STATE OF FLORIDA
DIVISION OF ADMINISTRATIVE HEARINGS

DACCO BEHAVIORAL HEALTH, INC.; OPERATION PAR, INC.; and ASPIRE HEALTH PARTNERS, INC.,

Petitioners,

and

CRC HEALTH TREATMENT CLINICS, LLC; RIVERWOOD GROUP, LLC; SYMETRIA, LLC; CFSATC, d/b/a CENTRAL FLORIDA SUBSTANCE ABUSE; and BAY COUNTY HEALTHCARE SERVICES, LLC,

Intervenors,

v. Case No. 17-6655RU

DEPARTMENT OF CHILDREN AND FAMILIES,

Respondent,

and

PALM BEACH DRUG TESTING, LLC, d/b/a RELAX MENTAL HEALTH CARE; COLONIAL MANAGEMENT GROUP, L.P.; and METRO TREATMENT OF FLORIDA, L.P.; and PSYCHOLOGICAL ADDICTION SERVICES, LLC,

Intervenors.
_____/

FINAL ORDER

Pursuant to notice, a final hearing was conducted in this case on April 9, 2018, in Tallahassee, Florida, before

Administrative Law Judge R. Bruce McKibben of the Division of Administrative Hearings ("DOAH").

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STATEMENT OF THE ISSUE

The issue in this case is whether Florida Administrative Code Emergency Rule 65DER17-2 (the "Emergency Rule") constitutes an invalid exercise of delegated legislative authority as defined in section 120.52(8), Florida Statutes. (Unless specifically stated otherwise herein, all references to Florida Statutes will be to the 2017 version.)

More specifically, on September 19, 2017, the Florida Department of Children and Families (the "Department"), published the Emergency Rule, which dealt with the need for and licensing of new methadone medication-assisted treatment centers for persons dealing with opioid addiction. Pursuant to the Emergency Rule, the Department decided which providers would receive approval notices to submit licensure applications in certain counties based on the order in which complete and responsive applications were received by the Department. A number of parties are challenging the validity of the Emergency Rule.

PRELIMINARY STATEMENT

The Department issued emergency rule 65DER17-1 on August 25, 2017. That emergency rule was amended on September 19, 2017, to change filing dates; the changes were codified as 65DER17-2, the Emergency Rule under consideration in this proceeding. The Emergency Rule purports to establish a method whereby interested persons could apply to open methadone medication-assisted treatment facilities. Petitioners filed a challenge to the Emergency Rule on December 11, 2017, asserting the invalidity of the Emergency Rule on several bases set forth in section 120.52(8). In accordance with section 120.56(5), the final hearing in this matter was scheduled on the date and place set forth above.

On April 6, 2017, just three days prior to the final hearing in this matter, parties who had intervened in this proceeding in support of the Department filed a motion to dismiss the petitions challenging the Emergency Rule's validity. The basis of the motion was that the Emergency Rule had already expired by the time Petitioners filed their petitions challenging the rule. Intervenors' rationale is that the Emergency Rule is merely an amendment to the first emergency rule, 65DER17-1, and does not extend the time of the first rule. As published in the Florida Administrative Register ("FAR"), 65DER17-1 had an effective date of

August 25, 2017, and expired on November 23, 2017. Petitioners did not file their challenges to the Emergency Rule until December 11, 2017. The Emergency Rule, as published in the FAR, conversely, had an effective date of September 19, 2017. Pursuant to section 120.54(4), the Emergency Rule was effective for 90 days, i.e., until December 18, 2017. As the petitions challenging the Emergency Rule were filed prior to that date, the motion to dismiss is denied.

An ore tenus motion in limine was made at final hearing by Intervenor, Psychological Addiction Services, LLC ("PAS"). In that motion, which is essentially a motion to dismiss for lack of jurisdiction, PAS argues that the Legislature has provided an exclusive judicial remedy for challenging the underlying declaration of an emergency by an agency. Thus, PAS contends, arguments as to whether there was a legitimate emergency must be made directly to the District Court of Appeal rather than to DOAH. PAS contends that all DOAH can do under section 120.56(5) is to determine the substantive validity of the proposed rule. However, no evidence was adduced at final hearing that any party claimed an emergency existed. The motion in limine is denied. See also Administrative Law Judge Chisenhall's scholarly review of this issue in Florida Association of Homes and Services for the

Aging, Inc., d/b/a LeadingAge Florida v. Agency for Health Care Administration and Department of Elder Affairs, Case No. 17-5388RP (Fla. DOAH Oct. 27, 2017).

At the final hearing, Petitioners called three witnesses: Diane Clarke, CEO of Operation Par, Inc. ("OPI"); Jonathan Essenburg, OPI's vice president for medication-assisted and HIV services; and Ute Gazioch, Director of Substance Abuse and Mental Health for the Department. CRC Health Treatment Clinics, LLC ("CRC"), called one witness: Anthony Ruscella, vice president of business development for Acadia Healthcare, parent company of CRC. Symetria, LLC ("Symetria"), called one witness: Paul Cassidy, director of New Clinic Development. No other parties herein called witnesses at the final hearing. The following exhibits were admitted pursuant to stipulation by the parties: Joint Exhibits 1 through 7; Department Exhibits 1 through 8; Petitioners Exhibits 1 through 24; PAS Exhibit 1; Symetria Exhibits 1 through 4; CFSATC Exhibits 2 through 4; Bay County Healthcare Services, LLC, Exhibits 1 through 3; and CRC Exhibit 1.

An expedited transcript of the final hearing was ordered, with an anticipated filing date of April 12 or 13, 2018. The parties were given seven days from the date the transcript was filed at DOAH to submit proposed final orders (PFOs); the parties requested entry of the final order on or before

April 26, 2018, due to the significant impact the final order might have on the parties, as well as the fact that the undersigned would not be able to address the matter after that date (until May 14, 2018). The Transcript was not filed, however, until April 16, 2018. The parties filed their PFOs on April 23, 2018, leaving two business days to complete and issue the final order. Nonetheless, each of the PFOs was considered in the preparation of this Final Order.

FINDINGS OF FACT

Parties and Standing

1. Respondent, the Department, is the state agency responsible for licensing providers of care in methadone medication-assisted treatment facilities. It is the agency, which promulgated the Emergency Rule.

2. Petitioner, Dacco Behavioral Health, Inc. ("Dacco"), is a not-for-profit corporation and is currently licensed to operate methadone medication-assisted treatment clinics within the state of Florida. Dacco submitted three applications for licensure under the Emergency Rule. Its applications were not approved by the Department. Dacco timely filed an administrative challenge to its denied applications. Dacco has standing in this proceeding.

3. Petitioner, OPI, is a not-for-profit corporation and is currently licensed to operate methadone medication-assisted

treatment clinics within the state of Florida. OPI submitted six applications for licensure under the Emergency Rule. None of its applications were approved by the Department. OPI timely filed an administrative challenge to its denied applications. OPI has standing in this proceeding.

4. Petitioner, Aspire Health Partners, Inc. ("Aspire"), is a not-for-profit corporation and is currently licensed to operate methadone medication-assisted treatment clinics within the state of Florida. Aspire submitted two applications for licensure under the Emergency Rule. Neither of its applications was approved by the Department. Aspire timely filed an administrative challenge to its denied applications. Aspire has standing in this proceeding.

5. Intervenor, CRC, is a Delaware limited liability company registered to do business in Florida. CRC is currently licensed to operate a methadone medication-assisted treatment clinic in Florida. CRC submitted 16 applications for licensure under the Emergency Rule. Its applications were not approved by the Department. CRC timely filed an administrative challenge to its denied applications. CRC has standing to intervene in this proceeding.

6. Intervenor, Riverwood Group, LLC ("Riverwood"), is a Delaware limited liability company authorized to do business in Florida. Riverwood is currently licensed to operate

methadone medication-assisted treatment clinics within the state of Florida. Riverwood submitted six applications for licensure under the Emergency Rule. Its applications were not approved by the Department. Riverwood timely filed an administrative challenge to its denied applications. Riverwood has standing to intervene in this proceeding.

7. Intervenor, Symetria, is a Florida limited liability company whose parent company is currently licensed to operate methadone medication-assisted treatment clinics within the state of Florida. Symetria submitted 11 applications for licensure under the Emergency Rule. One of its applications was approved; the other 10 were not approved by the Department. Symetria did not file an administrative challenge to the denial of its applications. Opposition to Symetria's standing was raised by Intervenors appearing in support of Respondent. Symetria was allowed to participate at final hearing pending adequate proof of standing. Symetria did not prove its standing at final hearing. Symetria does not have standing in this proceeding on behalf of Petitioners as it does not satisfy the two-prong test announced in Agrico Chemical Company v. Department of Environmental Regulation, 406 So. 2d 478 (Fla. 1st DCA 1978). (After entry of this Final Order, Symetria will be stricken from the style of the case.) It should be noted that Symetria apparently never

received notice as to its denied applications and may have challenged those denials, if notices had been issued, but that possibility is too speculative to award standing in this matter. It should also be noted that none of the parties hereto objected to Symetria's involvement in the final hearing, including its introduction of evidence and examination of witnesses.

8. Intervenor, CFSATC, d/b/a Central Florida Substance Abuse ("CFSATC"), is a Florida corporation and is currently licensed to operate methadone medication-assisted treatment clinics within the state of Florida. CFSATC submitted seven applications for licensure under the Emergency Rule. None of its applications were approved by the Department. CFSATC timely filed an administrative challenge to its denied applications. CFSATC has standing to intervene in this proceeding.

9. Intervenor, Bay County Healthcare Services, LLC ("Bay County Healthcare"), is a Georgia limited liability company and is currently licensed to operate a methadone medication-assisted treatment clinic in Florida. Bay County Healthcare submitted eight applications for licensure under the Emergency Rule. None of its applications were approved by the Department. Bay County Healthcare timely filed an

administrative challenge to its denied applications. Bay County Healthcare has standing to intervene in this proceeding.

10. Intervenor, Palm Beach Drug Testing, LLC, d/b/a Relax Mental Health Care ("Relax"), submitted 14 applications for licensure under the Emergency Rule; eight of its applications were approved. Invalidation of the Emergency Rule would substantially affect the business interests of Relax. Relax has standing to intervene in this proceeding.

11. Intervenor, Colonial Management Group, L.P. ("Colonial"), operates methadone medication-assisted treatment centers nationwide, including Florida. Colonial submitted 19 applications for licensure under the Emergency Rule; all 19 of its applications were approved. Invalidation of the Emergency Rule would substantially affect the business interests of Colonial. Colonial has standing to intervene in this proceeding.

12. Intervenor, PAS, submitted 48 applications for licensure under the Emergency Rule; twenty of its applications were approved. Invalidation of the Emergency Rule would substantially affect the business interests of PAS. PAS has standing to intervene in this proceeding.

Procedural History

13. On May 3, 2017, Governor Scott signed Executive Order No. 17-146, alluding to the nearly 4,000 deaths in Florida caused by opioids during calendar year 2015. Florida had nearly 10 percent of all opioid-related deaths in the entire country that year. The Governor declared that an opioid epidemic threatens the State and has created an emergency situation. He directed the State Health Officer and Surgeon General to announce a statewide public health emergency. The Governor's executive order noted that the United States Department of Health and Human Services had awarded a grant of $27,150,403 per year for two years to the Department to provide prevention, treatment, and recovery support services to address the opioid epidemic. The Governor said it was necessary to immediately draw down those federal grant funds in order to provide services to Florida communities, and that the State could not wait until the next fiscal year (which would start two months hence, on July 1, 2017) to begin that distribution.

14. On June 29, 2017, the Governor signed Executive Order No. 17-177, extending for an additional 60 days the state of emergency declaration set forth in Executive Order 17-146. This action was precipitated by hurricanes threatening the State.

15. The executive orders issued by the Governor appear to direct State agencies to utilize the federal grant monies to bolster existing providers of treatment. Nothing in the executive orders issued by the Governor directs the approval of additional opioid treatment centers. There is, however, an omnibus provision in the executive order directing the State Health Officer to "take any action necessary to protect the public health."

16. The Department's response to the executive orders was to publish emergency rule 65DER17-1 in the FAR on August 25, 2017. That rule was superseded by the Emergency Rule, which revised the dates during which applications for licensure could be submitted. This change was deemed necessary in response to the devastation wrought by Hurricane Irma, making travel to Tallahassee (for delivery of applications) somewhat difficult during the timeframes set forth in emergency rule 65DER17-1.

17. The Notice of Emergency Rule, as published in the Florida Administrative Register, states in full (with strikethrough/underline in original):

> Notice of Emergency Rule
>
> **DEPARTMENT OF CHILDREN AND FAMILIES**
> **Substance Abuse Program**

RULE NO.: RULE TITLE: 65DER17-2 Standards for Medication-Assisted Treatment for Opioid Addiction

SPECIFIC REASONS FOR FINDING AN IMMEDIATE DANGER TO THE PUBLIC HEALTH, SAFETY OR WELFARE: On May 3, 2017, the Governor of the State of Florida signed Executive Order Number 17-146 declaring that the opioid epidemic threatens the State with an emergency and that, as a consequence of this danger, a state of emergency exists. Also, in the executive order, the Governor directed the State Health Officer and Surgeon General to declare a statewide public health emergency, pursuant to its authority in section 381.00315, F.S. On June 29, 2017, the Governor signed Executive Order Number 17-177 to extend the state of emergency declaration.

The department was recently awarded a two-year grant to address this opioid epidemic. The department will use these funds in part to expand methadone medication-assisted treatment services in needed areas of the state as part of a comprehensive plan to address the opioid crisis. Revising the licensure requirements through an emergency rule is necessary to accommodate the critical need for more methadone medication-assisted treatment providers. Due to the impact of Hurricane Irma on providers and individuals in treatment, the department has determined that extending the submission dates for applicants is necessary.

REASON FOR CONCLUDING THAT THE PROCEDURE IS FAIR UNDER THE CIRCUMSTANCES: The procedure is fair under the circumstances because it ensures equitable treatment of methadone medication-assisted treatment providers.

SUMMARY: This rule makes changes to permanent Rule 65D-30.014 F.A.C., relating

to licensure requirements for methadone medication-assisted treatment programs.

THE PERSON TO BE CONTACTED REGARDING THE EMERGENCY RULE IS: Bill Hardin. He can be reached at William.Hardin@myflfamilies.com or Office of Substance Abuse and Mental Health, 1317 Winewood Boulevard, Building 6, Tallahassee, Florida 32399-0700.
THE FULL TEXT OF THE EMERGENCY RULE IS:

65DER17-2 (65D-30.014): Standards for Medication-Assisted Treatment for Opioid Addiction. 65DER17-2 supersedes 65DER17-1. In addition to Rule 65D-30.004, F.A.C., the following standards apply to Standards for Medication-Assisted Treatment for Opioid Addiction.

(1) State Authority. The state authority is the department's Office of Substance Abuse and Mental Health.

(2) Federal Authority. The federal authority is the Center for Substance Abuse Treatment.

(3) Determination of Need.

(a) Criteria. In accordance with s. 397.427, F.S., the department shall not license any new medication-assisted treatment programs for opioid addiction until the department conducts a needs assessment to determine whether additional providers are needed in Florida. The determination of need shall only apply to methadone medication-assisted treatment programs for opioid addiction. Department of Correction facilities are excluded from this process. The department shall use a methodology based on a formula that identifies the number of people who meet the criteria for dependence or abuse of heroin or pain relievers who did not receive any treatment, and the number of opioid-caused deaths. This formula will be weighted, with

70 percent driven by the number of people with an unmet need for treatment and 30 percent driven by the number of deaths. In its effort to determine need, the department shall examine the following data:

1. Population estimates by age and by county;

2. Number of opioid-caused deaths;

3. Estimated number of past-year nonmedical pain reliever users; and

4. Estimated number of life-time heroin users;

(b) Procedure. By August 28, 2017, the department will conduct a needs assessment to determine whether additional methadone medication-assisted treatment providers are needed in Florida. The department will publish a determination of need in the Florida Administrative Register and on the department's website at http://www.myfl families.com/service-programs/substance-abuse on August 30, 2017. If the department determines that additional providers are needed, the department will also publish instructions for submitting an appropriate application.

1. Applicants interested in providing methadone medication-assisted treatment must complete and submit CF-MH 4036 titled, "Methadone Medication-Assisted Treatment Provider Application in Response to Emergency Rule", June 2017, incorporated herein by reference. Form CF-MH 4036 is available from the department's website at https://eds.myflfamilies.com/DCFForms Internet/Search/DCFFormSearch.aspx and at http://www.myflfamilies.com/service-programs/substance-abuse.

Applications must be complete and responsive to all of the questions on this

form. Applications will be accepted at department headquarters from October 2, 2017 ~~September 22, 2017~~ at 8 a.m. Eastern Time until October 23, 2017 ~~October 13, 2017~~, at 5 p.m. Eastern Time. Applications must be delivered to~~ the following address~~: Florida Department of Children and Families, Office of Substance Abuse and Mental Health, 1317 Winewood Boulevard, Building 6, Tallahassee, Florida 32399-0700.

2. For the application review period in response to this emergency rule, the department will use CF-MH 4037 titled, "Review Form for Methadone Medication-Assisted Treatment Provider Application in Response to Emergency Rule", June 2017, incorporated herein by reference. Form CF-MH 4037 is available from the department's website at https://eds.myflfamilies.com/DCFFormsInternet/Search/DCFFormSearch.aspx and at http://www.myflfamilies.com/service-programs/substance-abuse.

3. Should the number of applications for a new provider in a Florida county exceed the determined need, the selection of a provider shall be based on the order in which complete and responsive applications are received by the Office of Substance Abuse and Mental Health headquarters.

4. Applicants who are approved to apply for licensure will receive notices from the department by November 17, 2017 ~~November 10, 2017~~.

5. Applicants who receive approval notices shall submit applications for licensure to the department's regional Substance Abuse and Mental Health office(s) where the service will be provided. The regional Substance Abuse and Mental Health office will process applications for licensure in accordance with the standards and requirements in 65D-30, F.A.C.

(4) through (6) No change.

Rulemaking Authority 397.321(5) F.S. *Law Implemented* 397.311(25)(a)7., *397.321(1)*, *397.419*, FS. *History–New 5-25-00, Amended 4-3-03, Amended 8-25-17, Amended 9-19-17.*
THIS RULE TAKES EFFECT UPON BEING FILED WITH THE DEPARTMENT OF STATE UNLESS A LATER TIME AND DATE IS SPECIFIED IN THE RULE.
EFFECTIVE DATE: 9/19/2017

18. Petitioners filed challenges to the Emergency Rule at DOAH on December 11, 2017, 83 days after the effective date set forth in the FAR. Respondent asserts that the Emergency Rule is merely an amendment to Rule 65DER 17-1, which had an effective date of August 25, 2017. Thus, reasons Respondent, challenges to the Emergency Rule were due on or before November 23, 2017, i.e., 90 days after August 25, 2017. However, emergency rules are not renewable so as to expand their validity beyond 90 days. § 120.54(4), Fla. Stat. As set forth above, the clear language appearing in the FAR establishes September 19, 2017, as the effective date of the Emergency Rule. Had the Department wished to retain the effective date from the prior rule, it certainly could have done so. It did not. Petitioners' challenge to the Emergency Rule was timely.

Background

19. Florida has had rules in effect for 18 years regarding the need for opioid treatment centers around the

State. Florida Administrative Code Rule 65D-30.014 is entitled, "Standards for Medication and Methadone Maintenance Treatment." This rule sets forth the process for providers to request licenses to establish new opioid treatment facilities, based on the Department's annual determination of need. According to the rule, the Department is to conduct an annual assessment of need, publishing the results of that assessment by June 30 of each year, although, inexplicably, no assessment was done for calendar years 2016 or 2017. After the need assessment is published, the Department directs interested parties to submit applications for licensure to the Department's district office in the area where the need exists. All such applications would have to be submitted no later than on a "closing date" to be provided by the Department.

20. The Department's district office would receive the application(s) and conduct a formal rating of the applicant(s). There were minimum requirements each applicant must meet in order to be considered for licensure. If the number of applicants exceeded the determined need, the selection of a provider would be done based on certain substantive criteria, e.g., number of years the applicant has

been licensed; the organizational capability of the applicant; and the applicant's history of noncompliance with Department rules.

21. Pursuant to rule 65D-30.014, the Department had conducted assessments in calendar years 2012, 2013, 2014, and 2015. The award of licenses based on the 2012 and 2013 need assessment was delayed by litigation. A need for 31 additional treatment centers was found in 2014, but no applications were accepted by the Department due to the ongoing litigation relating to the previous years. The following year, 2015, the Department found a need for only five additional treatment centers, even though none of the 31 treatment centers identified as needed in 2014 had been awarded to anyone. The 2015 assessment was lower than the prior year due to some changes in the methodology used by the Department. The Department did not accept any applications to meet the established need in 2015.

22. One rationale for not accepting applications, even though there was a need, was that the Department was drafting new rules. That process would give stakeholders an opportunity for input. The notices that the rules were being developed, however, were not filed until some 11 months after the 2015 need projections were published. The Department

explained that it was busy with other rulemaking duties during that time, causing some delay.

Developing the Emergency Rule

23. After entry of the Governor's executive orders, the Department began the process of distributing the federal grant money to existing treatment centers. The Department, though it never met with the Governor to discuss use of the grant funds, handed out the funds to various existing clinics in order to help them deal with the clinics' backlogs and waiting lists. There was no discussion between the Governor and the Department concerning the necessity for new clinics.

24. A needs assessment was apparently conducted by the Department. The Department based its assessment in part on data it had gathered when applying for the federal grant. Existing treatment centers had provided the Department waiting lists, indicative of a greater need than could be met by the existing clinics. That data, however, was only from public providers; private providers were not included. The public providers were essentially those contracting with the Department's "managing entities," who act as intermediaries between the provider and the Department.

25. An emergency rule was proposed as the vehicle for addressing the need and acquiring applications for licensure. Though the Department's Director of Substance Abuse and Mental

Health thought it best to simply proceed with the rule currently under development, the Emergency Rule was pursued. The thinking at the Department was that the existing rule had created considerable litigation that the Emergency Rule might avoid. That did not happen.

26. The emergent situation warranting an emergency rule was, according to the Department, the scenario described by the Governor in his executive orders. The Department of Health had declared a public health emergency, which was also used as a basis for creating the Emergency Rule. The federal grant funds, however, were not an impetus for creating the Emergency Rule.

27. The Emergency Rule relied upon data from calendar year 2015, as it was the latest data available to the Department at that time. The Governor's executive orders had also relied upon 2015 data. Some interim data had been available, but the only full year of information available at the time the rule was promulgated was for 2015. The interim data, however, indicated a sharp (approximately 30 percent) increase in need.

28. The Department published a determination of need on its website on August 30, 2017. Apparently the need determination was not published in the FAR despite the directive to do so in subsection (3)(b) of the Emergency Rule.

The Department found a need for one clinic each in 47 of Florida's 67 counties, as well as for two in Hillsborough County, for a total of 49 new clinics. Pursuant to the Emergency Rule, interested applicants were to file an application on the Department's approved form (CF-MH 4036, attached hereto as an Addendum) expressing an interest in becoming licensed in one or more of those counties. Such applications were to be "accepted at department headquarters from October 2, 2017, at 8 a.m., Eastern Time, until October 27, 2017 at 5 p.m., Eastern Time. Applications must be delivered to [the department]." In contrast to rule 65D-30.014, applications under the Emergency Rule were to be filed at the Department's headquarters in Tallahassee rather than in the various district offices around the State.

29. The application form utilized by the Department is a one-page document. The form requests minimal identification information concerning the applicant and its business (questions 1 through 10). Question 11 asks if the applicant plans to accept Medicaid-eligible, indigent, and/or pregnant women as patients. The 12th question directs the applicant to submit documentation concerning its target population, proof of a physician on staff, the anticipated date of initiation of services, and proof of registration with the Department of Revenue or Division of Corporations. The Department also

created a "review form," used to check the completeness of applications. The review form mirrors the application, providing a space for the Department reviewer to state whether the applicant had completed each section of the application form.

30. The Department maintains that the applicants' responses to Question 11 were not considered in its review of the applications submitted under the Emergency Rule. This was because, according to the Department, a response to that question might favor one applicant over another. The Department did not elaborate as to how this "favoritism" might negatively affect the process. The question had been used under the prior rules and had been deemed important, presumably because--as reported by some of the parties herein--a large majority of their patients were either Medicaid-eligible, indigent persons, or pregnant women. It certainly was reasonable that the Department would ensure that those groups of citizens, who were undoubtedly accounted for in the need assessment, had access to approved treatment centers under the Emergency Rule. Nonetheless, the Department did not utilize the Question 11 responses in its review. This is contrary to the plain language of the Emergency Rule, which

states: "Applications must be complete and responsive to all questions on this form." (emphasis added). See 65DER17-2(3)(b)1.

31. The Emergency Rule as published contained the following language: "REASON FOR CONCLUDING THAT THE PROCEDURE IS FAIR UNDER THE CIRCUMSTANCES: The procedure is fair under the circumstances because it ensures equitable treatment of methadone medication-assisted treatment providers." Neither the Emergency Rule language nor the Department at final hearing provided a persuasive rationale for that statement and conclusion. In fact, the Department acknowledged that if the first person in line had filed applications for all 49 new clinics, all the other applicants would have been denied the right to seek licensure. How is that fair?

32. What the Emergency Rule did was to set a window within which interested applicants could either mail, overnight-deliver, or hand-deliver a copy of the one-page application and attachments to the Department's headquarters in Tallahassee. The Department felt that allowing applications to be submitted via email would potentially crash its email system, so email submission was not allowed. The applications received first by the Department were to be approved, notwithstanding any substantive shortcomings or comparative failings of those applications as compared to

applications received later. No other criteria were considered; first was deemed best. What is fair about approving competing applications based on who filed first rather than on substantive differences in the services being proposed?

33. What actually transpired vis-à-vis submission of the applications was not foreseen by the Department or by most of the applicants. That is, some applicants either lined up at Department headquarters days prior to the 8:00 a.m. acceptance time on October 2, 2017, or had someone wait in line for them. Then, when the doors opened at 8:00 a.m., the first person in line presented applications for 19 of the 49 sites identified by the Department as having a need. The second applicant in line submitted 17 applications, etc. By the time each of the Petitioners reached the front of the line, only minutes after the doors had opened, applications for their prospective counties of interest had already been filed. Under the Emergency Rule, the earlier filed applications were accepted without comparison to competing applications. As a result, Colonial was approved for 19 licenses; PAS was approved for 20; and Relax obtained eight; i.e., 47 of the 49 licenses were obtained by just three individual applicants. Again, the

Department acknowledged that "[a]fter it, you know, happened the way it did, there were many considerations that we should have made." Ute Gazioch, Jt. Exh. 6, page 81.

34. Interestingly, the first application accepted by the Department was by an applicant who did not even appear at Department headquarters. That applicant, Lakeview Center, Inc., submitted its application via FedEx. The FedEx box containing Lakeview Center's application was received and clocked in by an office at Department headquarters, other than the Substance Abuse and Mental Health office, at 7:40 a.m., i.e., prior to the window for filing. When the application made its way to the appropriate office, it was deemed received at 8:00 a.m. As a result, it was "first in line." The incongruity of that situation was not persuasively justified by the Department. In fact, the Department testified that if all of the applications had been filed at the wrong office, it would likely have simply defaulted to an 8:00 a.m. arrival time for each one.

35. Upon being approved, an applicant would then be allowed to submit an application for licensure. Under the licensure process, the applicant would be vetted in order to assure it met at least minimal requirements for obtaining a license. No comparison of the approved applicant to other applicants was made by the Department to ascertain whether

another applicant might be superior as to services provided. Rather, if the approved applicant could satisfy, even minimally, the licensure requirements, it would be granted the right to seek a license.

36. Once licensed, it could take considerable time and financial resources to effectuate the opening of a new opioid treatment clinic. There are many factors to be addressed and resolved, including but not limited to: acquisition of an appropriate site, whether by way of purchase of undeveloped property and new construction or lease/purchase of an existing building; construction or renovation, as needed; zoning concerns; permitting by state, county, and/or municipal bodies; staffing; coordination of state and federal licenses or certifications; etc. It is not uncommon for the process to take up to two years, sometimes more. In addition, the financial expenditures could be in the hundreds of thousands of dollars (and even as much as a million dollars) for each project. For this reason, the Department did not foresee that any entity might apply for so many applications as actually transpired.

37. The likelihood that a single entity would have the time, money, or other resources to move forward on multiple products at one time is small. It is more likely that a single entity receiving approval for multiple new clinics

might "bank" the approvals, expending time and money for only a few at a time, at best. If so, that could result in far fewer new clinics coming on line than the 49 projected by the Department under the Emergency Rule. As the applications contained no requirement to provide financial information, it is impossible for the Department to determine whether the approved entities, which received multiple approvals, could successfully--and timely--complete their projects. There is no specific time frame for which a granted applicant must commence operations once approved. However, as the approvals were done pursuant to an "emergency," it follows that clinics should be opened as soon as practicable.

38. Petitioners assert that the "first in line" scheme enunciated in the Emergency Rule is arbitrary, capricious, and patently contrary to a determination of the applicants' ability to provide care to persons suffering opioid addiction. The facts bear that assertion out.

CONCLUSIONS OF LAW

39. The Division of Administrative Hearings has jurisdiction over the parties to and the subject matter of this proceeding. § 120.56, Fla. Stat.

40. Petitioners have standing pursuant to section 120.56(1), Florida Statutes, to participate in this proceeding as persons substantially affected by the emergency

rule. Each of the intervenors, except Symetria, has standing to participate.

41. There are significant differences between "regular" rules and emergency rules. Section 120.54(4) sets forth the law governing emergency rules and provides that:

> (a) If an agency finds that an immediate danger to the public health, safety, or welfare requires emergency action, the agency may adopt any rule necessitated by the immediate danger. The agency may adopt a rule by any procedure which is fair under the circumstances if:
> 1. The procedure provides at least the procedural protection given by other statutes, the State Constitution, or the United States Constitution.
>
> 2. The agency takes only that action necessary to protect the public interest under the emergency procedure.
>
> 3. The agency publishes in writing at the time of, or prior to, its action the specific facts and reasons for finding an immediate danger to the public health, safety, or welfare and its reasons for concluding that the procedure used is fair under the circumstances. In any event, notice of emergency rules, other than those of educational units or units of government with jurisdiction in only one or a part of one county, including the full text of the rules, shall be published in the first available issue of the Florida Administrative Register and provided to the committee along with any material incorporated by reference in the rules. The agency's findings of immediate danger, necessity, and procedural fairness shall be judicially reviewable.

42. The Supreme Court of Florida has held that, "[I]f an agency finds that 'an immediate threat to the public health, safety, or welfare requires emergency action,' it may adopt 'any rule necessitated by the immediate danger,' i.e., an emergency rule. See § 120.54(4), Fla. Stat. (2010)." Whiley v. Scott, 79 So. 3d 702, 711-12 (Fla. 2011). In the present case, the Department deemed the Governor's executive orders sufficient evidence of a threat to the public health, safety, or welfare.

43. Petitioners contend that no immediate danger exists because: 1) the data relied upon is three years old; 2) there is already a rule in place to address the stated emergency; and 3) the executive order only directed distribution of funds to treatment centers that already exist. While those concerns are valid, they do not form the basis for the ultimate finding in this Final Order.

44. Petitioners seek a final order determining that the Department's emergency rule 65DER17-2 constitutes an invalid exercise of delegated legislative authority in violation of section 120.52(8). They are challenging the validity of the rule in accordance with section 120.56, which states in pertinent parts:

120.56 Challenges to rules.-

(1) GENERAL PROCEDURES FOR CHALLENGING THE VALIDITY OF A RULE OR A PROPOSED RULE.

(a) Any person substantially affected by a rule or a proposed rule may seek an administrative determination of the invalidity of the rule on the ground that the rule is an invalid exercise of delegated legislative authority.

* * *

(e) Hearings held under this section shall be de novo in nature. The standard of proof shall be the preponderance of the evidence. Hearings shall be conducted in the same manner as provided in ss. 120.569 and 120.57, except that the administrative law judge's order shall be final agency action. Other substantially affected persons may join the proceedings as intervenors on appropriate terms which shall not unduly delay the proceedings . . . .

(2) CHALLENGING PROPOSED RULES/SPECIAL PROVISIONS.

(a) [T]he petitioner has the burden of going forward. The agency then has the burden to prove by a preponderance of the evidence that the proposed rule is not an invalid exercise of delegated legislative authority as to the objections raised.

* * *

(c) When any substantially affected person seeks determination of the invalidity of a proposed rule pursuant to this section, the proposed rule is not presumed to be valid or invalid.

* * *

> (5) CHALLENGING EMERGENCY RULES; SPECIAL PROVISIONS. [Contains timeframes for emergency rules which were waived by the parties in this matter.]

45. Petitioners met their initial burden of going forward in this case through the presentation of their cases-in-chief. They showed the arbitrariness of a process that ignores substance in favor of blind luck, i.e., where you might find yourself in line. The burden therefore shifted to the Department to prove by a preponderance of the evidence that the Emergency Rule is not an invalid exercise of delegated legislative authority. Id.; see also Fla. Bd. of Med. v. Fla. Acad. of Cosmetic Surg., Inc., 808 So. 2d 243, 251 (Fla. 1st DCA 2002).

46. Rulemaking is a legislative function and, as such, it is within the exclusive authority of the Legislature under the separation of powers provision of the Florida Constitution. See Sw. Fla. Water Mgmt. Dist. v. Save the Manatee Club, Inc., 773 So. 2d 594, 598-99 (Fla. 1st DCA 2000). An administrative rule is valid only if adopted under a proper delegation of legislative authority. See Id., Chiles v. Children A, B, C, D, E, and F, 589 So. 2d 260 (Fla. 1991); Askew v. Cross Keys Waterways, 372 So. 2d 913 (Fla. 1978).

47. A proposed (or emergency) rule may be challenged pursuant to section 120.56, Florida Statutes, only on the ground that it is an "invalid exercise of delegated legislative authority," defined in section 120.52(8), as:

> [A]ction which goes beyond the powers, functions, and duties delegated by the Legislature. A proposed or existing rule is an invalid exercise of delegated legislative authority if any one of the following applies:
>
> * * *
>
> (d) [T]he rule is vague, fails to establish adequate standards for agency decisions, or vests unbridled discretion in the agency.
>
> (e) The rule is arbitrary or capricious. A rule is arbitrary if it is not supported by logic or the necessary facts; a rule is capricious if it is adopted without though or reason or is irrational . . . .

48. The legislation addressing substance abuse services is known as the "Hal S. Marchman Alcohol and Other Drug Services Act" (the "Act"). See § 397.301, Fla. Stat. The particular statutes being implemented by the Emergency Rule are sections 397.311(25)(a)7., 397.321(1), and 397.419, Florida Statutes. The rulemaking authority is found in section 397.321(5), which says the Department shall "Assume responsibility for adopting rules as necessary to comply with this chapter, including other state agencies in this effort, as appropriate."

49. Pertinent portions of the Act include:

> Section 397.305(3) – "It is the purpose of this chapter to provide for a comprehensive continuum of accessible and quality substance abuse prevention . . . while protecting and respecting the rights of individuals, primarily through community-based, private, not-for-profit providers . . . ."
>
> Section 397.305(6) – "It is the intent of the Legislature to ensure within available resources a full system of care for substance abuse services based on identified needs, delivered without discrimination and with adequate provision for specialized needs."
>
> Section 397.321(1) – "Develop a comprehensive state plan for the provision of substance abuse services. The plan must include: [N]eed for services . . . [C]ost of services . . . and [S]trategies to address the identified needs and priorities.

(Emphasis added).

50. The Department's interpretation of the Act is entitled to great deference because the Department is charged with administering those statutory provisions. Verizon Fla., Inc. v. Jacobs, 810 So. 2d 906, 908 (Fla. 2002); BellSouth Telecomms, Inc. v. Johnson, 708 So. 2d 594, 596 (Fla. 1998). The deference to an agency interpretation of a statute it is charged with enforcing applies even if other interpretations or alternative rules exist. Atlantic Shores Resort v. 507 S. St. Corp., 937 So. 2d 1239, 1245 (Fla. 3d DCA 2006); Miles v. Fla. A&M Univ., 813 So. 2d 242, 245 (Fla. 1st DCA 2002);

Bd. of Trs. of Int. Imp. Trust Fund v. Levy, 656 So. 2d 1359, 1363 (Fla. 1st DCA 1995).

51. Likewise, agency rulemaking efforts are afforded deference. Agrico Chem. Co. v. State, Dep't of Envtl. Reg., 365 So. 2d 759 (Fla. 1st DCA 1978). "Agencies are afforded wide deference in the exercise of lawful rulemaking authority which is clearly conferred or fairly implied and consistent with the agency's general statutory duties." Charity v. Fla. State Univ., 680 So. 2d 463, 466 (Fla. 1st DCA 1996). Petitioners' burden to establish that an agency's rulemaking efforts are an invalid exercise of delegated legislative authority "is a stringent one indeed." Agrico, 365 So. 2d at 763.

52. Emergency Rule 65DER17-2 provides that an immediate danger to the public health, safety, or welfare exists, and that it is necessary to expand the methadone medication-assisted treatment services in needed areas of the state as part of a comprehensive plan to address the opioid crisis. The Emergency Rule does not address whether the services to be provided will be "accessible" to all persons within identified areas of need, specifically, those who are on Medicaid, are indigent, or are pregnant. Likewise, the Emergency Rule does not assume a "full system of care . . . delivered without discrimination . . . ." § 397.305(6), Fla. Stat. Failure to

provide assurance that all people identified in the need assessment will be served calls into question the validity of the Emergency Rule.

53. The system for accepting applications on a first-come, first-served basis is arbitrary. It is illogical to assume that the first applications filed, containing scant information, are equal or superior to later filed applications. This scheme contravenes the basic expectation of law for reasoned agency decision making. See Agrico Chem. Co., 365 So. 2d at 763; see also the learned analysis of this issue by Administrative Law Judge Watkins in Costa Farms, LLC v. Dep't of Health, Case No. 14-4296RP (Fla. DOAH Nov. 14, 2014).

54. Generally, where an agency receives mutually exclusive applications, i.e., where only a limited number can be approved from the totality of the submissions, a comparative review is warranted. See Bio-Med. Applications of Clearwater, Inc. v. Dep't of HRS, Off. of Cmty. Med. Facilities, 370 So. 2d 19 (Fla. 2d DCA 1979), where the Court, referring to Ashbacker Radio Corp. v. F.C.C., 326 U.S. 327 (1945), said:

> In Ashbacker, the Supreme Court laid down a general principle that an administrative agency is not to grant one application for a license without some appropriate consideration of another Bona

> fide and timely filed application to render the same service; the principle, therefore, constitutes a fundamental doctrine of fair play which administrative agencies must diligently respect and courts must be ever alert to enforce. Railway Express Agency, Inc. v. United States, 205 F. Supp. 831 (S.D.N.Y.1962).
>
> We agree that Ashbacker should apply whenever an applicant is able to show that the granting of authority to some other applicant will substantially prejudice his application. Great Western Packers Express, Inc. v. United States, I.C.C., 263 F. Supp. 347 (D.Col.1966). In such a case fairness requires that the agency conduct a comparative hearing at which the competing applications are considered simultaneously. Only in that way can each party be given a fair opportunity to persuade the agency that its proposal would serve the public interest better than that of its competitor.

55. When one applicant would be substantially prejudiced by the approval of another applicant, fairness requires some comparison of the competing applications. Id.

56. Under the Administrative Procedure Act, there must be reasoned justification for an agency's denial of a license (or, as in the present case, the right to seek a license). See generally § 120.60, Fla. Stat. The Emergency Rule does not provide any justification whatsoever; it deprives the denied applicants the due process afforded by the Legislature. See Ashbacker Radio, 326 U.S. at 333.

57. The unbridled discretion by the Department to accept an application submitted by way of FedEx before the designated

time for filing, and deeming it timely filed, is significant. Obviously, the process was inconsistent, at best, and flawed. Recognizing the Department's legitimate efforts to respond as quickly as possible to a declared emergency, the Emergency Rule is, nevertheless, inadequate.

58. In total, it is clear the Emergency Rule, as published and enforced, is arbitrary, constituting an invalid exercise of the Department's delegated legislative authority.

ORDER

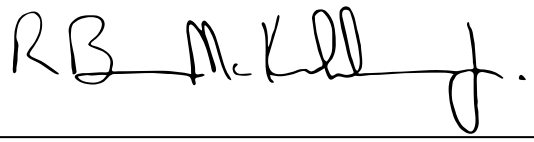
Based on the foregoing Findings of Fact and Conclusions of Law, it is hereby

ORDERED that:

Emergency Rule 65DER17-2 of the Florida Administrative Code is an invalid exercise of delegated legislative authority as defined in section 120.52(8), Florida Statutes; and

Jurisdiction is reserved for the undersigned to consider motions for fees and costs pursuant to section 120.595(3), Florida Statutes.

DONE AND ORDERED this 26th day of April, 2018, in Tallahassee, Leon County, Florida.



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NOTICE OF RIGHT TO JUDICIAL REVIEW

A party who is adversely affected by this Final Order is entitled to judicial review pursuant to Section 120.68, Florida Statutes. Review proceedings are governed by the Florida Rules of Appellate Procedure. Such proceedings are commenced by filing one copy of a Notice of Administrative Appeal with the agency clerk of the Division of Administrative Hearings and a second copy, accompanied by filing fees prescribed by law, with the District Court of Appeal, First District, or with the District Court of Appeal in the appellate district where the party resides. The Notice of Administrative Appeal must be filed within 30 days of rendition of the order to be reviewed.

METHADONE MEDICATION-ASSISTED TREATMENT PROVIDER APPLICATION IN RESPONSE TO EMERGENCY RULE

MYFLFAMILIES.COM

Submission Date (Month, Day, Year)

Date Received by DCF (Office Use Only) (Month, Day, Year)

I. APPLICANT INFORMATION

1. Location of Proposed Site: County:	2a. Legal Name of Business/Service Provider **(If multiple locations, enter CORPORATE HEADQUARTERS name)**
	2b. Federal Identification Number
	2c. National Provider Identifier (NPI)
3a. Name of Service Provider	4a. Business Website Address
3b. Name of Owner	4b. Point of Contact Email Address

5. Business/Owner's Mailing Address

5a. City	5b. State	5c. Zip Code	5d. County

6. Street Address (if different than mailing address)

6a. City	6b. State	6c. Zip Code	6d. County

7. Telephone (Area Code & Number)	8. Fax No. (Area Code & Number)

9. Please check the applicable box(es) below:

☐ Publicly Funded Provider ☐ Privately Funded Provider

10. Is the applicant currently licensed to provide substance abuse services in Florida? ☐ Yes ☐ No If yes, complete 10a thru 10b. If no, go to question 11.	10a. Name of Licensing Agency
	10b. Current License Number **Provide copies of current licenses with application, andmost recent inspection report.**

11. Do you plan to accept the following recipients (check all that apply)? ☐ Medicaid ☐ Indigent Persons ☐ Pregnant Women

Please submit documentation of the provider's ability to treat the select population(s).

II APPLICANT'S CAPABILITY OF PROVIDING SERVICE

12. Please submit documentation related to the following:

☐ A description of the target population (including demographics) and the geographical areas to be served.

☐ Proof of a physician, on staff, holding a valid license to operate in Florida.

☐ Written timeframe and supporting documentation of the anticipated initiation of services if approved to open a facility.

☐ Proof of registration with the Department of Revenue or the Florida Department of State Division of Corporations.

13a. Name of the Chief Executive Officer (print)	14. Date (Month, Day, Year)
13b. Name of the Chief Executive Officer (original signature only)	