MJ FREEWAY
SOFTWARE SOLUTIONS

Comments of MJ Freeway Regarding

Proposed Regulations (Sec. 21a-408-1 to 21a-408-70)

Implementing Public Act 12-55

An Act Concerning the Palliative Use of Marijuana

Introduction

MJ Freeway LLC would like to thank the Connecticut Department of Consumer Protection for the opportunity to provide comments about the proposed rules to implement Public Act 12-55, An Act Concerning the Palliative Use of Marijuana.

MJ Freeway provides a business software platform to medical marijuana enterprises – both non-profit and for-profit - in 12 states, the District of Columbia, Canada, and Spain. MJ Freeway has developed its tracking and reporting systems specifically for the medical marijuana industry with one paramount goal in mind: to provide accurate, real-time data to medical marijuana cultivators, medically infused products manufacturers, producers, and dispensaries, accounting for every gram of product in every phase of production – ensuring both internal and external accountability, including the ability to interface with state run reporting systems and to allow regulatory access to such data in real time.

Based on our experience in multiple states, each with different regulatory structures, with various sized and types of customers, and with different societal needs, we would like to provide the following comments.

Comments

The draft rules reflect a comprehensive and detailed approach for which the Department should be commended. This springs from the skill of the internal team the Department created, the scope of the research undertaken, and the open/accessible public hearings the Department held. In reviewing the proposed rules we have a number of suggestions for the Department's consideration, with a view toward making the final rules more comprehensive in the area of tracking, recording, and reporting. These suggestions come from our experience in other states, our knowledge of state-of-the-art information system functionality, and our above all goal of ensuring that the ability of the Department to fulfill its responsibilities for oversight and regulation of dispensary and production facilities is robust and functional.

Following are specific comments keyed to, or referenced to, specific sections or portions of the proposed rules.

1. Tracking and Reporting

The ability of the Department to regulate production and dispensary facilities is linked directly to how comprehensive the data collection systems are for tracking and reporting by the facilities and the functionality of the Department's own information systems to receive information from production and dispensary facilities, patients, and physicians, and to analyze such information.

As we understand the proposed rules and the documentation provided by the Department, there will be at least two information systems involved in the production, sales, and agency oversight of medical marijuana:

- Tracking and reporting systems of each production and dispensary facility.
- PMP, currently in place, to be used to monitor physician recommendations for specific patients and daily sales by the dispensary facility.

We believe it is imperative that the tracking and reporting systems used by production and dispensary facilities be electronic, and that those systems and the Department's medical marijuana systems be integrated, maximizing the value of each system.

In regard to the dispensary and production facilities information collection and reporting requirements in the proposed rules, simplicity will be challenged by a number of factors unique to the medicine. Medical marijuana is derived from a cultivated plant, it is harvested and processed for use by qualified patients, and the product is sold in small quantities (grams or ounces.) These factors are further compounded by the physical attributes of the product such as moisture content and evaporation, which changes the weight of the product, plant failure, or disease requiring proper disposal of product, and transportation security of the medicine. Moreover, the proposed rules envision keeping additional information unique to the medicine, e.g. test results.

Based on the multiple mandatory provisions in the proposed rules for collecting data and the unique characteristics of the medicine itself, the Department should require each dispensary and production facility to have and maintain the required information/data in an accessible, real-time format, and that system must be available for Department access in real time on a read only basis. The proposed rules contain requirements for cultivation, inventory, product movement, sales, personnel, etc. Each piece of this data is important to the Department to ensure quantity and quality and to avoid diversion. An electronic tracking and reporting system requirement should be inserted in the sections of the proposed rules for applying for a registration and for operating a dispensary or production facility. [See, sections 21a-408-34 and 21a-408-52]. Such systems are available and are in use in other jurisdictions. Their sophistication and use reflect concerns by regulatory agencies to avoid

and/or identify diversion of product, as well as the needs of production and dispensary facilities to match product to patient demand and to accurately avoid over/under production.

The final regulations should require a robust electronic system for tagging and tracking "from seed to sale," including data points along the way of the product's production and dispensing, reported in real time and accessible in real time to the Department as "read only." We suggest that the following definition of "seed to sale" be used to clarify that a software tracking system is necessary for production facilities and that those systems in turn should be integrated with the Department's own system. We would suggest the following wording be added in section 21a-408-52:

> "Each production facility shall maintain using a software system to capture everything that happens in an individual plant's life from creation, through growth and harvest, to packaging of finished product, chronicling every step, every ingredient, every activity, every transaction, and every person who touches the product by utilizing unique plant identification and unique batch identification."

From our experience, for the information and data requirements envisioned in the proposed rules, the Department must be able to identify individual plants of the strain making up a batch. So we suggest a specific reference in the rules requiring a production or dispensary facility system to link specific plants to specific batches. For this tracking, it is important to define "batch." We suggest a modification of the definition of "batch" in section 21a-408-1(9):

> "Batch" means marijuana or marijuana products harvested on one day that are identifiable by batch number and consist of all product of one strain or brand.

We recommend removing the portion of the definition currently in the draft regulations which reads "...every portion or package of which is uniform within recognized tolerances for the factors that were subject to a laboratory test and that appear in the labeling". The "batch" simply consists of a certain quantity of product, of a certain strain, harvested on a certain day. The requirements for testing in sections 21a-408-58 and 21a-408-59 will determine what is required of the batch in terms of meeting recognized tolerances, labeling and distribution.

2. Labeling

In regard to proposed rule 21a-408-40 regarding labeling requirements, we believe each individually packaged item must have a unique "serial number," batch number, exact weight, and harvest date. We applaud the Department's inclusion of this information and recommend that this requirement remain in the final regulations.

In regard to labeling, we suggest that the Department itemize in the final rules the specific information that must be on the individual package label and separately information that can be given to the patient as a hand-out, "insert," or available on a secure website accessible to a patient. This is a

viable and manageable approach given the amount and detail being required, including test results in 21a-408-56. An "insert" method such as that used for most prescription medications now, and which the public is accustomed to seeing, allows for more information to get to the patient and for that information to be presented in a user friendly way. To accomplish this, the final rules should affirmatively allow information to be "dispensed" or "given" to the patient at point of purchase.

Finally, the label the patient sees should include information listing any nutrients or other ingredients applied to the plant. Such a requirement should be added to sections 21a-408-40 and 21a-408-56. Patients should know exactly what was used in the cultivation and production of their medicine.

3. Patient Services

Given how robust the electronic tracking and reporting systems of production and dispensary facilities and the Department will be, we believe it is wise to utilize such functionality for the benefit of patients. In this regard, we suggest that patients be allowed and encouraged to order their medication on-line, but not to actually pay for it on-line. The actual buying transaction would take place at the dispensary facility. By using such an approach, production and dispensary facilities would be better informed about how much medicine to have on hand and how much to grow. Online ordering is like reordering a prescription by the patient for a specific amount and purchase date for the actual buying of medicine. This suggestion to allow online ordering is consistent with the Department's thrust in the rules to match grow and inventory based on the one-month supply needs of registered patients at the dispensary facility.

4. Testing and Batches

Following the definition of "batch" as we recommended above, there are two modifications we would request to section 21a-408-58. We suggest that use of the word "homogenized" is unnecessary and potentially confusing. If a batch is defined as all of one product or "brand" harvested on one day, then by definition the batch is already homogenized. There should be no marijuana in a batch that is not of the same brand and from the same harvest. We would recommend that 21a-408-58(a) be struck from this section, as it is unnecessary. We would further recommend the following change to 21a-408-58(c):

> (c) From the time that a batch of marijuana has been made available at the production facility for testing until the laboratory provides the results from its tests and analysis, the entire batch of marijuana, except the samples that have been removed by the laboratory for testing, shall be segregated and withheld from use. During this period of segregation, the marijuana batch shall be maintained in a secure, cool and dry location so as to prevent the marijuana from becoming contaminated or losing its efficacy. Under no circumstances shall marijuana be included in a marijuana product or sold to a dispensary facility prior to the time

that the laboratory has completed its testing and analysis and provided those results, in writing, to the producer or other designated production facility personnel.

In section 21a-408-59(b), the regulations discuss a requirement that no two products be labeled with the same brand name unless the testing results for each active ingredient are within a 3% variance. While we recognize and applaud the Department's commitment to ensuring that patients are able to rely on consistent potency and efficacy in their medicine, we do not believe that a 3% tolerance is a reasonable standard. Given the agricultural nature of this product, variations from one plant to the next, as well as between one flower to the next, are to be expected. In addition, the science of cannabis potency testing is in its infancy, particularly for active ingredients other than THC. There are few testing standards or methodologies available to labs to ensure that they are following consistent, industry-accepted practices in performing the tests. Our suggestion is that the Department modify this section to permit a 10% variance.

5. Confidentiality of Information

While we applaud the Department's commitment to confidentiality as outlined in 21a-408-33, when read together with the definition of an Electronic Data Intermediary in 21a-408-1(33) and with the reporting requirements in section 21a-408-50, we believe some clarification is needed. Section 21a-408-33(b) indicates that electronic data intermediaries shall not have access to protected data, however section 21a-408-50 requires the electronic transmission through an intermediary of precisely such data. We suggest that section 21a-408-33(b) and (c) be amended as follows:

> "Each electronic data intermediary system shall maintain the confidentiality of patient information in accordance with any applicable federal or state statute or regulation. Each electronic data intermediary system shall establish mechanisms in accordance with current electronic transmission standards that contain:
> (1) encryption technology to maintain security;
> (2) controls on employee access;
> (3) protections against unauthorized access by outsiders;
> (4) procedures for the permanent deletion of patient information."

Conclusion

On behalf of MJ Freeway, we want to thank the Department for this opportunity to comment on the proposed regulations for implementation of Public Act 12-55. The Department has demonstrated an admirable level of commitment in developing fundamental rules to implement the law, and to do so comprehensively and quickly. As we have experienced in other jurisdictions, regulatory systems and tracking/reporting systems will ultimately be informed by experience over time – seeing what works and what does not work. Starting with demanding regulations, as the proposed rules are, is the right approach.

The suggestions in our comments above spring from the dynamic evolution we have observed and participated in over the years in the many jurisdictions where we work. Our mission is to provide comprehensive electronic systems for the growing, processing, and dispensing of medical marijuana to avoid diversion and to increase the public's confidence that this medicine is being handled properly.

If you have any questions about our comments, please contact us.

Respectfully submitted,

MJ Freeway,

Amy Poinsett

Co-founder & CEO
888-932-6537, ext. 701
amy@mjfreeway.com

Jessica Billingsley

Co-founder & COO
888-932-6537, ext. 702
jessica@mjfreeway.com

April 25, 2013