PACKAGING AND LABELING

Labeling

Purpose: set minimum standards; usable MM received/sold by dispensary must meet requirements; dispensary must return noncompliant MM to entity or dispose of

Medical marijuana labeling requirements: prior to sale, label must include: processor name & license no., grower name & license no., unique ID no., harvest date, strain name, net weight, beginning May 15, 2019 concentration of THC & CBD & terpenes, activation time, lab name(s) & batch no. & test date, universal symbol, warning stating "For use by ~~qualified~~ Oklahoma medical marijuana patients only. Keep out of reach of children.", warning stating "Marijuana use during pregnancy or breastfeeding poses potential harms.", warning stating "This product is not approved by the FDA to treat, cure, or prevent any disease." and if product has not been lab tested in accordance with these rules, a warning stating "THIS PRODUCT HAS NOT BEEN TESTED AND CANNOT BE VERIFIED TO BE SAFE FOR USE."

Cannabinoid concentrates: prior to sale, label must include: dispensary name or license no., processor name, unique ID no., product identity, date made, net weight or volume, serving size & no. of servings if applicable, beginning May 15, 2019 concentration or amount by weight/volume of THC & CBD & terpenes, activation time, lab name & batch no. & test date, universal symbol, statement reading "This product is not approved by the FDA to treat, cure, or prevent any disease.", statement reading "For use by Oklahoma medical marijuana patients only. Keep out of reach of children.", statement reading "DO NOT EAT" in bold capital letters", statement reading "Marijuana use during pregnancy or breastfeeding poses potential harms.", if processed for patient a statement reading "Not for resale" and if product has not been lab tested in accordance with these rules, a warning stating "THIS PRODUCT HAS NOT BEEN TESTED AND CANNOT BE VERIFIED TO BE SAFE FOR USE."

General label requirements, prohibitions and exceptions: containers w/ usable MM must have principal display panel; if container is in packaging, packaging must have principal display panel; principal display panel must have product identity, universal symbol and if applicable net weight; label must: be placed on container and any packaging, comply w/ NIST Handbook 130 (2017) Packaging and Labeling Regulation, be no smaller than 8 pt. Times New Roman/Helvetica/Arial font (or 18 pt. for certain concentrate warnings), be in English and be unobstructed & conspicuous; usable MM may have one or more labels; if not enough space on usable MM container, may have label including: info required on principal display panel, processor name and license no., package unique ID no., beginning May 15, 2019 concentration of THC & CBD & terpenes and required warnings; if not enough space on container, must include remaining info on outer

container/package; universal symbol: must be at least 0.5 in. x 0.5 in. & printed in red, may only be used by processor or researcher licensees and may be downloaded from ok.gov/health; label may not: contain untruthful or misleading statements including health claims or be attractive to minors; usable MM must comply with all categories' requirements it falls under, except "DO NOT EAT" if for human consumption; THC, CBD and terpene amounts on label must be calculated by lab that did testing; usable MM label must include all test batch nos. and test dates if more than one; if package reused, must remove old labels and use new labels; exit packaging must have label reading "Keep out of reach of children."; al MM and products must be in child resistant packaging; ~~must have warning stating "Women should not use marijuana or medical marijuana products during pregnancy because of the risk of birth defects.";~~ must have warning stating "The intoxicating effects of the product may be delayed up to two hours. Use of marijuana and medical marijuana impairs your ability to drive a car or operate machinery."; label must contain: name & address & phone no. of dispensary, date & ID no., ~~name of patient,~~ ~~directions~~ recommendations for use, ~~name of recommending physician,~~ initials of dispenser, required precautionary information of CDS's, other cautionary info as required and MM product name & strength & no. of units; DMIC must implement policies and procedures for discontinued and outdated products and defective containers/labels to be quarantined and disposed of; MM packaging can't bear resemblance to any commercially available product; must minimize appeal to children; MM product packages must be: plain, designed to maximize shelf life, tamper-evident, childproof, able to protect product from contamination, opaque and can't depict images or commercial logos

Prohibited products

No commercial establishment shall manufacture/sell any MM product intended to be attractive to children including: gummy bears/worms, lollipops, animal shapes, fake cigarettes, products bearing resemblance to human/animal/fruit/familiar shapes including cartoons/caricatures; ~~no commercial establishment shall sell seedlings or mature plants;~~ no mature plants authorized in commercial licensee or patient licensee until 60 days past Aug. 27, 2018; no seedlings authorized in possession of commercial licensee until 7 days past Aug. 27, 2018

LABORATORY TESTING

General provisions

Laboratory accreditation: beginning May 15, 2019, labs must be accredited by NELAC Institute (TNI), ANSI/ASQ or similar entity determined by Dep't using ISO/IEC Standard 17025, except for labs

operating under provisional approval; lab can't be connected to any commercial establishment for which it conducts test

Testing laboratory approval: beginning May 15, 2019, labs must be approved by Dep't

Testing categories: lab must be able to test for cannabinoids, residual pesticides, heavy metals, microbiological impurities, residual solvents and processing chemicals, water activity and moisture content, foreign materials, sterility, terpenes and "other" determined by Dep't

Laboratory approval: lab must submit MM Laboratory Testing Request and supporting documents to Dep't; no testing until approval; approval valid for 12 months; to renew approval, lab must submit MM Laboratory Testing Request and appropriate documentation w/in 30 days of expiration; if not approved before expiration, no testing until approval

Request materials: MM Laboratory Request form and electronic versions of: management systems, facilities, security systems, employees, procedures and quality systems

Provisional testing laboratory approval: lab may request provisional license approval prior to accreditation provided meets all other requirements, complies with ANSI/ASQ protocol and submits request and attestation that intends to seek accreditation; valid for 12 months; to renew provisional approval, lab must submit MM Laboratory Testing Request w/in 30 days of expiration; if approval not renewed, no testing until approval; approval renewal form contains: name of lab, approval number and expiration date, lab's address of records and premises and attestation that information is accurate and current; Dep't may renew provisional approval for initial 12 months; after one renewal, Dep't may renew for additional 12 months if lab has submitted request for accreditation; lab must notify Dep't of approval/denial of accreditation w/in 5 business days, Dep't may terminate provisional approval if accrediting body approves/denies accreditation request; Dep't may revoke provisional approval at any time

Notification of changes: lab must notify Dep't w/in 10 days of any change in Request for Approval form; change in location requires new request; licenses not transferrable, new request required when new owner added

Physical plant: lab premises must meet physical plant requirements of commercial establishments in subchapter 6; lab shall ensure: adequate space for operations, provision of one or more secure controlled-access area and compliance w/ all local ordinances

Identification cards: cards are property of Dep't, must be returned to Dep't upon termination of employment, suspension, revocation or demand of Dep't

Term of approval: 1 year or upon lab closure, lab must apply for renewal w/in 30 days of expiration

Termination: Dep't may deny, withdraw or suspend lab approval upon determination of violation of this rule, upon failure of proficiency testing, upon refusal of lab to provide requested access to premises or materials, or upon failure to comply w/ an standard/procedure/protocol developed pursuant to this rule

Requirements for Testing

Testing requirements for usable marijuana: beginning May 15, 2019, growers must test every batch of usable marijuana intended for processor prior to sale/transfer for water activity and moisture content, unless processor has method that results in effective sterilization

Testing requirements for concentrates and extracts: beginning May 15, 2019, processors can't accept unsampled or untested marijuana; processors must test every process lot of concentrate or extract, including for individual patients, for: THC, ~~and~~ CBD and terpene concentration, water activity and moisture content, residual pesticides, heavy metals, mycotoxins, microbiological impurities, foreign materials and residual solvents and processing chemicals (exception for mechanical extraction and water/fat/oil solvent separation)

Audit and random testing: beginning May 15, 2019, Dep't may require grower or processor to submit samples to lab of licensee's choosing for testing, Dep't may require additional testing not required by rules

Standards for Testing

Cannabinoids: beginning May 15, 2019, lab must test for and report measurements of: THC, THCA, CBD, CBDA, CBG, ~~and~~ CBN and terpenes; lab may test for additional cannabinoids upon request; for each sample of useable marijuana from harvest-lot, lab must report concentration (mg/g) and dry-weight percentage of cannabinoids; for each sample of marijuana product, lab must report concentration (mg/g) of cannabinoids; lab must report pass/fail (fail when potency of THC ~~or CBD~~ exceeds ±15% of labeled potency); if sample fails, cannot be sold, must be destroyed

Water activity and moisture content: beginning May 15, 2019, lab must analyze usable marijuana for water activity level and moisture content percentage; pass if water activity does not exceed 0.65 Aw, must report pass/fail; moisture content pass if does not exceed 15%, must report pass/fail; if sample fails either test, batch may be returned to grower for further drying and curing, then re-tested

Residual pesticides: beginning May 15, 2019, lab must analyze marijuana or product for residual pesticides; lab must report (ppm) on COA, pass/fail; pass if pesticides does not exceed action levels in provided table; if batch fails, cannot be released for sale; temporary pesticide testing requirements: if insufficient lab capacity for pesticide testing, Dep't may permit random samples to be tested rather than every batch; at least one batch from every

harvest lot must be tested; if any random sample fails, every batch from harvest lot must be tested; if all random samples pass, entire harvest lot passes, may be transferred or sold

Heavy metals: beginning May 15, 2019, lab must analyze marijuana or product for heavy metals; lab must report (µg/g) on CIA, indicated pass/fail; pass if presence of heavy metals doesn't exceed provided action levels in table (match to FSSB recommendations: lead – max limit < 1 ppm, arsenic – max limit < 0.4 ppm, cadmium – max limit < 0.44 ppm and mercury – max limit < 0.2 ppm); if sample fails, batch fails and can't be released for sale

Microbiological impurities: beginning May 15, 2019, lab must analyze marijuana or product for microbial impurities; lab must indicate pass/fail on COA; pass if E. coli and salmonella not found in 1 gram; if sample fails, batch fails and can't be released for sale

Foreign materials: beginning May 15, 2019, lab must analyze marijuana or product for foreign materials, using 10X-40X microscope; must report pass/fail on COA; testing on primary sample prior to homogenization; lab must examine interior and exterior of marijuana or sample; sample passes if foreign material presence does not exceed: 1/4 of totals sample area covered by sand/soil/cinders/dirt, 1/4 covered by mold, 1 insect fragment/1 rodent hair/1 human hair/1 count of mammalian excreta per 3 grams, or 1/4 covered by embedded foreign material; if sample fails, batch fails, bust not be released for sale unless can be remediated and pass re-testing; failed batches or products must be destroyed

Residual solvents and processing chemicals: beginning May 15, 2019, lab must analyze marijuana products for residual solvents or processing chemicals; lab must report results (µg/g) on COA, indicated pass/fail; pass if: presence of solvents or chemicals listed in Category I of provided table not detected and solvents/chemicals in Category II fall within action levels provided (match to FSSB recommendations: acetone < 1,000 ppm, benzene < 2 ppm, butanes/heptanes < 1,000 ppm, hexane < 60 ppm, isopropyl alcohol < 1,000 ppm, pentane < 1,000 ppm, propane < 1,000 ppm, toluene < 180 ppm, total xylenes (m, p, o-xylenes) < 430 ppm); if sample fails testing, batch fails and may be remediated to reduce concentration of solvents and re-tested; otherwise, must be destroyed

Sampling Requirements and Procedures

General requirements: only samplers (trained individuals) employed by lab may collect samples; samplers must: follow lab's sampling policies and procedures, follow chain of custody procedures and hold transportation license; lab personnel may collect samples in field or grower/processor may transport batches to lab for sampling; lab may obtain samples only from batches in final form; lab must collect both primary sample and field duplicate for quality control only; lab must ensure that transportation and storage prevents degradation, contamination and tampering; sampler must use sample

field log to record for each sampled batch: lab name/address/license no., sampler's name & title, dates/times of sampling, grower/processor name/address/license no., batch no., sample matrix, total batch size, total amount of sample, total amount of field duplicate sample, unique sample ID no. and sampling conditions; lab must complete chain of custody form for each sample; lab must maintain documents for 2 years, provide to Dep't upon request

Sampling standard operating procedures: lab must develop and implement written sampling policies and procedures, SOP to include: guide to obtaining samples, accepted sample types, minimum sample size, recommended testing containers, test sample labeling, transport and storage conditions, other requirements, chain of custody documentation, and statements that the sampler must: follow lab's sampling SOP, ensure sampling area free of contaminants, sanitize tools/equipment (unless disposable) between each batch, wear specified sanitary gear, change gloves between each batch, weigh samples to w/in 0.1 g, collect both primary & field duplicate sample, place sample in container to prevent degradation/contamination & w/ tamper-evident seal, assign unique identifier to both samples, record sample conditions, follow chain of custody protocols and complete sample field log to include: lab name & license no., sampler's name/title/other personnel, dates/times of sampling, distributor name/address/license no., name/business address/license no. of transporter, sample matrix, requested analyses, composite sample weight/count, dates/times sampling obtainment, batch size, problems encountered/corrective, each sample weight & count/unique identifier, location taken, any relevant observations, sampling conditions, and batch/lot number of matrix; sampling SOP signed and dated by lab director; lab must retain copy of sampling SOP for sampler

Sampling and sample size: useable marijuana: may only be sampled after cured; harvest lot can't be larger than 10 lbs.; grower may combine batches for sampling only if intended for concentrate/extract and each lot was: cultivated w/ same growing practices & in close proximity, harvested at same time and cured under uniform conditions; primary sample and field duplicate must each weight minimum of 0.5% total harvest batch weight per sample; multiple sample increments must be collected as per provided table; sampler must collected 7-9 increments from each harvest batch (see table); sampler may collect more if needed for testing; concentrates, extracts, products: may only be sampled in final form; lot limited to 10 lbs.; grower/processor must assign unique batch no., which must be documented in records for at least 2 years & available to Dep't, provided to sampler, included on batch label and unique & non-reusable; sampler must obtain both primary and field duplicate sample from each batch; enough samples must be taken to ensure homogeneity and consistency; multiple sample increments must

be obtained as per table; sampler may collect more increments if needed

Grower and processor requirements for labeling and recordkeeping: after sampling, growers and processors shall: label batch with certain info (licensee number, harvest/process lot unique ID no., name & accreditation no. of lab(s), test batch/sample unique ID nos. from sampler, date of sampling, "PRODUCT NOT TESTED"), store & secure on grower/processor premises to prevent tampering, and be able to easily locate batch upon request; if samples pass testing, product may be sold/transferred; if fail, licensee must follow post-testing procedures

Chain of custody (COC) protocol: lab must implement COC protocol; COC protocol must include COC form w/: lab name/address/license no., grower/processor name/address/license no., unique sample identifier, date & time of sample collected and printed & signed name(s) of growers/processors & samplers & receiving lab employee; each time custody changes or is destroyed or transported, date/time/names must be recorded

Receipt of test samples: lab may accept and analyze samples only if accompanying COC form; lab shall not analyze sample if: received w/out COC form, tamper-evident material broken, or evidence of sample comingling/contamination/degradation/related occurrence rendering unusable; lab must record receipt of sample, including: name/contact info of grower/producer, description of sample, whether initial or remediated sample, date of receipt, sample quantity and unique sample identifier

Laboratory Analyses

Standard operating procedures: lab must implement SOP for: sample preparation (sample homogenization, handling & storage, preservation and hold time) and test methods (method name, applicable analytes & matrices, method sensitivity, potential interferences, analytical instruments, type/frequency/acceptance criteria for quality control samples & calibration standards, procedure for analyzing samples, calculation of results and reagent solution standards); supervisor or lab manager must review and sign each SOP and revision; lab must keep each SOP on premises for employees; lab must make each SOP available for Dep't

Test methods: lab must implement methods for sample analysis; lab must comport w/: FDA Bacterial Analysis Manual, FDA Guidelines for Validation of Chemical Methods, AOAC Contaminant Testing Methods, US Pharmacopeia & Formulary for Contaminant Testing

Validation of test methods: lab may use modified test method; lab must follow most recent version of following guidelines to validate test methods: FDA Validation of Methods for Microbial pathogens, FDA Validation of Chemical Methods; lab must address specified criteria for microbial analyses and chemical analyses (see tables)

Required testing: lab must test each sample for: cannabinoids and terpenes, foreign materials, heavy metals, microbial impurities, moisture content/water activity (usable marijuana only), residual pesticides and residual solvents/processing chemicals (products only)
Analyses: licensed lab shall: utilize appropriate analytical methods, require analysts to demonstrate proficiency, maintain written procedures for analytical methods, ensure no deviations from protocols/SOP, use only primary or secondary standards
Recording of analytical data: lab must ensure all data is recorded; in automated systems, individual must be identified at time of input; changes can't obscure original entry; for each final result, lab must verify that: calculations/other steps performed correctly, date meet quality requirements, reference standards were appropriate purity & w/in expiration dates, volumetric solutions properly standardized, and test/measuring equipment properly verified
Sample handling, storage and disposal: lab must establish sample tracking procedures to prevent diversion; lab must store samples to protect physical and chemical integrity; analyzed samples must be segregated and controlled; any marijuana sample not destroyed during analysis shall be: returned to individual/entity, transported to law enforcement office or destroyed in accordance w/ post-testing procedures
Data reporting: lab must generate COA only for primary samples analyzed; lab must issue COA to requester w/in 2 bus. days; COA must include: name/address/license no./contact info of lab, name/address/license no. of requester, form of sample & total weight (g), unique sample identifier, batch no., sample history, analytical methods used, analyst reporting limit, unspecified harmful compounds detected, and ID of supervisory personnel; lab must report test results on COA including: appropriate measurement units, pass/fail, analytes below LOQ, ND for analytes below LOD, NT for tests not performed, synthetic cannabinoids = fail; Dep't may initiate investigation for tentatively identified compounds, may require additional samples submitted for testing
Retention of testing records: lab must retain results for 7 years, make available to Dep't upon request

Post-Testing Procedures

Post-testing sample retention: lab must retain reserve sample for 45 bus. days, then destroyed; lab must securely store reserve sample to prohibit degradation, contamination and tampering; lab must provide reserve sample to Dep't upon request
Remediation and retesting, general: if sample fails test or reanalysis, batch: may be remediated/sterilized or destroyed if can't be remediated/sterilized; harvest or product batch processed after failed test must be re-tested; no remediated harvest or product batches can be sold until re-tested and pass;

growers/processors may remediate provided does not impart toxic/deleterious substance; remediation solvents or methods must be disclosed to lab, processor or dispensary, or consumer upon request; entire failed harvest/product batch must be remediated w/ same technique; growers and processors must: have detailed sterilization procedures to remove microbiological contaminants & foreign materials & to reduce solvents, provide lab w/ document specifying remediation prior to retesting, and document all re-sampling/re-testing/sterilization/remediation/destruction; harvest batch or product batch may only be remediated twice (after second attempt, no release for sale); if harvest batch/product batch fails after remediation/sterilization, must be destroyed; Dep't may authorize re-test to validate failed test at request of grower/processor at personal expense; growers/processors must inform lab prior to sampling if batch has failed; harvest/product batch that fails due to incorrect labeling may be re-labeled

Remediation and retesting, microbiological impurities testing: if usable marijuana sample fails microbiological contaminant testing, batch may be used for concentrate/extract if effectively sterilized; if concentrate/extract sample fails microbiological contaminant testing, batch may be further processed if effectively sterilizes; batch sterilized must then be sampled and tested for contaminants, solvents and pesticides; batch that fails after sterilization must be destroyed

Remediation and retesting, residual solvent and processing chemicals testing: if sample fails residual solvent/processing chemical testing, batch may be remediated to reduce concentration of solvents; batch remediated must be sampled and tested; batch that fails after remediation must be destroyed

Remediation and retesting, moisture content and water activity testing: if usable marijuana sample fails moisture content/water activity testing, batch may: be used to make concentrate/extract or continue to dry/cure; batch that undergoes additional drying/curing must be sampled and tested

Remediation and retesting, foreign materials testing: if usable marijuana sample fails foreign materials testing, must be remediated to reduce foreign materials; must be sampled and tested

Remediation and retesting, residual pesticide testing: if sample fails residual pesticide testing, may not be remediated, must be destroyed; Dep't must report failed pesticide tests to Dep't of Ag.

Remediation and retesting, heavy metals testing: if sample fails heavy metals testing, batch may not be remediated, must be destroyed; Dep't must report failed heavy metals tests to Dep't of Ag.

Remediation and retesting, mycotoxin testing: if sample fails mycotoxin testing, batch may not be remediated, must be destroyed

Remediation and retesting, cannabinoid testing: if usable marijuana sample fails cannabinoid testing, may be repackaged to meet cannabinoid testing standards, must be sampled and tested

Laboratory quality assurance and quality control

Laboratory quality assurance (LQA) program: lab must implement LQA program to address: quality control procedures, lab organization & employee training/ responsibilities, LQA objectives, traceability of data/results, instrument maintenance & calibration procedures, performance/system audits, processes changes, record retention, test procedure standardization and method validation; supervisory employee must annually review LQA program and as necessary when: LQA program & manual created and change in methods/equipment/supervisor

Laboratory quality control samples: lab must use LQC samples; lab must analyze LQC samples in same manner as marijuana and products; lab must use +/- controls for microbial testing; lab must analyze at least 1 LQC sample for each set of 20 for: method blank, continuing calibration verification, lab replicate sample and matrix spike/duplicate sample; if result outside specified chart, lab must determine cause and remedy; lab must generate LQC sample report for each batch

Reagants, solutions and reference standards: shall be: secured as per lab policy, labeled for identity/date received/expiration date, and concentration/storage requirements/date opened; stored to minimize degradation/deterioration; and used only win item's expiration/requalification date; deteriorated/outdated reagents and solutions must be properly disposed; lab may acquire commercial reference standards for testing or may produce internally; lab must obtain/create COA for each lot

Equipment: equipment used must be inspected, cleaned, maintained, calibrated; lab operation must document maintenance procedures and specify remedial action; records must be maintained, including date, personnel, procedure and deviations; computer systems must ensure reliable electronic records

Data storage: raw data stored for 7 years; lab must designate individual for record maintenance; lab must maintain records: to allow for retrieval, under conditions that minimize deterioration and in manner that prevents unauthorized alteration

Materials to be maintained on premises: personnel documentation, lab operation requirements, standards for handling, equipment information, reagants/solutions/reference standards, reference standards including COA, sample analysis procedures, documentation of methods, standards for data recording/reporting, chemical safety data sheets, and "other" by Dep't

Proficiency testing: lab subject to PT by Dep't, must cooperate; if lab fails PT, Dep't may deny application/withdraw approval, require additional tests or require remedial action

Inspection of the laboratory and records: labs subject to Dep't inspections of premises, equipment and written materials
Department access to materials and premises: lab must provide Dep't access to testing reports/data and premises