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Members of the Independent Regulatory Review Committee and the Department of Health:

Ilera Healthcare holds a Grower/Processor permit in the Southcentral Region and a Dispensary permit in the Southeast Region of the Commonwealth. The Company's mission is to improve the lives of Pennsylvanians suffering from serious medical conditions. Ilera Healthcare offers the following insights and comments to the proposed permanent regulations published by the Pennsylvania Department of Health in the *Pennsylvania Bulletin*, Vol. 51, No. 10, March 6, 2021.

28 Pa. Code Section 1151a.24(a).
The Program will benefit from consistently scheduled periods to import seeds.

Presently, Grower/Processors are limited to importing seeds only in the 30 days after the Department declares them operational. Beyond that window, Grower/Processors cannot import seeds. This restriction has two principal adverse effects. First, Pennsylvanians are excluded from new genetics, which stifles research and development of medical marijuana in the Commonwealth. And second, increasing demand for medical marijuana means that Grower/Processors have planted more seeds than initially anticipated at the outset of the Program; as seed supplies are depleted at a faster-than-anticipated rate, consistency of supply is jeopardized.

Proposed Regulation Section 1151a.24(a) attempts to address these issues by providing 30-day windows to import seeds "if the Department [of Health] determines that the importation of seeds is necessary." This standard – *i.e.,* if the Department determines that importation is necessary – is insufficiently clear and it is too subjective. Grower/Processors are left to guess whether their necessity aligns with the Department's "necessary".

Ilera Healthcare proposes that Section 1151a.24(a) provides four open importation periods per calendar year set at defined intervals – for instance, the four 30-day open importation periods would begin on January 1, April 1, July 1, and October 1 of each year. This proposal would accomplish the same objective of the Proposed Section 1151a.24(a) but resolve the inherent uncertainty of a subjective, undefined standard; it would also encourage research and development, maintain the consistency of supply, and facilitate the introduction of fresh offerings to patients.

28 Pa. Code Sections 1151a.34(d)(17) and 1161a.28(c)(15).
Proposed labeling requirements are in conflict.

The Regulations specify requirements for packaging, labeling, and sealing medical marijuana products. Proposed Sections 1151a.34(d)(17) and 1161a.28(c)(15) sets forth a new requirement for permittees – Grower/Processors and Dispensaries must affix their respective labels "to the container directly holding medical marijuana and be firmly affixed to outer packaging if used". At present, labels are only affixed to the outer packaging and Ilera believes this should remain the rule.

In order for Dispensaries to affix and inspect container compliance labels (as required by Proposed Section 1161a.28(c)(15)), Dispensaries must *break the seal of the outer packaging*.

If Dispensaries break the packaging seal, patient will be *unable to determine whether the product has been tampered*; these Proposed Regulations shatter confidence in the integrity of the product. And breaking the seal would also be a direct violation of Section 1161a.28(b), which requires medical marijuana to be dispensed in a "*sealed* and properly labeled package".

Moreover, applying two labels makes production and dispensing of medicine more complicated, more expensive, and more time consuming – for no discernible benefit to patients. Sections 1151a34(d)(17) and 1161a.28(c)(15) should be removed from the Permanent Regulations.

28 Pa. Code Section 1141a.22(b).
The Department should allow application programming interfaces into MJ Freeway.

The Department of Health has administratively banned application programming interfaces (API) to MJ Freeway, the Medical Marijuana Program's Electronic Tracking System. APIs let two software programs share information securely and automatically. MJ Freeway offers API access to its Electronic Tracking System. Businesses and marijuana industry operators across the nation in other highly regulated programs – except for those in Pennsylvania – use APIs to share data with powerful business intelligence and analytics software. The ban on APIs is a significant setback for the Program because:

- Analytic tools can analyze inventory data to better assess demand, supply chain and logistics, warehousing, and delivery operations. Operators leverage API technology to increase efficiency, accelerate production, and reduce product cost.

- Dispensaries across the country use APIs to keep their online reservation menus current in real time, provide better demand planning analysis, manage their inventory, and make focused product recommendations to improve patient outcomes. The confidentiality of patient information is not an issue as it can be addressed by anonymizing information.

APIs will increase efficiencies in production, decrease the administrative burdens that occur with the manual transfer of information into accounting systems, and facilitate better inventory management. These systems are secure, HIPAA-compliant, readily available, and used throughout the healthcare industries. Permittees and patients would significantly benefit from the introduction of secure APIs into the Electronic Tracking System.

28 Pa. Code Section 1171a.29(c).
Mandating testing by two different laboratories will reduce confidence in test results.

Proposed Regulation Section 1171a.29(c) provides that different laboratories must test the harvest lot and the process lot. The Department states that this change will provide "checks and balances" but does not define what that means.

Testing by a single lab guarantees samples are tested using same practices, equipment, and methods. It is inevitable that different laboratories will have variances in sampling and testing methodologies that will diminish the integrity of the data from their laboratory tests. These variances will diminish the integrity of the product and patient confidence in the medication. Moreover, this proposed two-lab system could stifle research and development of medical marijuana in the Commonwealth because the industry would lose valuable data points that would otherwise exist between harvest and processing – we will know less about what happens to marijuana when it is processed.

Additionally, using two laboratories will introduce inefficiencies in the process of collecting samples. Rather than having one laboratory enter facilities to collect samples, there will be two, which makes the process of providing samples more complicated and, likely, slower which delays medication making its way into the hands of the patient that needs the medicine.

28 Pa. Code Sections 1151a.26(d) and 1161a.31(d).
Requiring securely locked doors "at all times" is ambiguous, unclear, and a fire safety hazard.

Proposed Sections 1151a.26(d) and 1161a.31(d) provide that "at all times" the entrances and exits to Grower/Processor and Dispensary facilities "must be securely locked". Surely, doors to businesses cannot be securely locked "at all times". Moreover, securely locking people on the inside of buildings presents a significant safety hazard that *must* be balanced against building safety laws – in the event of a fire or similar emergency, a securely locked door delays safe exit and are an extreme safety issue. The corollary Temporary Regulations provide that entrances and exits must be securely locked during nonworking hours; the intention underlying the change is not apparent.

28 Pa. Code Section 1161a.26(a).
Curbside pick-up benefits patients and should remain a fixture of the Program.

Many patients suffering from Serious Medical Conditions suffer from decreased mobility and anxiety issues and compromised immune systems. When the Department authorized the use of curbside pick-up in response to the COVID-19 pandemic, these patients discovered that they could get their medicinal marijuana as easily as prescriptions from a pharmacy – via a curbside pick-up. Over the past year, Dispensaries refined their curbside systems and security protocols to meet the patients' demand for access to medical marijuana. Patients with mobility issues have come to appreciate the more compassionate system. Patients with anxiety have become used to a process by which they can acquire their medicine from the calm of their cars and avoid the rush of the dispensary. Patients with compromised immune systems can acquire their medicine without risk of exposure. It would be a significant and meaningful permanent benefit to the patients to make curbside pick-up a fixture of the Program.

28 Pa. Code Sections 1151a.26(a)(4) and 1161a.26(a)(4).
Retaining surveillance footage for two years is onerous and unreasonable.

The Regulations require Grower/Processors and Dispensaries to retain surveillance system footage for at least two (2) years. Ostensibly, this requirement is intended to provide a long record of

activity to aid diversion and crime investigations. However, the requirement is onerous and unreasonable due to the high cost of maintaining high-resolution digital “footage” from hundreds of cameras recording every second of every day. The cost of retention is tens of thousands of dollars per year because the unusually long retention period requires highly specialized equipment and maintenance. Given the extraordinarily comprehensive inventory controls in Program, it is unreasonable to expect that a diversion or crime would go undiscovered for more than six months, which should be the retention duration.

Respectfully submitted,

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