IN THE COMMONWEALTH COURT OF PENNSYLVANIA

AES Compassionate Care, LLC, BAY, LLC, Chamounix Ventures, LLC, Cresco Yeltrah, LLC, GTI Pennsylvania, LLC, GuadCo, LLC, Ilera Healthcare, LLC, Keystone Center of Integrative Wellness, LLC, Pennsylvania Medical Solutions, LLC, Standard Farms, LLC, and The Healing Center, LLC, Petitioners	:	
	:	No. 233 M.D. 2018
v.	:	
	:	Heard: May 2, 2018
Rachel L. Levine, MD, Acting Secretary, Pennsylvania Department of Health, Respondent	:	

BEFORE: HONORABLE PATRICIA A. McCULLOUGH, Judge

OPINION NOT REPORTED

MEMORANDUM OPINION
BY JUDGE McCULLOUGH

FILED: May 22, 2018

Before this Court is a request for a preliminary injunction regarding the regulations enacted pursuant to the Medical Marijuana Act (Act)[1] to the extent they might unlawfully permit the commercial sale of medical marijuana in contravention of the Act. Specifically, an application for preliminary injunction was filed by AES Compassionate Care, LLC, BAY, LLC, Chamounix Ventures, LLC, Cresco Yeltrah, LLC, GTI Pennsylvania, LLC, GuadCo, LLC, Ilera Healthcare, LLC, Keystone Center

[1] Act of April 17, 2016, P.L. 84, 35 P.S. §§10231.101-10231.2110.

of Integrative Wellness, LLC, Pennsylvania Medical Solutions, LLC, Standard Farms, LLC, and The Healing Center, LLC (collectively, Petitioners) for special relief in the nature of a preliminary injunction, seeking to enjoin Rachel L. Levine, MD, Acting Secretary of Health, from applying the March 17, 2018 temporary regulations (Regulations), 28 Pa. Code §§1210.21-1210.37, relating to implementation of the academic research provisions of Chapter 20 of the Act, 35 P.S. §§10231.2001-10231.2003.

The Medical Marijuana Act and the Chapter 20 Regulations

The Act, which took effect on May 17, 2016, establishes a framework for the legalization of medical marijuana in the Commonwealth for certain medical conditions. The expressed legislative intent of the Act is to

> (i) Provide a program of access to medical marijuana which balances the need of patients to have access to the latest treatments with the need to promote patient safety.
>
> (ii) Provide a safe and effective method of delivery of medical marijuana to patients.
>
> **(iii) Promote high quality research into the effectiveness and utility of medical marijuana.**

35 P.S. §10231.102 (emphasis added).

The Act identified the Pennsylvania Department of Health (Department) as the Commonwealth agency responsible for administering the Act and authorized the Department to promulgate regulations, including temporary regulations to carry out the same. 35 P.S. §§10231.301, 1023.1107. In accord with this authority, the Department promulgated the Regulations at issue here, which were published on March 17, 2018, and made immediately effective.

A. Chapter 6 of the Act

Under section 603(d) of the Act, the Department established six medical marijuana regions. 35 P.S. §10231.603(d).[2] Chapter 6 of the Act set forth two types of entities authorized to receive a permit to operate as a medical marijuana organization and grow, process, or dispense marijuana: grower/processors and dispensaries. 35 P.S. §10231.601.[3] Section 616 of the Act set forth limitations on the number of permits the

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[2] This section states:

> The [D]epartment shall establish a minimum of three regions within this Commonwealth for the purpose of granting permits to grower/processors and dispensaries and enforcing this [A]ct. The [D]epartment shall approve permits for grower/processors and dispensaries in a manner which will provide an adequate amount of medical marijuana to patients and caregivers in all areas of this Commonwealth. The [D]epartment shall consider the following when issuing a permit:
>
> (1) Regional population.
>
> (2) The number of patients suffering from serious medical conditions.
>
> (3) The types of serious medical conditions.
>
> (4) Access to public transportation.
>
> (5) Any other factor the [D]epartment deems relevant.

35 P.S. §10231.603(d).

[3] This section states:

Department could initially issue. Specifically, the Department was authorized to issue up to 25 grower/processor permits and 50 dispensary permits, the recipients of which would be limited to dispensing at **a maximum of three separate locations**. 35 P.S. §10231.616 (emphasis added).[4] Further, section 616 provided, "No more than five

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> The following entities shall be authorized to receive a permit to operate as a medical marijuana organization to grow, process or dispense medical marijuana:
>
> (1) Grower/processors.
>
> (2) Dispensaries.

35 P.S. §10231.601.

[4] This section states:

> The following limitations apply to approval of permits for grower/processors and dispensaries:
>
> (1) The [D]epartment may not initially issue permits to more than 25 growers/processors.
>
> (2) The [D]epartment may not initially issue permits to more than 50 dispensaries. Each dispensary may provide medical marijuana at no more than three separate locations.
>
> (3) The [D]epartment may not issue more than five individual dispensary permits to one person.
>
> (4) The [D]epartment may not issue more than one individual grower/processor permit to one person.
>
> (5) No more than five grower/processors may be issued permits as dispensaries. If the number of growers/processors is increased under section 1202[] no

grower/processors may be issued permits as dispensaries." *Id.* These five entities are referred to as "vertically integrated" entities. *See* 35 P.S. §10231.1901.[5]

In January 2017, the Department announced it would issue permits in phases. In Phase I, it would issue up to 12 grower/processor permits, with no more than 2 permits in each of the 6 medical marijuana regions, and up to 27 dispensary permits distributed throughout the 6 regions, apparently in accordance with population concentration. Department of Health, Office of Medical Marijuana Bulletin No. 17-21, at 73 (Issued Jan. 7, 2017).

From February 20, 2017, through March 20, 2017, the Department accepted applications for medical marijuana grower/processor permits and/or dispensary permits. The Department received 457 applications: 177 for growers/processors and 280 for dispensaries. On June 20, 2017, the Department issued 12 grower/processor permits and, on June 29, 2017, the Department issued 27 dispensary permits.

> more than 20% of the total number of growers/processors may also be issued permits as dispensaries.
>
> (6) A dispensary may only obtain medical marijuana from a grower/processor holding a valid permit under this [A]ct.
>
> (7) A grower/processor may only provide medical marijuana to a dispensary holding a valid permit under this [A]ct.

35 P.S. §10231.616.

[5] Section 1141.21 of the Regulations defines "Health care medical marijuana organization" as a "vertically integrated health system approved by the Department to dispense medical marijuana or grow and process medical marijuana, or both, in accordance with a research study under sections 1901--1908 of the [A]ct." 28 Pa. Code §1141.21.

On March 24, 2018, the Department indicated that it would accept applications for Phase II from April 5, 2018, to May 18, 2018, after which it would grant the 13 remaining grower/processor permits and the 23 remaining dispensary permits. Department of Health, Office of Medical Marijuana Bulletin No. 18-462, at 1782-83 (Issued Mar. 24, 2018).

B. Chapter 19 of the Act

The Act also designed two types of medical marijuana research programs. The first, found in Chapter 19, directed the Department to develop a research program in which "vertically integrated health systems," as that term is defined in Chapter 19,[6] approved by the Department, would be able to grow and process medical marijuana to conduct research studies involving patients with serious medical conditions, upon authorization by the United States Food and Drug Administration (FDA) and the United States Drug Enforcement Administration (DEA). *See generally* 35 P.S. §§10231.1901-10231.1908. However, as Petitioners note in their petition for review, this program has not come to fruition since marijuana remains an illegal Schedule I drug under the Federal Controlled Substances Act, and health systems, which rely heavily on federal reimbursement funds via Medicaid and Medicare, are unwilling to jeopardize that funding by engaging in federally prohibited activity, *i.e.*, growing, processing, and dispensing marijuana. (Petitioners' Amended Petition for Review at 22-23.) Further, Petitioners note that, even if such health systems were willing to take that risk, the FDA and DEA are unlikely to grant their approval. *Id.*

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[6] Section 1901 of the Act defines "Vertically integrated health system" as "[a] health delivery system licensed under the act of July 19, 1979 (P.L. 130, No. 48),[1] known as the Health Care Facilities Act, in which the complete spectrum of care, including primary and specialty care, hospitalization and pharmaceutical care, is provided within a single organization." 35 P.S. §10231.1901.

C. Chapter 20 of the Act

The second research program contemplated by the Act is set forth in Chapter 20. By way of background, the Act originated in the Pennsylvania Senate as Senate Bill 3 of 2015; however, in March 2016, Chapter 20 of the Act, entitled "Academic Clinical Research Centers," was added by House amendment. Chapter 20 permits qualifying Academic Clinical Research Centers (ACRCs) to form partnerships with Clinical Registrants (CRs) to conduct research studies. 35 P.S. §§10231.2001-10231.2003. Section 2001 of the Act defines an ACRC as "[a]n accredited medical school within this Commonwealth that operates or partners with an acute care hospital licensed within this Commonwealth," and a CR as an entity that

> (1) holds a permit as both a grower/processor and a dispensary; and
>
> (2) has a contractual relationship with an [ACRC] under which the [ACRC] or its affiliate provides advice to the entity, regarding, among other areas, patient health and safety, medical applications and dispensing and management of controlled substances.

35 P.S. §10231.2001. Pertinent here, the aforementioned limitations of section 616 of the Act, 35 P.S. §10231.616, which restricted the Department to initially issuing no more than 25 grower/processor permits and 50 dispensary permits (5 of which could be vertically-integrated), does not apply to this Chapter. Section 2002 of the Act, entitled "Clinical registrants,"[7] states,

> **Notwithstanding the limitations in section 616,**[] the [D]epartment may register u**p to eight [CRs]**. Each entity may provide medical marijuana **at not more than six separate locations.** The total number of locations authorized to dispense medical marijuana under this section

[7] Throughout the proceedings, Petitioners refer to these entities as "super-permittees."

> **shall not exceed 48**. The following apply with respect to this category of [CR]:
>
> > (1) A [CR] must pay the fees and meet all other requirements under this [A]ct for obtaining a permit as a grower/processor and a dispensary, except as provided under section 607(1)(vi) and (2)(vi).[]
> >
> > (2) The [CR] must have a minimum of $15,000,000 in capital. The [D]epartment shall verify the capital requirement.
> >
> > (3) The [CR] must comply with all other requirements of this [A]ct regarding growing, processing and dispensing medical marijuana.

35 P.S. §10231.2002 (emphasis added).

The final section of Chapter 20, section 2003, entitled "Research Study," states the following:

> Notwithstanding any provision of this [A]ct to the contrary, the [D]epartment may, upon application, **approve the dispensing of medical marijuana by a [CR] to the [ACRC] for the purpose of conducting a research study.** The [D]epartment shall develop the application and standards for approval of such dispensing by the [CR]. The following apply to the research study:
>
> > (1) The [CR] shall disclose the following information to the [D]epartment in its application:
> >
> > > (i) The reason for the research project, including the reason for the trial.
> > >
> > > (ii) The strain of medical marijuana to be used and the strength of the medical marijuana to be used in the research study.

> (iii) The anticipated duration of the study.
>
> (iv) Evidence of approval of the trial by an accredited institutional review board, including any other required regulatory approvals.
>
> (v) Other information required by the [D]epartment, except that the [D]epartment may not require disclosure of any information that would infringe upon the [ACRC]'s exclusive right to intellectual property or legal obligations for patient confidentiality.
>
> (2) The [ACRC] shall provide its findings to the [D]epartment within 365 days of the conclusion of the research study or within 365 days of publication of the results of the research study in a peer-reviewed medical journal, whichever is later.
>
> (3) The [D]epartment shall allow the exchange of medical marijuana seed between [CRs] for the conduct of research.

35 P.S. §10231.2003 (emphasis added).

D. Chapter 20 Regulations

Pursuant to section 1107 of the Act,[8] on March 17, 2018, the Department published Regulations promulgating Chapter 20 of the Act, which took effect immediately. 28 Pa. Code §§1210.21-1210.37.

[8] As noted previously, this section authorizes the Department to promulgate temporary regulations, which would expire two years following their publication, in order to "facilitate prompt

The Regulations define an ACRC as "[a]n accredited medical school in this Commonwealth that operates or partners with an acute care hospital licensed and operating in this Commonwealth." 28 Pa. Code §1210.21. In order to become a certified ACRC, an entity must file an application that includes:

> (1) The legal name, address and telephone number of the accredited medical school and the name, telephone number and professional e-mail address of an individual at the accredited medical school who will be the primary contact for the Department during the Department's review of the application.
>
> (2) The legal name, address and telephone number of the acute care hospital that is operated by or partnered with the accredited medical school and the name, telephone number and professional e-mail address of an individual at the accredited medical school who will be the primary contact for the Department during the Department's review of the application.
>
> (3) An affidavit, on a form prescribed by the Department, disclosing any payments to the accredited medical school or any of its affiliates made by a person with whom **the accredited medical school intends to enter into a research contract for purposes of operating as an approved [CR]** or by any principal or financial backer of the person, up to

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implementation" of the Act. 35 P.S. §10231.1107(a). Further, the Regulations were not to be subject to sections 201 to 205 of the Commonwealth Documents Law, Act of July 31, 1968, P.L. 769, *as amended*, 45 P.S. §§1201–1205; the Regulatory Review Act, Act of June 25, 1982, P.L. 633, *as amended*, 71 P.S. §745.1–745.15; or sections 204(b) and 301(10) of the Commonwealth Attorneys Act, Act of October 15, 1980, P.L. 950, *as amended*, 71 P.S. §§732-204(b), 732-301(10); and 35 P.S. §1107(a). The Department allowed a period of time for interested parties to submit written comments, suggestions, or objections regarding the temporary regulations. Department of Health, Office of Medical Marijuana Bulletin No. 10-201, at 7631 (Issued Dec. 10, 2016).

and including the date of the submission of the application. The affidavit must include the amount and purpose of each payment made.

(4) A statement that the accredited medical school is currently accredited by the Liaison Committee of Medical Education or the Commission on Osteopathic College Accreditation.

(5) A statement that the acute care hospital designated by the accredited medical school under paragraph (2) holds a valid license from the Department.

(6) The State and Federal tax identification numbers of the accredited medical school.

(7) A statement that a false statement made by the accredited medical school submitting the application is punishable under the applicable provisions of 18 Pa.C.S. Chapter 49 (relating to falsification and intimidation).

(8) Any other information deemed necessary by the Department.

28 Pa. Code §1210.25(c) (emphasis added).

Further, the Regulations define "Approved clinical registrant" as

An entity that applied for and received the approval of the Department to do all of the following:

(i) Hold a permit as both a grower/processor and a dispensary

(ii) Enter into a research contract with a certified ACRC.

28 Pa. Code §1210.21. Section 1210.27 of the Regulations lists the contents required of a CR application:

> (a) An applicant shall file an application for approval of a [CR] with the Department on a form prescribed by the Department. The Department will publish a notice in the Pennsylvania Bulletin announcing the availability of applications and the time period during which the Department will accept applications.
>
> (b) An application for approval of a [CR] submitted under this section must include all of the following information:
>
> > (1) The legal name, address and telephone number of the applicant and the name, telephone number and professional e-mail address of an individual who will be the primary contact for the Department during the Department's review of the application.
> >
> > (2) The name of the certified ACRC under § 1210.25 (relating to certifying ACRCs).
> >
> > (3) The applicant's State and Federal tax identification numbers.
> >
> > (4) An affidavit, on a form prescribed by the Department, **disclosing any payments** made by the applicant, a principal or financial backer of the applicant to a certified ACRC or any affiliates of a certified ACRC, up to and including the date of the submission of the application. The affidavit must include the amount and purpose of each payment made.
> >
> > (5) The name of an institution of higher education, if any, that will be participating in an approved research project.
> >
> > (6) An affidavit and release under § 1210.24 (relating to capital requirements).

(7) Evidence that the applicant is responsible and capable of successfully operating as an approved [CR], including all of the following:

(i) **A copy of the research contract between the applicant and the certified ACRC.**

(ii) A description of the research projects the applicant and the certified ACRC intend to conduct.

(iii) A statement that the applicant may not engage in the business of selling, dispensing or offering to dispense medical marijuana products at an applicant's dispensary until the dispensary is ready, willing and able to dispense medical marijuana products.

(8) Except as provided in subsection (d), an application for a grower/processor permit under Chapters 1141 and 1151 (relating to general provisions; and growers/processors).

(9) Except as provided in subsection (d), an application for a dispensary permit under Chapter 1141 and Chapter 1161 (relating to dispensaries).

(10) A statement that a false statement made by the applicant is punishable under the applicable provisions of 18 Pa.C.S. Chapter 49 (relating to falsification and intimidation).

(11) Any other information deemed necessary by the Department.

(c) An applicant may only include one certified ACRC in its application for approval of a [CR].

> (d) Subject to the limitations in § 1210.23 (relating to limitation on permits), an applicant that already holds a grower/processor permit or a dispensary permit, or both, under sections 601-616 of the [A]ct (35 P.S. §§ 10231.601-10231.616), shall include in its application for approval of a [CR] a request for conversion of an existing permit under § 1210.28 (relating to request for conversion of an existing permit).
>
> (e) The following documents provided to the Department under this chapter are confidential and not subject to disclosure under the Right-to-Know Law (65 P.S. §§ 67.101-67.3104):
>
> (1) A research contract.
>
> (2) A description of a research project.
>
> (3) A certified ACRC's intellectual property.
>
> (4) An approved [CR]'s intellectual property.

28 Pa. Code §1210.27 (emphasis added).

As noted by the Honorable Katharine M. Watson in her amicus brief, pursuant to section 1210.28(b) of the Regulations, if an existing permittee under Chapter 6 becomes registered as a CR, the permittee must surrender its commercial permits, which are placed back into the pool of available commercial permits. 28 Pa. Code §1210.28(b).

Section 1210.31 of the Regulations addresses the requirements of an application for renewal of a CR permit. With regard to denial of a CR's renewal application, section 1210.31(c) states,

> The Department will **not renew an approval** for a [CR] under this section if the Department determines that **none** of the dispensary locations under the dispensary permit held by the approved [CR] are participating in an approved research project and the approved [CR] does not intend to commence

> any additional approved research projects within the first 6 months following the approval of its application for renewal.

28 Pa. Code §1210.31(c) (emphasis added).

Finally, section 1210.23 of the Regulations sets forth certain limitations on permits:

> (a) An approved [CR] may not hold more than one grower/processor permit and one dispensary permit.
>
> (b) A dispensary permit held by an approved [CR] for use under this chapter may be used to dispense medical marijuana products at no more than six separate locations as approved by the Department. An approved [CR] may dispense medical marijuana products to a patient or caregiver who presents a valid identification card to an employee who is authorized to dispense medical marijuana products at a dispensary location operated by an approved [CR] under this chapter.
>
> (c) An approved [CR] may not locate more than three of its approved dispensaries in the same medical marijuana region or in the same county.

28 Pa. Code §1210.23.

In March 2018, the Department announced that ACRC applications would be available on April 5, 2018, and must be filed as of May 3, 2018, and that CR applications would be available on May 24, 2018, and must be filed as of July 12, 2018. Department of Health, Office of Medical Marijuana Bulletin No. 18-461, at 1781 (Issued Mar. 24, 2018).

Facts and Procedural History

Petitioners are "medical marijuana organizations" as that term is defined by section 103 of the Act,[9] of which six are growers/processors, nine are dispensaries, and four are vertically integrated entities (holding permits as both grower/processors and dispensaries). Petitioners initiated this action on April 10, 2018, by filing a petition for review in this Court's original jurisdiction against Dr. Rachel Levine, Secretary of Health. Petitioners sought declaratory relief and a permanent injunction enjoining the Department from enacting the Regulations implementing Chapter 20 of the Act. Petitioners simultaneously filed the present application for special relief in the nature of a preliminary injunction, seeking to enjoin the Department from enforcing these Regulations.

Petitioners contend that, while the Act allows up to eight existing permittees to achieve CR status so as to grow and dispense medical marijuana solely for research purposes in conjunction with an ACRC, the Regulations permit any entity—even a previously denied permit applicant under Chapter 6—to acquire what Petitioners deem a "super-permit" to engage in "virtually unfettered trade in medical marijuana products in competition with Petitioners, at double the number of dispensaries Petitioners' permits allow, with only a minimal commitment to research." (Petition for review at 2.) Further, Petitioners contend that the Regulations impermissibly delegate CR approval decisions to ACRCs by requiring, as the primary requisite for applying for CR status, that the applicant already have a privately-negotiated contract with an ACRC. As such, Petitioners suggest that the Regulations

[9] Section 103 defines "Medical marijuana organization" as "[a] dispensary or a grower/processor. The term does not include a health care medical marijuana organization under Chapter 19." 35 P.S. §10231.103.

are inconsistent with the Act and violate the non-delegation doctrine of the Pennsylvania Constitution.[10]

The Department filed an answer to Petitioners' application for a preliminary injunction, denying that Petitioners were entitled to relief and raising as a new matter the assertion that section 2001's definition of a CR is not limited to an entity that *already* holds a grower/processor and dispensary permit and that section 2002 makes clear that the Act intended the eight CRs to be additional entities beyond the limits of section 616.

Petitioners filed a brief in support of their application, and the Department filed a brief in opposition. In the Department's brief, it raises for the first time the argument that Petitioners' case is not justiciable in that they lack standing, the matter is unripe, and they have failed to exhaust administrative remedies. Petitioners filed a reply brief arguing that the case is justiciable. On May 2, 2018, the Court heard argument on Petitioners' application for a preliminary injunction.[11]

Discussion

A. Justiciability

Since standing is a threshold issue, the Court must first address whether the matter is justiciable.

1. Standing

[10] Article 2, section 1 states: "The legislative power of this Commonwealth shall be vested in a General Assembly, which shall consist of a Senate and a House of Representatives." PA. CONST. art. 2, §1.

[11] During the hearing on May 2, 2018, the Court also heard argument on the application of a prospective CR, MLH Explorations, LLC, for leave to intervene, which it ultimately denied.

The Department alleges that Petitioners lack standing because, although they have the opportunity to submit applications to become CRs, Petitioners' interest in this lawsuit is in operating free of competition, which is insufficient for the purposes of standing. The Department asserts that Petitioners have not alleged facts indicating that they are aggrieved. Specifically, the Department argues they have not pleaded that the Regulations have caused or required them to invest money to ensure compliance with the Regulations, that there are or will be delays in the operations of their businesses because of the Regulations, that the Regulations impose operational uncertainties with regard to their permits, or that the Regulations have resulted in any loss of their property rights. The Department contends that Petitioners "wholly fail to allege how the [] [R]egulations even apply to them—and, indeed, unless they seek to have their permits converted to CR permits, the [] [R]egulations will not apply to them." (Department's brief at 13.)

In response, Petitioners assert that they do not seek to operate free of competition, nor as a monopoly. Instead, Petitioners contend that they have a "direct, immediate and substantial interest in 'operating free of competition from the CR "super-permittees" the Chapter 20 [R]egulations create.'" (Petitioners' Reply Brief at 2.) Petitioners assert that the testimony of Mr. Jonathon Goldrath, the CFO of a vertically integrated entity under Chapter 6, and Mr. Drew D. Mooney, a certified public accountant and consultant, during the May 2, 2018 hearing demonstrated that Petitioners are adversely impacted by the Regulations and that their harm is not abstract but real. More specifically, Petitioners cite the witnesses' testimony that the promulgation of the Regulations on March 17, 2018, immediately lowered the market value of Petitioners' businesses because it signaled to investors that the Department would treat the Act's statutory limit on permits as a suggestion rather than a mandate. This, Petitioners contend, made it certain that existing permit holders will lose market

share as soon as the super-permittees are operational because the Regulations expanded Chapter 20's research purpose to allow for commercial use as well. Petitioners argue that this was contrary to the permissible scope of Chapter 20 and was not known to Petitioners at the time of their application to become Chapter 6 permittees. Petitioners assert that, although the deterioration of their market share will not occur until CRs are awarded permits, their witnesses' testimony showed that the dilution effect is "inevitable." *Id.* at 3.

Petitioners further assert that pre-enforcement challenges are not limited to the facts of *Arsenal Coal Co. v. Department of Environmental Resources*, 477 A.2d 1333, 1339-40 (Pa. 1984), in which the Pennsylvania Supreme Court determined pre-enforcement was appropriate where 55 coal mine operators and producers were challenging regulations that directly and immediately affected the anthracite industry by, *inter alia*, requiring the expenditure of substantial sums to comply, and where the lengthy process to challenge the regulations' validity would have resulted in ongoing uncertainty in the industry's business operators. Petitioners assert the "core concept" of *Arsenal Coal* was that pre-enforcement challenges are permitted where "the effect of the challenged regulations upon the industry regulated is direct and immediate" such that the "hardship thus presented suffices to establish the justiciability of the challenge in advance of enforcement." (Petitioners' Reply Brief at 4) (citing *Arsenal Coal*, 447 A.2d at 1339).

Our Supreme Court has stated that in order to have standing, the individual initiating the action must be "aggrieved," which can be demonstrated by showing a "substantial, direct, and immediate interest in the outcome of the litigation." *Pittsburgh Palisades Park, LLC v. Commonwealth*, 888 A.2d 655, 659-60 (Pa. 2005).

> An interest is "substantial" if it is an interest in the resolution of the challenge which "surpasses the common interest of all

> citizens in procuring obedience to the law." Likewise, a "direct" interest mandates a showing that the matter complained of "caused harm to the party's interest," *i.e.*, a causal connection between the harm and the violation of law. Finally, an interest is "immediate" if the causal connection is not remote or speculative.

Id. at 660 (internal citations omitted).

Here, the Court finds that Petitioners have demonstrated standing to initiate this action. In *Arsenal Coal*, the Supreme Court addressed "whether a court of equity may properly exercise its jurisdiction to resolve [a] pre-enforcement challenge to the validity of a regulatory scheme grounded in a claim that the regulations were promulgated in excess of the statutory authority by which the regulatory agency is empowered to enact such regulations," and held that it could. 477 A.2d at 1338. Petitioners, like those in *Arsenal Coal*, assert that a set of regulations were promulgated in excess of the statutory authority by which the regulatory agency was empowered to enact them. Specifically, Petitioners allege that the Department's Regulations are inconsistent with the text and intent of the Act and, further, are unconstitutional to the extent that the CR application process would violate the non-delegation clause of Article 2, section 1 of the Pennsylvania Constitution.

Petitioners have demonstrated a substantial, direct, and immediate interest by establishing the following: their interest, as permittees under Chapter 6 of the Act, is unique from other citizens; their businesses lost value immediately upon the publication of the Regulations, testimony about which was presented during the hearing; and, finally, the deterioration of their market share is inevitable upon award of the CR permits, which was also addressed during testimony at the hearing.[12]

[12] As discussed below, the Court found this testimony credible.

Accordingly, the Court finds that Petitioners have sufficiently demonstrated standing to pursue their claims.

2. Ripeness

For the same reasons as with standing, the Department asserts that Petitioners' claims are not ripe and that post-enforcement review is sufficient. The Department relies on *Pennsylvania Dental Hygienists' Association, Inc. v. State Board of Dentistry*, 672 A.2d 414 (Pa. Cmwlth. 1996). In that case, the petitioners sought pre-enforcement review of newly-enacted regulations promulgated by the State Board of Dentistry, which the petitioners argued would have caused changes in their work schedules, reduction in services and income, possible unemployment, and uncertainty in the ongoing day-to-day operations. *Id.* at 418. Ultimately, this Court held that the petitioners' allegations were anticipatory and too remote to support a claim of direct and immediate harm. *Id.*

In response, Petitioners cite to *EQT Production Co. v. Department of Environmental Protection*, 130 A.3d 752, 753 (Pa. 2015), in which the Supreme Court held that "a company threatened by an administrative agency with ongoing, multi-million-dollar penalties per such agency's interpretation of a statutory regime has the right, immediately, to seek a judicial declaration that the agency's interpretation is erroneous." Petitioners assert that theirs is a substantial pre-enforcement challenge to the Regulations in which there is a real or actual controversy, that there are "no material factual dynamics involved in evaluating the validity" of the Department's interpretation of the Act, and that the Regulations will have a profound effect on Petitioners and Pennsylvania's entire medical marijuana industry. (Petitioners' Reply Brief at 5) (quoting *EQT Production Co.*, 130 A.3d at 759).

In *EQT Production Co.*, the Supreme Court outlined a history of its holdings with regard to pre-enforcement review:

> [I]n *Arsenal Coal*, a group of coal mine operators and producers were permitted to proceed with a pre-enforcement challenge to comprehensive regulatory requirements promulgated by the Environmental Quality Board, so as to clarify the operators' and producers' obligations under the law and avoid unnecessarily protracted proceedings. *See Arsenal Coal*, 477 A.2d at 1339–40. In *Bayada Nurses*[*v. Department of Labor and Industry*], 8 A.3d 866 (Pa. 2010), **a pre-enforcement challenge** advanced by a home health care provider was found to be **justiciable, since judicial review would eliminate substantial expense and uncertainty in the day-to-day operations of such providers and alleviate costly and inefficient piecemeal enforcement measures**. *See Bayada Nurses*, 8 A.3d at 876. In [*Commonwealth v.*] *Donahue*, [98 A.3d 1223 (Pa. 2014),] the Office of the Governor appropriately pursued declaratory relief in challenging the Office of Open Records' interpretation of statutory provisions governing the submission of open-records requests, in light of the adverse, direct, and immediate impact of that interpretation on Commonwealth agencies. *See Donahue*, 98 A.3d at 1230–31. And, in the present case, EPC will be permitted to pursue its substantial challenge to the Department's continuing-violation interpretation in the Commonwealth Court, given the company's potential exposure to potent, ongoing civil penalties for which DEP maintains the company is liable.

EQT Production Co., 130 A.3d at 758 (emphasis added).

Upon review, the Court agrees that the matter is sufficiently ripe in that there are no "material factual dynamics" involved in the evaluation of the validity of the Department's interpretation of the Act expounded in the Regulations and, thus, pre-enforcement review is appropriate in this case. Further, the Court agrees with Petitioners that it is prudent for the Court to resolve the issue of the validity of the Regulations prior to their implementation "since judicial review would eliminate

substantial expense and uncertainty in the day-to-day operations" of potential CRs and Petitioners alike. Moreover, should the Court ultimately deem the Regulations invalid, pre-enforcement review prior to the Department's grant of CR permits will eliminate the need for CRs to rescind or invalidate contracts they negotiated based upon the invalid Regulations.[13] Thus, the Court agrees that, in this instance, it is preferable to stay the implementation of the Regulations pending their review, rather than to allow interested parties to attempt to "unwind" the Regulations after they have already been implemented. (Petitioners' Reply Brief at 8.)

3. Exhaustion of Administrative Remedies

Finally, the Department argues that the Court lacks subject matter jurisdiction over this action because Petitioners failed to exhaust their administrative remedies. Although the Act contains no provision that requires or permits Petitioners to seek redress, the Department asserts that Petitioners could have sought review of the Regulations under section 35.9 of the General Rules of Administrative Practice and Procedure (GRAPP), which states that a party "complaining of anything done or omitted to be done by a person subject to the jurisdiction of an agency, in violation of a statute or regulation administered or issued by the agency may file a complaint with the agency." 1 Pa. Code §35.9. The Department further asserts that Petitioners could have filed a formal petition for a declaratory order with the Department under section 35.19 of GRAPP, which states,

[13] During argument on MLH's application to intervene, counsel for MLH stated that it had already located and negotiated leases for its dispensary operations; however, under questioning by the Court, MLH's counsel acknowledged that its "real estate deals" and "equipment purchase orders and the like" were *contingent upon* the Department's approval of its CR application. (Notes of Testimony (N.T.), 5/2/18, at 19.)

> Petitions for the issuance, in the discretion of an agency, of a declaratory order to terminate a controversy or remove uncertainty, shall state clearly and concisely the controversy or uncertainty which is the subject of the petition, shall cite the statutory provision or other authority involved, shall include a complete statement of the facts and grounds prompting the petition, together with a full disclosure of the interest of the petitioner.

1 Pa. Code §35.19.

In response, Petitioners argue that they lack an adequate statutory or administrative remedy. Citing *Fletcher v. Pennsylvania Property and Casualty Insurance Guarantee Association*, 985 A.2d 678, 692 (Pa. 2009), Petitioners state that litigants are only required to exhaust administrative remedies where such remedies are capable of providing the relief sought and note that, where there is no adequate statutory procedure, there is no basis for a claim of failure to exhaust.

With regard to this issue, "[t]he courts of this Commonwealth have long held that a party challenging administrative decision-making must first exhaust administrative remedies before seeking judicial review; where such remedies exist, courts lack jurisdiction. This doctrine is not inflexible, and it is not applied where administrative remedies are not available or are not adequate." *Pennsylvania Pharmacists Association v. Department of Public Welfare*, 733 A.2d 666, 672 (Pa. Cmwlth. 1999) (internal citations omitted) (holding that the petitioners, who sought a declaration that certain rates implemented under a managed care program were invalid and who had already commenced the administrative process under 1 Pa. Code §35.9, had failed to exhaust their administrative remedy). Further, "[c]ourts should not lightly assume the futility of a party's pursuing an administrative remedy; instead, it is to be assumed that the administrative process, if given the opportunity, will discover and correct its errors." *Pennsylvania Pharmacists Association*, 733 A.2d at 673.

However, courts have also noted,

> A remedy is not adequate if it does not allow for adjudication of the issue raised or if it permits irreparable harm to occur to the plaintiffs during the pursuit of the statutory remedy. In addition, exhaustion has not been required in some cases where a complaint stated a direct constitutional attack upon a statute, such that administrative proceedings would contribute little to the ultimate adjudication, or where pursuit of an existing remedy would be futile.

Id. at 672 (internal citations omitted).

Here, unlike in *Pennsylvania Pharmacists Association*, Petitioners have not already commenced administrative proceedings under section 35.9 of GRAPP. Further, Petitioners are not challenging the Department's decision making, but instead challenge the validity of certain portions of the Regulations. Finally, Petitioners have also alleged a constitutional challenge to the Regulations. *Pennsylvania Pharmacists Association*, 733 A.2d at 672. Thus, in this case Petitioners' recourse necessarily lies with the courts.

B. Preliminary Injunction

We turn now to the merits of Petitioners' application for a preliminary injunction. A party seeking a preliminary injunction must show that each of the following essential elements are met:

> (1) an injunction is necessary to prevent immediate and irreparable harm that cannot be adequately compensated by damages; (2) greater injury would result from refusing an injunction than from granting it, and, concomitantly, that issuance of an injunction will not substantially harm other interested parties in the proceedings; (3) a preliminary injunction will properly restore the parties to their status as it existed immediately prior to the alleged wrongful conduct; (4) the activity sought to be restrained is actionable, that the right to relief is clear, and that the wrong is manifest, or, in

> other words, must show that it is likely to prevail on the merits; (5) the injunction is reasonably suited to abate the offending activity; and (6) a preliminary injunction will not adversely affect the public interest.

Summit Towne Centre, Inc. v. Shoe Show of Rocky Mount, Inc., 828 A.2d 995, 1001 (Pa. 2003). "A preliminary injunction may only be granted if each element is fully and completely established." *McClusky v. Washington Township*, 700 A.2d 573, 576 (Pa. Cmwlth. 1997).

Furthermore, a preliminary injunction is intended to preserve the *status quo* and prevent imminent and irreparable harm that might occur before the merits of the case can be heard and determined. After a preliminary injunction is awarded or denied, the case proceeds for a final hearing on the merits. *Soja v. Factoryville Sportsmen's Club*, 522 A.2d 1129, 1131 (Pa. Super. 1987). The preliminary injunction proceeding is distinct from the final hearing on the merits. *Kee v. Pennsylvania Turnpike Commission*, 743 A.2d 546, 549 (Pa. Cmwlth. 1999). Indeed,

it is well established that separate standards govern a request for a preliminary injunction and a request for permanent injunctive relief: a preliminary injunction looks for the presence of imminent, irreparable harm, whereas a permanent injunction is warranted if no adequate remedy at law exists for a legal wrong.[14] *City of Chester v. Chester Redevelopment Authority*, 686 A.2d 30, 35 (Pa. Cmwlth. 1996). Consequently, this Court has held that it is inappropriate for a court to treat a hearing for a preliminary injunction as a final hearing and as a basis for a permanent injunction, unless the parties stipulate to the contrary. *Kee*, 743 A.2d at 549; *Berger by and Through Berger v. West Jefferson Hill School District*, 669 A.2d 1084 (Pa. Cmwlth. 1995).

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[14] A court's final disposition of a request for permanent injunctive relief is independent of its determination relating to preliminary injunctive relief and the denial of the latter does not foreclose an order for a permanent injunction. *Soja*, 522 A.2d at 1131.

The Court will address each of these requisites for a preliminary injunction in turn, but will begin with Petitioners' argument regarding a clear right to relief.

1. Clear Right to Relief

Petitioners state that they have a clear right to relief because the Regulations are contrary to the Act's prescribed structure for CR/ACRC authorizations in four key respects and because the Regulations, as interpretative regulations, fail to track the meaning of the Act, are unwise, and are violative of legislative intent.

Petitioners begin by highlighting that one of the Act's central legislative goals is to "**[p]romote high quality research** into the effectiveness and utility of medical marijuana." 35 P.S. §10231.102(3)(iii) (emphasis added). To that end, Petitioners assert that the legislature implemented Chapter 20 of the Act to accomplish that particular goal.

With regard to alleged discrepancies between the Act and the Regulations, Petitioners first argue that the Regulations allow entities that are not existing permit holders to apply for CR status in violation of the plain language of the Act. Petitioners note that under section 2001, a CR is defined as one who "(1) holds a permit as both a grower/processor and a dispensary" (First Requirement), and "(2) has a contractual relationship with an [ACRC] under which the [ACRC] or its affiliate provides advice to the entity, regarding, among other areas, patient health and safety, medical applications and dispensing and management of controlled substances" (Second Requirement). 35 P.S. §10231.2001. Petitioners state that, despite these two items being prerequisites to applying for CR status under the Act, section 1210.27 of the Regulations does not treat the First Requirement as a prerequisite. As noted above this section, *inter alia*, requires the Applicant to provide the name of the ACRC with which it intends to partner, a copy of the contract with the ACRC, evidence that the applicant

is capable of operating as a CR, and applications for grower/processor and dispensary permits. 28 Pa. Code §1210.27. Petitioners argue that the omission of the First Requirement as a prerequisite is contrary to the plain words of the Act and that the Department cannot "treat one as a pre-requisite [sic] but not the other." (Petitioners' Application for Preliminary Injunction at 13.)

Further on this point, Petitioners argue that the notion that the General Assembly intended only existing permittees to be able to apply for CR status is supported by the fact that it strictly limited the number of grower/processor and dispensary permits, which created competition and resulted in a rigorous application process and the selection of the best applicants. Petitioners state that it would be "an absurd result" for the General Assembly to make high quality medical marijuana research the goal of the Act, only to allow entities other than ones that "emerged victorious" from that competitive permitting process to partner with ACRCs to do the "high quality" research. *Id.*

Second, Petitioners argue that the Regulations create a CR/ACRC structure that violates the Act in numerous ways. Petitioners assert that the Regulations' requirement that the applicant have a contractual relationship with an ACRC as a prerequisite creates a situation in which the ACRC, not the Department, vets and chooses medical marijuana permittees, in violation of the Act and Article 2, section 1 of the Pennsylvania Constitution, which requires governmental functions to be conducted by governmental bodies.[15] Specifically, Petitioners state that by making the Second Requirement a prerequisite for a CR application but not the First Requirement—that applicants hold a permit—the Regulations arbitrarily delegate to

[15] This section states: "The legislative power of this Commonwealth shall be vested in a General Assembly, which shall consist of a Senate and a House of Representatives." PA. CONST. art. 2, §1.

each ACRC the Department's governmental duty to vet and approve medical marijuana grower/processor and dispensary applicants for permits, which is unconstitutional. Petitioners explain that, under the Regulations, the primary criterion for CR status is that the CR applicant have a contract with an ACRC, and note that the CR applicant need only include one ACRC in its application. 28 Pa. Code §1210.27.

Thus, Petitioners contend that the result is that the ACRC determines, by privately-negotiated contract, the single entity that may apply to be that ACRC's CR, and the CR applicant need not already be vetted and permitted by the Department as a grower/processor and dispensary. Petitioners observe that the Department has provided no criteria to evaluate the quality of a CR, which leaves that determination to the ACRCs and equates to an unconstitutional delegation of authority. Further, according to Petitioners, this would result in the Department being faced with a *fait accompli* with regard to CR applicants that are not existing grower/processor and dispensary permittees under Chapter 6—either accept the ACRC's choice or deny the CR's application—instead of the Department exercising its discretion to select the best applicant from a pool. Petitioners also assert that nothing in the Regulations allows the Department to reject a CR application based upon the conclusion that a CR is not fit to operate a grower/processor or dispensary facility.[16]

The third way in which Petitioners argue that the Regulations are inconsistent with the Act is that the Regulations permit CRs to engage in the

[16] Petitioners contend that the only reason listed in the Regulations for rejecting a CR applicant is under section 1210.30(b), which permits the Department to deny a CR application for failure to comply with the Department's measures designed to eliminate "pay to play" concerns—specifically, according to Petitioners, the concern that an applicant or its affiliates would circumvent the application process by "buying" its way into permits via direct or indirect financial payments to ACRCs in order to secure the prerequisite ACRC contract. *See* 28 Pa. Code §1210.30.

unrestricted sale of medical marijuana products, whereas the Act limits a CR to growing and dispensing medical marijuana for research purposes only. Petitioners argue, "**Titles matter in statutory construction**, 1 Pa. C.S. § 1924, and the title the General Assembly chose for **Chapter 20** speaks volumes: '**Academic Clinical Research Centers.**'" (Petitioners' Brief at 24) (emphasis added). Petitioners contend that 28 Pa. Code §1210.23(b),[17] which permits CRs to dispense medical marijuana products to those presenting a valid identification card, violates the text and intent of the Act because section 2002 does not state that a CR is permitted to provide medical marijuana for non-research purposes. In this instance, Petitioners state that it is just as important to "listen attentively to what [the Act] does not say." (Petitioners' Brief at 25) (quoting *Hanaway v. Parkesburg Group, LP*, 168 A.3d 146, 154 (Pa. 2017)).

Petitioners observe that section 2003 of the Act "expressly acknowledges and reserves" to the CR and ACRC the confidentiality and value of intellectual property acquired through research authorized under the Regulations, thereby recognizing that the economic value of intellectual property that can be acquired through research is sufficient to justify the investment required for a medical marijuana grower/processor

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[17] This portion of the Regulations states:

> A dispensary permit held by an approved clinical registrant for use under this chapter may be used to dispense medical marijuana products at no more than six separate locations as approved by the Department. **An approved clinical registrant may dispense medical marijuana products to a patient or caregiver who presents a valid identification card** to an employee who is authorized to dispense medical marijuana products at a dispensary location operated by an approved clinical registrant under this chapter.

28 Pa. Code §1210.23(b) (emphasis added).

facility dedicated solely to research. (Petitioners' Application for Preliminary Injunction at 16.) Here, Petitioners cite to a fiscal note by the House Appropriations Committee accompanying the passage of the Act on April 13, 2016, which states, in pertinent part, "A clinical registrant is an entity registered as a grower/processor and a dispensary that has a contractual relationship with a hospital/medical school. The clinical registrant, upon approval the of rhw Department, may dispense medical marijuana to the hospital/medical school in order to conduct research projects." Ann Bertolino, House Committee on Appropriations Fiscal Note, available at http://www .legis.state.pa.us/WU01/LI/BI/FN/2015/0/SB0003P1690.pdf.[18]

Finally, Petitioners argue that the Regulations[19] ignore the text and intent of the Act by impermissibly expanding the Act's limited permission for CRs to "exchange . . . medical marijuana seed" amongst themselves for "the conduct of research" by permitting unrestricted commerce unrelated to research in all medical marijuana products, including immature plants, mature plants, and medical marijuana products, between and amongst CRs and other medical marijuana growers and dispensaries. 35 P.S. §10231.2003(3). Petitioners argue that the Act is "unequivocal" in limiting these exchanges to seed only, noting that the only reference to a CR's sales outside of the confines of the CR relates exclusively to research, and the Regulations directly flout that restriction. (Petitioners' Application for Preliminary Injunction at 17.)

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[18] It is unclear, however, what precedential value the fiscal note has with regard to this Court's interpretation of the Act.

[19] 28 Pa. Code §1210.36 allows the grower/processor of an approved CR to sell or exchange seeds, immature and mature marijuana plants, and medical marijuana products with other grower/processors of approved CRs for the purposes of conducting research.

In sum, Petitioners argue that the first reason they are likely to succeed on the merits is because the Act created CRs as research laboratories, which would recoup their investments by creating valuable intellectual property; however, Petitioners state that the Regulations "turn CRs into super-permittees chosen by ACRCs in privately-negotiated contracts that compete directly with Petitioners and other existing permittees to produce and sell medical marijuana products to patients." (*Id.* at 5.) Thus, Petitioners conclude that the Regulations have "little relation" to the language or intent of the Act. (Petitioners' Brief at 27.)

With regard to Petitioners' second argument regarding likelihood of success on the merits, Petitioners argue that the Regulations fail to track the meaning of the Act, are unwise, and are violative of legislative intent. Petitioners contend that the Regulations, as interpretative regulations rather than legislative, are entitled to less deference, and in this case, are entitled to no deference at all because of their inconsistency with the Act under which they were promulgated.

Petitioners also argue that the manner in which the Department promulgated the Regulations is likewise troubling. Petitioners assert that, although section 1107 of the Act provided that the Department may promulgate temporary regulations without regard to the Commonwealth Documents Law, the Regulatory Review Act, and the Commonwealth Attorneys Act, the Department could have utilized the process required under those laws and "arrived at the same point with regulations adopted using the appropriate procedural requirements." (Petitioners' Brief at 30.)

The Court concludes that, at this preliminary point in the proceedings, Petitioners have presented sufficient evidence demonstrating a reasonable likelihood of success on the merits in at least two aspects. First, based upon the arguments advanced by Petitioners, the Regulations appear to be inconsistent with the legislative

intent of Chapter 20, which was to permit distribution of medical marijuana for purposes of and in conjunction with research studies conducted jointly with ACRCs. This is supported by the titles the legislature chose for Chapter 20, "Academic Clinical Research Centers," and for section 2003, "Research study." Further section 2003 specifically states, "[T]he [D]epartment may, upon application, **approve the dispensing of medical marijuana by a [CR] to the [ACRC] for the purpose of conducting a research study**." 35 P.S. §10231.2003 (emphasis added). Nothing in Chapter 20 of the Act appears to contemplate the sanctioning of commercial distribution of medical marijuana on a level that surpasses that which is permitted under Chapter 6.

It is of note that under Chapter 6, permittees are limited to dispensing at a maximum of **three separate locations**, with a restriction of no more than two grower/processor permits in each of the medical marijuana regions, whereas, under the Regulations, Chapter 20 permittees are permitted to distribute medical marijuana at up to **six locations**, with no more than three of its dispensaries to be located in the same medical marijuana region or county. *Compare* 28 Pa. Code §1141.23 (limitations on permits under Chapter 6), *and* Department of Health, Office of Medical Marijuana Bulletin No. 17-21, at 73 (Issued Jan. 7, 2017) (announcing Phase I), *with* 28 Pa. Code §1210.23(c) (limitations on permits under Chapter 20).

The Court also notes Petitioners' observation that, despite Chapter 20's apparent goal of research, the Regulations appear to require only a minimal commitment to research in order for a CR to obtain and retain a permit. Specifically, with regard to its plan for research, a CR applicant need only include a copy of its contract with a certified ACRC and a "description of the research projects the applicant and the certified ACRC intend to conduct." 28 Pa. Code §1210.27(7)(i)-(ii).

Moreover, under section 1210.31 of the Regulations, the only instance listed in which the Department will not renew a CR's approval is

> if the Department determines that **none** of the dispensary locations under the dispensary permit held by the approved [CR] are participating in an approved research project and the approved [CR] does not intend to commence any additional approved research projects within the first 6 months following the approval of its application for renewal.

28 Pa. Code §1210.31 (emphasis added). As Petitioners note in their application for a preliminary injunction, "[s]tated differently, the Chapter 20 Regulations as adopted required a CR to focus only 8% of its efforts on research (that is, during a one-year operating horizon, it must state that it 'intends' to conduct research over a 6-month period at 16% of its dispensary locations)." (Petitioners' Application for Preliminary Injunction at 11.)

Additionally, the legislature's choice to include a specific provision in section 2003(1)(v) of the Act regarding the reservation of intellectual property rights further supports the notion that Chapter 20 permittees were designed as research facilities and were not intended to engage in commercial distribution. Section 2003(1)(v) states that "the department may not require disclosure of any information that would infringe upon the [ACRC]'s exclusive right to intellectual property or legal obligations for patient confidentiality." 35 P.S. §10231.2003(1)(v). The Court finds meritorious Petitioners' argument that this section could be construed as the legislature's recognition that "the economic value of intellectual property that can be acquired through medical marijuana research studies and clinical trials is sufficient to justify the investment required for a medical marijuana grower/processor facility and related dispensaries dedicated solely to research, without any additional income stream

from the commercial sale of medical marijuana products outside of research studies and clinical trials." (Petitioners' Application for Preliminary Injunction at 16.)

In sum, it appears to the Court that the legislature did intend for CRs to exist exclusively for research purposes, since, otherwise, Chapter 20 would serve no purpose. If the legislature desired to simply increase the number of grower/processor and dispensary permits in urban areas, as Mr. John J. Collins, Director of the Office of Medical Marijuana testified, it could have done so by adding such a provision with specific geographical restrictions in Chapter 6. Likewise, if, as the Department contends, the legislature intended for some commercial medical marijuana entities to *also* conduct research, it could have added such a provision in Chapter 6. However, as Petitioners observe, since the legislature did neither of these things and instead chose to create a separate Chapter 20, this would suggest that it desired for these organizations to perform a function separate and unlike that of the organizations set forth in Chapter 6—namely, research, as the title of the chapter suggests. This interpretation is corroborated by the remarks of representatives of the General Assembly during floor debate. *See* Pa. Legislative Journal, Session of 2016, 200th of the General Assembly, No. 12, at 370 (Mar. 16, 2016) (Representative Joseph A. Petrarca) ("[The Act] creates a serious research component as has been asked for by many."); Pa. Legislative Journal, Session of 2016, 200th of the General Assembly, No. 23, at 636 (Apr. 13, 2016) (Representative Ron Marsico) ("[**The Senate's amendments did not change] the robust research component, one run by the Department of Health and the other by medical schools and hospitals.**" (emphasis added)). The two types of research programs Representative Marsico referred to are those set forth in Chapters 19 and 20, as outlined above.

In her amicus brief in support of the Department, Representative Watson makes several points, including that Chapter 20 was passed with two important goals in mind:

> First, to build an unprecedented collaboration between the most important research institutions in the Commonwealth and medical cannabis organizations with a research-based, clinically-oriented focus. Second, to make Pennsylvania a pioneer by mandating the development and execution of meaningful research on the efficacy of medical marijuana, the measurement of public health outcomes and patient quality of life.

(Rep. Watson's amicus brief at 2.) Representative Watson also states that the requirement that CRs have a minimum of $15,000,000 in capital is evidence "that the General Assembly meant to promote a separate pool of applicants for CRs with sufficient resources to invest in state-of-the art [sic] facilities and mechanisms to provide research." *Id.* at 8. These arguments, however, provide further support for the notion that the Department exceeded the scope of the Act by permitting CRs, *which were designed to conduct research*, to commercially sell medical marijuana on a scale that exceeds that which is authorized under Chapter 6.

Representative Watson observes that the Regulations require an entity possessing commercial permits under Chapter 6 that desires to become registered as a CR under Chapter 20 to surrender its permits, which are then placed back into the pool of available commercial permits. 28 Pa. Code §1210.28. However, this would suggest that CRs are not to conduct "commercial" activity and supports the point that CRs were designed to make their profits from intellectual property rather than commercial sales.

Representative Watson goes on to address Chapter 19 of the Act, stating, "In contrast [to Chapter 20], Chapter 19 establishes a medical marijuana research program for commercial permittees to engage in research if desired." (Rep. Watson's

amicus brief at 12.) She states that Chapter 19 directs the Department to develop the research program "to study the impact of medical marijuana on the treatment and symptom management of serious medical conditions," but notes that the program "shall not include a [CR] or [ACRC] under Chapter 20." *Id.* (quoting 35 P.S. §10231.1902). Representative Watson then cites to a February 13, 2018 letter to Mr. Collins that she authored along with Senator Mike Folmer, the "prime sponsor of Senate Bill 3":

> [C]linical registrants are medical marijuana organizations and are therefore allowed to sell medical marijuana products to any dispensary. This is because clinical registrants hold both a permit as a grower/processor and as a dispensary and because the exception to the definition of "medical marijuana organization" only includes a health care medical marijuana organization under Chapter 19. Under the act, a dispensary may obtain medical marijuana products from any grower/processor.

(Rep. Watson's amicus brief at 13.)[20] She contends that, had it been the legislature's intent, it could have included a provision limiting the ability of a CR to dispense medical marijuana, similar to that in Chapter 19, which excepts CRs and ACRCs from that research program.

Representative Watson is correct that Chapter 6 of the Act provides that both grower/processors and dispensaries "shall be authorized to receive a permit to operate as a medical marijuana organization to grow, process or dispense medical marijuana." 35 P.S. §10231.601. However, Representative Watson's point that the Act implicitly designates CRs as medical marijuana organizations authorized to commercially dispense medical marijuana is not supported by the Act. Only section

[20] Notably, this letter does not constitute legislative history and it is unclear what precedential value the letter has, if any, upon this Court.

1210.30(d) of the Regulations raises this issue, where it states that CRs shall have the same rights and obligations as "medical marijuana organizations." 28 Pa. Code §1210.30(d).[21] The Act does not make reference to nor designate CRs as medical marijuana organizations, which is simply further evidence that the Regulations do not track the language of the Act.

Thus, for the foregoing reasons, the Court cannot agree with the Department that, at this juncture, Petitioners have not demonstrated any likelihood of success on the merits because the "[R]egulations at issue in this case merely mirror the requirements of the [Act]." (Department's Brief at 18.)

Petitioners have also demonstrated a reasonable likelihood of success on their argument that the Regulations, by delegating the choice of CRs to ACRCs, may run afoul of Article 2, section 1 of the Pennsylvania Constitution. Pursuant to Article II, section 1 of the Pennsylvania Constitution, legislative power rests solely with the legislature. "Legislative power is the power to make a law and, thus, the General Assembly 'cannot constitutionally delegate the power to make law to any . . . other body or authority.'" *Washington v. Department of Public Welfare*, 71 A.3d 1070, 1087 (Pa. Cmwlth. 2013) (quoting *Blackwell v. State Ethics Commission*, 567 A.2d 630, 636 (Pa. 1989)).

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[21] This section states:

> An approved clinical registrant shall have the same rights and obligations as a medical marijuana organization that holds a grower/processor permit or a dispensary permit under sections 601-616 of the [A]ct (35 P.S. §§ 10231.601-10231.616) and Chapters 1141, 1151 and 1161 (relating to general provisions; growers/processors; and dispensaries), as applicable, subject to any modifications or limitations in sections 2001-2003 of the [A]ct (35 P.S. §§ 10231.2001-10231.2003) and this chapter.

28 Pa. Code §1210.30(d).

> Nevertheless, the legislature can make a law to delegate a power to determine some fact or state of things upon which the law makes, or intends to make, its own action depend. The legislature must make the basic policy choices, but it can impose upon others the duty to carry out the declared legislative policy in accordance with the general provisions of the statute. In that situation, it is the legislature which has legislated and not the administrative body.

Washington, 71 A.3d at 1088 (internal citations and quotation marks omitted). However, when the legislature delegates such power, it "must surround such authority with definite standards, policies and limitations to which such administrative officers, boards or commissions, must strictly adhere and by which they are strictly governed. If the legislature fails . . . to prescribe with reasonable clarity the limits of the power delegated or if those limits are too broad its attempt to delegate is a nullity." *Bell Telephone Co. of Pennsylvania v. Driscoll*, 21 A.2d 912, 915-16 (Pa. 1941).

In her amicus brief, Representative Watson argues that the Regulations do not delegate to ACRCs the authority to approve CRs and emphasizes that the requirement for a CR to have a contractual relationship with an ACRC is "one of *many* requirements imposed on the CR for registration under the Act." (Rep. Watson's amicus brief at 10.) However, the Court observes that, under the current Regulations, ACRCs apply for and receive approval *prior* to CRs. Within its application, an ACRC must list any payments it received from the CR with which it intends to partner. 28 Pa. Code §1210.25(c)(3). Moreover, under the Regulations, a CR applicant must produce a copy of its contract with the ACRC in conjunction with its application form. As Petitioners note, this may raise constitutional concerns in that it creates the appearance that the Department has delegated its duty to regulate the medical marijuana program by allowing ACRCs, at the very least, to narrow the field of CR applicants, given that ACRCs must already have selected the CR with which they intend to partner by the

time they submit their applications. Prospective CRs who have not, at that point, partnered with an ACRC seem to be *per se* disqualified from obtaining CR approval.[22] This is of particular concern in light of the fact that, during the hearing, the Court heard testimony that some of the potential CRs with which ACRCs have partnered were previously rejected by Department under Phase I.[23] Accordingly, for the these reasons, the Court concludes that Petitioners have demonstrated a reasonable likelihood of success on the merits.

2. Immediate and Irreparable Harm

Petitioners argue they will be irreparably harmed if the Regulations remain in effect pending resolution of this litigation because, by permitting non-permit winners to apply for CR status based solely upon the ability to secure a contract with an ACRC, the Regulations "rob Petitioners, who are existing permit winners, of significant value that will be lost forever" if the Regulations are implemented and the CR application process commences. (Petitioners' Application for Preliminary

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[22] In their applications, a potential CR must list the name of the certified ACRC with which it intends to partner, any payments made by the applicant to the ACRC, and a copy of its research contract with a certified ACRC, as well as a description of the research projects it intends to conduct with the certified ACRC. 28 Pa. Code. §1210.27(b)(2), (4), (7)(i), 7(ii). Thus, if a CR applicant is unable to form a partnership with an ACRC, it would not be able to include those required sections in its application and, as such, would presumably be denied approval. *See* 28 Pa. Code §1210.27(b) (stating that "[a]n application for approval of a [CR] submitted under this section **must** include" all of the listed items (emphasis added)).

[23] The Court is specifically referencing the testimony of Mr. Goldrath, who testified that Palliatech PA LLC, a company that applied for and was rejected during Phase I having been ranked 105 out of 177 applicants, has partnered with an ACRC. *See also* PENNSYLVANIA DEPARTMENT OF HEALTH, "Phase 1 Grower/Processor Applicant Evaluation Category Score Cards," at 9, http://www.health.pa.gov/My%20Health/Diseases%20and%20Conditions/M-P/MedicalMarijuana/Documents/PA%20DOH%20Phase%201%20Grower-Processor%20Evaluation%20Category%20Score%20Cards.pdf. The Court found Mr. Goldrath's testimony credible in its entirety.

Injunction at 4.) Additionally, Petitioners state that expanding the universe of potential CR applicants beyond existing permittees to include entities that have not already been approved as "worthy permit holders" by the Department—including entities who sought and were denied permits—dilutes Petitioners' hard-won rights as permittees and diminishes the value of their permits and, further, violates section 2001 of the Act, which defines a CR as an entity possessing both a grower/processor and dispensary permit. *Id.*

Petitioners further argue that the Regulations will cause immediate and irreparable harm to Petitioners because the "super-permits" they create will allow what the Act intended as research-only CR assets to be used to flood the commercial market for medical marijuana with products from up to 8 additional grower/processors and 48 additional dispensary locations. *Id.* Additionally, Petitioners state that, if non-permit holders are permitted to compete with Petitioners for CR status, Petitioners will be irreparably harmed because the pool of potential CR applicants will increase dramatically and their chances of securing CR status will decrease—a scenario, Petitioners state, they were not aware of when they invested in the permit process under Chapter 6 of the Act. Finally, Petitioners state that the CR process the Regulations initiate, once underway, will not be easily halted, reversed, or unwound even with a future ruling on the merits that invalidates the Regulations.

In response, the Department asserts that increased competition in a free market and potential lost profits due to that increased competition does not equate to irreparable harm. The Department cites *County of Luzerne v. Luzerne County Retirement Board*, 882 A.2d 531, 535 (Pa. Cmwlth. 2005), in which this Court held that the county did not demonstrate immediate and irreparable harm because the payment of current and prospective legal fees would not have impaired the actuarial soundness of a retirement fund.

The Department is correct that courts have held that there is no immediate and irreparable harm where a solely monetary injury is able to be adequately compensated by money damages, *id.*, or where the nature of the irreparable harm is speculative, *Novak v. Commonwealth*, 523 A.2d 318, 320 (Pa. 1987). However, courts have also held that, "[w]ith respect to equitable relief, the impending loss of a business opportunity is considered to be irreparable harm. An irreparable injury causes damage which can be estimated only by conjecture and not by an accurate pecuniary standard." *Carlini v. Highmark*, 756 A.2d 1182, 1188 (Pa. Cmwlth. 2000) (internal citations and quotation marks omitted).

Here, Petitioners have alleged an immediate loss of business value when the Regulations were implemented, as well as an imminent erosion of their market share when the permits are granted. Given that neither of these types of losses appear to lend themselves to precise valuation by an accurate pecuniary standard, Petitioners' imminent harm is fairly classified as immediate and irreparable.[24]

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[24] Here, the Court relies on Mr. Mooney's testimony during the hearing that Petitioners' "[m]arket share is going to go down relative to what it would be absent [the increase in supply of medical marijuana created by the Regulations]. So while we can't quantify that necessarily, it is . . . going to happen." (N.T., 5/3/18, at 93-94.) Mr. Mooney further testified,

> [Petitioners] would not [be able to realize the return that they originally anticipated] because, again, the volume of sales which all flows into the model of returns and [] value of a company, that all feeds the profits that investors value companies off of. That volume of sales will decrease and it will never come back. And these companies have not been able to establish themselves in the market to the level where they know, I've achieved this level of sales and then I know what it's going to drop to. That is—this is a new market, again. It's unknown what their sales record is going to be. They just started.

Id. at 94. The Court found Mr. Mooney's testimony, which establishes that it is not possible at this stage to assign an economic value to Petitioners' impending loss, credible in full.

Furthermore, courts of this Commonwealth have held that irreparable harm is demonstrated where a party credibly alleges violation of a statute and/or the Pennsylvania Constitution. *See SEIU Healthcare Pennsylvania v. Commonwealth*, 104 A.3d 495 (Pa. 2014) (reversing this Court's denial of a preliminary injunction holding that irreparable harm was demonstrated where the offending conduct was alleged to have violated both state statute and the Pennsylvania Constitution); *Milk Marketing Board v. United Dairy Farmers Co-op Association*, 299 A.2d 191 (Pa. 1973) (plurality) (affirming a finding of irreparable harm where the petitioners violated a state statute by selling milk below the minimum prices mandated by state law); *Pennsylvania Public Utility Commission v. Israel*, 52 A.2d 317 (Pa. 1947) (affirming the issuance of a preliminary injunction where the petitioners violated a state statute requiring taxicabs to have a certificate of public convenience); *Commonwealth ex rel Corbett v. Snyder*, 977 A.2d 28 (Pa. Cmwlth. 2009) (affirming the issuance of a preliminary injunction and a finding that irreparable harm is presumed where there was a credible violation of the consumer protection law).

Here, the Court finds that Petitioners have also sufficiently demonstrated immediate and irreparable harm where they have credibly alleged that the Department has adopted Regulations that violate the Act under which they were promulgated and violate the Pennsylvania Constitution. Accordingly, the Court concludes that Petitioners have met the immediate and irreparable harm requisite.

3. Greater Harm from Refusing Injunction

Petitioners contend that the harm they will suffer if refused a preliminary injunction is greater than the harm that would result for the Department or any other party if the injunction were granted. Specifically, Petitioners allege that neither the Department, nor potential CR applicants, will suffer harm if the process is put on hold

until the disparity between the Act's research-only intent for CRs and the Regulations' permit implementation is resolved. Petitioners state that if the CR/ACRC process is put on hold pending resolution of the fundamental CR/ACRC issues Petitioners raise, the only effect will be to delay implementation of the Regulations' "watered-down" research program while the Court considers whether the Act requires, as Petitioners contend, a much more robust research-only CR program to be conducted by permittees that the Department has already found to be most qualified. (Petitioners' Application for Preliminary Injunction at 20.)

Further, Petitioners state that a stay of the Regulations will provide existing permittees that desire CR status clarity on the issue of whether CR status is research-only, which may have a determinative effect on their decision to seek CR status at all. Likewise, Petitioners argue that entities seeking CR status that are not existing permittees will benefit from that determination. Thus, overall, Petitioners urge that the balancing of harms weighs heavily in favor of granting a preliminary injunction.

The Department responds by arguing that "[a]ny delay in implementation of the research provisions of the Act will result in grave harm to the public, which will face a delay in receiving the fruits of that research." (Department's Brief at 28.)

The Court takes particular note of the testimony of Mr. Collins at the hearing that it will take the Office of Medical Marijuana "a considerable amount of time" to review the CR applications, which are due July 12, 2018, and that, based upon what the Department observed during Phase I of the Chapter 6 process, it will take approximately one year from receipt of a permit for a CR to be able to release medical marijuana product and to "hav[e] it available for sale." (N.T., 5/2/18, at 124-25.) Mr. Collins' testimony was that the grant of a preliminary injunction in this case would be "quite simply, horrific" in that it would be "extremely disruptive to the patients that are

suffering in Pennsylvania." *Id.* at 125.[25] However, Mr. Collins' testimony overlooks the fact that Chapter 6 permittees already are currently dispensing medical marijuana to patients in Pennsylvania with a valid identification card. Moreover, notwithstanding Mr. Collins' testimony, nothing in the Act provides that CRs are permitted to dispense directly to patients or to "have it available for sale." Rather, they are permitted under section 2003 to dispense to ACRCs. 35 P.S. §10231.2003.

Thus, the Court finds Petitioners have satisfied this requisite because the potential harm Petitioners would suffer from the denial of a preliminary injunction is greater than that of the Department should the preliminary injunction be granted.

4. Restoration of *Status Quo*

The Court must also inquire as to whether a preliminary injunction will properly restore the parties to their status as it existed immediately prior to the alleged wrongful conduct. *Summit Towne Center, Inc.*, 828 A.2d at 1001. Petitioners assert that a preliminary injunction will restore all interested parties to the *status quo* that existed prior to the Regulations' implementation, noting that (1) the Regulations were implemented on March 17, 2018; (2) ACRC applications were available on April 5, 2018, and filed as of May 3, 2018; and (3) CR applications will be made available on May 24, 2018, and filed as of July 12, 2018. The Court agrees with Petitioners that a preliminary injunction issued now, enjoining the Department from applying the

[25] Relatedly, in her amicus brief, Representative Watson acknowledges that "like the *entirety* of Chapter 19, the provisions contained in Section 2003 (relating to research study) are not yet operative. This section only becomes operative when [the Department] approves the dispensing of medical marijuana by a CR to an ACRC." (Rep. Watson's Amicus Brief at 12) (emphasis in original). This point reinforces that there is no public harm in granting a preliminary injunction, given that the harm the Department contends the public will suffer—lack of research and commercial availability of medical marijuana under Chapter 20—is *already* occurring in that section 2003 is *not presently* operative and, according to Mr. Collins' testimony, is not likely to be for approximately one year, even under the best of circumstances.

Regulations, will leave all parties as they were until the underlying issues are resolved. As such, the Court concludes that Petitioners have satisfied this requisite.

5. Reasonably Suited to Abate Offending Activity

The Court must also determine whether the preliminary injunction Petitioners seek is "reasonably suited to abate the offending activity." *Id.* Here, the issuance of a preliminary injunction enjoining the Department from applying the Regulations is reasonably suited to abate the Department's offending conduct because it will prohibit the Department from awarding permits under the alleged unconstitutional Regulations.

6. Not Contrary to Public Interest

Finally, the Court must determine whether Petitioners have demonstrated that a preliminary injunction will not adversely affect the public interest. *Id.* Petitioners argue that it is in the public's interest to foster "high quality" research in medical marijuana and its uses. 35 P.S. §10231.102(3)(iii). However, Petitioners contend that the Regulations, as promulgated, "will do little to advance that goal" because they impose only a *de minimis* obligation on CRs to undertake research, despite Chapter 20's exclusive focus on research and intention to authorize the production and dispensing of medical marijuana for use only in clinical trials and other research purposes. (Petitioners' Application for Preliminary Injunction at 5.) Petitioners contend that the public's interest lies in "taking the time to get it right" before the Regulations go into effect and the CR application process commences because the short wait that will be occasioned by a preliminary injunction will be worth the properly-structured formal CR/ACRC program. *Id.* at 6.

The Court finds that Petitioners have satisfied this final requisite for a preliminary injunction. As noted above, should it be determined that the Regulations

are in violation of either the Act or the Constitution, their application is *per se* injurious to the public. As such, maintenance of the *status quo* will protect, rather than harm, the public.

C. Bond and Automatic Supersedeas

Finally, Petitioners request that the bond required by Pa.R.C.P. No. 1531[26] be set at the nominal amount of $100.00, arguing that no entity will sustain reasonably foreseeable damages in the event that it is later determined that the requested preliminary injunction was wrongfully issued. Further, Petitioners request relief from an automatic supersedeas pursuant to Pa.R.A.P. 1736(b),[27] given that the standards for

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[26] Rule 1531(b) provides,

> Except when the plaintiff is the Commonwealth of Pennsylvania, a political subdivision or a department, board, commission, instrumentality or officer of the Commonwealth or of a political subdivision, a preliminary or special injunction shall be granted only if
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> > (1) the plaintiff files a bond in an amount fixed and with security approved by the court, naming the Commonwealth as obligee, conditioned that if the injunction is dissolved because improperly granted or for failure to hold a hearing, the plaintiff shall pay to any person injured all damages sustained by reason of granting the injunction and all legally taxable costs and fees, or
> >
> > (2) the plaintiff deposits with the prothonotary legal tender of the United States in an amount fixed by the court to be held by the prothonotary upon the same condition as provided for the injunction bond.

Pa. R.C.P. No. 1531(b).

[27] This rule provides:

vacating an automatic supersedeas are substantially similar to those required for granting a preliminary injunction.

In order for the Court to vacate automatic supersedeas under Pa.R.A.P. 1736, Petitioners "must make a substantive case on the merits, demonstrating the stay will prevent [P]etitioner[s] from suffering irreparable injury, and establishing other parties will not be harmed and the grant of the stay is not against the public interest." *Department of Environmental Resources v. Jubelirer*, 614 A.2d 199, 203 (Pa. 1989). Petitioners have met this standard for the reasons set forth in the preceding analysis regarding the application for preliminary injunction, and Petitioners' request to vacate the automatic supersedeas, should the Department appeal this order, is hereby granted. Likewise, the Court grants Petitioners' request to set the bond at the nominal amount of $100.00, as no party is likely to be monetarily harmed in the event it is later determined that the preliminary injunction was improperly granted.

Conclusion

In conclusion, this matter is justiciable because Petitioners have standing, the matter is sufficiently ripe, Petitioners' remedy lies with this Court, and pre-enforcement review is appropriate in this case given that Petitioners have alleged a constitutional violation, for which administrative proceedings would do little to resolve. Further, Petitioners have satisfied the stringent criteria for the grant of a preliminary injunction by sufficiently demonstrating at this stage of the proceedings a

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> Unless otherwise ordered pursuant to this chapter the taking of an appeal by any party specified in Subdivision (a) of this rule shall operate as a supersedeas in favor of such party, which supersedeas shall continue through any proceedings in the United States Supreme Court.

Pa.R.A.P. 1736.

likelihood to succeed on the merits in that the Regulations apparently fail to genuinely track the meaning of the Act or to uphold the legislature's intent to implement a robust research program and, instead, appear to authorize commercial activity not provided for in the Act. In addition to the above, the Regulations appear to unlawfully delegate the Department's duty to issue the CR permits instead to ACRCs by first requiring from the CR applicant a contract with an ACRC, in violation of the non-delegation clause of the Pennsylvania Constitution. PA. CONST. art. 1, §2. There is *per se* harm when the Regulations violate the Act and Article 2, section 1 of the Pennsylvania Constitution. The issuance of the preliminary injunction will restore the parties to their prior *status quo* and promote the public interest by allowing a determination on the merits of this claim as to whether the Chapter 20 Regulations are consistent with the General Assembly's expressed intent to create a "high quality research" program for Pennsylvania's residents as opposed to another commercial component. The preliminary injunction will not impact current dispensation under Chapter 6 of the Act, nor research conducted pursuant to Chapter 19.[28]

Accordingly, the Court hereby grants Petitioners' application for a preliminary injunction enjoining the Department from applying the Regulations set forth in 28 Pa. Code §§1210.21-1210.37.

Patricia A. McCullough

PATRICIA A. McCULLOUGH, Judge

[28] Mr. Collins testified that, as of the date of the hearing, there were approximately "34,500 patients [] registered [for patient identification cards]" and "almost 15,000 [patient identification] cardholders." (N.T., 5/2/18, at 127.) Mr. Collins further testified that "24,800 dispensing events have occurred since February 15th [2018]." *Id.*

IN THE COMMONWEALTH COURT OF PENNSYLVANIA

AES Compassionate Care, LLC, BAY, LLC, Chamounix Ventures, LLC, Cresco Yeltrah, LLC, GTI Pennsylvania, LLC, GuadCo, LLC, Ilera Healthcare, LLC, Keystone Center of Integrative Wellness, LLC, Pennsylvania Medical Solutions, LLC, Standard Farms, LLC, and The Healing Center, LLC, Petitioners	:	
	:	No. 233 M.D. 2018
v.	:	
Rachel L. Levine, MD, Acting Secretary, Pennsylvania Department of Health, Respondent	:	

ORDER

AND NOW, this 22nd day of May, 2018, the Court hereby orders the following:

1. The application for special relief in the nature of a preliminary injunction enjoining the Pennsylvania Department of Health (Department) from applying its March 17, 2018 temporary regulations, 28 Pa. Code §§1210.21-1210.37 (Regulations), relating to implementation of the academic research provisions of Chapter 20 of the Medical Marijuana Act (Act), Act of April 17, 2016, P.L. 84, 35 P.S. §§10231.2001-10231.2003, filed by AES Compassionate Care, LLC, BAY, LLC, Chamounix Ventures, LLC, Cresco Yeltrah, LLC, GTI Pennsylvania, LLC, GuadCo, LLC, Ilera Healthcare, LLC, Keystone Center of Integrative Wellness, LLC, Pennsylvania Medical Solutions, LLC,

Standard Farms, LLC, and The Healing Center, LLC (Petitioners) is hereby granted.

2. Petitioners shall post a bond pursuant to Pa.R.C.P. No. 1531 in the amount of $100.00.

3. In the event that Dr. Rachel Levine, Acting Secretary of Health, appeals this order, such appeal shall not act as an automatic supersedeas pursuant to Pa.R.A.P. 1736(b).

Patricia A. McCullough

PATRICIA A. McCULLOUGH, Judge

Certified from the Record

MAY 22 2018

and Order Exit