NCDQS C-QAS Accreditation Standards – Dispenser

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13 sections, 82 standards

Cannabis Products:
This standard applies to the dispensing of any product containing, comprised of, or derived from, cannabis or hemp. Dispensing entities may include dispensaries, pharmacies and healthcare practitioners.

Section 1: Business Information

1. The business is registered with the state and has an EIN.
2. The facility has and maintains appropriate current, valid licensure, permits and/or registrations for handling cannabis products in the state in which it is located.
3. The facility dispenses cannabis products to customers in other states (deliver, mail or send) only where it is legal to do so and the facility has the appropriate non-resident license, permit or registration, and complies with the nonresident state regulations for cannabis dispensing.
4. There is a defined organizational structure with clear lines of authority.
5. The business carries an appropriate amount of general and product liability insurance.
6. The business has an appropriate financial management system or process in place that includes a relationship with a bank or financial institution, the use of a CPA, development of a business plan or budget, and review of periodic financial reports.
7. There are appropriate procedures in place for financial transactions including security and accountability for handling cash.
8. There is a manager in charge of the facility with appropriate education, training, and experience, that is involved in the day-to-day operations of the facility.
9. If there are co-located businesses that handle cannabis or cannabis-related products, there is physical and electronic segregation of products and operations as appropriate.

Section 2: Administration

1. There are policies and procedures that address all aspects of the operation.
2. There is a document control policy and procedure that describes how policies and procedures are developed, reviewed, revised, approved, and archived.
3. There is a record retention policy including how and where records are securely stored, how records are accessed and by whom, how long each type of record is

kept, and the process for record destruction at the end of the required storage time.

4. There is a compliance policy and procedure that addresses:
    a. Federal law
    b. State law
5. There is a process for ensuring compliance and keeping up to date with:
    a. State and federal laws, rules and regulations.
    b. Accreditation requirements and standards.
    c. Industry best practices.
6. There is a policy and procedure that addresses routine reporting to state and/or federal agencies when required, for performing self-inspections when required, and for the reporting of suspicious or illegal activity.
7. There is a marketing and advertising policy in place that clearly restricts advertising and claims to only those allowed by the FDA. Any signage, advertising, or social media communications are reviewed prior to posting to ensure compliance.

Section 3: Safety and Crisis Operations

1. A safety and crisis plan is developed and a hard copy of the safety and crisis plan is kept on the premises and with key personnel.
2. Contact lists are maintained for emergency services and for repair vendors (electric company, HVAC repair, alarm company, etc.). A list of employee contact information is maintained.
3. The plan addresses natural disasters or emergencies (geographically appropriate, fire, flood, hurricane, tornado, earthquake, etc.), man-made crises (active shooter, medical emergency, blood borne pathogen, strike, prolonged electrical outage, etc.)
4. People safety and training is performed.
5. Business continuity plan including notifications if business is closed for a length of time.
6. Product security and integrity plan if the facility cannot be used or secured.
7. Data security (devices/computer hardware that contain data) plan if the facility cannot be used or secured.

Section 4: Environment

1. Neat, clean, sanitary, and well-lit. Facility is an appropriate size for the volume of business.
2. There is access to a sink with hot and cold running water.
3. There is a restroom for staff.
4. There is appropriate room for storage and display of products and public access is limited and supervised.

5. The facility is ADA compliant.
6. Adequate reference materials are available in hard copy or online including state and federal regulations and clinical references.
7. Appropriate patient confidentiality is maintained.
8. Products are stored within conditions indicated on the packaging or labeling for the products. If there is no indication of storage conditions, product will be stored at USP-defined controlled room temperature.
9. Temperature and humidity are monitored, recorded at least once daily, and excursions are detected real-time or retroactively (minimum and maximum recorded). There is a process to evaluate products that have experienced an excursion.
10. Waste handling and removal procedures are in place to deter diversion or theft.

Section 5: Security

1. Authorized employee access with unique alarm codes, access is tracked.
2. Building is secured during business hours.
    a. Appropriate commercial grade locks in use
    b. Doors cannot be opened from the inside undetected.
3. Building is fully secured (locked) after hours.
4. All entry points are included on the alarm system (doors, windows, roof hatch, etc.)
5. Additional security is in place as appropriate (glass-break detectors, motion sensors, etc.)
6. 24/7 alarm, battery back-up
7. 24/7 camera, security of recordings, retention time
8. IT security (remote access and on site)

Section 6: Human Resources

1. Hiring and initial verifications and screening
    a. Verification of employment and education history
    b. Verification of certification/registration if required.
    c. Drug testing
    d. Background check
2. Job descriptions for all positions including any required credentials.
3. There is an Employee Handbook (HR policies)
4. Training is documented.
    a. Initial training and orientation
    b. Ongoing training (annual, updates, etc.)
5. Ongoing evaluation
    a. Routine, random and for-cause background checks and drug testing.
    b. Performance review process.

c. Stepped disciplinary process.
d. Resignation/termination process that includes immediate deactivation of security system codes, alarm codes, and computer access codes and retrieval of company property such as keys.

Section 7: Vendors/Ordering product

1. Selection of vendors includes assessing the quality of the products to be purchased. Growing, harvesting, extraction and manufacturing of final products follows quality standards. Production, storage and transportation of products protects the quality, integrity, and security of the products.
2. Verification of vendors initially
    a. Verification of licensure directly with the licensing agency in the state in which they are located.
    b. If the vendor is out of state, verification that the vendor is allowed to ship products into your state and has appropriate nonresident license, permit or registration to do so.
    c. Ongoing verification of vendors is performed is annually and at the time the license(s) expire.
    d. Process including reporting if unable to verify appropriate licensure.
3. Product is ordered only from verified vendors.

Section 8: Product Receipt

1. Deliveries are received when the facility is open – no orders are left outside the door or on a dock.
2. Physical inspection of the products includes review for:
    a. Damage
    b. Appropriate packaging and labeling
3. The products in the order match the purchase order
4. The products in the order match the invoice/packing slip
5. Receipt of Certificates of Analysis (COA) for each batch/lot OR product testing is performed and reviewed (if required).
    a. COA from a certified laboratory and testing is to the appropriate standards.
6. Receipt and review of any tracking information
7. Product not meeting the quality standards or with any discrepancies not resolved is quarantined for return or disposal.

Section 9: Inventory Management Process

1. Appropriate inventory frequency and documentation.
2. Inventory discrepancy procedure for documentation, investigation and reporting.

3. Inventory adjustments performed only by authorized staff and tracked.
4. Process to remove outdated or damaged product.

Section 10: Recall, Quarantine and Destruction

1. Process to quarantine and procedures for handling:
    a. Products received with discrepancies (held until verified).
    b. Expired and short-dated products.
    c. Products that are damaged or have experienced a temperature/humidity excursion.
    d. Products that have been recalled or withdrawn from the market.
2. Process for the handling, evaluation and disposition of customer returns.
3. Disposition/destruction process and documentation

Section 11: Customers and Customer Orders

1. Legitimate Sales
    a. Verifying legitimate customers
        i. Recreational use
        ii. Legitimate medical use
        iii. Age restrictions
    b. Legitimate quantity (daily limits)
    c. Dispensing
        i. In-person
        ii. Delivery by staff
        iii. Delivery by carrier (if/when allowed)
    d. Process to prevent delivery or shipment into other states (unless allowed and has nonresident permit, registration, or license to do so).
    e. Process to document sales and collect payment.
    f. Process to document deliveries including tracking and proof of receipt (signature), vehicle shipping manifests.
2. Patient communications and safety
    a. Packaging and labeling including product information provided, including COAs. Provide electronic access to or provide a copy of COA routinely or when requested by the customer/patient.
    b. Health care consultations (clinical questions appropriately answered by health-care provider)
    c. Appropriate confidentiality is maintained for medical-use customers
    d. There is a nondiscrimination policy.
3. Patient returns policy.
4. Free goods/samples policy including documentation

Section 12: Quality Program

1. There is a quality committee, meetings are held annually (recommended quarterly) and are documented.
2. Quality Related Event (QRE) is defined:
    a. Adverse event or reaction
    b. Errors (product, quantity, labeling, etc.)
    c. Inventory issues (theft, loss, etc.)
    d. Recalls or other product quality issues (damage, etc.)
    e. Customer complaints
    f. Internal or external audits or inspection results
    g. Any other quality issue (HR, recordkeeping, nonadherence to SOPs, financial or money-handling issues, etc.)
3. QRE Data is gathered, analyzed (root cause, if appropriate), and trended
4. Improvements are created and the effectiveness of the improvement is evaluated.
5. Feedback is solicited from:
    a. Customers
    b. Referral sources
    c. Employees
6. Reporting to appropriate agency or law enforcement process in place.

Section 13: Additional Items if Filling Cannabis Prescriptions

1. Patient profile is complete (demographics, allergies, disease states, other medications used, etc.)
2. Legal, legitimate prescription received and reviewed for completeness.
3. Required drug utilization review (DUR) is performed.
4. If billed to a third-party (insurance, etc.), processes in place for preventing fraud, waste and abuse including compliance to anti-kickback statutes.
5. Prescription documentation is performed.
6. If compounded, must be compliant with USP Chapter <795> Nonsterile Compounding or <797> Sterile Compounding including appropriate environment and documentation.
7. If products or components are hazardous drugs (HDs) as defined by the National Institute of Occupational Safety and Health (NIOSH), must be compliant with USP Chapter <800> Hazardous Drugs Handling including appropriate environment and documentation.
8. Data entry and filled prescription final check performed and documented.
9. Appropriate prescription packaging and labeling including provision of product information.