

MMCP Rules – CSI Comment Response Memo - DRAFT

Rule Number	Entity	Comment	DRAFT Board Response
3796:6-2-02	Cresco	<p>Cresco seeks further clarity with respect to paragraph (C) of OAC 3796:6-2-02, which describes the manner in which measurements are taken to determine the distance between a dispensary and any facility described in paragraph (B)(2)(k). Specifically, Cresco respectfully requests that the BOP provide additional information as to its definition of the phrase “parcel of real estate.” As currently undefined, the potential for confusion exists, as, depending on the particular pieces of real estate involved, the starting and ending points for calculating the 500-foot may not be apparent. For example, if a facility described in paragraph (B)(2)(k) is part of a larger parcel of real estate such as a mall or a multi-story building, it is not clear from the above whether the “external boundary” is the wall of the facility or another structure that is part of the larger property. In order to provide operators further clarity, Cresco proposes that the Board either define the term “parcel” further or specify exactly how measurements should be taken, accounting for the situations such as those described in this comment.</p>	<p>By way of clarification, the Board notes that the external boundaries of the real estate parcel are determined by the county auditor’s website. If multiple structures are included on the same “parcel” as defined by the county auditor, the 500-foot boundary will be calculated from the entire property or “parcel,” not from that specific building only. The Board did not incorporate this comment.</p>
3796:6-2-04	Cannamed Therapeutics LLC	<p>The Board should not strike current Rule 04(G)(2). R.C. 3796.05(B) requires that the Board consider geographic distribution of dispensary sites, and eliminating this division inhibits the Board’s ability to consider related geographic factors such as whether a local government has prohibited or limited the number of dispensaries in a community under R.C. 3796.29. Geographic considerations also could prevent a regional district from dispensary saturation.</p> <p>Additionally, proposed division (J)(3) should be amended to provide existing licensees, who are also certificate of operation holders, a first opportunity to apply for any provisional license the Board has rescinded, provided the licensee has not exceeded the five dispensary maximum and the licensee has previously applied in the same region. Certificate of operation holders have already established the ability to meet Board operation standards.</p> <p>The Medical Marijuana Act leaves this issue to the Board’s discretion. In at least two other legal cannabis states (IL and MI), laws direct the regulating agency to first accept applications from an existing dispensary to secure a new license before opening licensure to new applicants. The other benefit is that owners and managers will have already passed background checks, management models will have already been vetted and approved and should be in a position to obtain a certificate of operations much more quickly than a new licensee.</p>	<p>The Board has amended this rule to allow more flexibility in determining the factors that should be considered when evaluating whether new dispensaries should be licensed. The Ohio Revised Code requires the Board to consider geographic distribution when allocating additional dispensary licenses in a future request for application process, and this factor will continue to be considered in any requests for application; however, the Board prefers to be able to tailor any future requests for application to the circumstances at the time of the request.</p> <p>Preference will not be given to existing dispensary operators. The Board believes that any eligible applicant should be treated equally and current dispensary owners can present their qualifications in any dispensary application.</p> <p>The Board has concluded that dispensaries should not be located in the near vicinity of an</p>

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		<p>The Board should strike current and proposed Rule (04)(E)(3). Neither R.C. 3796.10(B)(4), 3796.04(B)(9), 3796.30, 5119.371 nor 5119.37 require or reference an opioid treatment program as a facility to be included within the 500-foot prohibited area. The latter two statutes were amended after passage of the Medical Marijuana Act, yet neither refers to medical marijuana or dispensaries. It is already very difficult to locate suitable real estate for a dispensary, and the current and proposed division only adds to the difficulty.</p>	<p>opioid treatment facility. While the Board recognizes this may present a challenge to dispensary applicants, the health and safety of the patients is paramount to this concern.</p> <p>The Board declines to incorporate these comments.</p>
<p>3796:6-2-05, 3796:6-2-06</p>	<p>Cannamed Therapeutics LLC</p>	<p>The Board should provide more clarity concerning the conditions under which it would increase the number of available licenses in a geographical area, the frequency of a potential increase, and a preference to applicants that are existing licensees that have not reached the maximum allowable number of licenses. The proposal seeks to strike current Rule 05(A) and essentially eliminates the maximum number of 60 dispensaries statewide.</p> <p>Under proposed Rules 05(A) & (B) and current Rule 06(F), an owner may be awarded up to five dispensary licenses unless a “biennial” Board analysis supports licensing more than 60 dispensaries. In the event the Board licenses greater than 60 dispensaries, existing licensees who have not reached the 5-dispensary maximum should have the first opportunity to apply for licenses as a preference before other applicants may submit.</p> <p>Our reasoning is one of overall fairness and, similar to our comments to Rule 04(J)(3) above. Initial provisional license applications required applicants to submit proposed budgets and financial plans, which were based upon a number of factors, including the potential size of the patient pool, the number of licenses available and regional location.</p> <p>Eliminating this existing rule in favor of a more discretionary position marginalizes the utility of budgets and financial plans applicants submitted based on a fully supplied and operational program.</p> <p>Additionally, proposed Rule 5(A) adds to R.C. 3796.05(B) by requiring the Board to consider the number of available licenses “each biennial licensing term.” We note that it is unclear when this is to occur, as there are several “biennial licensing terms” within the existing rules. For example, each dispensary has a biennial term that begins upon certificate of operation issuance.</p>	<p>The Board has removed the language in 3796:6-2-05(A) because the language limiting the number of provisional dispensary licenses to 60 applied only until September 8, 2018; that date has now passed and the Board may authorize in excess of 60 dispensaries to operate. As indicated in the remaining rule, the Board will consider the population of the state, the number of patients seeking to use medical marijuana, and the geographic distribution of dispensary sites in determining whether additional provisional dispensary licenses should be issued.</p> <p>Preference will not be given to existing dispensary operators. The Board believes that any eligible applicant should be treated equally and current dispensary owners can present their qualifications in any dispensary application.</p> <p>This comment is not incorporated into the rule.</p>
<p>3796:6-2-07</p>	<p>Cresco (suggested)</p>	<p>(G) Every applicant for a dispensary associated key employee license shall comply with Chapter 3796. of the Revised Code and this division and be included on the</p>	<p>The Board has not approved any amendments to (G) of this rule; however, the Board</p>

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<p>edits in green)</p>	<p>dispensary license application or renewal application. A dispensary wishing to add a dispensary associated key employee who is not included in the dispensary license application or renewal application, or who did not submit with the dispensary application the required items under this rule, shall apply for a change of ownership pursuant to rule 3796:6-2-12 of the Administrative Code and remit the required fee.</p> <p><u>(M) A dispensary associated key employee or dispensary key employee who fails to renew their license in accordance with this rule is prohibited from engaging in the activities authorized by Chapter 3796. of the Revised Code and Chapter 3796. of the Administrative Code: until the Board approved any renewal.</u></p> <p><u>(N) A dispensary associated key employee or dispensary key employee with an expired license may apply to reinstate their license in accordance with this rule.</u></p> <p><u>(O) If any information contained in the application or accompanying documents changes after being submitted to the state board of pharmacy, the applicant shall immediately notify the state board of pharmacy in writing and provide corrected information within fourteen days of the change.</u></p> <p>Comment:</p> <p>As set forth in amended paragraphs (A), (G), (N), and (O) of OAC 3796:6-2-07, above, associated key employee and dispensary key employee licenses are tied to an operator's application for licensure. As a result, to add and/or subtract an associated key employee or a dispensary key employee, a dispensary must seek to amend its original application. Cresco advocates that the BOP take steps to untether this process from a dispensary's application, which would ease the ability of dispensary operators to effectuate any necessary change without having to revisit its application, which may be several years old. Indeed, the process, as written, does not take into consideration the realities of operating a business where employee turnover can occur, sometimes with frequency. Rather than tying changes to a licensee's application, Cresco proposes the BOP require operators to make changes to their operating plans and approved standard operating procedures. Such would balance the BOP's interest in having such changes well documented and ensuring dispensaries continue to operate in a compliant manner with the burdens on the dispensary associated with adding or subtracting these employees. Additionally, Cresco seeks to add the above language to subpart (M), clarifying that a dispensary associated key employee or dispensary key employee who fails to renew his or her license is only prohibited from engaging in dispensary-related</p>	<p>continues to consider potential changes to 3796:6-2-12 (not included in this rule set) and may consider altering the definition of a "change of ownership" when those amendments are considered. Accordingly, the Board will further consider this comment when it considers any amendment to 3796:6-2-12. Because the language in 3796:6-2-12 is not currently being amended, it would not be appropriate to modify the language in (G) at this time.</p> <p>As noted in (L), if an employee does not timely renew his or her license, the license will expire; however, the employee may apply to reinstate their expired license as indicated in (N). The Board has no provisions to permit the renewal of an expired license because there is no longer a valid license to renew. Accordingly, the Board submits that the current language addressing reinstatement of a license addresses the concerns raised in the comment.</p> <p>The Board will not incorporate these comments at this time.</p>
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<p>3796:6-2-08</p>	<p>Cresco (suggested edits in green)</p>	<p>activities until his or her license is renewed.</p> <p><u>(K) An individual who fails to renew their license in accordance with this rule is prohibited from engaging in the activities authorized by Chapter 3796. of the Revised Code and Chapter 3796. of the Administrative Code- until the Board approved any renewal.</u></p> <p><u>(L) A dispensary support employee with an expired license may apply to reinstate their license in accordance with this rule.</u></p> <p><u>(M) If any information contained in the application or accompanying documents changes after being submitted to the state board of pharmacy, the applicant shall immediately notify the state board of pharmacy in writing and provide corrected information within fourteen days of the change.</u></p> <p>Comment:</p> <p>Similar to our comments related to OAC 6-2-07, Cresco asks that the Board take steps to separate the process of adding and/or subtracting dispensary support employees from the dispensary's application, which would ease the ability of dispensary operators to make any necessary changes to its workforce without having to revisit its application. Again, as stated above, the process described in the amended regulations does not adequately take into consideration the realities of operating an Ohio dispensary where employee turnover can occur. Cresco proposes the BOP require operators make changes to their operating plans and approved standard operating procedures in the case of a change to any of its support employees. Such would effectively balance the BOP's interests with the potential hardships for a dispensary associated with managing its workforce. Additionally, Cresco seeks to add the above language to subpart (K), clarifying that a dispensary support employee who fails to renew his or her license is only prohibited from engaging in dispensary-related activities until his or her license is renewed.</p>	<p>As noted in (J), if an employee does not timely renew his or her license, the license will expire; however, the employee may apply to reinstate their expired license as indicated in (L). The Board has no provisions to permit the renewal of an expired license because there is no longer a valid license to renew. Accordingly, the Board submits that the current language addressing reinstatement of a license addresses the concerns raised in the comment.</p> <p>The Board will not incorporate these comments at this time.</p>
<p>3796:6-2-10</p>	<p>Cresco</p>	<p><u>(E) A dispensary is only permitted to renew its certificate of operation with the existing ownership and location as originally awarded with the certificate or any subsequent approval by the board. A dispensary that is eligible to apply for a change of ownership pursuant to rule 3796:6-2-12 of the Administrative Code or a relocation pursuant to rule 3796:6-2-14 of the Administrative Code must request such changes separate from the renewal application.</u></p> <p>Comment:</p>	<p>By way of clarification, the Board notes that it considers change of ownership applications on a case-by-case basis. The Board will coordinate with dispensaries so that the timing of the review of multiple processes will occur in the most efficient manner; however, the Board cannot incorporate the order of such processes in rule because it varies based on the circumstances.</p>

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		In light of the amended language to OAC 3796:6-2-10, Cresco seeks clarification from the Board as to the timeline for submitting ownership changes to the BOP to ensure approval prior to submitting materials to renew a certificate of operation. Specifically, is there a time by which ownership changes need to be submitted to be approved prior to a renewal? Such clarification would provide necessary transparency and a line of sight for operators who may need to go through both processes near the time of renewal.	
3796:6-2-13	Cresco	<p>(1) An application for a relocation of a dispensary may not be combined with an application for renewing a dispensary certificate of operation or a request for a change of ownership. The state board of pharmacy shall process each application separately.</p> <p>Comment:</p> <p>Related to the amended language to OAC 3796:6-2-13, Cresco seeks clarification from the Board as to the timeframe for seeking to relocate a dispensary prior to renewing a certificate of operation so as not to delay the renewal process. Such clarification would provide necessary transparency and a line of sight for operators who may seek to go through both processes near the time of renewal.</p>	The renewal process for dispensary certificates of operation occurs on a fixed schedule and is entirely determinable for dispensaries. The Board recommends that any dispensary seeking to relocate not pursue such movement during the approximately 90-day window prior to renewal each biennium. However, the rule does not prohibit a dispensary from pursuing both renewal and relocation at the same time, just through separate processes. The Board does not incorporate this comment.
3796:6-3-01	OMCIA	<p>Concern: Under the current program rules, a dispensary can only acquire medical marijuana from a processor or cultivator holding a plant-only processor designation. For dispensary owners with more than one dispensary location in Ohio, this provision prevents the transfer of marijuana inventory between locations. There are many times when a dispensary may have a stockpile of inventory at one location that sells better in another location. Rather than allow that inventory to age, it is better for the dispensary to be able to transfer the inventory to the other store.</p> <p>Current Rule Language:</p> <p>(D) A dispensary shall not obtain, cultivate, deliver, transfer, transport, sell or dispense marijuana except:</p> <p>(1) It may acquire marijuana from a processor or cultivator holding a plant-only processor designation;</p> <p>(2) It may sell expired plant material to a processor licensed by the department of commerce, if all original tamper-resistant seals from the original cultivator's container remain intact;</p> <p>(3) Dispensary employees may dispense and sell marijuana only to a patient or caregiver, in a dispensary department, in accordance with Chapter 3796. of the Revised Code and this division; and</p>	The Board declines to incorporate this comment into the rule at this time. First, the Board notes that there is a risk of diversion anytime medical marijuana is transported from one location to another and authorizing additional transfers between dispensary locations will increase this diversion risk. Secondly, the Department of Commerce currently regulates licensees who can transport medical marijuana from one location to another, not the Board of Pharmacy, and dispensary employees are not authorized to transport medical marijuana. Therefore, the Board would have no regulatory control over individuals transporting medical marijuana from one dispensary to another or would need to create new regulations to monitor these activities and license these individuals.

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		<p>(4) It may initiate a transfer of inventory over the course of discontinuing business pursuant to rule 3796:6-2-14 of the Administrative Code.</p> <p>Proposed Revised Language:</p> <p>(D) A dispensary shall not obtain, cultivate, deliver, transfer, transport, sell or dispense marijuana except:</p> <p>(1) It may acquire marijuana from a processor or cultivator holding a plant-only processor designation;</p> <p>(2) It may sell expired plant material to a processor licensed by the department of commerce, if all original tamper-resistant seals from the original cultivator's container remain intact;</p> <p>(3) It may transfer medical marijuana inventory between dispensaries of the same ownership if medical marijuana transportation occurs in compliance with rule 3796:5-3-01 of the Administrative Code;</p> <p>(3) (4) Dispensary employees may dispense and sell marijuana only to a patient or caregiver, in a dispensary department, in accordance with Chapter 3796. of the Revised Code and this division; and</p> <p>(4) (5) It may initiate a transfer of inventory over the course of discontinuing business pursuant to rule 3796:6-2-14 of the Administrative Code.</p>	
<p>3796:6-3-01</p>	<p>Cresco</p>	<p>(G) Upon a patient or caregiver's request, a dispensary may provide the patient or caregiver to whom medical marijuana has been dispensed by the dispensary, with a container that is intended to be used for the transport of medical marijuana aliquots.</p> <p>(1) Meet the requirements in paragraph (A) of rule 3796:8-1-01 of the Administrative Code except;</p> <p>(a) Upon written request from a patient or caregiver a container that is not child-resistant may be furnished in accordance with requirements of this paragraph;</p> <p>(b) All written requests must be maintained by the dispensary as part of the patient's official record; and</p> <p>(c) Accompanying documentation must include the form and method of administration for which the container was furnished, the date it was furnished, and the name and signature of the dispensary</p>	<p>The Board understands the concerns raised in this comment and agrees with the concerns regarding the implementation of these changes. Accordingly, the Board has removed this language from the rule amendments.</p>

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		<p style="text-align: center;">employee furnishing the container.</p> <p>Comment:</p> <p>Among other amendments to OAC 3796:6-3-01 is the directive to dispensaries that upon written request from a patient or caregiver, a dispensary may provide that patient or caregiver with a container that is not child-resistant, which is intended to be used for the transport of medical marijuana aliquots. Cresco is supportive of this amendment, as it will provide additional flexibility to patients in transporting their medical and benefits those in particular who may have difficulty opening child-resistant packaging. However, Cresco seeks clarification from the BOP as to the packaging approval process and requirements associated with this new rule. In particular, Cresco respectfully requests that the BOP explain whether this new rule will require dispensaries to maintain a supply of non-child-resistant packaging and, if so, how much of it. Sourcing and storing such packaging will result in operators incurring costs, which may not be insignificant depending on the demand for such packaging. Further, Cresco seeks information from the BOP with respect to the approval process for these containers and additional requirements, if any, beyond that they must meet the requirements in Paragraph (A) of rule 3796:8-1-01.</p>	
3796:6-3-03	FRX Health	<p>3796:6-3-03(B)(3)</p> <p>We believe it is unreasonable to require that the dispensary maintain any change in scheduled hours of operation for a minimum of forty-five days before requesting another change in operating hours. Forty-five days is a substantial amount of time in a competitive retail environment, and that time can have a significant impact on the operations and health of a business. Should there be an unexpected event (traffic changes or road closures, public health crisis, staff emergencies, supplier changes, etc) that could dramatically impact the ability of the dispensary to function normally, forty-five days is an unreasonable amount of time to be required to wait to adjust operating hours if necessary. We do respect Ohio MMCP patients' and caregivers' need to have consistent and predictable access to medical marijuana and understand that part of this is reasonable predictability in dispensary operating hours. However, the other part of this equation is giving dispensaries a fair chance to operate a healthy and sustainable business, and therefore ask that this waiting period between requests of operational changes be reduced to fourteen days.</p>	<p>The Board accepts this comment in part and will reduce the waiting period between requests for changes of hours to 30 days. The Board also notes that changes can be requested after less than 30 days if an unusual situation occurs.</p>
3796:6-3-05	Cresco	<p>(G) If advanced notification of a change of designated representative to the state board of pharmacy is impracticable due to such events as death, incapacity, or termination, the dispensary shall immediately notify the state board of pharmacy and request a temporary certificate of authority allowing the</p>	<p>The Board currently allows dispensaries to identify an interim or temporary designated representative through the variance request process. The removal of this language from the</p>

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		<p>continuing operation.</p> <p>(1) The request shall include the name of an interim designated representative until a replacement is identified, or shall include the name of the replacement. If an interim designated representative is named, the interim designated representative shall be a licensed dispensary employee.</p> <p>(2) The state board of pharmacy shall issue the temporary certificate of authority promptly after it receives the request.</p> <p>(3) If a dispensary fails to immediately notify the state board of pharmacy and request a temporary certificate of authority after the separation of the designated representative, its certificate of operation shall become ineffective until the state board of pharmacy approves the temporary certificate of authority or registers a new designated representative.</p> <p>(4) No temporary certificate of authority shall be valid for more than ninety days.</p> <p>(5) The succeeding designated representative shall register with the state board of pharmacy as a dispensary key employee under this division. Once the permanent designated representative replacement is licensed as a dispensary key employee, the temporary certificate of authority is void.</p> <p>Comment:</p> <p>Cresco seeks clarity from the BOP with respect to the elimination of the above language from the current rules. Such would appear to eliminate the option for dispensaries to identify an interim or temporary designated representative, including in emergency situations. Doing so would take away necessary flexibility for dispensary operations, particularly at this time, in the midst of a global pandemic when a designated representative may need to be changed quickly in order to ensure continued operations so that patients are able to continue to obtain their medication. Accordingly, if this amendment does indeed result in the elimination of the ability of an operator to name an interim/temporary designated representative, Cresco asks the BOP to reconsider its position.</p>	<p>rule simply reflects the Board's current process as the Board does not issue temporary certificates of authority as described in the rule and instead utilizes the variance process to handle emergency coverage requests when the designated representative is unable to work. The Board has not incorporated this comment.</p>
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<p>3796:6-3-08</p>	<p>Cresco (suggested edits in green)</p>	<p><u>(O) No medical marijuana shall be sold, dispensed, or distributed to a patient or caregiver via a delivery service or any other manner outside of a dispensary, except that a caregiver may deliver medical marijuana to the caregiver's registered patient, or any other manner not approved by the Board of Pharmacy.</u></p> <p>Comment:</p> <p>The above amendment to OAC 3796:6-3-08 prohibits the selling, delivery, or distribution of medical marijuana to a patient or caregiver via a delivery service or other manner. However, this amended rule does not account for temporary measures currently in place allowing for sales to patients and caregivers outside the dispensary department during the COVID-19 pandemic (curbside delivery). Cresco encourages the BOP to further amend the above rule to account for this measure, which was instituted to reduced opportunities for exposure of patients and caregivers to the virus. This measure is especially important in light of the fact that patients in need of medical marijuana to treat their qualifying conditions may have compromised immune systems or other health concerns that put them at increased risk for developing significant complications of COVID-19. By allowing curbside delivery of medical marijuana, the BOP has allowed patients (and caregivers) to avoid unnecessary close contact with dispensary staff and other patients and caregivers.</p> <p>Beyond the above change, Cresco urges the BOP to approve curbside delivery as a proper method of dispensing on a permanent basis. While prior to the pandemic, the BOP may have been hesitant to allow for the implementation of these measures, Ohio operators have proven over the course of the past several months that the industry can operate with curbside delivery in place in a safe, secure, and responsible way. By permitting operators and patients to continue to engage in curbside delivery, the state will avoid reimplementing unnecessary barriers for patients to access their essential medication. Also, allowing the efficiencies of curbside delivery to remain in place will promote revenue growth for operators and increased tax revenue for the state at a time when both are crucial, as the nationwide economic downturn continues. For these reasons, Cresco exhorts the BOP to consider allowing curbside delivery as a permanent legal means of dispensing medical marijuana to patients.</p>	<p>The Board continues to allow curbside delivery in response to COVID-19 but does not agree that it should permanently be permitted pursuant to rule. The Board will continue to monitor the situation but does not incorporate this comment into rule at this time.</p>
<p>3796:6-3-08</p>	<p>FRX Health</p>	<p>3796:6-3-08(O) Curbside pickup should continue to be permitted in the Ohio MMCP program because it has been instituted without problems during the COVID-19 Pandemic of 2020. The</p>	<p>The Board continues to allow curbside delivery in response to COVID-19 but does not agree that it should permanently be permitted</p>

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		<p>method of sale has been helpful for patients who not only had trepidation entering a dispensary due to the virus but also for patients who feared entry into a dispensary due to being uncomfortable in a retail dispensary environment. The staff of our dispensary has felt safer dispensing to patients outside the building during this pandemic and has not expressed any concern over their general safety or the safety of patients. Further, exterior security cameras capture each transaction as well as the parking lot and outsides of the buildings, and our security ambassador continuously monitors the security camera throughout the day. We believe this is a great benefit to patients who are trepidatious about entering the dispensary, and that curbside pickup on the dispensary premises can be achieved safely and securely, and therefore should continue to be allowed.</p>	<p>pursuant to rule. The Board will continue to monitor the situation but does not incorporate this comment into rule at this time.</p>
<p>3796:6-3-11</p>	<p>Cresco (suggested edits in green)</p>	<p><u>(G) The following shall be reported to the board:</u></p> <p>(1) Except as provided in paragraph (G)(1)(a) of this rule, conduct indicating a dispensary employee is addicted to or is suspected to be abusing alcohol, drugs or other chemical substances or impaired physically or mentally to such a degree as to render the individual unfit to carry out their professional duties.</p> <p>(a) A dispensary employee shall not be required to report in accordance with this rule if the dispensary employee becomes aware of any condition described in paragraph (G)(1) of this rule as a result of either:</p> <p>(i) The employee's treatment of the individual for the condition; or</p> <p>(ii) The employee having access to the individual's protected health information.</p> <p>Comment:</p> <p>Cresco asks the BOP to reconsider the above mandate that would require the reporting of an employee learned to be addicted or suspected to be abusing alcohol, drugs, or other chemical substances or is impaired physically or mentally to such a degree as to render the individual unfit to carry out their professional duties. While Cresco understands and appreciates the BOP's intent in drafting this requirement, the implementation of such a rule would potentially place dispensary operators in the positions of being in conflict with competing obligations under the ADA, FMLA, or other</p>	<p>The Board has implemented this rule to ensure the safe dispensing of medical marijuana. This rule mimics traditional pharmacy rules which require the reporting of situations where an employee is physically or mentally impaired in the workplace such that patient care and safety may be negatively impacted. Dispensary employees are not required to report medical conditions of fellow employees. The Board declines to incorporate this comment.</p>

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		<p>state or local laws designed to encourage/require employers to work with an employee to provide leave or other reasonable accommodations so that they may seek appropriate treatment for substance abuse issues. Such a rule requiring dispensary employee to report to the Board about the conduct of their coworkers also raises concerns as it relates to efforts to create an inclusive and collaborative work environment. Additionally, the rule's use of the terms "suspected" and "unfit" are vague and impose an unreasonably burden on operators and dispensary staff to determine when they must report certain behavior. For these reasons, Cresco advocates to the BOP that this rule not be implemented.</p>	
<p>3796:6-3-11</p>	<p>Cresco</p>	<p><u>(1) A dispensary employee shall notify the board of any of the following:</u></p> <p><u>(1) Any criminal conviction within ten days after the date of conviction, except for minor traffic violations such as parking violations, speeding tickets and violations such as failure to obey a red light, failure to use a turn signal or expired registration.</u></p> <p><u>(2) The employee is convicted of, pled guilty to, is subject to a judicial finding of eligibility for intervention in lieu of conviction in this state under section 2951.041 of the Revised Code or the equivalent thereof in another jurisdiction within ten days after the individual is deemed eligible.</u></p> <p><u>(3) The employee is granted entry into a diversion program, deferred prosecution program, or the equivalent thereof within ten days after the individual is granted entry into a program.</u></p> <p><u>(4) Any arrest for a felony within ten days after the arrest.</u></p> <p>Comment:</p> <p>With respect to the imposed duty on dispensary employees to report the conduct described in OAC 3796:6-3-011, as amended, Cresco asks the BOP to ensure that the above comports with OAC 3796:6-4-03, which sets forth the grounds for discipline against operators and dispensary employees. For example, while the above amended regulation requires the reporting of any felony arrest within ten days of the arrest, being arrested for a felony—other than a disqualifying offense—is not grounds for discipline under OAC 3796:6-4-03. Similarly, that a dispensary employee is subject to a judicial finding of eligibility for intervention in lieu of conviction in Ohio under section 2951.041</p>	<p>The Board has implemented this rule to ensure the safe dispensing of medical marijuana. This rule mimics traditional pharmacy rules which requires that licensees report criminal events which may subject them to discipline. Although not all events would result in discipline, the Board should be able to determine whether investigation is warranted. The Board declines to incorporate this comment.</p>

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		of the Revised Code or the equivalent thereof in another jurisdiction is not listed as one of the grounds for discipline in OAC 3796:6-4-03. Cresco respectfully suggests that only that which would subject a dispensary employee to discipline should be required to be reported to the BOP.	
3796:6-3-11	FRX Health	<p>3796:6-3-11(G)(1)</p> <p>We do not believe that dispensary employees should be required to report to the board “conduct indicating suspected to be abusing alcohol, drug, or other chemical substance, or impaired physically or mentally to a degree to as to render the individual unfit to carry out their professional duties”. This statement is sufficiently vague to the point of compelling employees to create harm to an individual’s personal and professional reputation and therefore also their ability to earn a living based on “suspicion.” Our company has a high standard of conduct and high-quality standards for all its employees and sets internal training, metrics, and reviews such that they can maintain a high level of patient care. We believe that making it a duty for dispensary employees to report “suspicion” for why another employee may not be meeting performance standards to the Board opens up a highly unnecessary avenue for misinterpretation. The company has internal mechanisms to report underperformance, and coaching techniques for performance improvement plans if necessary. Any employee not able to fulfill their job duties after a reasonable attempt at coaching and training will be terminated. Any employee who violates our company’s drug and alcohol policy will be forced to follow the consequences outlined in this policy. We do, however, believe that it is reasonable to require dispensary employees to report any diversion or theft and all of our employees are trained and familiar with this requirement and our Company’s SOP.</p>	The Board has implemented this rule to ensure the safe dispensing of medical marijuana. This rule mimics traditional pharmacy rules which require the reporting of situations where an employee is physically or mentally impaired in the workplace such that patient care may be negatively impacted. Dispensary employees are not required to report medical conditions of fellow employees. The Board declines to incorporate this comment.
3796:6-3-13	Cresco (suggested edits in green)	<p><u>(A) The dispensary designated representative shall report an error in dispensing to the state board of pharmacy, in a manner determined by the board, within twenty-four forty-eight hours of learning of such error.</u></p> <p>Comment:</p> <p>The above amendment to OAC 3796:6-3-13 requires the reporting of dispensing errors to the BOP within 24 hours of learning of such error. Cresco respectfully requests that the BOP extend this reporting deadline an additional 24 hours, allowing for the reporting of dispensing errors with 48 hours of learning of such error. The basis for this extension is that upon learning of an error, it is necessary to investigate, as an initial matter, whether a true dispensing error has occurred or if the “error” is actually a clerical or systems-based one. Twenty-four hours is simply not enough time to validate an error,</p>	The Board accepts the comment.

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		particularly as the patient will need to be contacted. For these reasons, Cresco proposes that the BOP allow for reporting of errors within 48 hours.	
3796:6-3-14	OMCIA	<p>Concern: Under the proposed draft rule, the dispensary “must” reimburse patients for recalled medical marijuana products when they are returned within thirty days of the product recall notice.</p> <p>We agree that it is in everyone’s best interest to ensure patients are reimbursed appropriately when a product is recalled. Our concern is that this new rule puts the entire financial responsibility on the dispensary and does not obligate the cultivator or processor that produced the recalled product to reimburse the dispensary. In general, we believe reimbursement should remain a business decision and should not reside in the program rules.</p> <p>Draft Rule: “(G) Recalled products must be returned to the dispensary where they were purchased by a registered patient or registered caregiver for the exclusive purpose of being destroyed. The dispensary shall provide the patient or caregiver to whom the product was dispensed a refund if the product is returned within thirty days of the product recall notice.”</p> <p>Proposed Revision: “(G) Recalled products must be returned to the dispensary where they were purchased by a registered patient or registered caregiver for the exclusive purpose of being destroyed. The dispensary shall may provide the patient or caregiver to whom the product was dispensed a refund if the product is returned within thirty days of the product recall notice.”</p>	The Board has an interest in ensuring the return of medical marijuana products that have been recalled. If patients are not guaranteed reimbursement for these returned products, there is a decreased likelihood of their return. The Board understands the concern raised in this comment and will work with the Department of Commerce to request that a similar mandate to accept returns be imposed on cultivators/processors under their regulations. The Board also notes that dispensaries may require that they be reimbursed for such returns when negotiating purchases from cultivators/processors. The Board declines to incorporate this comment.
3796:6-3-17	Firelands Scientific	<p>While we understand the Board’s record preservation objectives, we are concerned that the proposed language (as currently written) could be considered a requirement that dispensaries maintain security camera footage for a period of three years. This would place a heavy financial and technological burden on Ohio dispensaries.</p> <p>Proposed Solution: We suggest that the Board clarify that this section excludes security camera footage from the three-year recordkeeping requirement.</p>	The Board does not interpret this rule as applying to security camera footage but only to records relating to the surveillance system itself. The six-month retention policy for security footage is clearly specified in 6-3-16(E)(6); nonetheless, the Board will incorporate this comment.
3796:6-3-20	Firelands Scientific	<p>We believe the proposed requirement of having an annual audit conducted by a licensed independent auditor could place an undue financial burden on dispensaries. We believe that the Board could remove this proposed requirement and still achieve its financial accounting objectives without placing an unnecessary financial burden on dispensaries.</p> <p>Proposed Solution: We suggest that the Board strike, “a licensed independent auditor” from its proposed language.</p>	The Board has received multiple comments on this rule and has amended the rule based on all comments.

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<p>3796:6-3-20</p>	<p>GTI</p>	<p>First, GTI understands the need for the Board to receive financial disclosures related to the business. As you know the current rule currently requires each GTI dispensary to submit quarterly financial audit statements. The proposed amendment to the Rule requires the quarterly financial statements be prepared by a CPA and also requires an audit prepared and certified by a licensed certified auditor. We respectfully request changes to this rule to comport with current business practices for publicly traded companies.</p> <p>GTI is ultimately owned and controlled by Green Thumb Industries Inc. ("GTII") which is a publicly traded company. GTII has an audit performed on an annual basis based on GAAP / GAAS standards and the quarterly financials are reviewed by a CPA for the entire company, which includes GTI.</p> <p>Our recommendation for the Rule is to seek clarification that a dispensary can submit the required financial statements and independent audit, but through a dispensary's parent company. As is typical for a publicly traded parent/subsidiary relationship, GTII has consolidated financials that are audited based on GAAP / GAAS standards and that cover their five Ohio subsidiaries that hold the dispensary licenses. Based on this background, we submit the following proposed amendment:</p> <p>PROPOSED DRAFT 3796:6-3-20(D)(4) Every medical marijuana dispensary shall complete or cause to be completed quarterly financial statements prepared by a certified public accountant under generally accepted accounting principles (GAAP) that includes, at a minimum, an income statement, balance sheet, and cash flow statement. Following the end of every fiscal year, a medical marijuana dispensary shall cause an audit to be prepared and certified by a licensed independent auditor under generally accepted auditing standards (GAAS).</p> <p>Notwithstanding the forgoing, a dispensary owned and controlled by a parent corporation who is a publicly traded company can comply with this section if such dispensary submits consolidated audited financial statements from the dispensary's parent corporation as long as such statements have the same information for the required dispensary complying with this section and are audited annually. (proposed changes in bold).</p> <p>We believe the proposed language has merit and should be added to the proposed rule because the changes:</p> <ul style="list-style-type: none"> • Comply with the intent of the rule. 	<p>The Board has received multiple comments on this rule and has amended the rule based on all comments.</p>
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		<ul style="list-style-type: none"> • Recognize that a publicly traded company prepares its own financial statements, which is consistent with industry practice and recognizes that publicly traded companies must file financial statements quarterly. • Reduce costly and burdensome standards because requiring separate CPA statements and audits for each dispensary would be redundant and would add considerable cost if such statements and audits are already being conducted through their parent corporation. The estimated cost of implementing this change would be in excess of \$100,000 per year. Without this change the Rule would have an adverse impact on business. <p>Are consistent with requirements for other Ohio industries, which promotes consistency in Ohio regulations and for businesses.</p>	
<p>3796:6-3-20</p>	<p>OMCIA</p>	<p>Concern: The proposed draft rule increases the quarterly and annual auditing requirements for dispensaries. A CPA is currently required to perform the quarterly audit and the annual audit must be prepared and certified by a licensed independent auditor. An independent audit can cost \$10,000 - \$20,000 per dispensary. Depending on the company’s organizational structure, the independent audit could trigger a full audit of other licenses. For a full vertical business with five dispensary licenses, cultivation and processing, the cost of this rule change could be between \$70,000 and \$140,000 depending on the auditor hired to perform the work. We instead recommend requiring an annual review performed in compliance with standards established by the American Institute of Certified Public Accountants (AICPA).</p> <p>Draft Rule: “Every medical marijuana dispensary shall complete or cause to be completed quarterly financial-statements prepared by a certified public accountant under generally accepted accounting principles (GAAP) that includes, at a minimum, an income statement, balance sheet, and cash flow statement. Following the end of every fiscal year, a medical marijuana dispensary shall cause an audit to be prepared and certified by a licensed independent auditor under generally accepted auditing standards (GAAS).”</p> <p>Proposed Revised Rule: “Every medical marijuana dispensary shall complete or cause to be completed quarterly financial-statements prepared by a certified public accountant under generally accepted accounting principles (GAAP) that includes, at a minimum, an income statement, balance sheet, and cash flow statement. Following the end of every fiscal year, a medical marijuana dispensary shall cause an audit review to be prepared and certified by a licensed independent auditor certified public accountant under generally accepted auditing standards (GAAS) Statements on Standards for Accounting and Review Services (SSARs) issued by the American Institute of Certified Public Accountants (AICPA).”</p>	<p>The Board has received multiple comments on this rule and has amended the rule based on all comments.</p>

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<p>3796:6-3-20</p>	<p>FRX Health</p>	<p>Concerns about the Proposed Amendment: 6-3-20 (D) (4)</p> <ul style="list-style-type: none"> • When the regulations state that quarterly financial statements be prepared by a certified public accountant, are they talking about an independent CPA firm that has been engaged to prepare the financial statements, or can these statements be completed by internal staff according to GAAP? • [We] have concerns about the cost of requiring an actual audit engagement from an independent CPA firm under GAAS. • Please note that the professional standards for independent CPA firms are very different for “compilation” engagements versus “attest” engagements. • If the board is proposing that each dispensary is required to engage an independent outside CPA firm to perform a bona fide financial statement audit under the professional standards that the public accounting industry, I we believe this would create an undue burden for dispensaries such as FRX for three reasons: <ul style="list-style-type: none"> ○ Very few CPA firms are willing to undertake “Attest” engagements for the Cannabis industry under current federal law. My biggest concern is that a qualified resource would be very hard to find, especially if all dispensary businesses in Ohio are impacted. ○ In my experience, an audit engagement for a small business can easily cost over \$30,000 per year because there are minimum standards for the amount transaction testing that an independent CPA firm would be required to perform in order to meet its professional standards. ○ Our company holds all of our licenses under the same legal entity, so adding this requirement would either require the company to reorganize, or would require that all of the company’s licensed operations be audited. <ul style="list-style-type: none"> ▪ Legal fees to reorganize could quickly become expensive, and we would incur significant accounting costs to restructure the way the company keeps its books. ▪ The cost of an actual audit engagements under GAAS would increase significantly if all aspects of a vertical license are impacted. ○ A significant advance notice time period would be requirement in order for this rule to be implemented. ○ Under GAAS, a CPA firm performing an audit of the financial statements listed in the proposed text would not be able to provide an unqualified 	<p>The Board has received multiple comments on this rule and has amended the rule based on all comments.</p>
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		<p>opinion (which is the point of having an audit) unless the firm was engaged prior to the start of a fiscal year because they would be required to test the accuracy of the beginning of the year balance sheet values, such as inventory. So, for practical purposes, it would be difficult to implement this rule change for 2021 because all dispensaries would be rushing to engage qualified CPA Firms.</p>	
3796:6-3-22	Firelands Scientific	<p>We believe that the Board should consider a home delivery/virtual dispensary pilot program. A sizeable percentage of the Ohio patient population is over the age of 60 and many are considered to be at high-risk for severe COVID-19 illness. We believe it is critical to continue to evaluate what else we can do to keep our patients, employees and community members safe. As a result of the recent number of COVID-19 confirmed case in Ohio, the Ohio Department of Health has extended (indefinitely) many of its various COVID-19 related orders, including the order that urges high risk individuals to stay in their residences. Accordingly, we propose that the Board permit a home delivery program, similar to what other states have done. We believe that a home delivery initiative would improve patient accessibility while helping to prevent the spread of COVID-19 in Ohio.</p> <p>Proposed Solution: We suggest that the Board strike the following language:</p> <p><u>No medical marijuana shall be sold, dispensed, or distributed to a patient or caregiver via a delivery service or any other manner outside of a dispensary, except that a caregiver may deliver medical marijuana to the caregiver's registered patient.</u></p>	<p>The Board will not incorporate this comment into the rule at this time. The Board declines to permit home delivery of medical marijuana products at this time due to concerns for patient safety as well as the safety of dispensary employees and/or others employed to make deliveries.</p>
3796:6-3-22	FRX Health	<p>We are invested in our employee's health and wellbeing, and therefore believe that we should be able to offer and implement programs to our employees that support them. We suggest being able to offer employees who are registered patients or caregivers discounts on medical marijuana products that are not available to all patients but only offering them discounts that are within a reasonable range (not exceeding 50% discount off menu price on any product). We believe this is an important part of supporting the registered patients and caregivers of the program and supporting our employee's health and wellbeing. Benefits and programs, such as employee health and wellness programs, are important aspects of attracting the right quality of talent and employee retention in this competitive landscape.</p>	<p>The Board has concerns that allowing special discounts for employees leads to abuse of the program and employees' purchase limits. The Board declines to incorporate this comment at this time.</p>
3796:6-3-23	Cresco	<p>(A) In addition to authorized dispensary employees, cultivator employees, and processor employees, the following may be granted access to a dispensary so long as presence is maintained in the dispensary visitor log and obtain a visitor identification badge from the <u>is provided by a dispensary employee</u>, prior to entering the dispensary:</p>	<p>The Board accepts this comment as relates to allowing patients and caregivers to be accompanied by an individual waiting the waiting area.</p>

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		<p style="color: red;">(1) One individual accompanying each patient or caregiver who shall remain in the waiting area. Such visitors shall remain under supervision of a dispensary employee while on dispensary premises;</p> <p>Comment:</p> <p>Cresco respectfully requests that the BOP reconsider the proposed amendment above, which would prohibit the ability of one individual accompanying each patient or caregiver to wait in a waiting area under the supervision of a dispensary employee. While Cresco understands the BOP may be seeking to eliminate this rule in light of the coronavirus pandemic and the need to social distance inside dispensary facilities, a rule change is not necessary to ensure dispensary staff maintain proper distance among themselves and patient and/or an individual accompanying patients. This amendment also does not account for the fact that a patient or caregiver may need to visit a dispensary while accompanied by another person. Prohibiting an individual accompanying a patient or caregiver from waiting in a designated waiting area, as has been the practice until now, does not advance any security concern and only serves to erect an unnecessary barrier for a patient seeking his or her medication. In that same vein, in addition to continuing to allow a visitor to accompany a patient or caregiver, Cresco urges the BOP to clarify that children under 18 years old are permitted as visitors, accompanying a patient or caregiver. Allowing children to accompany their parents provides for easier access to the dispensary by patients and caregivers and alleviates difficult situations for dispensary employees in the circumstances of a patient or caregiver arriving at the dispensary with a minor in tow.</p>	<p>The Board does not accept the comment that children under the age of 18 who are not patients should be permitted as visitors when accompanied by a patient or caregiver. Children who are not patients are not permitted in dispensaries for security reasons and because medical marijuana should not be promoted to children who are not patients.</p>
<p>3796:6-3-23</p>	<p>Cannamed Therapeutics LLC</p>	<p>The Board should make clear the reasoning under which a visitor access request will be denied. Absent a clear breach of rule or policy (e.g., permitting a minor onsite or access to patients), licensee requests for visitor access should generally be granted.</p>	<p>The Board declines to accept this comment. Under the amendments to the rule, the approval process for visitor access is streamlined and any appropriate visitors without associated security risks should be granted access. Denials of access are on a case by case basis and the reasons for denial cannot adequately be summarized in rule.</p>
<p>3796:6-3-23</p>	<p>OMCIA</p>	<p>Concern: Badged cultivation and processing employees should be allowed to access the medical marijuana dispensary, including the dispensary department, for the purpose of conducting sales meetings with dispensary staff. The Board has previously approved this request and issued guidance allowing badged employees access to the dispensary using the Visitor Log. However, we recommend revising the rules to incorporate this change.</p>	<p>This comment will not be incorporated into the rule. As noted in the rule comment, salespeople from cultivators/processors are currently permitted access to the dispensary using the visitor log. Blanket authority for such visits may lead to interaction between</p>

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		<p>Current Rule: “(A) Except as provided under this division, no person, except a dispensary employee, or a cultivator or processor employee who is delivering medical marijuana, shall be allowed in the dispensary department without an active qualifying patient or caregiver registration issued by the state board of pharmacy.”</p> <p>Proposed Revised Language: “(A) Except as provided under this division, no person, except a dispensary employee, or a badged cultivator or processor employee who is delivering medical marijuana, shall be allowed in the dispensary department without an active qualifying patient or caregiver registration issued by the state board of pharmacy.</p>	cultivators/processors and dispensary employees that is in violation of the promulgated rules.
3796:6-3-23	OMCIA	<p>Concern: The proposed rule change removes the provision under dispensary access that allows one individual to accompany each patient or caregiver into the dispensary waiting area. It is our understanding the Board will continue to allow patients or caregivers to be accompanied by one individual in the waiting area after this change has been applied and, therefore, we have no objection at this time.</p> <p>Draft Rule: “(B)(1) One individual accompanying each patient or caregiver who shall remain in the waiting area. Such visitors shall remain under supervision of a dispensary employee while on dispensary premises;”</p>	The Board accepts this comment as relates to allowing patients and caregivers to be accompanied by an individual waiting the waiting area.
3796:6-3-23	OMCIA	<p>Concern: The restrictions to dispensary access outlined in this section of the draft rules are overly strict and unnecessarily limiting.</p> <p><i>Media Access:</i> Credentialed members of the media are typically working on stories that are time sensitive. The very nature of media and “the news” does not lend itself to a seven-day review and approval period. We request the Board allow credentialed members of the media to enter the dispensary outside of operating hours without advance notice using the Visitor Log following procedures outlined in 3796: 6-3-23 (B).</p> <p><i>CTR Physicians and Government Officials:</i> Licensed medical professionals including, but not limited to, CTR physicians and government officials should be allowed access to a medical marijuana dispensary for educational and policy making purposes without advance notice using the Visitor Log following procedures outlined in 3796: 6-3-23 (B). It is in the best interests of the patients, the program, and the licensees to educate these members of the community about medical marijuana and the safeguards put in place to protect the patients of the state.</p>	The Board has not incorporated this comment into the rule. The goal of the amendments to this rule is to reduce the number of visitors in a dispensary as patient privacy is of the highest level of concern while permitting access for those individuals who have good reason to visit the dispensary. Further, the Board requires ample time to vet all visitor requests to ensure the confidentiality and safety of the patients.

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		<p>“(C) Upon prior written request, on a form approved and provided by the board, the state board of pharmacy may authorize persons who are otherwise prohibited from being on dispensary premises, temporary access to a dispensary.</p> <p>(1) Such access shall only be permitted as follows:</p> <p>(a) Credentialed members of the media may access dispensaries only during non-operating hours. A credentialed member of the media is an individual who operates or is employed by a media organization and whose primary professional employment is through the media organization that has issued the individual’s credentials. The media organization must have a record of substantial and original news coverage. The request shall be made a minimum of seven days prior to the requested date of access.</p> <p>(b) Physicians with a Certificate to Recommend (CTR) and government officials and their staff may access dispensaries for educational and policy making purposes. The request shall be made a minimum of seventy-two hours prior to the requested date of access.”</p> <p>Proposed Revised Language: Move these visitors under (B) of the same section to capture visitor protocol requirements, and add; “(C) Upon prior written request, on a form approved and provided by the board, the state board of pharmacy may authorize persons who are otherwise prohibited from being on dispensary premises, temporary access to a dispensary. (1) Such access shall only be permitted as follows: (3) Credentialed members of the media may access dispensaries only during non-operating hours. A credentialed member of the media is an individual who operates or is employed by a media organization and whose primary professional employment is through the media organization that has issued the individual’s credentials. The media organization must have a record of substantial and original news coverage. The request shall be made a minimum of seven days prior to the requested date of access. (4) Licensed medical professionals Physicians with a Certificate to Recommend (CTR) and government officials and their staff may access dispensaries for educational and policy making purposes. The request shall be made a minimum of seventy-two hours prior to the requested date of access.”</p>	
3796:6-3-23	OMCIA	As Ohio citizens move their regular purchases to delivery services to maintain social distancing mandates implemented by Governor DeWine, we should consider if the regulations put in place before COVID are still serving the best interests of patients. Is	The Board will not incorporate this comment into the rule at this time. The Board declines to permit home delivery of medical marijuana

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		<p>medical marijuana delivery more of a threat to public safety than exposing “at risk” patients to COVID by forcing them to leave their homes. We recommend the Board reconsider their position on delivery and work with the licensees and patients to devise a delivery protocol that reduces the opportunity for diversion while protecting “at risk” patients from exposure.</p> <p>Draft Rule Language: The draft rules propose to strike this section of the Administrative Code and move it, verbatim, to 6-3-08 (O) and 6-3-22 (K). (D) No medical marijuana shall be sold, dispensed, or distributed to a patient or caregiver via a delivery service or any other manner outside of a dispensary, except that a caregiver may deliver medical marijuana to the caregiver’s registered patient.</p> <p>Proposed Revised Language: (D) No Medical marijuana shall may be sold, dispensed, or distributed to a patient or caregiver by a dispensary via a delivery service or any other manner outside of a dispensary, except that a caregiver may deliver medical marijuana to the caregiver’s registered patient. -if the delivery service operates in compliance with rule 3796: 5-3-01 of the Administrative Code.</p>	<p>products at this time due to concerns for patient safety as well as the safety of dispensary employees and/or others employed to make deliveries.</p>
<p>3796:6-4-03</p>	<p>Cresco (suggested edits in green)</p>	<p>(A) The state board of pharmacy, after notice and hearing in accordance with Chapter 119. of the Revised Code, may revoke, suspend, limit, place on probation, or refuse to grant or renew a dispensary provisional <u>dispensary</u> license, certificate of operation, or a dispensary employee license, or may impose a monetary penalty or forfeiture if the board finds that the licensee:</p> <p style="padding-left: 40px;">(1) Has violated any state or federal law or rule <u>related to violent conduct or controlled substances, other than the lawful participation in a state-run legal marijuana program, regardless of jurisdiction in which acts were committed, except for minor traffic violations such as parking violations, speeding tickets and violations such as failure to obey a red light, failure to use a turn signal or expired registration.</u> Acts in accordance to Chapter 3796. of the Revised Code and this division that constitute a violation of federal law shall not be considered as grounds for discipline;</p> <p style="padding-left: 40px;">(17) Was <u>arrested, charged, and/or</u> convicted of a disqualifying offense <u>or failed to report an arrest or charge with a disqualifying offense;</u></p> <p>Comment:</p>	<p>The Board declines to accept this comment. The language included in this rule amendment mimics the rule language applicable to pharmacists and pharmacies, and the Board has determined that dispensaries and their employees should be held to those same standards. The Board desires consistency and a standard for all entities that are responsible for the security and distribution of controlled substances.</p>

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		<p>While Cresco understands the BOP's intent in reserving the right to take disciplinary action against a licensee for violating any state or federal law or rule other than minor traffic violations, Cresco submits that the BOP can adequately safeguard the industry by limiting disciplinary action to circumstances where an individual has committed a crime involving violence or related to controlled substances (other than that individual's lawful participation in a state-run legal marijuana program). Such other crimes/infractions, including misdemeanor conduct, should not rise to the level of disciplinary action and only limit the ability of employees to work in the industry. Further, Cresco advocates to the BOP that it amend paragraph (A)(17) of OAC 3796:6-4-03 to reflect that disciplinary action can only be taken against a licensee for being convicted of a disqualifying offense or failing to report an arrest or charge related to the same. Being charged or arrested for a crime is very different from being convicted of the same. While Cresco supports the BOP being aware of a licensee who has been arrested or charged with a disqualifying offense, an individual should not be subject to discipline simply based on an arrest or charge, which may or may not have a legitimate basis.</p>													
<p>3796:6-5-01</p>	<p>OMCIA</p>	<p>Concern: Licensees are required to submit every name, logo sign, and advertisement for review and pay a \$100 fee. Advertisements include press releases, web pages, social media posts, flyers, brochures, etc. Over the course of the year, these fees can add-up for dispensaries who are the most public facing component of the program. A survey of our dispensary licensee members revealed an average annual expenditure of between \$5,000 and \$15,000 for advertising fees.</p> <p>Licensees already pay a substantial fee to the state to maintain their license (see Table 1 below). While advertising fees under 3796: 6-5-01 apply to dispensaries, the same advertising fee is applied to cultivators and processors under 3796: 5-1-01. We ask the Board to consider reducing the advertising fee by 50% to reduce the cost burden to licensees.</p> <table border="1" data-bbox="908 1166 1529 1396" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th colspan="2" style="text-align: center;">TABLE 1: LICENSE FEES</th> </tr> <tr> <th style="text-align: center;">License Type</th> <th style="text-align: center;">Annual Licensing Fee</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">Level 1 Cultivator</td> <td style="text-align: center;">\$200,000</td> </tr> <tr> <td style="text-align: center;">Level 2 Cultivator</td> <td style="text-align: center;">\$20,000</td> </tr> <tr> <td style="text-align: center;">Processor</td> <td style="text-align: center;">\$100,000</td> </tr> <tr> <td style="text-align: center;">Dispensary</td> <td style="text-align: center;">\$70,000 (biennial)</td> </tr> </tbody> </table>	TABLE 1: LICENSE FEES		License Type	Annual Licensing Fee	Level 1 Cultivator	\$200,000	Level 2 Cultivator	\$20,000	Processor	\$100,000	Dispensary	\$70,000 (biennial)	<p>The advertising fees help to support staff that review these submissions and sustain the program for Ohio patients. Moreover, the MMCP is still a new program and it is too early to determine whether reductions in fee amounts are appropriate without long-term financial information. The Board declines to accept this comment but, as the program matures, will consider reductions in fees.</p>
TABLE 1: LICENSE FEES															
License Type	Annual Licensing Fee														
Level 1 Cultivator	\$200,000														
Level 2 Cultivator	\$20,000														
Processor	\$100,000														
Dispensary	\$70,000 (biennial)														

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		<p>Current Rule Language: “The non-refundable advertising approval fee is one hundred dollars per advertisement.”</p> <p>Proposed Solution: “The non-refundable advertising approval fee is one hundred fifty dollars per advertisement.”</p>	
<p>3796:6-5-01</p>	<p>Firelands Scientific</p>	<p>Licensees already pay a substantial fee to maintain their license. Similar to the OMCIA’s request, we ask that the Board to consider reducing the advertising fee by 50% to reduce the cost burden to licensees.</p> <p>Proposed Solution: We propose that the Board adopt the following language proposed by the OMCIA:</p> <p>“The non-refundable advertising approval fee is fifty dollars per advertisement.”</p>	<p>The advertising fees help to support staff that review these submissions and sustain the program for Ohio patients. Moreover, the MMCP is still a new program and it is too early to determine whether reductions in fee amounts are appropriate without long-term financial information. The Board declines to accept this comment but, as the program matures, will consider reductions in fees.</p>
<p>3796:7-2-02</p>	<p>Cresco (suggested edits in green)</p>	<p>(A) Unless otherwise <u>approved by the board, or</u> provided in paragraph (B) of this rule, only natural persons twenty-one years of age or older may register with the state board of pharmacy to serve as a caregiver for a qualifying patient. in order to be eligible to serve a a qualifying patient, a caregiver must be:</p> <p><u>(1) A natural person;</u></p> <p><u>(2) At least twenty-one years of age or older;</u></p> <p>(3) A resident of the state of Ohio.</p> <p>Comment:</p> <p>OAC 3796: 7-2-02 was amended to require, except with BOP permission (as outlined in paragraphs (F) and J)), that a caregiver be a resident of the state of Ohio. While the BOP is able to provide written approval for an out of state caregiver to practice in Ohio, this new requirement adds an unnecessary burden for patients and will potentially cause difficulty for caregivers already participating in the program who are not Ohio residents. This is especially true at a time when the country is in the midst of a pandemic and access to caregivers is imperative to provide excellent patient care. Indeed, while this new prohibition makes it more difficult for an out of state caregiver to continue to provide services to the medical program’s patients, it seemingly does little to safeguard the</p>	<p>As the comment notes, the rule was previously amended to allow for a waiver process for out of state caregivers. The Board amended the rule because it was previously unclear whether out of state caregivers were permitted under the rules and there was no process for conducting out-of-state database checks of non-Ohio residents who applied to be caregivers. The Board’s intention is to allow for existing caregivers to remain as caregivers, regardless of their residency, because their status has already been approved. The Board declines to adopt this comment.</p>

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		<p>patient population, which has operated effectively to date by utilizing out of state caregivers as necessary. As an alternative, if the BOP is disinclined to eliminate the Ohio residency requirement set forth in the amended language above, Cresco proposes that OAC 3796:-2-02 be further amended to grandfather in all existing out of state care givers to avoid any disruptions in patient care.</p>	
<p>3796:7-2-08</p>	<p>Cresco (suggested edits in green)</p>	<p>(A) The state board of pharmacy, after notice and hearing in accordance with Chapter 119. of the Revised Code, may revoke or impose any one or more of the following sanctions on a patient or caregiver if the board finds the individual engaged in any of the conduct set forth in paragraph (B) of this rule:</p> <p><u>(26)The patient or caregiver violated any state or federal law or rule, related to violent conduct or controlled substances, other than the lawful participation in a state-run legal marijuana program, regardless of jurisdiction in which acts were committed, except for minor traffic violations such as parking violations, speeding tickets and violations such as failure to obey a red light, failure to use a turn signal or expired registration. Acts in accordance with Chapter 3796. of the Revised Code and this division that constitute a violation of federal law shall not be considered as grounds for discipline.</u></p> <p>Comment:</p> <p>As stated with respect to the comments regarding OAC 6-4-03, while Cresco understand the BOP's intent in reserving the right to take disciplinary action against a patient or caregiver for violating any state or federal law or rule other than minor traffic violations, Cresco submits that the BOP can adequately safeguard the industry by limiting disciplinary action to circumstances where an individual has committed a crime involving violence or related to controlled substances (other than that individual's lawful participation in a state-run legal marijuana program). Such other crimes/infractions, including misdemeanor conduct should not rise to the level of disciplinary action and only limit the ability of patients to obtain their critical medication.</p>	<p>This is the standard of conduct applied to all of the Board's licensees and the Board seeks consistent standards across all license types. The rule allows the Board to ensure the integrity of the program, that patients are following all of Ohio's laws, and that the program is not being abused while maintaining flexibility to determine if discipline is warranted under the circumstances. The Board does not accept this comment at this time.</p>
<p>3796:7-2-09</p>	<p>Patient</p>	<p>I read through the above listed proposed rules changes and amendments and have a lot of concerns. First 3796:7-2-09 is troubling to me, I thought we were patients treating illness? Why are you writing plans to suspend my medication? And why aren't you dictating these same parameters on big Pharma?</p>	<p>This is the standard of conduct applied to all of the Board's licensees and the Board seeks consistent standards across all license types. The rule allows the Board to ensure the integrity of the program, that patients are</p>

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			following all of Ohio’s laws, and that the program is not being abused while maintaining flexibility to determine if discipline is warranted under the circumstances. The Board does not accept this comment at this time.
3796:8-3-01	Firelands Scientific	<p>We support the OMCIA’s request that the Board consider reducing the administrative fee by 50% (to \$50) to lighten the financial burden placed on the licensees.</p> <p>Proposed Solution:</p> <p>We propose that the Board adopt the following language proposed by the OMCIA:</p> <p>“The non-refundable fee for the assignment of a product identifier is fifty dollars plus a service fee.”</p>	The administrative fees help to support staff that review these submissions and sustain the program for Ohio patients. Moreover, the MMCP is still a new program and it is too early to determine whether reductions in fee amounts are appropriate without long-term financial information. The Board declines to accept this comment but, as the program matures, will consider reductions in fees.
3796:8-3-01	OMCIA	<p>Concern: A product identifier (or Item Brand) must be purchased for every medical marijuana product a cultivator or processor produces. A producer may be required to purchase multiple product identifiers for the same product if the product tests outside of the 5% testing variance. For instance, a strain of plant material may test at 25% THC for one harvest, then 28% for the next harvest, triggering the purchase of another item brand.</p> <p>Currently, every item brand registered will cost the producer \$100 (plus a service fee). OMCIA surveyed our members to determine the average annual cost of purchasing item brands, and the response ran from \$15,000 - \$27,000 per year, depending on the number of SKU’s the cultivator or processor produces. Now that the program has been operational for almost two years, we believe sufficient data should be available to determine if the administrative fee of \$100 is appropriate. We ask the Board to consider reducing the administrative fee by 50% (to \$50) to lighten the financial burden placed on the licensees. As noted in our response to the advertising fee, licensees already pay heavy annual licensing fees to the state to participate in the program.</p> <p>Draft Rule: “The non-refundable fee for the assignment of a product identifier is one hundred dollars plus a service fee.”</p> <p>Revised Proposed Language:</p>	The administrative fees help to support staff that review these submissions and sustain the program for Ohio patients. Moreover, the MMCP is still a new program and it is too early to determine whether reductions in fee amounts are appropriate without long-term financial information. And, under previous rule amendments, the Board has expanding the testing variance to 10% which will decrease the number of new product identifiers needed due to testing variance. The Board declines to accept this comment but, as the program matures, will consider reductions in fees.

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		"The non-refundable fee for the assignment of a product identifier is one hundred fifty dollars plus a service fee."	
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BIA - Dispensaries		BIA – Dispensary Operations		BIA – Dispensary Enforcement and Fees		BIA – Patients and Methods of Administration	
Rule Number	Comments	Rule Number	Comments	Rule Number	Comments	Rule Number	Comments
3796:6-2-01	N	3796:6-3-01	Y	3796:6-4-02	N	3796:7-2-02	Y
3796:6-2-02	Y	3796:6-3-02	N	3796:6-4-03	Y	3796:7-2-03	N
3796:6-2-04	Y	3796:6-3-03	Y	3796:6-4-05	N	3796:7-2-07	N
3796:6-2-05	Y	3796:6-3-05	Y	3796:6-4-06	N	3796:7-2-08	Y
3796:6-2-06	Y	3796:6-3-06	N	3796:6-4-07	N	3796:7-2-09	Y
3796:6-2-07	Y	3796:6-3-08	Y	3796:6-4-09	N	3796:7-2-10	N
3796:6-2-08	Y	3796:6-3-11	Y	3796:6-5-01	Y	3796:8-2-02	N
3796:6-2-14	N	3796:6-3-15	N			3796:8-3-01	Y
		3796:6-3-16	N				
		3796:6-3-17	Y				
		3796:6-3-18	N				
		3796:6-3-19	N				
		3796:6-3-20	Y				
		3796:6-3-21	N				
		3796:6-3-22	Y				
		3796:6-3-23	Y				