#### IN THE COMMONWEALTH COURT OF PENNSYLVANIA

Drug and Alcohol Service Providers : Organization of Pennsylvania, :

Petitioner

:

v. : No. 271 M.D. 2021

Heard: October 28, 2021

FILED: December 9, 2021

Commonwealth of Pennsylvania,

Department of Drug and Alcohol

Programs and Commonwealth of :

Pennsylvania, Department of Human

Services, :

Respondents:

BEFORE: HONORABLE MICHAEL H. WOJCIK, Judge

OPINION NOT REPORTED

MEMORANDUM OPINION BY JUDGE WOJCIK

Before the Court is Drug and Alcohol Service Providers Organization of Pennsylvania's (Petitioner) application for special relief in the nature of a preliminary injunction (Application), and the answer in opposition thereto (Answer) filed by Respondents Commonwealth of Pennsylvania, Department of Drug and Alcohol Programs (DDAP) and Department of Human Services (DHS) (together, Respondents). At the core of Petitioner's Application is the requirement in Act 70 of 2021 that "drug and alcohol treatment provider[s] shall align service delivery conditions with the American Society of Addiction Medicine [ASAM] Criteria, 3rd Edition, 2013." Section 2302-A of the Administrative Code of 1929 (Administrative Code), Act of April 9, 1929, P.L. 177, No. 175, as amended, added by the Act of July 9, 2021, P.L. 377, No. 70 (Act 70), 71 P.S. § 613.2. Essentially, Petitioner

argues that Respondents' guidance to treatment providers regarding the ASAM Criteria constitutes rulemaking subject to the regulatory review process and is an unconstitutional delegation of authority to private entities. After a hearing, argument, and written submissions, the Application is ripe for disposition.

# I. Background

The pertinent facts are as follows. Petitioner is a statewide non-profit organization of drug and alcohol addiction treatment and prevention programs. Petitioner's membership includes approximately 300 licensed addiction treatment programs located throughout the Commonwealth, spanning the full continuum of drug and alcohol treatment including outpatient services, intensive outpatient services (IOP), inpatient services, and both hospital and non-hospital detoxification.

DDAP oversees and administers certain funding sources for drug and alcohol treatment providers throughout the Commonwealth. DDAP is also responsible for licensing drug and alcohol treatment providers and establishing standards for staffing at treatment facilities. In turn, DHS is the agency responsible for administering the Commonwealth's Medicaid program, known as Medical Assistance (MA), which provides payment for certain healthcare services, including drug and alcohol treatment, for many Pennsylvanians.

Drug and alcohol treatment services in the Commonwealth are set up at the county level through a multi-step process. DHS enters into agreements with counties, which in turn create or contract with behavioral health managed care organizations (BH-MCOs). It is the BH-MCOs that actually contract with providers for addiction treatment services. DHS oversees the BH-MCOs in order to implement and enforce applicable federal and state laws and regulations.

<sup>&</sup>lt;sup>1</sup> This function was previously performed by the Office of Drug and Alcohol Programs within the Department of Health. DDAP was created as a separate department in 2010.

Of note herein, DHS is required to "[u]se criteria developed by [DDAP] for governing the type, level and length of care or treatment, including hospital detoxification, as a basis for the development of standards for services" for individuals eligible for MA. Section 2334 of the Administrative Code, 71 P.S. § 611.14(b)(2).<sup>2</sup> In accordance with this statutory direction, DDAP developed the Pennsylvania Client Placement Criteria (PCPC), a set of guidelines used by DHS, DDAP, and the BH-MCOs regarding service delivery conditions for drug and alcohol treatment providers. DDAP has updated the PCPC twice since the initial version was developed. Neither the initial version of the PCPC nor the updates went through the formal regulatory review process.

In July 2021, Act 70 was passed by the General Assembly and signed into law by the Governor. In pertinent part, Act 70 effected a change in the guidelines to be used by DHS and DDAP regarding the provision of drug and alcohol treatment services—specifically, a change from the PCPC to the ASAM Criteria. *See* 71 P.S. § 613.2. The relevant Section of Act 70, titled "Service alignment", provides:

- (a) Requirement.--Except as provided under subsection (b), a drug and alcohol treatment provider shall align service delivery conditions with the [ASAM] Criteria, 3rd Edition, 2013.
- (b) Exception.--Substantial compliance with alignment of service delivery conditions under the [ASAM] Criteria, 3rd Edition, 2013, shall be required by July 1, 2021, except if [DDAP] grants an application as follows:
- (1) A drug and alcohol treatment provider may file an application requesting an extension in substantially aligning with service delivery conditions by July 9, 2021.

<sup>&</sup>lt;sup>2</sup> Section 2334 was added by the Act of December 15, 1988, P.L. 1239, No. 152.

- (2) A submitted application shall address a provider's reasons for needing the extension for substantial compliance. Extensions under this subsection may be granted until December 31, 2021.
- (c) Development.--[DDAP], in consultation with [DHS], shall develop the application under subsection (b).

*Id.* Act 70 went into effect on September 7, 2021.

#### II. The Petition for Review

On August 12, 2021, Petitioner filed a petition for review (Petition) in this Court's original jurisdiction seeking both declaratory and injunctive relief. The Petition asserts that Respondents' transition from the PCPC to the ASAM Criteria constitutes rulemaking subject to the regulatory review process established by the Commonwealth Documents Law (CDL),<sup>3</sup> the Regulatory Review Act (RRA),<sup>4</sup> and the Commonwealth Attorneys Act (CAA).<sup>5</sup> Petitioner argues that Respondents failed to undertake this mandatory process and, instead, have attempted to communicate with providers and carry out the transition through a series of informal means, including memoranda, guidance documents, FAQs, etc. According to Petitioner, the changes brought about through these informal means are changes to existing regulations that have immediate effect and the force of law and, therefore, must go through the formal rulemaking process in order to be valid.

More pointedly, the Petition asserts that "DDAP has used the purported transition to ASAM 'service delivery conditions' as a pretense for establishing

<sup>&</sup>lt;sup>3</sup> Act of July 31, 1968, P.L. 769, as amended, 45 P.S. §§ 1102-1602; 45 Pa.C.S. §§ 501-907.

<sup>&</sup>lt;sup>4</sup> Act of June 25, 1982, P.L. 633, as amended, 71 P.S. §§ 745.1-745.14.

<sup>&</sup>lt;sup>5</sup> Act of October 15, 1980, P.L. 950, as amended, 71 P.S. §§ 732-101 – 732-506.

burdensome, new and needless requirements that (i) change, and extend far beyond, existing regulations, and (ii) are found nowhere in the ASAM Criteria . . . . " Petition ¶ 33. Petitioner takes issue with what it categorizes as three "new requirements" that are being advanced by Respondents:

- 34. For example, as part of its "ASAM transition" project, DDAP purports to require a 15:1 counselor to client ratio for [IOP] services. . . . This mandatory 15:1 ratio would require [IOP] programs to more than double their counselor staff, at a time when the addiction treatment field is already facing serious workforce shortages; leaves no room for treatment programs to plan around inevitable no-shows; and requires programs to promptly discharge no-show patients in order to protect their ratios (because the program cannot get paid for a patient who does not show), no matter what the reason was for the patient's failure to attend.
- 35. For another example, as part of its ASAM transition project, DDAP purports to establish new levels service for residential addiction treatment. including 6-8 hours of clinical services 7 days a week, and requires programs to run a minimum of two 2hour group therapy sessions every day. . . . These requirements appear nowhere in current Pennsylvania regulations and nowhere in the ASAM Criteria . . . . Petitioner hastens to add that while additional services might sound salutary to those unfamiliar with addiction, the 7-day undifferentiated workload mandated by DDAP would deprive patients of the time they need to do assigned homework, do family work, attend educational seminars that are not therapy, and process and consolidate all they have learned. More generally, DDAP's approach gives altogether too little credit to how hard the necessary work of early recovery can be.
- 36. For another example, as part of its "ASAM transition" project, DDAP purports to **impose new licensure and certification requirements** that extend beyond the qualifications for clinical supervisors,

counselors, and counselor assistants set forth in current Pennsylvania regulations. . . .

Petition ¶¶ 34-36 (emphasis added).<sup>6</sup> Petitioner asserts that because Respondents failed to undertake the formal rulemaking process with respect to these "new requirements," they must be declared a nullity. In addition, Petitioner maintains that the "new requirements" have imposed and will continue to impose significant, additional costs on drug and alcohol treatment providers, and have made it more difficult for providers to hire and retain qualified staff. According to Petitioner, some program providers will be forced to close their doors due to additional costs or their sheer inability to meet the "new requirements."

The Petition also claims that the ASAM transition is an unconstitutional delegation of authority to private entities in violation of article II, section 1 of the Pennsylvania Constitution.<sup>7</sup> The Petition maintains that Respondents have left the work of establishing the standards that regulate treatment facilities—and the determination of what care MA patients receive, where they receive it, and for how long—to unaccountable, wholly private organizations, namely ASAM and the forprofit company that publishes the ASAM Criteria. Petitioner argues that drug and alcohol treatment providers must now use these private entities for training, written materials, and computer software, which must be purchased by providers when the PCPC criteria was available to anyone, free of cost, via Respondents' websites.

<sup>&</sup>lt;sup>6</sup> For ease of reference, the three criteria outlined in paragraphs 34 through 36 of the Petition will be referred to throughout the rest of the opinion as the "new requirements."

<sup>&</sup>lt;sup>7</sup> That section provides that "[t]he 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. II, § 1.

Given the above averments, the Petition requests an order from this Court declaring that Respondents are required to use the PCPC in making addiction treatment, placement, continued stay, and discharge decisions; enjoining Respondents from using or requiring the use of the ASAM Criteria; and enjoining further implementation of the transition from the PCPC to the ASAM Criteria. Further, the Petition requests a declaration that requiring the use of the ASAM Criteria constitutes an unconstitutional delegation of authority to private entities in violation of article II, section 1 of the Pennsylvania Constitution. In the alternative, the Petition seeks an order from this Court declaring that the transition from the PCPC to the ASAM Criteria constitutes a regulation subject to the formal notice, comment, and review procedures; and enjoining further implementation of the ASAM transition pending Respondents' completion of the regulatory review process.

# **III. The Present Application**

On September 15, 2021, after Act 70 went into effect, Petitioner filed the instant Application along with a supporting brief. In further support of the Application, Petitioner also submitted declarations from various elected officials and addiction treatment professionals attesting to the costs and other purported harms they believe will befall drug and alcohol treatment providers—and the Commonwealth citizens who require their services—if the ASAM transition is allowed to continue. The declarations were provided by the following individuals: Gene DiGirolamo, Bucks County Commissioner and former member of the Pennsylvania House of Representatives; Kim Bowman, retired Director of Human Services for Chester County and former Deputy Secretary for DDAP; John E. Dillensnyder, III, Executive Director of Treatment Trends, Inc., a non-profit

organization providing drug and alcohol treatment services in Lehigh County; Robert N. Dellavella, J.D., Chief Executive Officer (CEO) of Self Help Movement, Inc., a non-profit organization providing drug and alcohol treatment services in Northeast Philadelphia; David Blenk, President and CEO of Livengrin, an addiction treatment services provider; Louis E. Wagner, Jr., President and CEO of SpiritLife, Inc., a non-profit, faith-based inpatient detoxification and rehabilitation facility; and Chet Leech, President and CEO of Davis Archway, an addiction treatment services provider in Butler County. *See* Application, Exhibits A through H, respectively.

As for the relief sought, Petitioner's Application specifically requests that the Court

enter an Order enjoining Respondents, its agents, servants, and officers, and others from implementing, enforcing, or taking any steps to implement or enforce the transition from the PCPC to ASAM or the alignment of service delivery conditions with or under the ASAM Criteria . . . pending final determination of this case.

Application, Wherefore Clause, at 17-18. Petitioner's Application also states that it seeks an Order from this Court

that preserves the status quo by (a) requiring DDAP and DHS to follow the established rulemaking process of Pennsylvania law and (b) preventing DDAP and DHS from enforcing or moving forward with the ASAM alignment and other aspects of the ASAM transition, until such formal regulatory review process has been completed and until the Constitutional issues raised in the Petition . . have been resolved.

# Application ¶ 1.

Respondents subsequently filed an Answer in opposition to the Application, as directed by this Court, as well as Preliminary Objections to the

Petition (POs).<sup>8</sup> Respondents submitted declarations from the following three individuals in support of their Answer: Dawn Hamme, Director for the Bureau of Financial Management and Administration in DHS's Office of Mental Health and Substance Abuse Services (OMHSAS); Benny Varghese, Division Director for OHMSAS; and Jennifer Smith, Secretary for DDAP (Secretary Smith). *See* Answer, Exhibits 1 through 3, respectively.

Respondents claim that Petitioner is not able to establish any of the prerequisites for a preliminary injunction to issue, let alone all of them. Respondents argue that the ASAM transition outlined in Act 70 is a self-executing legislative mandate and, therefore, Respondents are not required to promulgate the ASAM Criteria as regulations. Moreover, Respondents contend that the mandate is not an unconstitutional delegation of authority because it requires the use of a specific, and existing, set of service requirements, i.e. the ASAM Criteria, 3rd Edition, 2013.

Respondents also maintain that the requested injunctive relief should be denied because it would create more harm than it would abate, as attested to in Respondents' supporting declarations. Specifically, Respondents assert that halting the ASAM transition would render DHS in non-compliance with a waiver it received from the Centers for Medicare and Medicaid Services (CMS), thus jeopardizing the Commonwealth's receipt of millions of dollars in annual federal Medicaid funding for drug and alcohol treatment services. Respondents further argue that the asserted harm that would befall providers is speculative, noting that Act 70 explicitly gave providers the ability to request an extension of time until December 31, 2021, to come into full compliance with the ASAM Criteria. In addition, Respondents note

<sup>&</sup>lt;sup>8</sup> Respondents assert POs to the Petition on the basis of demurrers, pursuant to Pa.R.Civ.P. 1028(a)(4). Because those POs are not before the Court at this time, the specific arguments raised therein will not be discussed.

that they first signaled their intention to transition to the ASAM Criteria in 2017 and, since that time, DDAP has been providing training courses for drug and alcohol program staff. Moreover, DHS asserts that its agreements with the counties and, where applicable, the BH-MCOs, have required providers to comply with the ASAM Criteria since January 1, 2019. Given these facts, Respondents maintain that implementation of the ASAM Criteria has already occurred and providers are now aligned, or have substantially aligned their service delivery conditions with it. Therefore, granting the injunction would cause confusion among providers and would not preserve the status quo, but disrupt or unwind it.

The Court held a hearing on the Application on October 28, 2021, at which Petitioner and Respondents both presented witness testimony as well as documentary evidence. Petitioner presented the following witnesses, each of whom also provided a declaration in support of the Application: Kim Bowman; David Blenk; Gene DiGirolamo; Louis Wagner, Jr.; John Dillensnyder; Robert Dellavella; and Chet Leech. Petitioner also called Secretary Smith, as on cross.

Respondents presented testimony from the following witnesses: Secretary Smith; Jamie Drake, Executive Director of the Carbon Monroe Pike Drug and Alcohol Commission; and Dawn Hamme. The parties also submitted posthearing memoranda of law for the Court's consideration.

The Court notes that during the hearing, Petitioner appeared to abandon its broad request for injunctive relief as outlined in the Petition and the Application itself. As Counsel for Petitioner explained during opening arguments:

The Commonwealth of Pennsylvania went down the road of using something called the . . . ASAM [C]riteria as a placement tool for people who were enrolled in Medicaid and needed addiction treatment services.

. . .

And we are not here today at the injunction stage to challenge that decision . . . .

We are not here today to challenge the use of the ASAM [C]riteria as a placement tool.

Hearing Transcript, 10/28/21, 9:14-19, 10:1-2 & 6-7.

Rather than seeking to enjoin Respondents from implementing the transition from the PCPC to the ASAM Criteria *in toto*, Petitioner instead focused at the hearing on DDAP's informal guidance on the transition, e.g. the "new requirements" discussed *supra*, arguing that these are new regulations that must go through the formal notice, comment, and review process in order to be valid. Moreover, the treatment providers who testified on behalf of Petitioner specifically discussed the harms they perceive as attendant to DDAP's "new requirements."

Petitioner subsequently confirmed the amendment of its requested injunctive relief in its post-hearing brief, stating that it "seeks a preliminary injunction[] prohibiting [DDAP] and [DHS] from implementing, enforcing, promulgating, or requiring compliance with" the three "new requirements." Petitioner's Brief, 11/8/2021 at 1-2. Petitioner's post-hearing brief also framed the question presented as follows:

Question: Whether Petitioner has established a right to a preliminary injunction prohibiting DDAP and DHS from implementing, enforcing, promulgating, or requiring compliance with standards regarding 1:15 counselor to client ratios for [IOP] [t]reatment; hours of clinical service requirements for residential treatment [] of 6-8 hours per day, 7 days a week with a minimum of two 2-hour group therapy session[s]; and a requirement that all staff be licensed by the Commonwealth of Pennsylvania or credentialed by the Pennsylvania Certification Board.

*Id.* at 3. With this in mind, the Court now turns to the merits of the Application.

# IV. Analysis A. Preliminary Injunction Standard

A preliminary injunction is an extraordinary remedy, the purpose of which "is to preserve the status quo and prevent imminent and irreparable harm that may occur before the merits of the case can be heard and resolved." *Nether Providence Township v. Coletta*, 133 A.3d 86, 91 (Pa. Cmwlth. 2016). It is well established that a court may grant a preliminary injunction only where a petitioner demonstrates<sup>9</sup> each of the following factors:

(1) the injunction is necessary to prevent immediate and irreparable harm that cannot be compensated adequately by damages; (2) greater injury would result from refusing the injunction than from granting it, and, concomitantly, the issuance of an injunction will not substantially harm other interested parties in the proceedings; (3) the preliminary injunction will properly restore the parties to their status as it existed immediately prior to the alleged wrongful conduct; (4) the party seeking injunctive relief has a clear right to relief and is likely to prevail on the merits; (5) the injunction is reasonably suited to abate the offending activity; and, (6) the preliminary injunction will not adversely affect the public interest.

SEIU Healthcare Pennsylvania v. Commonwealth, 104 A.3d 495, 502 (Pa. 2014) (citing Warehime v. Warehime, 860 A.2d 41, 46-47 (Pa. 2004); Summit Towne Centre, Inc. v. Shoe Show of Rocky Mount, Inc., 828 A.2d 995, 1001 (Pa. 2003)). Because a preliminary injunction is a harsh and extraordinary remedy, it "is to be granted only when and if each [factor] has been fully and completely established." Pennsylvania AFL-CIO v. Commonwealth, 219 A.3d 306, 318 (Pa. Cmwlth. 2019)

<sup>&</sup>lt;sup>9</sup> Pennsylvania Rule of Civil Procedure 1531(a) specifies: "In determining whether a preliminary . . . injunction should be granted . . . , the court may act on the basis of the averments of the . . . petition and may consider affidavits of parties or third persons or any other proof which the court may require." Pa.R.Civ.P. 1531(a).

(quotation omitted). For purposes of convenience and clarity, the Court begins with the fourth criterion for a preliminary injunction pertaining to the merits of Petitioner's claims.

## B. Clear Right to Relief

"For a right to be clear, it must be 'more than merely viable or plausible;' however, this requirement is not the equivalent of stating that no factual disputes exist between the parties." *Wolk v. School District of Lower Merion*, 228 A.3d 595, 611 (Pa. Cmwlth. 2020) (citing *Ambrogi v. Reber*, 932 A.2d 969, 980 (Pa. Super. 2007)). As our Supreme Court has further explained, "[t]o establish a clear right to relief, the party seeking an injunction need not prove the merits of the underlying claim, but need only demonstrate that substantial legal questions must be resolved to determine the rights of the parties." *SEIU Healthcare*, 104 A.3d at 506 (citing *Fischer v. Department of Public Welfare*, 439 A.2d 1172 (Pa. 1982)).

In this case, the Petition asserts that the ASAM transition mandated in Act 70<sup>10</sup> is an unconstitutional delegation of authority to private entities in violation of article II, section 1 of the Pennsylvania Constitution. Petitioner points out that "[t]o avoid violating this provision, the General Assembly must make the "basic policy choices involved in its 'legislative power'" when it authorizes some other entity to act." *Pennsylvania AFL-CIO*, 219 A.3d at 314 (quoting *Protz v. Workers' Compensation Appeal Board (Derry Area School District)*, 161 A.3d 827, 833 (Pa. 2017)). Petitioner contends that the General Assembly abdicated the initial, important policy choice of establishing criteria for the provision of drug and alcohol

<sup>&</sup>lt;sup>10</sup> Given the statements made during the hearing before this Court and in Petitioner's post-hearing brief, it is unclear whether Petitioner has now abandoned this argument. Notwithstanding, the Court will address the issue out of an abundance of caution.

treatment services to private entities, namely ASAM and the for-profit company that distributes the ASAM Criteria and attendant materials.

It is well settled, however, that "if the General Assembly **adopts an existing set of standards** as its own, there is **no delegation** and no violation of article II, section 1 of the Pennsylvania Constitution." *Pennsylvania AFL-CIO*, 219 A.3d at 314 (emphasis in original). As our Supreme Court has stated

it is important to clarify that the non-delegation doctrine does not prevent the General Assembly from adopting as its own a particular set of standards which already are in existence at the time of adoption. However, . . . the non-delegation doctrine prohibits the General Assembly from incorporating, sight unseen, subsequent modifications to such standards without also providing adequate criteria to guide and restrain the exercise of the delegated authority.

#### Protz, 161 A.3d at 838-39 (citation omitted).

The key fact here is that Act 70 requires drug and alcohol treatment providers to align their service delivery conditions with a **specific and existing** set of requirements—the ASAM Criteria, 3rd Edition, 2013. Moreover, Act 70 does not contemplate the incorporation of subsequent editions or modifications to the ASAM Criteria, sight unseen, as was the concern in *Protz*. Given the plain language of Act 70, it appears that there is no delegation of authority here and, thus, Petitioner is not likely to succeed on its article II, section 1 claim.

Next, the Court turns to Petitioner's claim that Respondents have instituted new regulations without going through the formal notice, comment, and review procedures. Again, the Court notes that Petitioner appears to have voluntarily abandoned its broad request for relief as stated in both the Petition and the Application, wherein Petitioner specifically sought to enjoin the transition to the

ASAM Criteria in its entirety. As stated during the hearing on the Application and in post-hearing briefs, Petitioner now appears to have limited its request for injunctive relief to the three "new requirements" that Respondents purportedly imposed upon providers through informal means. Irrespective of exactly what Petitioner is seeking to enjoin, it has not demonstrated a likelihood of success on the merits.

As Respondents note, Section 204 of the CDL specifically allows an administrative agency to "omit or modify" the notice, comment, and review requirements when "[t]he administrative regulation or change therein relates to[] . . . the interpretation of a self-executing act of Assembly . . . ." 45 P.S. § 1204(1). Self-executing statutes have been defined as "those which are mandatory in nature and require no further legislative action in order to become effective." *Success Against All Odds v. Department of Public Welfare*, 700 A.2d 1340, 1351 (Pa. Cmwlth. 1997). Here, the language of Act 70 is clear and no further legislation is necessary to effectuate the General Assembly's mandate that drug and alcohol service providers align their service delivery conditions with the ASAM Criteria. Therefore, it appears that Respondents were within their rights to omit the formal notice and comment requirements with respect to the ASAM Criteria itself.

Next, we address Petitioner's claim regarding the three purported "new requirements" outlined above. Petitioner maintains that the requirements go beyond mere guidance and instead create new, binding norms. As such, Petitioner maintains that they are regulations that must go through the formal notice, comment, and review process, and that Section 204 of the CDL does not apply.<sup>11</sup> However, a

Respondents do not dispute the fact that the three "new requirements" Petitioner complains of were not subject to the formal notice and comment procedures prior to being issued. (Footnote continued on next page...)

review of the evidence presented in the case, to date, demonstrates that the "new requirements" are not regulations but rather non-legislative rules or guidance documents.

The CDL mandates that, prior to promulgating a regulation, agencies must give notice to the public and an opportunity for comment. *See* Sections 201 & 202 of the CDL, 45 P.S. §§ 1201, 1202. However, the CDL further provides that agencies may omit or modify the notice and comment procedures when issuing policy statements, <sup>12</sup> otherwise known as interpretive rules. *See* Section 204(1) of the CDL, 45 P.S. § 1204(1); *see also Success Against All Odds*, 700 A.2d at 1351; *Eastwood Nursing and Rehabilitation Center v. Department of Public Welfare*, 910 A.2d 134, 142-43 (Pa. Cmwlth. 2006); *R.M. v. Pennsylvania Housing Finance Agency*, 740 A.2d 302, 306 (Pa. Cmwlth. 1999).

Rather, Respondents themselves assert that the "new requirements" were relayed to providers through a variety of informal means such as guidance documents, interpretive memoranda, and policy statements.

- (12) "Regulation" means any rule or regulation, or order in the nature of a rule or regulation, promulgated by an agency under statutory authority in the administration of any statute administered by or relating to the agency, or prescribing the practice or procedure before such agency.
- (13) "Statement of policy" means any document, except an adjudication or a regulation, promulgated by an agency which sets forth substantive or procedural personal or property rights, privileges, immunities, duties, liabilities or obligations of the public or any part thereof, and includes, without limiting the generality of the foregoing, any document interpreting or implementing any act of Assembly enforced or administered by such agency.

45 P.S. § 1102(12) & (13).

<sup>&</sup>lt;sup>12</sup> Section 102 of the CDL provides the following relevant definitions:

### As our Supreme Court has further explained

[n] on-legislative rules—more recently couched . . . as "guidance documents"—comprise a second category of agency pronouncements recognized in administrative law practice. These "come in an abundance of formats with a diversity of names, including guidances, manuals, interpretive memoranda, staff instructions, statements, circulars, bulletins, advisories, press releases Robert A. Anthony, Commentary, A and others." Taxonomy of Federal Agency Rules, 52 ADMIN. L.REV. 1045, 1046 (2000). When such documents fairly may be said to merely explain or offer specific and conforming content to existing statutes or regulations within the agency's purview, they are regarded as "interpretive rules," which generally are exempt from notice-andcomment rulemaking and regulatory-review requirements. Additionally, "statements of policy"—or agency pronouncements which are not intended to bind the public and agency personnel, but rather, merely express an agency's tentative, future intentions—also are not regulations subject to [the regulatory review process].

Northwestern Youth Services, Inc. v. Department of Public Welfare, 66 A.3d 301, 310-11 (Pa. 2013) (some internal citations omitted). Moreover, "interpretive rules or regulations[] which 'do not in themselves establish binding standards of conduct . . . need not be promulgated in accordance with the CDL to the extent they merely construe a statute and do not improperly expand upon its terms." Victory Bank v. Commonwealth, 219 A.3d 1236, 1243 (Pa. Cmwlth. 2019) (quoting Borough of Pottstown v. Pennsylvania Municipal Retirement Board, 712 A.2d 741, 743 (Pa. 1998)). Here, Petitioner has failed to present credible evidence that the three "new requirements" it takes issue with establish binding standards or improperly expand upon Act 70's terms.

To the contrary, Secretary Smith credibly testified that what Petitioner refers to as the "new requirements" are not actually mandates imposed by DDAP, but rather guidance DDAP has given to providers with respect to the ASAM transition. The following exchange between Respondents' Counsel and Secretary Smith is illustrative:

Q Secretary Smith, I want the record to be very clear. With respect to the 1 to 15 [counselor-to-client] ratio that you were being asked about, is that a requirement from the Department [DDAP]?

A It is not a requirement.

Q What is the requirement for the IOP level of service under the ASAM [C]riteria? And if you need to reference the document, you can do that.

A I've got that one down pat. The requirement according to the ASAM [C]riteria for [IOP] is 9 to 19 hours of service per week.

Q And so if a provider can show that they are [sic] meeting the ASAM [C]riteria, are they [sic] compliant with that level of care or requirement?

A Yes.

.

Q So is the six to eight hours [of clinical services] a hard and fast requirement?

A It is not.

Hearing Transcript, 10/28/21, 133:20-134:9, 135:16-18. *See also id.*, 138:11-16 (reiterating there is no requirement for two, two-hour blocks of service in any of the levels of drug and alcohol treatment).<sup>13</sup>

<sup>&</sup>lt;sup>13</sup> Secretary Smith's testimony is bolstered by that of Jamie Drake, Executive Director of the Carbon Monroe Pike Drug and Alcohol Commission. Ms. Drake testified that she has worked with Respondents since 2017 to aid in her agency's transition to the ASAM Criteria, that her agency is in substantial compliance with the ASAM Criteria, and that the 1-to-15 ratio is not a "black and white" requirement. Hearing Transcript, 10/28/21, 213:14-214:14.

As for the certification of drug and alcohol treatment staff, Secretary Smith testified as follows:

So [DDAP's] regulations allow for three different criteria to meet in order to provide clinical services. One is licensure. The second is credentialing certification. Then the third is a combination of experience and education.

So when you apply the ASAM [C]riteria, they are very specific in their language when they say that staff need to be licensed or credentialed. So you would make the assumption that that would eliminate the possibility that our regulations allow for which [is] that education and experience component.

What we've done is allow for some grandfathering of current individuals who are meeting that education and experience requirement in our regulations and are currently delivering clinical services, we have allowed them to continue to function in that role of providing clinical services as long as they remain in that position or within the same career track within the provider that they currently work for.

. . .

In addition to the grandfathering, we've also allowed for individuals the opportunity to be considered as working toward their certification.

*Id.*, 136:21-137:17, 137:25-138:3. Petitioner failed to present any credible evidence to refute this testimony.

Moreover, Respondents provided ample evidence that DDAP has repeatedly communicated to providers that the so-called "new requirements" are merely guidelines and not, in fact, strict requirements. Secretary Smith testified that (1) providers received "a slew" of guidance materials stating that the counselor-to-client ratio is merely a guideline, *see* Hearing Transcript, 10/28/21, 115:20-25; (2)

DDAP issued guidance to providers in April 2021 explaining that the daily clinical service hours were only recommendations, *see id.* at 117:4-11; and (3) DDAP's guidance specifically included information regarding the "grandfathering" of treatment staff credentialed through experience and education, *see id.* at 137:18-24. *See also* Exhibits R-12 (DDAP document titled "ASAM Clarification and Flexibility", dated 4/28/2021); Exhibit R-14 (The ASAM Criteria, 3rd Edition, 2013).

Given the above, it is clear to the Court that Respondents do not view the "new requirements" as mandatory, that the "new requirements" do not create a binding norm, and that Respondents have communicated this fact to providers. *See Eastwood Nursing*, 910 A.2d at 144 (to determine if there is a binding norm, courts consider the plain language of the provision, the manner in which the agency has implemented it, and whether the agency's discretion is restricted); *R.M.*, 740 A.2d at 306-07 (noting that "[i]n analyzing whether an agency pronouncement is a statement of policy or a regulation," courts consider the agency's own characterization of the rule and whether it establishes a binding norm) (citing *Pennsylvania Human Relations Commission v. Norristown Area School District*, 374 A.2d 671 (Pa. 1977)). Therefore, the "new requirements" Petitioner complains of do not appear to be new regulations but rather non-legislative or interpretive rules, and Petitioner is not likely to succeed on its claim that Respondents were required to go through the formal rulemaking and review processes.

For all of these reasons, Petitioner cannot establish that its right to relief is clear, which is a required element for injunctive relief. *See, e.g., Weeks v. Department of Human Services*, 222 A.3d 722, 731 (Pa. 2019) (affirming denial of preliminary injunction for failure to meet the likelihood-of-success-on-the-merits

factor and noting "that if a petitioner fails to establish any one of the multiple prerequisites for a preliminary injunction, the others need not be addressed"). Even if it could be said that Petitioner has established a clear right to relief, the Application must be denied for failure to meet several of the other necessary factors.

### C. Immediate and Irreparable Harm

Petitioner must also demonstrate that an injunction is necessary to prevent immediate and irreparable harm that cannot be compensated adequately by money damages. *Summit Towne Centre, Inc.*, 828 A.2d at 1001-02. To meet this burden, a petitioner generally must present actual proof of irreparable harm; "speculation and conjecture will not suffice." *Reed v. Harrisburg City Council*, 927 A.2d 698, 706 (Pa. Cmwlth. 2007).

Here, quite simply, Petitioner has failed to demonstrate irreparable harm beyond mere speculation. While Petitioner correctly notes that there is precedent establishing that violation of the constitution or a statute is *per se* irreparable harm, *see, e.g.*, *SEIU Healthcare*, for the reasons discussed above, Petitioner has not established that Respondents committed any such violation or a likelihood of success on these claims.

Petitioner did present several witnesses who testified to the increased costs they believe their respective drug and alcohol treatment programs will shoulder due to the transition to the ASAM Criteria, some projecting significant financial strain and the possible closing of facilities. However, these witnesses admitted that their testimony was based upon the incorrect assumption that DDAP's non-legislative, interpretive guidance are instead mandatory "new requirements." The

<sup>&</sup>lt;sup>14</sup> See Hearing Transcript, 10/28/21, 73:3-13 (testimony of Mr. Blenk that the calculations he testified to were based on the 1-to-15 counselor-to-client ratio being a requirement); 168:19-24 (Footnote continued on next page...)

Court is cognizant of the difficulties facing drug and alcohol treatment providers that service mostly MA patients, especially in light of the nation's opioid epidemic and the COVID-19 pandemic. However, Petitioner cannot demonstrate concrete harm based upon guidance from Respondents that does not establish binding requirements for providers. Thus, any harm Petitioner and its providers alleged they will suffer due to the ASAM transition is speculative and does not rise to the level of the concrete, irreparable harm necessary to impose injunctive relief. *Reed*, 927 A.2d at 704 ("a preliminary injunction . . . will only issue where there is an urgent necessity to avoid injury which cannot be compensated for by damages and should never be awarded except when the rights of the plaintiff are clear") (citation omitted); *accord Summit Towne Center, Inc.*, 828 A.2d at 1002.

## D. Balancing of Harms

For a preliminary injunction to issue, Petitioner must show that greater injury would result from refusing the injunction than granting it, and that issuing an injunction would not substantially harm other interested parties. *SEIU Healthcare*. Further, Petitioner must demonstrate that a preliminary injunction will not adversely affect the public interest. *Id.* Because these prongs are closely interrelated and require the Court to evaluate competing injuries and interests, or balance the harms, they will be addressed together.

As discussed above, Petitioner has failed to provide concrete evidence of immediate and irreparable harm. Respondents, on the other hand, have presented credible evidence of the harm an injunction would cause to the agencies, other

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and 169:20-25 (testimony of Mr. Wagner that the budgetary figures he testified to were based on what he believes to be specific requirements issued by Respondents); 182:9-15 (testimony of Mr. Dillensnyder regarding same); 192-195 (testimony of Mr. Dellavella); 200:9-15 (testimony of Mr. Leech regarding how Respondents' "new requirements" have impacted his facility).

service providers, and to the Commonwealth in general. Specifically, Dawn Hamme credibly testified<sup>15</sup> that CMS issued a rule change in 2016 that impacted more than \$30 million in annual federal Medicaid funding the Commonwealth receives for drug and alcohol treatment services. As a result of this rule change, the Commonwealth applied for and obtained a waiver from CMS which, in pertinent part, requires the transition to nationally recognized assessment and placement criteria, such as the ASAM Criteria. Ms. Hamme testified that issuing an injunction would put the Commonwealth in violation of its waiver with CMS and, therefore, risk its receipt of more than \$30 million annually. It is beyond cavil that the loss of such significant annual funding would adversely affect drug and alcohol treatment providers, those needing services, and the public in general. Moreover, enjoining the guidance documents Respondents issued to providers regarding the ASAM transition would cause confusion among providers as well as agency staff.

## E. Status Quo

Another essential prerequisite is that the preliminary injunction will maintain the status quo. *Summit Towne Centre Inc.* For preliminary injunction purposes, the status quo is "the last peaceable and lawful uncontested status preceding the underlying controversy." *Hatfield Township v. Lexon Insurance Company*, 15 A.3d 547, 556 (Pa. Cmwlth. 2011) (quoting *In re Milton Hershey School Trust*, 807 A.2d 324 (Pa. Cmwlth. 2002)).

Here, Petitioner argues that the injunction will preserve the status quo because it will require Respondents to stop imposing the so-called "new requirements." Petitioner's Brief at 35. Again, Respondents have not imposed any "new requirements," but merely provided non-legislative rules or guidance

<sup>&</sup>lt;sup>15</sup> Ms. Hamme's testimony can be found at pages 220 through 239 of the Hearing Transcript, and her declaration was admitted into the record as Exhibit P-96.

documents to providers with respect to aligning their service delivery conditions with the ASAM Criteria. It also bears noting, given Petitioner's shifting request for injunctive relief, that Respondents announced their intention to transition to the ASAM Criteria by 2017, at the latest. Further, DDAP released its flexibility guidance to providers in April 2021, and Act 70 was passed in July 2021, all prior to the Petition being filed. DDAP also presented credible evidence—corroborated by the testimony of Petitioner's own witnesses—that drug and alcohol treatment providers have already been trained on the ASAM Criteria and many providers have been in substantial compliance since July 2021. Thus, any effort to enjoin the transition to the ASAM Criteria itself would not maintain the status quo but disrupt it. *See County of Luzerne v. Luzerne County Retirement Board*, 882 A.2d 531, 535 (Pa. Cmwlth. 2005) (noting that third factor for granting a preliminary injunction was not "satisfied because the injunction itself disrupt[ed] the status quo as [] set forth by statute").

#### V. Conclusion

Upon review of the evidence, the Court concludes that Petitioner has not met its heavy burden of demonstrating all of the necessary factors for a preliminary injunction. *See Weeks* (preliminary injunction properly denied for failure to meet one of the required factors); *Pennsylvania AFL-CIO* (same). Accordingly, the Application is denied.

MICHAEL H. WOJCIK, Judge

#### IN THE COMMONWEALTH COURT OF PENNSYLVANIA

Drug and Alcohol Service Providers :

Organization of Pennsylvania, :

Petitioner :

:

v. : No. 271 M.D. 2021

Heard: October 28, 2021

Commonwealth of Pennsylvania,

Department of Drug and Alcohol : Programs and Commonwealth of :

Pennsylvania, Department of Human

Services, :

Respondents:

# ORDER

**AND NOW**, this 9<sup>th</sup> day of December, 2021, Petitioner's Application for Special Relief in the Nature of a Preliminary Injunction is DENIED.

MICHAEL H. WOJCIK, Judge