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April 5, 2021

Via Email: irrc@irrc.state.pa.us
Independent Regulatory Review Commission
333 Market St., 14th Floor
Harrisburg, PA 17101

Dear Honorable Members of the Independent Regulatory Review Commission ("IRRC"):

Thank you for the opportunity to comment on the proposed permanent regulations for the medical marijuana program. Cresco Yeltrah, LLC ("Cresco") holds two medical marijuana dispensary permits in the Commonwealth. Cresco also operates a grower/processor facility in Brookville. Cresco respectfully submits the following comments to the proposed permanent regulations (proposed additions underlined in blue, proposed deletions in strikethrough red), which balance the clarity and flexibility necessary for operators with the interests of the program's patients and the other objectives essential to the implementation of a safe, secure and effective program:

§ 1141a.21. Definitions.

[. . .]

Medical marijuana—Marijuana for certified medical use, limited to the following forms:

(i) Pill, including but not limited to capsule and/or chewable tablet.

(ii) Oil.

(iii) Topical forms, including gels, creams or ointments.

(iv) A form medically appropriate for administration by vaporization or nebulization, including dry leaf or plant form for administration by vaporization.

(v) Tincture.

(vi) Liquid.

[. . .]

§ 1151a.28. Forms of medical marijuana.

(a) A grower/processor may only process medical marijuana for dispensing to a patient or caregiver in the following forms:

(1) Pill, including but not limited to capsule and/or chewable tablet.

(2) Oil.

(3) Topical forms, including gel, creams or ointments.

(4) A form medically appropriate for administration by vaporization or nebulization, including dry leaf or plant form for administration by vaporization.

(5) Tincture.

(6) Liquid.

[. . .]

Comment:

Cresco respectfully urges the Department of Health (the "Department") to amend the medical marijuana program's rules to clarify that the term pill, as one of the forms of medical marijuana that can be processed and dispensed to patients under Act 16 and the program's rules, includes capsules and chewable tablets.

Act 16 sets forth that "[s]ubject to regulations . . . medical marijuana may only be dispensed to a patient or caregiver" in forms including a pill. Unfortunately, the term pill is not defined by the Act and the Act provides no further guidance as to how that term should be interpreted by the Department.

By the plain language of the statute, the Department would be acting well within its authority to provide clarity as to the Act's use of the term pill and the bounds within which growers/processors may have to develop a selection of products for patients throughout the Commonwealth. Indeed, the legislative intent in ensuring that traditional delivery methods for medical marijuana products is furthered by including the terms capsule and chewable tablet as forms of the more general "pill" that can be made and sold. Capsules/chewable tablets are a commonly accepted and standard methods of administration in states and even in some cases federally. For example, the drug Marinol, which is FDA-approved, is distributed as a capsule. Providing operators additional clarity directly and demonstrably benefits the Commonwealth's patient community by increasing the options patients have for administering their medical marijuana products. For instance, a patient who may have difficulty swallowing a pill or capsule may find it easier and more pleasant to chew a tablet. Additionally, clarifying that capsules and chewable tablets can be made and dispensed presents no safety, security, or other programmatic concerns, including products that may be appealing to children, as operators would still be bound to adhere to the standards set by the Department for medical marijuana products. For these reasons, Cresco urges the Department to consider implementing this change, which is consistent with Act 16 and would further the program's goals.

§ 1141a.21. Definitions.

[. . .]

Electronic tracking system—An electronic seed-to-sale system approved by the Department that is utilized by:

(i) A grower/processor to log, verify and monitor the receipt, use and sale of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products, the funds received by a grower/processor for the sale of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products to another medical marijuana organization, the disposal of medical marijuana waste and the recall of defective seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products.

(ii) A dispensary to log, verify and monitor the receipt of medical marijuana product from a grower/processor, the verification of the validity of an identification card presented by a patient or caregiver, the dispensing of medical marijuana product to a patient or caregiver, the disposal of medical marijuana waste and the recall of defective medical marijuana products.

(iii) An approved laboratory to log, verify and monitor the receipt of samples and test samples for testing, the results of tests performed by the approved laboratory, and the disposal of tested and untested samples and test samples.

(iv) Medical marijuana organizations shall be permitted to utilize the electronic tracking system of its choice as long as it meets the above requirements.

[. . .]

Comment:

Cresco asks the Department to consider the above addition to the definition of electronic tracking system to allow medical marijuana organizations to employ the tracking system of its choosing so long as that system complies with the above parameters. Specifically, operators should be permitted to use an API system that allows it to port information between its internal track and trace system and the Commonwealth's electronic tracking system. Such an allowance will not present any security concerns and would create better visibility and represent a significant operational efficiency for medical marijuana organizations that must currently track the above information on the Commonwealth's approved system and their internal systems.

§ 1141a.22. Records subject to disclosure; confidentiality.

(a) The following records are public records and are subject to disclosure under the Right-to-Know Law (65 P.S. §§ 67.101—67.3104):

[. . .]

(f) Nothing in this section shall preclude the Department from releasing de-identified data for research purposes, subject to approval and oversight by the Department and an IRB to ensure that the use of the data is limited to the specified research purposes. In the circumstances that the Department releases data or other information pursuant to this subsection, the Department must provide notice to a licensee within 7 calendar days as to what data or information was released, to whom the data or other information was released, and when the data or other information was released.

[. . .]

Comment:

Cresco respectfully requests that the Department consider further amendments to this new subsection, such as the above, which would require the Department to notify a permittee if data or other information regarding the permittee is released. Such a notification would not be overly burdensome on the Department and is a reasonable request that would allow permit holders to understand information about them that is being provided to external parties.

§ 1141a.31. Background checks.

(a) To provide the criminal history record check required under § 1141a.29 (relating to initial permit application), an applicant shall submit fingerprints of its principals, financial backers, operators and employees to the Pennsylvania State Police. The Pennsylvania State Police or its authorized agent will submit the fingerprints to the Federal Bureau of Investigation for the purpose of verifying the identity of the individuals whose fingerprints have been submitted and obtaining a current record of criminal arrests and convictions.

[. . .]

Comment:

Subsection (a) of the proposed permanent Section 1141a.31 of the program's rules sets forth the manner in which the Department conducts criminal background checks for applicants and their affiliates. This subsection would be enhanced by permitting applicants and their affiliates to submit fingerprints and FBI background check information electronically, including through an electronic portal. Allowing for the electronic submission of information would be more efficient and expeditious and would generally serve both the interests of the Department in the efficient processing of background checks and applicants in navigating the background check process without sacrificing the security of the process.

§ 1141a.39. Application for change in ownership of a medical marijuana organization.

(a) In the event of an impending change in ownership involving a change in control of a medical marijuana organization from the ownership listed in the initial permit application or a

permit renewal application, the medical marijuana organization shall submit an application for change in ownership, on a form prescribed by the Department, to the Department together with the fee required under § 1141a.28 (relating to fees).

(b) A medical marijuana organization's application for change in ownership will not be considered complete by the Department until all portions of the application are completed and the appropriate application fee under § 1141a.28 is submitted.

(c) For each individual that is part of the proposed change in ownership, the medical marijuana organization shall include all of the information required under § 1141a.29 (relating to initial permit application) for the individuals listed in those capacities in the medical marijuana organization's initial permit application or any previously submitted permit renewal application.

(d) A change in ownership of a medical marijuana organization that occurs without the Department's knowledge and written approval of all individuals affiliating with the medical marijuana organization is a violation of the act and this part.

Comment:

Cresco seeks additional clarity from the Department with respect to this amended rule. Therein, Cresco suggests the Department further amend this rule—or issue separate guidance—to specify precisely what information an operator is required to submit and the timeline for completing a change of ownership application. Such specificity will benefit both the Department and operators attempting to navigate the change of ownership process.

§ 1141a.27. General requirements for application.

(a) The types of applications to be submitted to the Department under this part include:

(1) An initial permit application.

(2) A permit renewal application.

(3) An application for change in ownership of a medical marijuana organization.

(4) An application for approval of a change of location ~~of an operational facility~~.

(5) An application for approval of alteration of a facility.

(6) An application for additional dispensary locations.

(7) An application for approval of a laboratory.

[. . .]

§ 1141a.40. Application for approval of a change in location of a~~n operational~~ facility.

(a) A medical marijuana organization wishing to change ~~the~~its location ~~of an operational facility~~ shall submit an application for approval of a change in location to the Department together with the fee required under § 1141a.28 (relating to fees).

(b) A change in location ~~of an operational facility~~ may not occur until the Department approves the change, in writing, under this section.

(c) The medical marijuana organization shall submit an application for approval of a change in location on a form prescribed by the Department.

(d) An application for approval of a change in location must include the reason for requesting the change and other information about the new location as the Department may require.

(e) The Department will issue a new permit to the medical marijuana organization for the new location if the request is approved, but approval shall not be withheld by the Department absent a showing by the Department that allowing the relocation would be detrimental to patient care or otherwise violate Act 16 or these regulations.

(f) Within 180 days of the issuance by the Department of a new permit under subsection (e), the medical marijuana organization shall change the location of its operation to the new location designated in the new permit. Simultaneously with the completion of the move, the medical marijuana organization shall cease to operate at the former location and surrender its existing permit to the Department. The following apply:

(1) At no time may a medical marijuana organization operate or exercise any of the privileges granted under the permit in both locations.

(2) At the discretion of the Department, the Department may extend the 180-day deadline for relocation for up to an additional 90 days.

(3) Once the new facility is determined to be operational by the Department, the medical marijuana organization may resume operations under the new permit at the new location.

(g) The Department will not approve a change of location that is outside the boundaries of the region for which the initial permit was issued unless the marijuana organization establishes that patients would be better served by a change of location outside the boundaries of the region.

Comment:

Cresco respectfully asks the Department to implement the above amendments to proposed permanent Sections 1141a.27 and 1141a.40 with respect to a marijuana organization's ability to change its location. As currently conceived, the proposed language does not account for the

possibility when circumstances outside of a marijuana organization's control might necessitate a change of location. For example, a marijuana organization may not be able to become operational due to circumstances outside of its control, including local zoning restrictions or other unforeseen circumstances including the discovery that a proposed location is ultimately unsuitable. Such an approach does not serve patients or marijuana organizations that may find themselves in a circumstance that fairly warrants an exception to the general preference that an operator become operational before moving. Section 609 of the Act, it sets forth that "[t]he department may approve an application from a medical marijuana organization to relocate within this Commonwealth or to add or delete activities or facilities." The Act does not state that a facility must be operational to move. Accordingly, Cresco asks the Department to consider the above amendments to Sections 1141a.27 and 1141a.40.

§ 1141a.42. Failure to be operational.

(a) Within 6 months from the date of issuance of a permit, or as otherwise permitted by the Department, a medical marijuana organization shall notify the Department, on a form prescribed by the Department, that it is operational.

[. . .]

Comment:

Cresco respectfully suggests that the Department consider further amending this proposed rule to afford the Department and operators flexibility to extend the time in which a permit holder must become operational. While in most circumstances 6 months may be a sufficient amount of time within which a medial marijuana organization can become operational, the above amendments would account for unforeseen circumstances and problems outside of both the operator and Department's control.

§ 1141a.50. Advertising by a medical marijuana organization.

(a) In the advertising and marketing of medical marijuana and medical marijuana products, a medical marijuana organization shall be consistent with the Federal regulations governing prescription drug advertising and marketing in 21 CFR 202.1 (relating to prescription-drug advertisements).

~~(b) Promotional, advertising and marketing materials shall be approved by the Department prior to their use.~~

(b~~c~~) This part does not apply to information provided by a grower/processor to a dispensary listing various medical marijuana products, instruments and devices that the grower/processor is offering for sale to the dispensary including information that may be used by a dispensary to educate patients regarding those medical marijuana products, instruments and devices.

Comment:

The Act requires the Department to "[r]estrict the advertising and marketing of medical marijuana, which shall be consistent with the Federal regulations governing prescription drug advertising and marketing." However, the Department's proposed (and current) regulations go beyond that mandate and require that promotional, advertising, and marketing materials must be pre-approved by the Department before those materials can be used. This additional requirement represents an unnecessary barrier for operators to overcome in order to employ responsible marketing campaigns designed to provide critical information to patients to understand the products and dispensary locations available to them. Ultimately, it is incumbent on each medical marijuana organization to the program's advertising and marketing standards and to produce compliant and responsible advertising and marketing content. Failure to do so may subject a medical marijuana organization to discipline by the Department. However, requiring all advertising and marketing materials to be approved by the Department does not serve that end and creates operational challenges for companies which must develop marketing and advertising campaigns and then navigate the Department's approval process rather than simply implement them as is the process in many other jurisdictions. For example, pre-approval for advertising and marketing is not required in Illinois which administers successful medical and adult use programs that restricts the content of marketing and advertising. Similarly, at the federal level, in most instances, federal law does not allow the FDA to mandate prior approval over drug company advertisements before the ads are run. The Department should take a similar approach here. Additionally, Cresco advocates that the Department consider clarifying and/or expanding the educational exception to the above rule, as set forth in subsection (c) and permit dispensaries to use information from growers/processors in order to education patients on products without those materials being considered advertising/marketing materials. Such a change would further the interests of patient education and safety and afford dispensaries the ability more latitude in engaging in patient education.

§ 1151a.24. Start-up inventory.

(a) A grower/processor may obtain seeds and/or immature medical marijuana plants from outside of this Commonwealth for the purpose of securing its start-up inventory. Seeds and/or immature medical marijuana plants obtained from outside of this Commonwealth shall be obtained within 30 days from the date that the Department determines that the grower/processor is operational or within any 30-day window established by the Department at least one time each calendar year, or if the Department determines that the importation of additional seeds and/or immature medical marijuana plants is necessary.

(b) A grower/processor may not obtain medical marijuana plants, other than immature medical marijuana plants as set forth in subsection (a), from outside of this Commonwealth at any time.

(c) Within 24 hours of receipt, a grower/processor shall, record in the electronic tracking system each seed and/or immature medical marijuana plants that enters the site during the 30-day period under subsection (a).

(d) Outside any 30-day period permitted under subsection (a), a grower/processor shall only grow medical marijuana plants from seeds or immature medical marijuana plants located physically in its facility, or purchase seeds, immature medical marijuana plants or medical marijuana plants from another grower/processor.

Comment:

Cresco advocates that the Department consider further amendments to the above rule to provide additional flexibility for growers/processors to import seeds and/or immature medical marijuana plants for the purposes of ensuring an ample supply and greater diversity of products to serve the Commonwealth's patient community. Mandating that the Department affirmatively allow the importation of seeds and/or immature medical marijuana plants on a yearly basis ensures patients are well served by operators that are able to meet industry demand and offer a selection of products that meets all patient needs across a variety of qualifying conditions. The need to offer a wide variety of products is especially true given that the effects experienced by patients varies and patients may need to try a number of products to identify one that works best for them. Additionally, while Cresco understands that Section 702(a) of the Act does not specifically authorize obtaining immature medical marijuana plants from outside the Commonwealth, neither does the statute prohibit the same, which is permitted under the current version of the rules. Immature medical marijuana plants present no additional safety, security, or other concerns that differ from the importation of seeds. Moreover, the importation of immature plant material is a common industry and agricultural practice. In restricting operators to seeds only, certain genetics may not be readily available, which would result in fewer products being available for patients. As a result, the Department should continue to permit this practice.

§ 1151a.25. Access to grower/processor facilities.

(a) A grower/processor facility may not be open to the general public. When an individual who is not approved to enter the facility requires access to the facility for purposes regarding the growing, processing or testing of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products, a grower/processor shall require the individual to sign a log, detailing the need for entry, and to wear a temporary identification badge that is visible to others at all times while on the site and in the facility.

(b) A grower/processor shall require an individual to present government-issued identification that contains a photo to gain access to the site and facility.

(c) No one under 18 years of age is permitted to enter a grower/processor site or facility.

(d) A grower/processor shall post a sign in a conspicuous location at each entrance of a site and a facility that states:

THESE PREMISES ARE UNDER CONSTANT VIDEO SURVEILLANCE. NO ONE UNDER THE AGE OF 18 IS PERMITTED TO ENTER.

(e) A grower/processor shall do the following when admitting an individual to a site or facility:

(1) Require the individual to sign a log and detail the need for entry upon entering and to sign the log when leaving the facility.

(2) Check the individual's government-issued identification to verify that the name on the identification provided matches the name in the log. A photocopy of the identification must be retained with the log.

(3) Issue a temporary identification badge with ~~the individual's name and company, if applicable, and~~ a badge number~~.~~

(4) Escort the individual while the individual remains in the facility or on the site.

(5) Ensure that the individual does not touch any seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products located in a limited access area.

(f) The following apply to the log required under subsections (a) and (e):

(1) The grower/processor shall maintain the log for 4 years and make the log available to the Department, State or local law enforcement, and other State or local government officials upon request if necessary to perform the government officials' functions and duties.

(2) The log must include the full name of each individual granted access to the facility, the temporary identification badge number, the time of arrival, the time of departure and the purpose of the visit, including the areas of the site and the facility visited and the name of each employee visited.

(g) This section does not limit the right of the Department or its authorized agents, State or local law enforcement or other Federal, State or local government officials, from entering any area of a grower/processor site or facility if necessary to perform the governmental officials' functions and duties that pertain to the act or this part.

(h) A principal, financial backer, operator or employee of a grower/processor may not receive any type of consideration or compensation for allowing an individual to enter a limited access area.

§ 1161a.30. Access to dispensary facilities.

(a) A dispensary shall post a sign in a conspicuous location at each entrance of the facility that reads:

THESE PREMISES ARE UNDER CONSTANT VIDEO SURVEILLANCE. ONLY EMPLOYEES, PATIENTS AND CAREGIVERS MAY ENTER. NO ONE UNDER THE AGE OF 18 IS PERMITTED TO ENTER UNLESS THE INDIVIDUAL IS A PATIENT AND IS ACCOMPANIED BY A PARENT, GUARDIAN OR CAREGIVER.

(b) Except as provided in subsection (c), only authorized employees of a dispensary may enter a limited access area.

(c) When an individual who is not approved to enter the facility requires access to a limited access area in the dispensary facility to provide goods or services to the facility, a dispensary shall require the individual to present government-issued identification, to sign a log for that specific facility, detailing the need for entry, and to wear a temporary identification badge that is visible to others at all times while in a limited access area.

(d) When admitting an individual under subsection (c) to a limited access area, a dispensary shall:

(1) Require the individual to sign a log and detail the need for entry upon entering and sign the log when leaving the limited access area.

(2) Check the individual's government-issued identification to verify that the name on the identification provided matches the name in the log. A photocopy of the identification must be retained with the log.

(3) Issue a temporary identification badge with ~~the individual's name and company, if applicable, and~~ a badge number.

(4) Escort the individual while the individual remains in a limited access area.

(5) Ensure that the individual does not touch any medical marijuana products located in a limited access area.

(e) The following requirements apply regarding the log required under subsections (c) and (d):

(1) The dispensary shall maintain the log for 4 years and make the log available to the Department, State or local law enforcement and other State or local government officials upon request if necessary to perform the government officials' functions and duties.

(2) The log must include the full name of each individual granted access to the facility's limited access area, the temporary identification badge number, the time of arrival, the time of departure and the purpose of the visit, including the areas visited and the name of each employee visited.

(f) This section does not limit the right of the Department or its authorized agents, State or local law enforcement or other Federal, State or local government officials, from entering any area of a dispensary if necessary to perform the government officials' functions and duties that pertain to the act or this part.

(g) A principal, financial backer, operator or an employee of a dispensary may not receive any type of consideration or compensation for allowing an individual to enter a limited access area.

Comment:

While Cresco recognizes and agrees that grower/processor and dispensary facilities are generally not open to the public and that the security of those facilities is of paramount importance, the Department's proposed permanent regulations go too far in restricting reasonable visitor access. Indeed, the Department proposed rules are so restrictive that they remove the term "visitor" altogether. Under the current temporary regulations, visitors are permitted in facilities under the careful supervision of grower/processor and dispensary employees and the substantial security measures employed at those facilities to prevent the diversion of marijuana. There is a legitimate interest and genuine need for visitors to have reasonable access to licensed facilities such as vendors and other non-agents who may need to conduct business at a facility. Similarly, other interested parties such as local community leaders should be able to tour facilities and understand the businesses in their communities. Additionally, reasonably access should be available for members of the community or other individuals who may be interested in learning about the industry, including members of the academic world. To that end, the Department should not implement these new rules, which go beyond any security or other requirement mandated by the Act, and permanently implement and follow its temporary rules which balance providing access to facilities with the need to maintain the integrity of facilities from a security standpoint.

§ 1151a.26. Security and surveillance.

(a) A grower/processor shall have security and surveillance systems, utilizing commercial-grade equipment, to prevent unauthorized entry and to prevent and detect an adverse loss. The security and surveillance systems must include all of the following:

[. . .]

(4) The ability to record and store all images captured by each surveillance camera for a minimum of ~~2 years~~ 90 days in a format that may be easily accessed for investigative purposes. The recordings must be kept:

(i) At the facility:

(A) In a locked cabinet, closet or other secure place to protect it from tampering or theft.

(B) In a limited access area or other room to which access is limited to authorized individuals.

(ii) At a secure location other than the location of the facility if approved in writing by the Department.

[. . .]

§ 1161a.31. Security and surveillance.

(a) A dispensary shall have security and surveillance systems, utilizing commercial-grade equipment, to prevent unauthorized entry and to prevent and detect an adverse loss. The security and surveillance systems must include all of the following:

[. . .]

(4) The ability to record and store all images captured by each surveillance camera for a minimum of 90 days ~~2 years~~ in a format that may be easily accessed for investigative purposes. The recordings must be kept:

(i) At the facility:

(A) In a locked cabinet, closet or other secure place to protect it from tampering or theft.

(B) In a limited access area or other room to which access is limited to authorized individuals.

(ii) At a secure location other than the location of the facility if approved by the Department.

[. . .]

Comment:

Under the above Sections, video surveillance footage for both growers/processors and dispensaries must be maintained for a minimum of 2 years. Such a requirement far exceeds those in other medical and adult use marijuana markets and burdens industry with the significant cost of storing video data. For example, across the industry, in markets including Arizona, California, Illinois, Maryland, Massachusetts, Michigan, and New York video surveillance footage is required to be maintained between 30 and 180 days absent notification of an ongoing investigation, lawsuit, or other law enforcement action. Cresco respectfully urges the Department to implement a similar common-sense standard, requiring that video footage need only be maintained for 90 days. Of course, security footage can still be required to be maintained for longer upon notification by the Department based on a need for the same. Given requirements in place that operators report the

loss of marijuana or other significant security occurrence, 90 days is ample time for the Department, law enforcement, or other interested parties to ensure that video footage is not erased.

§ 1151a.27. Requirements for growing and processing medical marijuana.

(a) A grower/processor shall use only a pesticide, fungicide or herbicide that is approved by the Department of Agriculture for use on medical marijuana plants and listed in Appendix A (relating to acceptable pesticide active ingredients for use) or as otherwise approved by the Department. The Department will periodically publish, not less than four times per year after soliciting and receiving input from industry and the Department of Agriculture, a notice in the *Pennsylvania Bulletin* updating the list of approved pesticides, fungicides and herbicides.

[. . .]

(h) A grower/processor may only process the parts of the medical marijuana plant that:

~~(1) Are free of seeds and stems.~~

(1~~2~~) Are free of dirt, sand, debris or other foreign matter.

(2~~3~~) Do not contain a level of mold, rot or other fungus or bacterial diseases higher than the minimum levels acceptable to the Department.

[. . .]

(j) If a batch of medical marijuana fails any test required under Section 1171a.29, the batch may be used to make a CO2 or solvent based extract. After processing, the CO2 or solvent based extract must still pass all requires tests.

Comment:

Cresco respectfully proposes the above further amendments to this section, which would permit growers/processors to remediate cannabis flower that may have failed any test required under Section 1171a.29. Remediation of medical marijuana product is a growing field with methods being actively researched, developed, and validated. For example, remediation of marijuana flower that fails initial testing is permitted in Illinois, Ohio, Maryland, Florida, Arizona, Michigan and California. Further testing is required when a processed product is in final form, which ensures the integrity of the products ultimately dispensed to patients. The Department's current position in disallowing remediation only serves to hurt both patients and operators who are forced to waste otherwise viable medical marijuana, resulting in products shortages for patients, higher product costs for patients, and lost tax revenue for the Commonwealth.

Further, as set forth above, Cresco asks the Department to consider removing the requirement that processed material be free from seeds and stems, as serving no meaningful purpose from either a

patient safety perspective or enhancing the final products. Seeds and stems do not affect final product safety for extracted products, as cannabinoids and terpenes are extracted, leaving behind the biomass.

Additionally, Cresco asks the Department to consider implementing the above language, which would encourage the Department to regularly consider changes to the pesticides allowed to be used by growers/processors. While Cresco understands that the Department may wish to proceed cautiously with respect to approving pesticide use in the cultivation of medical marijuana, the current list of permissible pesticides is not updated regularly and it is important that the Department commit to recurrently consider new additions to the list. Absent the use of pesticides, medical marijuana crops are at a greater risk of loss, which results in potential market shortages, ultimately hurting patient access to medical marijuana and medical marijuana products, and increasing costs for operators which is reflected in the cost of products for patients.

§ 1151a.29. Limit on medical marijuana processing.

(a) In the form intended to be sold to another medical marijuana organization, medical marijuana or a medical marijuana product must have a specific concentration of total THC and total CBD and must have a consistent cannabinoid profile. The concentration of the following cannabinoids, at a minimum, shall be reported to the Department by an approved laboratory and include the following on the label (CAS numbers need not be displayed on the label) if the cannabinoid component is at or exceeds 0.1%. To the extent that a cannabinoid's content is below 0.1% or information cannot reasonably fit on the label, information required under this section can be made available to patients via an electronic link printed on the label:

(1) THC.

~~(2) THCA.~~

~~(3) THCV.~~

(4) CBD.

(5) CBDA.

(6) CBDV.

(7) CBN.

(8) CBG.

(9) CBC.

~~(10) D8.~~

(11) Any other cannabinoid component at 0.1%.

[. . .]

§ 1171a.31. Test results and reporting.

[. . .]

(e) An approved laboratory shall issue to a grower/processor a certificate of analysis, including the supporting data, for each harvest batch, harvest lot or process lot sample that was tested at the request of the grower/processor. The certificate of analysis must include the following information:

(1) Whether the chemical profile of the harvest batch, harvest lot or process lot conforms to the chemical profile of the strain as determined by the Department for the following compounds:

(i) THC.

(ii) THCA.

(iii) CBD.

(iv) CBDA.

(v) CBC.

(vi) CBN.

~~(vii) THCV.~~

~~(viii) CBDV.~~

(ix) CBG.

~~(x) D8.~~

[. . .]

Comment:

Cresco supports full and accurate testing and recognizes the importance in ensuring that information about medical marijuana and medical marijuana products are easily accessible to patients. However, delta-9-THC, delta-9-THCA, CBD, CBDA, CBN, CBG, and CBC are the only main cannabinoids that currently have certified reference materials available to act as controls or standards in the validation of analytical measurement methods. As a result, while Cresco also supports efforts by the Department to ensure that intoxicating products, such as those containing delta-8 THC, are tested, accurately labeled, and only sold through the regulated market, Cresco proposes that only the above cannabinoids be required to be reported on a certificate of analysis

with respect to whether the chemical profile of the harvest batch, harvest lot or process lot conforms to the chemical profile of the strain.

Additionally, with respect to product labeling as set forth in Section 1151a.29, Cresco suggests that the DOH only require a product label to list the above cannabinoids if the cannabinoid component is at or exceeds 0.1%. To the extent that a cannabinoid's content is below 0.1% or information cannot reasonably fit on the label, information required under this section should simply be made available to patients via an electronic link printed on the label. This approach to labeling—particularly allowing the use of an electronic link—balances the need to ensure that patients have access to information regarding the products they purchase and consume and the difficulties for growers/processors in crafting cost-effective labels that effectively communicate information to patients. Absent these amendments, labels can become overcrowded and confusing for patients and present costly challenges for operators who will have difficulty developing packaging that contains excess information.

§ 1151a.34. Packaging and labeling of medical marijuana products.

[. . .]

(b) A grower/processor shall package the medical marijuana products in a package that minimizes exposure to oxygen and that is:

(1) Child-resistant.

(2) Tamper-proof or tamper-evident.

~~(3) Opaque.~~

(34) Resealable.

[. . .]

(d) A grower/processor shall obtain the prior written approval of the Department of all packaging and the content of any label to be affixed to a medical marijuana product package. A request for packaging and labeling approval shall be made to the Department via email using a form disseminated by the Department. The Department shall grant or deny approval, also via email communication, with 5 business days of the submission of a request for approval. If the Department denies the approval for packaging and/or labeling, it shall provide a detailed explanation of its decision, including a citation to the statutory or regulatory provision it asserts as a basis for the denial. Each label must meet the following requirements:

[. . .]

(6) List the number of individual doses contained within the package, the species and percentage of THC and CBD and other cannabinoids enumerated in § 1151a.29 (relating to limit on medical marijuana processing), and the individual terpenes and corresponding percentages if the cannabinoid component is at or exceeds 0.1%. To the extent that a cannabinoid's content is below 0.1% or information cannot reasonably fit on the label, information required under this section can be made available to patients via an electronic link printed on the label. CAS numbers need not be displayed on the label.

[. . .]

(17) Be firmly affixed to the container directly holding medical marijuana ~~and be firmly affixed to outer packaging if used~~.

(18) ~~List~~ Clearly indicate which number reflects THC ~~as the first number~~ when THC and CBD are listed on a label as a ratio.

[. . .]

Comment:

The proposed language of Section 1151a.34 reflects a number of substantive changes to the current rule governing the packaging and labeling of medical marijuana and medical marijuana products. As a general matter, Cresco is concerned that if these amended rules are implemented it and other operators will need time to source new technology/printing capabilities for new labels and may have quantities of products that it may not be able to sell to patients as they will have been produced and sold in packaging compliant under the current rules. As a result, operators would be forced to destroy products that have already been packaged and incur a loss of any unsold products. To protect against these circumstances, Cresco proposes that the Department implement a 180-day during which growers/processors can transition to the new packaging requirements and dispensaries can sell through any products containing packaging made under the current rule. Further, Cresco proposes that at the conclusion of the grace period dispensaries be permitted, in these limited circumstances, to return unsold products to growers/processors from which the product came and that, in turn, growers/processors would be permitted to repackage those products into compliant packaging. Allowing returns and repackaging under these unique circumstances would guard against the possibility that dispensaries and/or growers/processors would be forced to destroy otherwise viable products simply because they were not able to sell product to patients fast enough.

With respect to the requirement that product packaging be opaque, Cresco urges the Department to consider eliminating this requirement as one that does not protect patients and or ensure the safe delivery of medical marijuana and medical marijuana products. In particular, Cresco seeks the above modification to the proposed regulations, removing the opaque requirement, at least as to the container/dram holding medical marijuana or medical marijuana products. Absent the opaque requirement, containers/drams would still need to be child-resistant, resealable, and tamper-proof

or evident, which would ensure medical marijuana and/or products are secured and inaccessible to minors. The additional opaque requirement will not make medical marijuana and/or products more securely sealed or less appealing to minors. Rather, requiring opaque interior containers/drams only adds to the cost of operators, especially those who operate in multiple jurisdictions. For example, regulators in Illinois, Ohio, and New York, which have established, successful, and safe medical marijuana programs, do not require the use of opaque drams/containers. Should the Department continue to require opaque packaging for containers/drams, it should at least permit operators to affix stickers or other wrapping to containers/drams to obscure the contents of the drams.

Additionally, with respect to subsection (d) above, Cresco respectfully requests clarity from the Department as to how the formal approval process will work in practice such as a timeline for approval and what type of changes might require resubmission, including whether strain names need to be submitted. Cresco has suggested language to that effect above. Such information will provide operators needed clarity and transparency and will ultimately also benefit the Department as the process for receiving packaging approval will be clearly laid out.

Concerning the above language that requires all cannabinoids/terpenes to appear on labels Cresco suggests that the DOH only require a product label to list the above cannabinoids if the cannabinoid component is at or exceeds 0.1%. To the extent that a cannabinoid's content is below 0.1% or information cannot reasonably fit on the label, information required under this section should simply be made available to patients via an electronic link printed on the label. This approach to labeling—particularly allowing the use of an electronic link—balances the need to ensure that patients have access to information regarding the products they purchase and consume and the difficulties for growers/processors in crafting cost-effective labels that effectively communicate information to patients. Similarly, Cresco respectfully asks the Department to reconsider the requirement set forth in subsection (d)(17) that both outer packaging and the inner container/dram must contain a product's label. Such is a costly requirement for operators that is not required in other similarly-situated medical markets such as Ohio, New York, and Maryland and is unnecessary to the extent the goal of such a requirement is to ensure patients clearly understand the contents of the medical marijuana/product they purchase.

Finally, Cresco also asks that the Department to revise subsection (d)(18) as set forth above. Cresco supports the Department's aim in making packaging and labels easier for patients to read and digest but the proposed requirement that THC be the first number in any THC-CBD ratio is unnecessary and will result in operators, including Cresco, incurring costs to adjust its packaging. To achieve the same goal of improving patient understanding and safety, especially in light of the fact that packaging must be approved by the Department, Cresco proposes the above language.

§ 1151a.35. Transportation of medical marijuana.

(a) A grower/processor may transport and deliver seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products to a medical

marijuana organization or an approved laboratory in this Commonwealth in accordance with this section. The following requirements apply:

(1) Unless otherwise approved by the Department, a grower/processor may deliver seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products to a medical marijuana organization or an approved laboratory only between 7 a.m. and 9 p.m.

(2) A grower/processor may contract with a third-party contractor for delivery so long as the contractor complies with this section.

(3) A grower/processor may not transport seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana or medical marijuana products to any location outside of this Commonwealth.

(4) A grower/processor shall use a global positioning system to ensure safe, efficient delivery of the seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products to a medical marijuana organization or an approved laboratory.

(5) A grower/processor shall be permitted to deliver and temporarily store, for up to 48 hours, the seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products at a medical marijuana organization under common ownership as the grower/processor before completing deliveries to another marijuana organization(s).

[. . .]

(e) Except as provided in subsections (h) and (i), a delivery team shall proceed in a transport vehicle from a grower/processor facility, where the seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products are loaded, directly to a medical marijuana organization facility or approved laboratory, where the seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products are unloaded, without unnecessary delays. Notwithstanding the foregoing, a transport vehicle may make stops at multiple medical marijuana organization facilities or approved laboratories, as appropriate, to deliver seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products.

[. . .]

(i) As part of the delivery process, a grower/processor's delivery team is permitted to engage in cross-docking at any licensed marijuana organization whereby seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products are transferred to another transport vehicle(s) for the purposes of completing a delivery/deliveries to other marijuana organization(s).

Comment:

Cresco respectfully asks that the Department consider further amending its proposed permanent rules to provide growers/processors the necessary flexibility to deliver seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products in a safe, secure, and effective manner. The current regulatory framework appears only to contemplate deliveries that originate from a grower/processor and are delivered directly to a dispensary location or multiple sequential dispensary locations as part of one delivery trip. As a result, because growers/processors are located around the state and may be a great distance from the dispensaries they deliver to, a single delivery can take up to 10 to 14 hours. Such a scenario is inefficient and presents unnecessary logistical changes for growers/processors and also presents potential safety risks for delivery teams. For example, under the rules as currently drafted, a delivery vehicle might travel 4 to 5 hours from Cresco's Brookville grower/processor facility to the greater Philadelphia area to complete a series of deliveries to dispensaries before completing a several-hour return trip back to Cresco's Brookville facility. This method of delivery is burdensome on facilities and places unneeded stress on delivery teams. The above proposed changes to this rule would allow growers/processors to temporarily store the contents of a delivery at a dispensary under common ownership of a grower/processor or to engage in cross-docking whereby a larger delivery is divided into multiple smaller deliveries at a secure hub rather than requiring a single transport vehicle to travel a great distance and then complete several deliveries using a single vehicle. Such flexibility in growers/processors' ability to deliver products would result in cost savings that would benefit the program's patients and make it easier for growers/processors to supply dispensaries around the Commonwealth. Additionally, allowing the temporary storage of products before completing deliveries or permitting a larger delivery loads to be divided among several smaller delivery vehicles presents no safety risks and in fact reduces any potential safety risk by reducing the amount of products/materials a single vehicle is carrying. For these reasons, Cresco urges the Department to consider implementing the above changes—all of which would still be subject to careful planning and documentation and Department oversight—to allow for the more efficient and safe transport of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products.

§ 1151a.36. Transport manifest.

(a) A grower/processor shall generate a printed or electronic transport manifest that accompanies every transport vehicle and contains the following information:

[. . .]

(b) When a delivery team delivers seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products to multiple medical marijuana organizations or approved laboratories, the transport manifest must correctly reflect the specific seeds, immature medical marijuana plants, medical marijuana plants, medical

marijuana and medical marijuana products in transit. Each recipient shall provide the grower/processor with a printed receipt for the seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products received. Any errors in the manifest may be corrected but must be carefully documented and tracked via the state's electronic seed-to-sale tracking system.

[. . .]

(d) A grower/processor shall provide a copy of the transport manifest to the recipient receiving the seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana and medical marijuana products described in the transport manifest. To maintain confidentiality, a grower/processor may prepare separate manifests for each recipient. Any errors in the manifest may be corrected but must be carefully documented and tracked via the state's electronic seed-to-sale tracking system.

[. . .]

§ 1161a.36. Transport manifest.

(a) A dispensary shall generate a printed or electronic transport manifest that accompanies every transport vehicle and contains the following information:

[. . .]

(b) When a delivery team delivers medical marijuana products to multiple facilities, the transport manifest must correctly reflect the specific medical marijuana products in transit. Each recipient shall provide the dispensary with a printed receipt for the medical marijuana products received. Any errors in the manifest may be corrected but must be carefully documented and tracked via the state's electronic seed-to-sale tracking system.

[. . .]

(d) A dispensary shall provide a copy of the transport manifest to the recipient receiving the medical marijuana products described in the transport manifest. To maintain confidentiality, a dispensary may prepare separate manifests for each recipient. Any errors in the manifest may be corrected but must be carefully documented and tracked via the state's electronic seed-to-sale tracking system.

[. . .]

Comment:

Currently, when receiving errors occur, product must be quarantined due to the inability of dispensaries to send items back to growers/processors. Of course, this results in losses for

operators (and the Commonwealth in terms of tax revenue) and further results in products not being available for patients. To solve this problem, Cresco proposes the above amendments to proposed Sections 1151a.36 and 1161a.36. Under the language as suggested above, operators could accept deliveries with errors in the manifest as long as those errors are properly documented, including through the Commonwealth's seed-to-sale tracking system.

§ 1161a.25. Licensed medical professionals at facility.

(a) Except as provided in subsection (b), a dispensary shall ensure that a physician or a pharmacist is present at the facility at all times during the hours the facility is open to dispense or to offer to dispense medical marijuana products to patients and caregivers. If a dispensary is authorized to operate more than one facility under its permit, a physician or a pharmacist is considered present, for the purposes of this rule, if they are physically present at one of a permittee's facilities and otherwise available virtually at the up to two other locations.

(b) If a dispensary is authorized to operate more than one facility under its permit, a physician assistant or a certified registered nurse practitioner may be present onsite at each of the other locations instead of a physician or pharmacist. The physician, pharmacist, physician assistant or certified registered nurse practitioner may rotate coverage of the facilities, provided that a physician or pharmacist is always present at one of the facilities, or virtually pursuant to subsection (a).

[. . .]

Comment:

As written, a physician or pharmacist or physician assistant or a certified registered nurse practitioner is required to be physically onsite at a dispensary location during the hours the facility is open to dispense or to offer to dispense medical marijuana products to patients and caregivers. However, this amended rule does not account for temporary measures currently in place allowing for sales to patients and caregivers when medical professionals are working remotely. Cresco encourages the Department to further amend the above rule to account for this measure, which were instituted to reduced opportunities for exposure of patients, caregivers, and dispensary staff to the coronavirus. Commonwealth dispensary operators have proven over the course of the past year that the industry can operate with remote supervision in place in a safe, secure, and responsible way. By permitting operators to continue to staff its dispensaries in this way the Commonwealth will avoid reimplementing unnecessary barriers for patients to access their essential medication and allow for the more efficient oversight of dispensary operations by permit holders. Also, allowing this practice to remain in place will promote revenue growth for operators and increased tax revenue for the Commonwealth at a time when both are crucial. For these reasons, Cresco asks the Department to consider the above amendments.

~~**§ 1171a.26. Stability testing and retention of samples.**~~

~~(a) A grower/processor shall request that a sample be identified and collected by an approved laboratory from each harvest batch sufficient to perform stability testing at 6-month intervals for a 1-year period.~~

~~(b) The stability test shall be performed to ensure product potency and purity and provide support for expiration dating.~~

~~(c) An approved laboratory shall retain a sample from each harvest batch sufficient to provide for stability testing and properly store the sample for 1 year.~~

Comment:

Cresco respectfully urges the Department to consider eliminating the stability testing and retention of samples requirements as set forth above. While stability testing perhaps served a genuine aim during the early stages of the program when a products stability may have been a reasonable question, it is simply unnecessary to study each harvest batch, as the stability of medical marijuana and products is generally known. Patients are already well served by the one year expiration date for products and high demand ensures products do not sit for long on dispensary shelves. For these reasons, the Department should end stability testing.

§ 1171a.28. Selection protocols for samples.

(a) An employee of an approved laboratory may only enter a grower/processor facility for the purpose of identifying and collecting samples and shall have access to limited access areas in the facility for these purposes.

(b) An employee identifying and collecting samples under subsection (a) shall follow the chain of custody procedures included in the approved laboratory's application and approved by the Department.

(c) While at a grower/processor facility, an employee of an approved laboratory shall identify and collect the following for testing:

~~(1) Samples at the time of harvest.~~

(1~~2~~) Samples of medical marijuana product before being sold or provided to a dispensary.

(2~~3~~) Test samples at other times when requested by the Department.

Comment:

Cresco exhorts the Department to consider further changes to testing protocols and end the double-testing required of processed products, which are tested both at the flower stage and then again in final form. Pennsylvania stands as an outlier among other states with medical and adult use cannabis programs. Other jurisdictions, including Illinois, New York, Maryland, Massachusetts, Ohio, Arizona, Michigan and California, do not require such double testing because it does not

add to patient safety and represents a needless additional cost for operators to incur, a cost that ultimately increases the price of products for patients. Testing should only be required of medical marijuana and medical marijuana products in final form. Products that are only tested in final form will still need to pass testing thresholds and thereby ensuring patients are protected. Whether or not the same product would have failed testing before processing is irrelevant and is not an indicator that the final product is anything other than viable and appropriately dispensed to patients.

Thank you for the opportunity to comment on these proposed permanent rules. Cresco welcomes the opportunity to provide the IRRC with any additional feedback or information.

Sincerely,

Cresco Yeltrah, LLC