing issues, any event that could result in an inventory discrepancy (e.g. product is damaged) needs to be logged accurately and in a timely manner. The name of the employee who performed the sale, return for disposal or receipt of inventory from the manufacturer is logged and sent to the state in near real time.

The dispensary has 24 hours to reconcile after receiving an alert that the system inventory does not match. If there is suspected diversion, the dispensary is required to notify law enforcement within this time. If there is not suspected diversion, and more time is needed to reconcile to the system, the dispensary shall create an action plan that outlines what steps are being taken to reconcile. This action plan is due within two business days after reconciliation efforts have failed. For this reason, we recommend the dispensary conducts physical inventory every Thursday. This allows until Friday to reconcile and until the following Tuesday to have an action plan, if unable to reconcile by Friday. If there is a holiday on the Thursday where physical inventory is due, we recommend the physical inventory happens on the Wednesday prior to the holiday.

2. Product Recall -

The department is responsible for ensuring that any product that is unsafe for the public can be located and returned to the manufacturer for destruction. This would include product sold to patients or caregivers and unsold dispensary inventory. The state system allows recalled product to be traced back to the product lot, process lot, batch and plants from which it originated. The state and manufacturer may then be able to identify the cause of the defect. In the event of a recall (initiated by either the manufacturer or the department) this product tracking will enable us to notify all dispensaries, labs, patients and caregivers of procedures for returning the product to the manufacturer for disposal. The dispensary has a special role in this process to contact patients and caregivers that a recall has been declared and how to return product to the dispensary. The department and the manufacturer will determine together when the recall is over and when any unreturned product is no longer worth pursuing.

3. **Transfers -**
   The State is responsible for maintaining a chain of custody record of all medical CBD product that is transferred from the manufacturer to labs and dispensaries, as well as all returns back to the manufacturer. For this reason, the department system is the system of record for all transfers. The department has developed a mobile application that will be used by drivers to record the transport details of all product. Based on GPS data, the estimated time to complete the delivery will be determined and all stops (gas, restroom, other stops) will be recorded in the app to accurately capture drive time. If this expected drive time is exceeded by an unusual amount of time, the department is notified with an alert. The time that the delivery started and was accepted by the dispensary are all recorded. Upon arrival, the dispensary will inspect the contents of the shipment to verify its accuracy and that all items are in good condition. The driver and dispensary employee accepting the transfer are recorded in the app and are required to sign a paper copy of the transport manifest. The dispensary may choose to accept the entire delivery, reject the entire delivery or accept only part of the delivery.

4. **Transfer Return -**
   The manufacturers are responsible for all transport and destruction of medical CBD. If the dispensary or lab rejects the transfer in part or whole (wrong order, damaged contents etc), then the return of product will be executed by generating a return transfer. The manufacturer is the recipient of this return. Return transfers are logged in the same way as normal product transfers, including recording of stops, estimated drive time, driver and recipient information, and package inspections upon arrival. The only differences are that the manufacturer is the recipient and packages will not be rejected.

5. **Patient and Caregiver Verification -**
   The dispensaries are responsible for verifying that all patients and caregivers entering the dispensary and are active and eligible to make a purchase. The dispensary has limited access to the department's registry system, which includes the ability to look up patient or caregiver registration information, medical conditions and purchase history at the dispensary. Dispensary employees need to be able to search for and locate patient and caregiver information. If any contact or residential information has changed, the dispensary must send these changes to the department.

Additional Materials

Process Flow Diagrams for Iowa Seed to Sale Tracking

Manufacturer to Dispensary and Return Transfer

https://docs.google.com/drawings/d/16frnr4zig_p1Z2EowngUAD5W7TdB_Sggo53pLxlCWaA/edit

Employee Information

https://drive.google.com/open?id=11Gcy5A26C5Nh9IcV7l8nljTvB0kVNiTzEfMYPJgVXs8

Transfer Information

Insert link to transfer app diagram

Frequently Asked Questions for the employees:

1. What are the critical events that the department tracks to ensure the dispensary is compliant with Iowa regulations? Why is the state tracking each of these events?
    a. Inventory records and reconciliation- identify diversion or system issues
    b. Transfers and return records- Record where all product is at any given time. Ensure the contents match the transport manifest. Understand what is causing returns.
    c. Recall records - Identify where recalled product is in the supply chain and ensure department procedures are followed to collect recalled product from patients, caregivers and dispensary inventory for disposal by the manufacturer.
    d. Employee Records - Ensure employee records are maintained with current contact information and background check approval status.
    e. Patient/Caregiver Records - Ensure patient and caregiver records are maintained with current contact information.

2. What will happen if physical inventory does not match the system inventory records?
    a. An alert is sent to the department and dispensary that records do not match
    b. An inquiry will be made of the dispensary to determine discrepancy
    c. Root cause will be determined and steps taken to avoid in the future
    d. Law enforcement will be notified if diversion is suspected.
    e. If reconciliation does not happen within the required 24 hours, an action plan with steps that are being taken to reconcile is due to the department within two business days after reconciliation attempts have failed.

3. What are the records that need to be maintained for a product recall to be effective?
    a. Product sale transaction and unique product ID sold (Dispensary)
    b. Product lot ID on all products sold (Manufacturer)
    c. Associated to process lot (Manufacturer)
    d. Current location of all recalled products, including patients and caregivers who purchased them. (Department)
    e. Sales records to identify recalled products which were sold to patients and caregivers (Dispensary)
    f. Real-time inventory records to determine quantity of recalled product on the shelves at a dispensary (Department)

g. Traceability of a packaged product to the product lot from which it was formulated (Manufacturer)
h. Traceability of the bulk product lot to the process lot of purified medical CBD from which it was manufactured. (Manufacturer)

4. What are the important factors to consider in a transfer or return? What signifies completion of a transfer?
    a. Drivers have a mobile app to enter all data for the transfer
    b. GPS data calculates an estimated trip duration for the transfer
    c. All stops along the route are logged.
    d. The trip is timed to ensure reasonable delivery times are maintained without gaps
    e. Both the driver and the recipient will sign the transport manifest
    f. Any partial or full rejection of shipment will result in a return transfer
    g. The manufacturer is responsible for all transfers and disposals from returns
    h. The items on the transport manifest match the contents in the vehicle.

Other Materials

- **Screenshots of Salesforce system**
- **Screenshots of Mobile Transfer Application**
- **Contact information for additional questions**