Summary of Express Terms

These amendments add a new Part 1005 to Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York, regulating the processing and retail sale of cannabinoid hemp in New York State.

Section 1005.1 defines terms used in Part 1005, including but not limited to "cannabinoid hemp product," "cannabinoid hemp processor," "cannabinoid hemp retailer," "hemp extract," and "used for human consumption."

Section 1005.2 establishes licensure and application requirements for cannabinoid hemp processors in New York State. Any person extracting or manufacturing cannabinoid hemp in New York State is required to obtain a license from the New York State Department of Health (Department). Among other requirements, cannabinoid hemp processor applications must be accompanied by a summary and description of the products the applicant intends to make, proof of product liability insurance, evidence of good manufacturing practices, and copies of the organizational documents of the applicant. Cannabinoid hemp processor applications must be submitted with a $1,000 application fee or a $500 application fee for applicants seeking only to manufacture, and not extract, cannabinoid hemp.

Section 1005.3 sets out the requirements to apply as a cannabinoid hemp retailer in New York State. Any person selling cannabinoid hemp to consumers must obtain a license from the Department. Among other requirements, cannabinoid hemp retail applications must be accompanied by a summary and description of the type of cannabinoid hemp products the

retailer intends to sell, the name and state or country of origin of any manufacturers the retailer intends to source from, an attestation that the applicant will not sell inhalable cannabinoid hemp products to consumers under 21 years old, and proof of a certificate of authority from the Department of Taxation and Finance. All applications must be submitted with a $300 license fee for each retail location to be licensed by the Department.

Section 1005.4 describes the criteria the Department will use to determine if an applicant's license should be approved or denied. If an applicant is approved as a cannabinoid hemp processor, the approved applicant must submit the following before receiving the final license: a copy of the certificate of occupancy for the facility, a copy of the applicant's evidence of a Good Manufacturing Practices (GMP) audit, and the license fee of $4,500 for extracting or $2,000 for manufacturing only. Processor licenses are valid for two years and retailer licenses are valid for one year.

Section 1005.5 outlines the requirements for license renewal.

Section 1005.6 sets out the rules around transfers and amendments to licenses, including changes in ownership. All licenses under this Part are non-transferable, except with the prior written approval of the Department.

Section 1005.7 outlines the requirements for cannabinoid hemp processors. Cannabinoid hemp processors are required to maintain qualified third-party GMP certification for the duration of the license term. Processors must retain records of the extraction and manufacturing process including but not limited to the source of hemp or hemp extract, the calibration and inspection of

all equipment or instruments, the disposal of hemp extract or hemp by-product, the tracking and documentation of Δ9-Tetrahydrocannabinol (THC), and all testing records of samples from lots or batches of product. This section also imposes security and sanitary standards on the licensee to keep unauthorized individuals from entering the licensed premise and to ensure the facility is safe and sanitary to create products for human consumption. Intermediate sales of hemp extract containing up to 3.0% THC are authorized, provided that the sale is between licensed processors in New York State and the proper documents accompany the extract during transport. All solvents and methods used to extract hemp extract must be approved by the Department.

Section 1005.8 outlines the cannabinoid hemp product requirements to be sold at retail. Product requirements include but are not limited to: not containing more than 0.3% total Δ9-Tetrahydrocannabinol concentration; not containing tobacco or alcohol; not being in the form of an injectable, transdermal patch, inhaler, suppository, flower product including cigarette, cigar or pre-roll, or any other disallowed form as determined by the department; if sold as a food or beverage product, not have more than 25mg of cannabinoids per product; and, if sold as an inhalable cannabinoid hemp product, a number of additional safety measures.

Section 1005.9 is added to outline the requirements of cannabinoid hemp packaging and labeling. All cannabinoid hemp products need to be labeled with the amount of cannabinoids in the product and the amount of milligrams per serving. If the product contains THC, the amount of THC in the product needs to be stated on the label in milligrams on a per serving and per package basis. All products are required to have a scannable code which links to a certificate of analysis and the packaging is prohibited from being attractive to consumers under 18 years old. Products are also required to list appropriate warnings for consumer awareness.

Section 1005.10 establishes laboratory testing requirements for cannabinoid hemp products. Cannabinoid hemp processors must have cannabinoid hemp products tested at a laboratory approved to test medical marijuana or that meets minimum requirements established in this section, including maintaining ISO/IEC 17025 accreditation and validating the methods used for testing. This section describes which analytes are part of required testing and further establishes limits for cannabinoids, heavy metals, microbial impurities, mycotoxins, residual pesticides, residual solvents and processing chemicals. Cannabinoid hemp products that contain levels of analytes that deviate from the allowable limits are considered adulterated and must be destroyed.

Section 1005.11 outlines requirements for cannabinoid hemp retailers. Cannabinoid hemp retailers can only sell products that are manufactured, packaged, labeled and tested according to the standards outlined in regulations and can only sell inhalable cannabinoid hemp products to consumers over 21 years old. All licensees must post their license in a conspicuous manner and maintain sufficient inventory and sales records. The Department also has the authority to inspect cannabinoid hemp retailers, require cannabinoid hemp products be displayed separately from other products, and take samples of cannabinoid hemp products to ensure compliance with this Part.

Section 1005.12 establishes advertising requirements for cannabinoid hemp processors and retailers, including the prohibition on false or misleading statements and medical claims.

Section 1005.13 gives the Department the authority to establish additional standards and requirements to certify a product as a New York Hemp Product.

Section 1005.14 outlines general prohibitions, including the requirement that all entities manufacturing or selling cannabinoid hemp products in New York State must hold a valid license under this Part. All cannabinoid hemp products must comply with manufacturing, laboratory testing, and packaging and labeling requirements outlined in the proposed regulations. All cannabinoid hemp products offered for retail sale in New York State must have a concentration of no more than 0.3% total Δ9-Tetrahydrocannabinol. Requirements are also established for the transportation of hemp extract, including the requirement that it be transported in a fully enclosed vehicle or container and accompanied by proof of origin and a certificate of analysis. Additionally, smoking cannabinoid hemp products is prohibited in any location where smoking is currently prohibited under the Public Health Law. Finally, this section requires that anyone distributing cannabinoid hemp products manufactured out of state, to cannabinoid hemp retailers within the state, be permitted by the Department.

Section 1005.15 describes specific prohibitions that pertain to cannabinoid hemp processors including the transfer of a license without approval from the Department and the manufacture of a potentially hazardous food containing cannabinoid hemp. Further, no cannabinoid hemp processor may conduct final product testing for the licensee's own products to satisfy the testing requirements established in the proposed regulations. Cannabinoid hemp processors may not sell cannabinoid hemp products directly to consumers for final sale without obtaining a cannabinoid hemp retail license and cannabinoid hemp processors may not sell cannabinoid hemp extract to anyone in New York unless the purchaser is a cannabinoid hemp processor or a registered organization in the Department's Medical Marijuana Program.

Section 1005.16 describes specific prohibitions for cannabinoid hemp retailers, including age restrictions for the sale of inhalable cannabinoid hemp products and a prohibition on the sale of cannabinoid hemp products that do not meet product requirements or consumer safety standards outlined in this Part.

Section 1005.17 establishes penalties for non-compliance with this Part and with the requirements of Article 33-B of the Public Health Law. Penalties include a series of civil penalties that increase with the number of violations, such that the first violation incurs a fine of up to $1,000, the second violation within a three year period incurs a fine of up to $5,000, and the third violation or any additional violation incurs a fine of up to $10,000. This section further allows the Department to limit, suspend, revoke or annul a license. If a licensee violates the proposed regulations three times in a five-year period, the licensee may be deemed ineligible to manufacture or sell cannabinoid hemp products for a period of five years.

Section 1005.18 provides the Department authority to issue permits for distribution of out of state cannabinoid hemp products, delivery of cannabinoid hemp products, temporary retail sale and to persons holding a CBD processor research partnership agreement with the New York State Department of Agriculture and Markets. Permits are valid for one year unless otherwise established by the Department.

Section 1005.19 adds a severability clause for the Part.

Section 1005.20 incorporates by reference certain federal regulations.

Pursuant to the authority vested in the Commissioner of Health by Section 3398-a of the Public Health Law (PHL), Chapter XIII of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is hereby amended, and a new Part 1005 is added, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

The title of Chapter XIII is amended to read as follows:

Chapter XIII

MEDICAL [USE OF] MARIHUANA AND CANNABINOID HEMP

A new Part 1005 is added to read as follows:

Part 1005

CANNABINOID HEMP

Section 1005.1 Definitions

For purposes of this Part, the following terms shall have the following meanings:

(a) *Broad spectrum* means a concentrate extracted from hemp containing multiple cannabinoids, but where all Δ9-Tetrahydrocannabinol (THC) has been removed.

(b) *Cannabidiol* or *CBD* means the naturally occurring phytocannabinoid cannabidiol found in hemp but does not include synthetic cannabidiol.

(c) *Cannabinoids* means any phytocannabinoid found in hemp, including but not limited to, Tetrahydrocannabinol (THC), tetrahydrocannabinolic acid (THCA), cannabidiol (CBD), cannabidiolic acid (CBDA), cannabinol (CBN), cannabigerol (CBG), cannabichromene (CBC), cannabicyclol (CBL), cannabivarin (CBV), tetrahydrocannabivarin (THCV), cannabidivarin (CBDV), cannabichromevarin (CBCV), cannabigerovarin (CBGV), cannabigerol monomethyl ether (CBGM), cannabielsoin (CBE), cannabicitran (CBT). Cannabinoids do not include synthetic cannabinoids as that term is defined in subdivision (g) of section 3306 of the Public Health Law and section 9-1.1 of this Title.

(d) *Cannabinoid hemp product* means hemp or any product manufactured or derived from hemp, including hemp derived terpenes, in its final form, that are used for human consumption. Cannabinoid hemp product shall not include cosmetics.

(e) *Cannabinoid hemp retailer* means a person licensed by the department to sell cannabinoid hemp products, including via the internet, to consumers in New York State.

(f) *Cannabinoid hemp processor* means a person licensed by the department to extract hemp extract and/or manufacture cannabinoid hemp products, whether in intermediate or final form, to be used for human consumption.

(g) *Certificate of analysis* means a certified report from an independent third-party laboratory meeting all of the requirements of section 1005.10 of this Part, describing its analytical testing and results.

(h) *Corrective action plan* means a plan submitted by a licensee and approved by the department under this Part for the licensee to correct a violation or non-compliance with this Part.

(i) *Cosmetic* means a cosmetic meeting the requirements of section 321 of Title 21 of the United States Code and recognized as such by the department.

(j) *Distillate* means a concentrate where a segment of cannabinoids from an initial extraction are selectively concentrated through heating and cooling, with all impurities removed.

(k) *Distribute* means to offer or sell cannabinoid hemp products to a cannabinoid hemp retailer, for retail sale to consumers within New York state.

(l) *Extract* or *Extraction* means the process of concentrating or isolating one or more cannabinoids from hemp or cannabinoid hemp.

(m) *Flower product* means any form of cannabinoid hemp product consisting of the flower, buds, leaves, or stems of the hemp plant, including trimmings thereof, intended for retail sale to consumers without further processing.

(n) *Full spectrum* means a cannabinoid hemp product that is:

(1) derived from a hemp extract;

(2) contains cannabinoids, aromatics, essential vitamins and minerals, fatty acids, protein, chlorophyll, flavonoids, or terpenes; and

(3) has not been reformulated or has not had cannabinoid isolates or distillates added to it.

(o) *Hemp* means the plant Cannabis sativa L. and any part of such plant, including the seeds thereof and all derivates, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a Δ9-Tetrahydrocannabinol concentration of not more than three-tenths of a percent on a dry weight basis.

(p) *Hemp extract* means all derivatives, extracts, cannabinoids, isomers, acids, salts of isomers derived from hemp and used for human consumption, with a Δ9-Tetrahydrocannabinol concentration of not more than an amount determined by the department. Hemp extract shall not include:

(1) any food, food ingredient or food additive that is generally recognized as safe pursuant to federal law; or

(2) any extract derived from hemp that is not used for human consumption.

(q) *Isolate* means a concentrate that is more than 95 percent comprised of a single cannabinoid compound created by a chemical extraction process.

(r) *Lot* or *batch* means any cannabinoid hemp product produced during a period of time under similar conditions and identified by a specific code that allows traceability.

(s) *Manufacture* means to prepare, treat, modify, compound, process, package or otherwise manipulate hemp or hemp extract into a cannabinoid hemp product. Manufacturing shall not include:

(1) growing, cultivating, cloning, harvesting, drying, curing, grinding or trimming when authorized pursuant to Article 29-A of the Agriculture and Markets Law; or

(2) extraction as defined in subdivision (k) of this Section.

(t) *New York Hemp Product* means a cannabinoid hemp product that is derived from hemp exclusively grown, extracted and manufactured in New York, in compliance with section 1005.13 of this Part.

(u) *Person* means an individual, partnership, corporation, limited liability company, association, or any business entity or institution of higher education, by whatever name designated and whether or not incorporated.

(v) *Serious adverse event* means a medical occurrence associated with the use of a cannabinoid hemp product in a human that results in one or more of the following outcomes: death, a life-threatening event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect.

(w) *Total Δ9-Tetrahydrocannabinol concentration* means [Δ9-Tetrahydrocannabinol] + (0.877 x [tetrahydrocannabinolic acid]).

(x) *Used for human consumption* means intended by the manufacturer or distributor to be:

(1) used for human consumption for its cannabinoid content; or

(2) used in, on or by the human body for its cannabinoid content.

Section 1005.2 Application for cannabinoid hemp processor license.

(a) No person or entity shall extract hemp extract or manufacture cannabinoid hemp product, or hold itself out as a cannabinoid hemp processor, unless it is in compliance with Article 33-B of the Public Health Law and this Part and is licensed by the department.

(b) An application for licensure shall be submitted to the department on a form prescribed by the department which shall include the following:

(1) the name, address, telephone number and email address of the applicant;

(2) identification of all real property, buildings and facilities that will be used in the extracting or manufacturing of cannabinoid hemp;

(3) the days and hours of operation;

(4) the Federal employer identification number of the applicant;

(5) for applicants extracting cannabinoid hemp, identification of all extraction methods that will be used to carry out the extracting of cannabinoid hemp;

(6) proof of New York State Workers' Compensation and Disability Insurance coverage, or a Certificate of Attestation of Exemption from coverage;

(7) a summary and description of the applicant's:

(i) source(s) of hemp and hemp extract to be used by the licensee; and

(ii) cannabinoid hemp products to be manufactured;

(8) a statement that the applicant's standard operating procedures will incorporate any language or requirements provided by the department and adequately address quality assurance, security, and a plan to ensure all hemp and hemp extract obtained by the applicant meets the requirements of this Part.

(9) evidence that Good Manufacturing Practices (GMP) will be used in the extraction of hemp extract and manufacturing of cannabinoid hemp products. Such evidence shall include one of the following:

(i) proof of a qualified third-party GMP audit of the applicant's extraction and manufacturing processes; or

(ii) a detailed plan for obtaining a qualified third-party GMP audit within six months of approval of the application and before beginning operations as a cannabinoid hemp processor in New York State;

(10) a copy and description of any other license(s) issued by state or federal authorities related to the operations of the licensee or the facility where licensed activity will occur;

(11) a description of any other businesses or business activities conducted on the premises to be licensed;

(12) copies of the organizational documents of the applicant;

(13) a statement attesting that the applicant and those in control of the entity, meaning a person that has the ability to direct the activity of the applicant or licensee, including principals, officers or others with such control are of good moral character;

(14) a statement that the applicant will comply with all applicable state and local laws and regulations relating to the activities in which it intends to engage under the license;

(15) a statement that the applicant has the experience and competency to undertake the activities for which licensure is sought; and

(16) any other information as may be required by the department.

(c) Applications under this section shall be accompanied by a non-refundable application fee of $1,000 for extraction and manufacturing, and $500 for a license to manufacture only.

(d) Applicants shall verify the truth and accuracy of the information contained in the application. The department, in its discretion, may reject or deny an application if it determines that information contained therein is false, inaccurate or omits a material fact.

Section 1005.3 Application for Cannabinoid Hemp Retail License.

(a) No person shall offer or sell cannabinoid hemp products to consumers in New York State, or hold itself out as a cannabinoid hemp retailer, unless it is in compliance with Article 33-B of the Public Health Law and this Part and is licensed by the department.

(b) An application for licensure shall be submitted to the department on a form prescribed by the department, which shall include the following:

(1) the name, address, telephone number and email address of the applicant;

(2) the physical address of any real property where the applicant intends to operate, the days and hours of operation of such retail facility, and for any online retailer, the internet address of the applicant;

(3) the name of the manufacturer or cannabinoid hemp processor, and state or country of manufacture, for all cannabinoid hemp products the applicant intends to offer for sale;

(4) a summary and description of the types and forms of cannabinoid hemp products the applicant intends to offer for sale;

(5) a statement that the applicant will not sell inhalable cannabinoid hemp products to consumers under 21 years of age;

(6) a statement that the applicant and those in control of the entity, meaning a person or persons that have the ability to direct the activity of the applicant or licensee, including principals, officers or others with such control, are of good moral character;

(7) a statement that the applicant will comply with all applicable state and local laws and regulations relating to the activities in which it intends to engage under the license;

(8) a statement that the applicant will not distribute or sell any cannabinoid hemp product in the form of an injectable, transdermal patch, inhaler, suppository, flower product including cigarette, cigar, pre-roll or any other disallowed form as determined by the department;

(9) proof of a certificate of authority from the New York State Department of Taxation and Finance, as applicable; and

(10) any other information as may be required by the department.

(c) All applications under this section shall be accompanied by refundable license fee of $300 for each retail facility to be licensed by the department.

(d) Applicants shall attest to the truth and accuracy of the information contained in the application. The department, in its discretion, may reject or deny an application if it determines that information contained therein is false, inaccurate or omits a material fact.

Section 1005.4 License issuance and denial.

(a) An application for licensure under this Part shall only be approved by the department if:

(1) a complete application has been submitted to the department, along with all necessary fees;

(2) the application demonstrates, to the satisfaction of the department, that the applicant will operate in accordance with Article 33-b of the Public Health Law and this Part;

(3) the applicant is ready, willing and able to properly carry on the activities set forth in the application; and

(4) the applicant is of good moral character.

(b) In determining whether to deny a license application, including an application for renewal, the department may consider the following factors with respect to the applicant, its owner(s) and any affiliated person, including parties with a controlling interest:

(1) false representation or omission of a material fact in filing the license application;

(2) failure to supply further information necessary to process the license application, within thirty days of the department's written request, without satisfactory explanation;

(3) conviction of any crime or sustained charges of administrative violations of state or federal laws, rules or regulations, related to the operation of a site growing, extracting, manufacturing or selling marihuana, hemp or cannabinoid hemp, in accordance with Article 23-A of the Correction Law;

(4) a pattern of deficiencies, including but not limited to:

(i) refusal or inability to produce records or reports as requested by the department;

(ii) failure to correct deficiencies in accordance with an approved corrective action plan;

(iii) deviation from regulations or standard operating procedures so as to jeopardize the quality of hemp extract or cannabinoid hemp products; and

(iv) refusal to provide department employees with access to the premises;

(5) knowledge of sale of cannabinoid hemp products not meeting the requirements of this Part; and

(6) general failure to comply with the requirements of this Part.

(c) Denial of a license shall preclude the applicant from being licensed as a cannabinoid hemp processor or cannabinoid hemp retailer, either directly or indirectly through any other person.

(d) No license application shall be considered for any applicant who is substantially the same as an applicant who has been denied a license within six months of a determination by the department denying such application. In the event an applicant receives two successive license denials, no license application shall be considered for that applicant within two years of the last determination by the department denying a previous application.

(e) The department will prioritize applications from applicants who previously held a valid research partnership agreement with the New York State Department of Agriculture and Markets pursuant to Article 29-A of the New York State Agriculture and Markets Law. All other applications will be reviewed in the order they are received by the department.

(f) For applicants seeking licensure as a cannabinoid hemp processor, the department may provisionally approve the application. Before a cannabinoid hemp processor license is issued, and the applicant can begin extracting or manufacturing, the provisionally approved applicant must first satisfy the following requirements:

(1) a copy of a certificate of occupancy, or its equivalent, demonstrating compliance with all local building codes;

(2) a copy of the approved applicant's qualified third-party GMP certification;

(3) payment of licensure fee as follows:

(i) Cannabinoid Hemp Processor – Extraction and Manufacturing: $4,500 per location; or

(ii) Cannabinoid Hemp Processor – Manufacturing Only: $2,000 per location;

(4) proof of sufficient product liability insurance for all manufactured cannabinoid hemp products; and

(5) evidence, to the department's satisfaction, that the applicant will be able to comply with this Part, which may include an onsite inspection.

(g) If a provisionally approved applicant fails to satisfy the requirements in subdivision (f) of this section within six months, the provisional approval will be revoked and the application denied; provided the applicant may request additional time and shall have the opportunity to demonstrate to the department a reasonable documented effort to complete the requirements of subdivision (f) of this section.

(h) Cannabinoid hemp processor licenses shall be valid for two years from the date of issuance of the license.

(i) A cannabinoid hemp processor seeking to terminate its license shall submit a withdrawal notice to the department at least 30 days prior to termination, along with a plan for shutting down operations at the licensed facility. Any licensing fees paid or invoiced prior to notice of withdrawal are not eligible for refund.

(j) Cannabinoid hemp retailer licenses shall be valid for one year from the date of issuance of the license.

(k) Cannabinoid hemp retail applicants who submit a completed application to the department on or before April 1, 2021 may sell cannabinoid hemp products at retail to consumers before having their license approved or denied by the department, provided that the cannabinoid hemp retail applicant adheres to all requirements of this Part.

Section 1005.5 License Renewal

(a) An application to renew any license issued under this Part shall be filed with the department not more than 90 days nor less than 30 days prior to the expiration thereof. If a renewal application is not filed at least 30 days prior to the expiration thereof, the department may determine that the license shall expire and become void on such expiration date.

(b) Renewal applications shall be accompanied by a non-refundable application fee and a refundable license fee, as follows:

(1) Cannabinoid Hemp Processor – Extraction and Manufacturing: $1,000 application fee, $4,500 license fee;

(2) Cannabinoid Hemp Processor – Manufacturing Only: $500 application fee, $2,000 license fee; or

(3) Cannabinoid Hemp Retailer: $300 license fee per retail location.

(4) the license fee shall be returned if the licensee's renewal application is not granted.

(c) The application for renewal shall be submitted to the department on a form prescribed by the department and include such information as the department may require.

(d) The department shall determine whether to renew an applicant's license based on the relevant factors in section 1005.4 of this Part.

Section 1005.6 Transferability, License Amendment and Change in Ownership or Control

(a) Licenses issued under this Part shall be effective only for the licensee and shall specify the following information:

(1) name of the licensee;

(2) address of the real property, or if applicable the online retailer website, where the licensed activities may take place;

(3) date of issuance;

(4) date of expiration;

(5) license number; and

(6) list of activities the licensee is permitted to perform under the license.

(b) Licenses shall not be transferable or assignable, including, without limitation, to another licensee, without prior written approval of the department. A change in majority ownership or controlling interest in the license or person holding the license, shall constitute a transfer of the license.

(c) To obtain approval from the department for the transfer of a license, a transferee must submit an application to the department, on a form prescribed by the department, demonstrating an ability to operate the license in compliance with this Part, along with an application fee pursuant to section 1005.2 or 1005.3, as applicable.

(d) The department may deny an application for transfer of a license if the application fails to demonstrate that the transferee will comply with all of the requirements of this Part, or if the

licensee has a record of poor performance, meaning two or more violations pursuant to section 1005.17 of this Part, within the past two-years.

(e) A licensee may amend a license to add or delete permitted activities or change the location of a licensed facility by submitting a written request to the department along with an application fee pursuant to section 1005.2 or 1005.3, as applicable.

(f) A request to add permitted activities shall be reviewed by the department in accordance with section 1005.4 of this Part.

Section 1005.7 Requirements for Cannabinoid Hemp Processors

(a) All cannabinoid hemp processors shall:

(1) extract hemp extract and/or manufacture cannabinoid hemp products to GMP standards and maintain a qualified third-party certification, to the satisfaction of the department, for the applicable GMP standard(s) for the duration of the license;

(2) maintain standard operating procedures and quality control standards to ensure consistency of hemp extract and/or cannabinoid hemp products, including but not limited to product purity, strength and composition;

(3) maintain sufficient records to demonstrate that any hemp or hemp extract used by the licensee was grown, derived, extracted and transported in accordance with applicable laws and licensing requirements of the jurisdiction(s) from which such hemp or hemp extract was sourced. Such records shall include any pesticides used in the growing of such hemp, date(s) each shipment was received, adequate chain of custody to demonstrate from whom the licensee purchased such hemp or hemp extract, and certificates of analysis. For hemp received from an out-of-state grower, processors shall also maintain records of the out-of-state grower registration or license number in the respective jurisdiction;

(4) keep all designated extracting and manufacturing areas safe and sanitary, including but not limiting to ensuring that such areas are adequately lit, cleaned, smoke-free, and no food is consumed in such areas;

(5) provide all employees performing extraction or manufacturing with adequate training and proper safety equipment;

(6) manufacture cannabinoid hemp products in accordance with section 1005.8 of this Part;

(7) test a statistically significant number of cannabinoid hemp products per lot or batch at a third-party testing laboratory meeting all the requirements in section 1005.10 of this Part, and maintain a certificate of analysis for all samples tested;

(8) maintain sufficient records pertaining to the calibration and inspection of instruments used in extraction and manufacturing of cannabinoid hemp products;

(9) report, in a frequency and manner prescribed by the department, the total production and sales of the licensee during such reporting period;

(10) ensure the security of the licensed premises to prevent unauthorized individuals from entering the facility and to prevent hemp extract and/or cannabinoid hemp products from being diverted from the facility;

(11) not use synthetic cannabinoids in the extraction or manufacturing of any cannabinoid hemp products;

(12) assign a lot or batch number to each lot of hemp extract or cannabinoid hemp product, extracted or manufactured by a licensee; and

(13) maintain any and all records required by this Part for at least five years and immediately produce such records upon request of the department.

(b) Possession and the intermediate sale of hemp extract by and between licensed cannabinoid hemp processors, is permitted, provided when such extract leaves the licensed premises it is accompanied by a certificate of analysis certifying that the extract is less than three (3) percent THC and a copy of the cannabinoid hemp processor's license, and further provided such hemp extract is only transported intra-state.

(c) Licensees shall monitor complaints from cannabinoid hemp retailers and consumers and have a mechanism in place to notify the licensee's supply chain to recall products when directed by the department or as deemed appropriate by the licensee. Licensees shall notify the department within 24 hours of learning of a serious adverse event.

(d) Licensees shall ensure the proper disposal, beyond reclamation, of any hemp extract or by-product from the extraction and manufacture process with a total Δ9-Tetrahydrocannabinol concentration greater than three-tenths of a percent (0.3%) and which will not be used or subject to further processing. Such disposal shall render the hemp extract or by-product unusable for any intoxicating purpose. Licensees shall maintain records to document and track any Δ9-Tetrahydrocannabinol extracted from hemp or found within hemp extract throughout the extraction and manufacturing process, including records pertaining to the amount used in cannabinoid hemp products and the disposal of all hemp extract, Δ9-Tetrahydrocannabinol or by-product;

(1) licensees shall dispose of any cannabinoid hemp product that is outdated, damaged, deteriorated, contaminated or otherwise deemed not appropriate for sale; and

(2) licensees shall dispose of liquid, chemical and hazardous waste in accordance with applicable federal, state and local laws and regulations.

(e) The department may conduct random sampling and testing of hemp, hemp extract, cannabinoid hemp products, or any solvents, chemicals, or materials used by the licensee, unannounced, at any time during normal business hours of the licensee.

(f) If a cannabinoid hemp processor is authorized to perform extraction, the processor shall:

(1) only extract using methods approved by the department, on the licensed premises, and using employees and equipment sufficient to ensure safe extraction; and

(2) use only those solvents that are approved by the department. Solvent-based extraction must be completed in a commercial, professional grade, closed-loop system capable of recovering the solvent used for extraction

Section 1005.8 Cannabinoid hemp product requirements

(a) All cannabinoid hemp products distributed or offered for retail sale in New York State shall:

(1) be manufactured in accordance with Parts 101, 111 or 117 of Title 21 of the Code of Federal Regulations, as applicable or as otherwise determined appropriate by the department in guidance.

(2) contain no more than three-tenths of a percent (0.3%) total Δ9-Tetrahydrocannabinol concentration. The department shall have the ability to impose a total Δ9-Tetrahydrocannabinol cap in milligrams per serving and milligrams per package for cannabinoid hemp products based on the product form, volume, number of servings, and ratio of CBD to THC;

(3) not contain liquor, wine, beer, cider or meet the definition of an alcoholic beverage as defined in section 3 of the Alcohol Beverage Control Law;

(4) not contain tobacco or nicotine in the product;

(5) not be in the form of an injectable, transdermal patch, inhaler, suppository, flower product including cigarette, cigar or pre-roll, or any other disallowed form as determined by the department;

(6) accurately reflect testing results and not contain less than 90 percent or more than 110 percent of the concentration of total cannabinoid content as listed on the product label;

(7) comply with packaging and labeling standards in section 1005.9 of this Part;

(8) be prepackaged and not added to food or any other consumable products at the point of sale;

(9) be shelf stable; and

(10) comply with product testing standards in section 1005.10 of this Part.

(b) If the cannabinoid hemp product is a food or beverage manufactured under Part 117 of Title 21 Code of Federal Regulations, it shall not contain more than 25 milligrams of total cannabinoids per product. If the cannabinoid hemp product is a supplement manufactured under

Part 111 of Title 21 Code of Federal Regulations, it shall not contain more than 3,000 milligram of total cannabinoids per product.

(c) If the cannabinoid hemp product contains multiple servings which are not individually wrapped, it shall include a measuring device such as a measuring cap, cup or dropper with the product packaging. Hash marks on the package shall not qualify as a measuring device.

(d) All inhalable cannabinoid hemp products shall meet the following additional requirements:

(1) be a closed system with a pre-filled disposable cartridge that attaches to a rechargeable battery, or a single-use product that cannot be recharged;

(2) electronic vaporization devices shall have internal or external temperature controls to prevent combustion and have a heating element made of inert material such as glass, ceramic or stainless steel and not plastic or rubber;

(3) except for hemp-derived terpenes, excipients and ingredients must be pharmaceutical grade unless otherwise approved by the department, and shall not include:

(i) synthetic terpenes;

(ii) polyethylene glycol (PEG);

(iii) vitamin E acetate;

(iv) medium chain triglycerides (MCT oil);

(v) medicinal compounds;

(vi) illegal or controlled substances;

(vii) artificial food coloring;

(viii) benzoic acid;

(ix) diketones; and

(x) any other compound or ingredient as determined by the department;

(4) not contain any flavors or flavoring agents, except for hemp-derived terpenes; and

(5) starting on June 1, 2021, include a department approved symbol in a manner that is clear and conspicuous.

Section 1005.9 Packaging and labeling of cannabinoid hemp products.

(a) All cannabinoid hemp products distributed or offered for retail sale in New York State shall include the following information on the product label or packaging:

(1) a nutritional or supplement fact panel that must be based on the number of servings within the container and include:

(i) a list of all ingredients in descending order of predominance by weight in the product, including but not limited to total Δ9-Tetrahydrocannabinol concentration, CBD and any other cannabinoids over 0.05%; and

(ii) the number of servings per package or container, including the amount of measurable cannabinoids in milligrams per serving and the total cannabinoid content of the package. If applicable, the amount of total Δ9-Tetrahydrocannabinol in milligrams per serving and milligrams per package shall be stated on the label;

(2) an expiration date;

(3) a lot or batch number;

(4) the name of the cannabinoid hemp processor or out of state manufacturer;

(5) a scannable bar code or QR code linked to a downloadable certificate of analysis;

(6) the state(s) of origin from which hemp used in the product was sourced or, if sourced from outside of the United States, the country (or countries) of origin;

(7) a means for reporting serious adverse events or side effects; and

(8) any other marking, statement or symbol as required by the department.

(b) No cannabinoid hemp product shall be packaged or contained in such a manner so as to be attractive to anyone under 18 years of age, or for inhalable cannabinoid hemp products to anyone under 21 years of age.

(c) All cannabinoid hemp products shall be packaged in tamper-evident packaging that minimizes oxygen and light exposure to prevent degradation of the product and cannabinoids.

(d) All cannabinoid hemp products shall be accompanied by recommended dosing and clear usage instructions.

(e) All cannabinoid hemp products claiming to be “isolate,” “full spectrum,” “broad spectrum,” or “distillate” shall comply with the applicable definition contained in this Part.

(f) All cannabinoid hemp products offered for retail sale shall include the following warnings on the product label or packaging, in a manner that is clear and conspicuous, and be written in text no smaller than size 8-point font:

(1) keep out of the reach of children;

(2) a warning stating that the product is derived from hemp and may contain THC which could result in the consumer failing a drug test for marijuana;

(3) that the product has not been evaluated by the Food and Drug Administration for safety or efficacy;

(4) for those who are pregnant or nursing to consult their healthcare provider before use; and

(5) if the product is an inhalable cannabinoid hemp product, a warning stating that smoking or vaporizing is hazardous to your health.

Section 1005.10 Laboratory testing requirements for cannabinoid hemp

(a) For purposes of this Section, the following terms shall have the following meanings:

(1) “Accreditation body” means an impartial non-profit organization that operates in conformance with the International Organization for Standardization (ISO) / International Electrotechnical Commission (IEC) standard 17011 and is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) for Testing.

(2) “Certificate of accreditation” means a document issued by an accreditation body that attests to the laboratory’s competence to carry out specific testing and analysis.

(3) “Testing laboratory” means an independent, third-party laboratory, contracted by a cannabinoid hemp processor to test cannabinoid hemp products.

(b) To be recognized as a testing laboratory for purposes of testing cannabinoid hemp products as required by this Part, a laboratory must either be approved to test medical marijuana pursuant to Section 55-2.15 of this Title, or meet all of the following minimum requirements:

(1) maintain ISO/IEC 17025 accreditation for the premises and for the testing of:

(i) Cannabinoids;

(ii) Heavy metals;

(iii) Microbial impurities;

(iv) Mycotoxins;

(v) Residual pesticides;

(vi) Residual solvents and processing chemicals; and

(vii) If tested, terpenoids.

(2) maintain a valid certificate of accreditation, issued by an accreditation body, that attests to the laboratory's competence to perform testing of the analytes listed in subdivision (b)(1) of this section.

(3) maintain method validation reports for all testing performed; and

(4) maintain standard operating procedures for the sampling of cannabinoid hemp products.

(c) Cannabinoid hemp processors shall retain, and make available to the department upon request, all records associated with their testing laboratory's ISO/IEC 17025 accreditation, certificate of accreditation, method validation reports and standard operating procedures for the sampling of cannabinoid hemp products, as required by this section.

(d) Cannabinoid hemp products shall be considered adulterated and shall not be sold within New York State, if contaminants are detected at levels greater than provided for by the department in this Part or issued in further guidance.

(e) The department shall have the ability to impose additional testing requirements including but not limited to, testing for additional analytes, setting stricter contaminant limits and mandating the use of specific sampling methodologies per lot or batch manufactured.

(f) Pesticide Limits. The following list of contaminants does not constitute authorization to use or apply any of the following during hemp cultivation or processing:

1. Abamectin, 300 parts per billion.

2. Acephate, 3,000 parts per billion.

3.Acequinocyl, 2,000 parts per billion.

4. Acetamiprid, 3,000 parts per billion.

5. Aldicarb, 100 parts per billion.

6. Azoxystrobin, 3,000 parts per billion.

7. Bifenazate, 3,000 parts per billion.

8. Bifenthrin, 500 parts per billion.

9. Boscalid, 3,000 parts per billion.

10. Captan, 3,000 parts per billion.

11. Carbaryl, 500 parts per billion.

12. Carbofuran, 100 parts per billion.

13. Chlorantraniliprole, 3,000 parts per billion.

14. Chlordane, 100 parts per billion.

15. Chlorfenapyr, 100 parts per billion.

16. Chlormequat chloride, 3,000 parts per billion

17. Chlorpyrifos, 100 parts per billion.

18. Clofentezine, 500 parts per billion.

19. Coumaphos, 100 parts per billion.

20. Cyfluthrin, 1,000 parts per billion.

21. Cypermethrin, 1,000 parts per billion.

22. Daminozide, 100 parts per billion.

23. DDVP (Dichlorvos), 100 parts per billion.

24. Diazinon, 200 parts per billion.

25. Dimethoate, 100 parts per billion.

26. Dimethomorph, 3,000 parts per billion.

27. Ethoprop(hos), 100 parts per billion.

28. Etofenprox, 100 parts per billion.

29. Etoxazole, 1,500 parts per billion.

30. Fenhexamid, 3,000 parts per billion.

31. Fenoxycarb, 100 parts per billion.

32. Fenpyroximate, 2,000 parts per billion.

33. Fipronil, 100 parts per billion.

34. Flonicamid, 2,000 parts per billion.

35. Fludioxonil, 3,000 parts per billion.

36. Hexythiazox, 2,000 parts per billion.

37. Imazalil, 100 parts per billion.

38. Imidacloprid, 3,000 parts per billion.

39. Kresoxim-methyl, 1,000 parts per billion.

40. Malathion, 2,000 parts per billion.

41. Metalaxyl, 3,000 parts per billion.

42. Methiocarb, 100 parts per billion.

43. Methomyl, 100 parts per billion.

44. Methyl parathion, 100 parts per billion.

45. Mevinphos, 100 parts per billion.

46. Myclobutanil, 3,000 parts per billion.

47. Naled, 500 parts per billion.

48. Oxamyl, 500 parts per billion.

49. Paclobutrazol, 100 parts per billion.

50. Pentachloronitrobenzene, 200 parts per billion.

51. Permethrin, 1,000 parts per billion.

52. Phosmet, 200 parts per billion.

53. Piperonyl butoxide, 3,000 parts per billion.

54. Prallethrin, 400 parts per billion.

55. Propiconazole, 1,000 parts per billion.

56. Propoxur, 100 parts per billion.

57. Pyrethrins, 1,000 parts per billion.

58. Pyridaben, 3,000 parts per billion.

59. Spinetoram, 3,000 parts per billion.

60. Spinosad A & D, 3,000 parts per billion.

61. Spiromesifen, 3,000 parts per billion.

62. Spirotetramat, 3,000 parts per billion.

63. Spiroxamine, 100 parts per billion.

64. Tebuconazole, 1,000 parts per billion.

65. Thiacloprid, 100 parts per billion.

66. Thiamethoxam, 1,000 parts per billion.

67. Trifloxystrobin, 3,000 parts per billion.

(g) Residual Solvent Limits.

1. 1,2-Dichloroethene, 5 parts per million

2. 1,1-Dichloroethene, 8 parts per million

3. Acetone, 5,000 parts per million

4. Acetonitrile, 410 parts per million

5. Benzene, 2 parts per million

6. Butane, 2,000 parts per million

7. Chloroform, 60 parts per million

8. Ethanol, 5,000 parts per million

9. Ethyl Acetate, 5,000 parts per million

10. Ethyl Ether, 5,000 parts per million

11. Ethylene Oxide, 5 parts per million

12. Heptane, 5,000 parts per million

13. Hexane, 290 parts per million

14. Isopropyl Alcohol, 500 parts per million

15. Methanol, 3,000 parts per million

16. Methylene Chloride, 600 parts per million

17. Pentane, 5,000 parts per million

18. Propane, 2,100 parts per million

19. Toluene, 890 parts per million

20. Trichloroethylene (1,1,2-Trichloroethene), 80 parts per million

21. Xylenes, Total (ortho-, meta-, para-), 2170 parts per million

(h) Metals Limits.

1. Cadmium, 0.5 micrograms/gram.

2. Lead, 0.5 micrograms/gram.

3. Arsenic, 1.5 micrograms/gram.

4. Mercury, 3.0 micrograms/gram.

(i) Biological Limits.

1. Shiga toxin-producing Escherichia coli (STEC E. coli) and other pathogenic E. coli, none present.

2. Listeria monocytogenes, none present.

3. Salmonella, none present.

(j) Mycotoxin Limits.

1. Total Aflatoxin (B1, B2, G1, G2), 20 parts per billion.

2. Ochratoxin, 20 parts per billion.

(k) Cannabinoid Limits. Total Δ9-Tetrahydrocannabinol concentration for cannabinoid hemp products shall not exceed three-tenths of a percent (0.3%). If a cannabinoid hemp product fails, the processor may elect to re-extract the failing batch to reduce the total Δ9-Tetrahydrocannabinol of the batch to not more than three-tenths of a percent (0.3%) total Δ9-Tetrahydrocannabinol. If the re-extracted batch still exceeds the three-tenths of a percent (0.3%)

total Δ9-Tetrahydrocannabinol the processor shall destroy the batch in compliance with 1005.7(d).

(l) If a cannabinoid hemp product is found to contain levels of any pathogen, toxicant, residual solvent, metal, or pesticide not enumerated in this section or by New York State law, then the product shall be considered adulterated and shall not be sold in New York State and shall be destroyed in accordance with 1005.7(d).

Section 1005.11 Requirements for cannabinoid hemp retailers

(a) Cannabinoid hemp retailers shall only sell cannabinoid hemp products manufactured, packaged, labeled and tested in accordance with this Part.

(b) Cannabinoid hemp retailers shall not offer or sell inhalable cannabinoid hemp products to anyone under 21 years of age. Retailers shall have sufficient safeguards in place to verify that the individual presenting or submitting proof of age for an inhalable cannabinoid hemp product matches the identification and is 21 years of age or older.

(c) Cannabinoid hemp retailers shall post, visible to the consumer, any and all signs or posted placards required by the department, including posting of the cannabinoid hemp retail license issued by the department in a conspicuous location on the premises of each retail location.

(d) The department may require cannabinoid hemp products to be kept separate from other products on display and out of the reach of children.

(e) Cannabinoid hemp retailers shall maintain sufficient records of where cannabinoid hemp products were purchased from, including the name of the cannabinoid hemp processor, and the wholesaler or permitted distributor if applicable. Where cannabinoid hemp products are purchased from an out of state manufacturer, the cannabinoid hemp retailer shall also maintain the name, address, certificate of analysis and evidence that cannabinoid hemp products meet all of the requirements of this Part.

(f) The department may inspect any retail location offering cannabinoid hemp products. This inspection may include taking samples of cannabinoid hemp products to ensure compliance with all the requirements of this Part.

Section 1005.12 Advertising requirements

(a) An advertisement for a cannabinoid hemp product, cannabinoid hemp processor or cannabinoid hemp retailer shall not:

(i) make any false or misleading claims or statements;

(ii) contain claims that cannabinoid hemp or a cannabinoid hemp product can, or is intended to, diagnose, cure, mitigate, treat, or prevent disease;

(iii) lead a reasonable person to believe that a cannabinoid hemp product is marihuana, medical marihuana or that a licensee is authorized to sell or dispense marihuana or medical marihuana as those terms are defined in Article 33 of the Public Health Law;

(iv) have the purpose or effect of targeting or appealing to anyone under 21 years of age for inhalable cannabinoid hemp products. The use of images of children or minors consuming the product and the use of words, a design or brand that resembles a product that is commonly associated with children or minors or marketed to children or minors, is prohibited.

Section 1005.13 New York Hemp Product

(a) The department may establish standards and requirements above and beyond those established in this Part, and use such standards and requirements to certify products as New York Hemp Product.

(b) New York Hemp Product is a cannabinoid hemp product exclusively grown in New York State and processed in New York State by processors licensed under this Part, who demonstrate compliance with all requirements enumerated by the department;

(c) The department may revoke a cannabinoid hemp product's status as certified New York Hemp Product, without a hearing, if it has reason to believe that such product no longer meets one or more of the standards or requirements established by the department.

(d) No cannabinoid hemp product sold in New York state may use the term “New York Hemp Product” or hold itself out as being New York Hemp Product, or approved or certified by the department in any way, unless such product has been certified by the department pursuant to this section, in which case the cannabinoid hemp processor and cannabinoid hemp retailer may portray such product(s) as being certified New York Hemp Product. Violation of this subdivision constitutes grounds for suspension or revocation of a license.

Section 1005.14 General prohibitions

(a) No licensee shall engage in any activity relating to the processing, packaging, labeling manufacturing, extracting, distributing, selling or laboratory testing of cannabinoid hemp extract or cannabinoid hemp that does not comply with the requirements of Article 33-B of the Public Health Law or this Part.

(b) No person shall extract hemp extract or manufacture cannabinoid hemp products in New York State, unless licensed to engage in such activity by the department or otherwise authorized by the United States food and drug administration.

(c) Hemp extract shall be manufactured into cannabinoid hemp product before being offered for retail sale and shall not be distributed or sold directly to consumers within the state.

(d) No cannabinoid hemp product shall be distributed or offered for retail sale in New York State unless:

(1) it complies with the processing, packaging, labeling and testing requirements pursuant to sections 1005.8, 1005.9 and 1005.10 of this Part; and

(2) is sold by a cannabinoid hemp retailer licensed under this Part;

(e) No person shall transport hemp extract within the state, unless:

(1) it is in a fully enclosed vehicle or container; and

(2) accompanied by a manifest or proof of ownership, documenting the name, physical address, lot or batch number, certificate of analysis and license number of the originating licensed cultivator or processor, and the name and physical address of the recipient of the delivery when transporting between non-adjoining facilities.

(f) Hemp extract shall not be shipped or transported into New York State unless:

(1) it is in a fully enclosed vehicle or container;

(2) accompanied by proof of origin with a hemp cultivation or processor license number, or equivalent, from the jurisdiction of origin; and

(3) accompanied by a certificate of analysis showing that the hemp extract has a total Δ9-Tetrahydrocannabinol of no more than three tenths of a percent (0.3%).

(g) In no event shall any cannabinoid hemp product be smoked in any location in which smoking is prohibited under section 1399-o of the Public Health Law;

(h) No person shall distribute cannabinoid hemp products manufactured out of state, to a cannabinoid hemp retailer within New York State, unless permitted pursuant to section 1005.18 of this Part.

Section 1005.15 Cannabinoid hemp processor prohibitions

(a) No cannabinoid hemp processor may transfer a license issued under this Part without prior written approval of the department.

(b) No cannabinoid hemp processor shall manufacture a cannabinoid hemp product that is a potentially hazardous food, as defined by Section 14-1.31 of this Title.

(c) No cannabinoid hemp processor may conduct final product testing for the licensee's own products to meet the testing requirements of Section 1005.10 of this Part. Nothing in this Part prohibits a cannabinoid hemp processor from performing internal testing for research and product development or for quality assurance prior to final product testing by a third-party laboratory.

(d) No cannabinoid hemp processor may sell cannabinoid hemp products to consumers for final retail sale without first obtaining a cannabinoid hemp retail license.

(e) No cannabinoid hemp processor shall sell hemp extract to anyone in New York State, unless such person is licensed as a cannabinoid hemp processor under this Part or registered as a registered organization under Section 3365 of the Public Health Law.

Section 1005.16 Cannabinoid hemp retailer prohibitions

(a) No cannabinoid hemp retailer shall offer or sell cannabinoid hemp products in the form of an inhalable cannabinoid hemp product to anyone under 21 years of age.

(b) No cannabinoid hemp retailer shall sell a cannabinoid hemp product that is a potentially hazardous food, as defined by Section 14-1.31 of this Title.

(c) Cannabinoid hemp retailers shall only offer and sell cannabinoid hemp products that meet all of the standards and requirements of Sections 1005.8, 1005.9 and 1005.10 of this Part.

(d) Cannabinoid hemp retailers shall not offer or sell any cannabinoid hemp product to be added to food or any other consumable products at the point of sale.

Section 1005.17 Penalties

(a) Licensees under this Part shall comply with all applicable laws, rules and regulations as it relates to such licensure.

(b) Failure to comply with a requirement of Article 33-b of the Public Health Law or this Part may be punishable by a civil penalty, as follows:

(i) a fine of up to $1,000 for a first violation;

(ii) a fine up to $5,000 for a second violation within three-years; or

(iii) a fine up to $10,000 for a third violation and each subsequent violation thereafter, within a three-year period.

(c) Where a licensee willfully violates, refuses or neglects to comply with one or more sections of this Part, the department may limit, suspend, revoke or annul a license after providing notice and an opportunity for a hearing to the licensee. However, a license may be temporarily limited, suspended, revoked or annulled without a hearing for a period not to exceed 30-days, upon notice to the licensee, following a finding by the department that the public health, safety or welfare is in imminent danger.

(d) A licensee who negligently violates this Part three times in a five-year period shall be ineligible to process or sell cannabinoid hemp for a period of five years beginning on the date of the third violation. The department, for good cause shown, may choose to impose a lesser penalty.

Section 1005.18 Cannabinoid hemp permits

(a) The department may issue cannabinoid permits, expressly authorizing a permittee to conduct one or more of the following activities:

(1) distribute cannabinoid hemp products manufactured out of state, to cannabinoid hemp retailers within New York State;

(2) delivery of cannabinoid hemp products from a cannabinoid hemp retailer to consumers;

(3) retail sale of cannabinoid hemp products for a limited duration;

(4) continuation of operations for persons holding a valid CBD processor research partnership agreement with the New York State Department of Agriculture and Markets pursuant to Article 29-A of the New York State Agriculture and Markets Law;

(5) any other activity as determined by the commissioner.

(b) Applicants for a cannabinoid hemp permit must apply on a form prescribed by the department and submit a $100 application fee and permit fee as may be set by the department.

(c) Permits issued pursuant to this section shall be valid for one year from the date of issuance, unless the department prescribes a shorter time period for expiration.

Section 1005.19 Severability.

The provisions of this Part are severable. If any provision of this Part is found to be invalid, or if any application of this Part to any person or circumstance is found to be invalid, the invalidity shall not affect any other provisions or applications which can be given effect without the invalid provision or application.

Section 1005.20 Incorporation by reference.

The provisions of the Code of Federal Regulations which have been incorporated by reference in this Subpart have been filed in the Office of the Secretary of State of the State of New York, the publication so filed being the booklet entitled: Code of Federal Regulations, Title 21, Parts 101, 111, and 117, revised as of April 1, 2012, June 25, 2007, and January 1, 2019 respectively, published by the Office of the Federal Register, National Archives and Records Administration. The regulations incorporated by reference may be examined at the Records Access Office, New York State Department of Health, Corning Tower, Empire State Plaza, Albany, New York 12237 or can be directly obtained from the Superintendent of Documents, US Government Printing Office, Washington, D.C. 20402.

Regulatory Impact Statement

Statutory Authority:

The Commissioner of Health is authorized pursuant to Section 3398-a of the Public Health Law (PHL), to promulgate rules and regulations necessary to effectuate the provisions of Article 33-B of the PHL.

Legislative Objectives:

The legislative objective of Article 33-B of the PHL is to comprehensively regulate the processing and sale of cannabinoid hemp products in New York State. The regulation of cannabinoid hemp products will promote this objective and public health by instituting consumer protections ensuring products are manufactured, tested and labeled to comparative standards of similar products in the dietary supplement, food and cannabis industries. Further, the regulations will spur economic development of the New York States domestic hemp industry by providing clear rules and expectations of how and what type of cannabinoid hemp products can be sold.

Needs and Benefits:

The Federal Farm Bill of 2018 created a legal pathway for hemp cultivation by removing hemp, a subset of the *Cannabis Sativa L.* plant species, with less than 0.3% Δ9-Tetrahydrocannabinol from the Controlled Substance Act. Farmers from across the country began growing hemp, an extremely versatile crop that has a reported 25,000 different uses including in textiles, automotive parts, furniture, fuel, food and beverages, paper, construction materials and personal care items.

Over the past several years, the expansion of hemp cultivation has primarily been driven from a chemical component found in the hemp plant called cannabidiol or "CBD." CBD is one of many cannabinoids found in hemp and has become increasingly popular recently.

Although there has been a rapid increase in the use of cannabinoid hemp products, the Federal government has not implemented a regulatory system to effectively control the quality of products on the market. In this absence, unscrupulous actors have entered the market and sold cannabinoid hemp products that do not meet the quality control standards common in the established supplement, food and cannabis industries. Reports of cannabinoid hemp products that do not contain any cannabinoids at all or are contaminated with harmful toxins and pesticides are common.

The proposed regulations are intended to organize and legitimize the cannabinoid market in New York State by creating a license framework for cannabinoid hemp processors and retailers and by establishing quality control standards that all cannabinoid hemp products must meet or exceed. To accomplish this, the regulations propose the following:

1. License and hold cannabinoid hemp processors to federally-established standards of good manufacturing practices (GMP) at the dietary supplement or food standard depending on the finished product.
2. Require packaging and labeling standards that accurately inform the consumer of the quantity of cannabinoids in the product, include a link or QR code to the third-party tests results, and provide appropriate warnings of the potential risks associated with their consumption.
3. Impose laboratory testing requirements on all lots of cannabinoid hemp products, testing for cannabinoid profile, heavy metals, microbials, mycotoxins, pesticides and residual solvents.

4. License and hold retailers accountable to only sell approved forms of cannabinoid hemp products purchased from sources that manufacture to the standards of the program, and restrict sales to minors.
5. Authorize the Department to oversee and enforce against cannabinoid hemp products in the marketplace not meeting New York's standards and to take appropriate action to protect public health and impose consumer protections.

Costs:

Costs to the Regulated Entity:

The proposed regulations impose costs on licensees. Cannabinoid hemp processors will be required to pay an application fee of $1,000 or $500 and a license fee of either $4,500 or $2,000, depending on whether the licensee is authorized to extract hemp extract in addition to manufacturing cannabinoid hemp products. In addition, cannabinoid hemp processor licensees will be required to manufacture cannabinoid hemp products for human consumption to dietary supplement or food standards complying with good manufacturing processes and maintaining third-party audit documenting this standard. All cannabinoid hemp products are required to be tested by a third-party accredited laboratory and products must be packaged and labeled in a manner that is consistent with public health best practices. Finally, cannabinoid hemp retailers will be required to pay a $300 license fee for each location where cannabinoid hemp products are sold.

Costs to Local Government:

The proposed regulations do not require local governments to perform any additional tasks; therefore, it is not anticipated to have an adverse fiscal impact.

Costs to the Department of Health:

The proposed regulations will incur costs to the Department to develop a licensing system to review and approve applications from potential licensees, maintain the administrative and customer service aspects of the program, and inspect and enforce licensees to maintain the quality assurance standards of the program.

Local Government Mandates:

These proposed regulations do not impose any new programs, services, duties or responsibilities on local government.

Paperwork:

The proposed regulations will impose new requirements to track and maintain licensing and pertinent records of the regulated activities established in the proposed regulations. Licensees will need to retain all required records for a minimum of five years.

Duplication:

No relevant rules or legal requirements of the Federal and State governments duplicate, overlap or conflict with these proposed regulations.

Alternatives:

The Department is statutorily obligated to promulgate regulations pursuant to Section 3398-a of the Public Health Law. The Department considered not regulating inhalable products differently,

including not setting separate age limits. However, the Department ultimately decided to establish additional restrictions on inhalable products to deter smoking and youth-use.

Federal Standards:

The 2018 Farm Bill directed the United States Department of Agriculture (USDA) to establish a national regulatory framework for hemp cultivation in the United States and gave the authority to regulate cannabinoids to the Food and Drug Administration (FDA). USDA established the U.S. Domestic Hemp Production Program through an interim final rule; however, the FDA is just beginning the rulemaking process and therefore, there are currently no federal standards for cannabinoid hemp processors or cannabinoid hemp retailers.

Compliance Schedule:

There is no compliance schedule imposed by these proposed regulations, which shall be effective upon filing of a notice of adoption with the Secretary of State.

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Regulatory Flexibility Analysis for Small Businesses and Local Governments

Effect on Small Business and Local Government:

The proposed regulations require cannabinoid hemp processors to manufacture products to good manufacturing practices (GMP) found in the dietary supplement or food industries, test products at accredited third-party laboratories, and package and label products to promote consumer awareness and protect the integrity of the product. Many of these same standards were already imposed by the Department of Agriculture and Markets Industrial Hemp Research Pilot Program which, prior to Chapter 1 of the Laws of 2020, oversaw cannabinoid processors in New York State. Due to the confusion of the regulatory status of cannabinoid hemp products at the federal level, products have been left in an unregulated status. These regulations are intended to bring cannabinoid hemp products on par with other standards already developed in similar industries and is not meant to disadvantage small businesses. Many operators in the hemp industry are looking for regulations to legitimatize and standardize the neophyte industry.

The requirements placed on cannabinoid hemp retailers are less demanding and include licensure, record keeping, age verification and restrictions on the forms of cannabinoid hemp products which may be sold.

Large and small businesses that are creating or selling products that do not meet basic consumer protections and refuse to come into compliance will be penalized and have their products removed from the market.

Compliance Requirements:

Small businesses that apply as a cannabinoid hemp processor must meet third-party GMP certification within six months of approval of the application to obtain licensure, must test products at an accredited third-party lab and package, and must label products in conformance

with the requirements of the regulations. A small business that chooses to apply as a cannabinoid hemp retailer must comply with the proposed regulations including licensure, record keeping, age verification and restrictions on the forms of cannabinoid hemp products which may be offered for retail sale.

Professional Services:

The proposed regulations create a need for cannabinoid hemp processors to seek a third-party audit to certify their manufacturing process to good manufacturing practices (GMP) in accordance with Parts 101, 111 or 117 of Title 21 Code of Federal Regulations, depending on the final product.

Compliance Costs:

The proposed regulations will impose a cost to cannabinoid hemp processor licensee's seeking third-party GMP certification. Certification is based on the size of the facility and complexity of the manufacturing process. Several businesses will have to change operations to meet the higher standard to protect public health and consumer safety. Application and license fees in the amount of $1,000 and $4,500 respectively will be required for cannabinoid hemp processors, while a $500 application fee and $2,000 licensee fee will be required for those only manufacturing cannabinoid hemp. Retailers must pay a $300 license fee per location.

Cost to State and Local Governments:

There are no direct costs to Local Governments associated with the proposed regulations as the State will be incurring the costs of regulatory oversight and inspection of licensees.

Economic and Technological Feasibility:

This proposed regulation is economically and technically feasible, as these regulations mirror similar requirements that already exist in the dietary supplement, food and cannabis industries.

Minimizing Adverse Economic Impact:

The impact of this regulation is expected to be minimal for existing CBD processors operating in compliance under Agriculture and Markets Industrial Hemp Research Pilot Program which already imposed many of the same standards as the proposed regulations. The Department understands the current ambiguity in the cannabinoid hemp market nationally and is willing to work with entities to reach compliance.

Small Business and Local Government Participation:

The proposed regulations include recommendations from the hemp industry including the New York Cannabis Grower and Processor Association (NYCGPA). The Department will proactively contact existing research partners from the current pilot program to provide information on where they may locate the proposed regulations, how to provide public comments and work with them to transition over into the new program.

RURAL AREA FLEXIBILITY ANALYSIS

Types and Estimated Numbers of Rural Areas:

This rule applies uniformly throughout the state, including rural areas. Rural areas are defined as counties with a population less than 200,000 and counties with a population of 200,000 or greater that have towns with population densities of 150 persons or fewer per square mile. The following 43 counties have a population of less than 200,000 based upon the United States Census estimated county populations for 2010 (https://www.census.gov/quickfacts/).

Allegany County	Greene County	Schoharie County
Cattaraugus County	Hamilton County	Schuyler County
Cayuga County	Herkimer County	Seneca County
Chautauqua County	Jefferson County St.	Lawrence County
Chemung County	Lewis County	Steuben County
Chenango County	Livingston County	Sullivan County
Clinton County	Madison County	Tioga County
Columbia County	Montgomery County	Tompkins County
Cortland County	Ontario County	Ulster County
Delaware County	Orleans County	Warren County
Essex County	Oswego County	Washington County
Franklin County	Otsego County	Wayne County
Fulton County	Putnam County	Wyoming County
Genesee County	Rensselaer County	Yates County
Schenectady County		

The following counties have a population of 200,000 or greater and towns with population densities of 150 persons or fewer per square mile. Data is based upon the United States Census estimated county populations for 2010.

Albany County	Monroe County	Orange County
Broome County	Niagara County	Saratoga County
Dutchess County	Oneida County	Suffolk County
Erie County	Onondaga County	

Compliance Requirements:

Cannabinoid hemp processors and cannabinoid hemp retailers that are located in rural areas will be required to apply to the Department for licensure. Once licensed, cannabinoid hemp processors in rural areas will be required to extract hemp extract and/or manufacture cannabinoid hemp products using Good Manufacturing Practices (GMP) and to the standards set forth in these regulations, including requirements on packaging and labeling, product testing, and advertising. Cannabinoid hemp retailers in rural areas will be required to only sell cannabinoid hemp products meeting all of the standards set forth in these regulations, including restrictions on certain forms of administration and only sell inhalable cannabinoid hemp products to individuals 21 year of age or older.

Professional Services:

Cannabinoid hemp processors and cannabinoid hemp retailers in rural areas are expected to use existing staff to comply with the requirements of this regulation. Additionally, cannabinoid hemp processors are required to obtain a qualified third-party Good Manufacturing Practices (GMP) audit and will need to utilize independent third-party laboratories.

Compliance Costs:

The proposed regulations impose costs on rural area licensees. Cannabinoid hemp processors in rural areas will be required to pay an application fee of $1,000 or $500 and a license fee of either $4,500 or $2,000, depending on whether the licensee is authorized to extract hemp extract in addition to manufacturing cannabinoid hemp products. In addition, rural area cannabinoid hemp processors will be required to manufacture cannabinoid hemp products for human consumption to dietary supplement or food standards complying with good manufacturing processes and maintaining third-party audit documenting this standard. All cannabinoid hemp products are required to be tested by a third-party accredited laboratory and products must be packaged and labeled in a manner that is consistent with public health best practices. Finally, cannabinoid hemp retailers in rural areas will be required to pay a $300 license fee for each location where cannabinoid hemp products are sold.

Minimizing Adverse Impact:

The Department is statutorily obligated to promulgate regulations pursuant to Section 3398-a of the Public Health Law so no alternatives to the proposed regulations were considered. The impact of this regulation is expected to be minimal for existing CBD processors operating in compliance under Agriculture and Markets Industrial Hemp Research Pilot Program which already imposed many of the same standards as the proposed regulations.

Rural Area Input:

The proposed regulations include recommendations from the hemp industry including the New York Cannabis Grower and Processor Association (NYCGPA) which represents hemp growers and processors throughout the State, including rural areas.

Statement in Lieu of Job Impact Statement

No job impact statement is required pursuant to section 201-a(2)(a) of the State Administrative Procedure Act. It is apparent, from the nature of the amendment, that it will not have an adverse impact on jobs and employment opportunities.