

STATE OF LOUISIANA

COURT OF APPEAL

FIRST CIRCUIT

NUMBER 2003 CA 0643

OPIATE REPLACEMENT THERAPY CENTERS OF AMERICA, INC.

VERSUS

THE STATE OF LOUISIANA THROUGH THE DEPARTMENT OF HEALTH AND HOSPITALS, BUREAU OF HEALTH STANDARDS

Judgment Rendered: February 23, 2004

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Appealed from the Nineteenth Judicial District Court in and for the Parish of East Baton Rouge, State of Louisiana Suit Number 489,346

Honorable Timothy E. Kelley, Judge

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BEFORE: FOIL, FITZSIMMONS, AND GAIDRY, JJ.

*Foil, J., concurs in the result. [Signature]*

## **FITZSIMMONS, J.**

The State of Louisiana, through the Department of Health and Hospitals, Office of Addictive Disorders (department), functioned as the State Authority for Methadone (SMA) clinics. The department, in fulfilling its duty as SMA, required an application be submitted by all prospective opiate replacement therapy clinics before a license could be granted by another department agency, the Bureau of Health Services Financing, Health Standards Section. Upon receiving a request to operate an opiate replacement therapy or methadone program, the department sent each applicant a “standard” letter, which required the applicant to follow an established protocol pursuant to agency regulations. See LAC 48:I.7443A & 48:VII.501B. Specifically, since about 1980, an applicant was required to submit sufficient information to establish that a “need” existed in the community; that is, the area that would be reasonably served by the proposed treatment facility. The informational report was called a “needs assessment.” If a true need in the community was shown, the need was certified by the department and approval to establish a facility or clinic was given. A license could be subsequently granted, if other federal and state requirements were met. If no need was shown, the application was denied.

In October of 2000, the department approved Opiate Replacement Therapy Centers of America, Inc.’s (ORTC) request to establish the Breaux Bridge Treatment Center, contingent on all other state and federal requirements. Subsequently, by letter dated November 21, 2000, Dr. Alex John, Jr., Ed.D., requested permission to open a similar clinic in the same general Lafayette area. After review of the “needs assessment” submitted by Dr. John, the department found that Dr. John failed to demonstrate a need for two clinics in the area that would be reasonably served. Specifically, the application was denied based on the

capacity of the existing clinics within the area and their occupancy rate. On February 7, 2001, the department denied Dr. John's request.

Effective April 3, 2001, ORTC was granted a license to "operate at the geographical address listed on the enclosed license." In May of 2001, Dr. John asked for reconsideration of his denied application. While reviewing the request for reconsideration, the department was advised by its legal counsel that it did not have statutory authority to require a certification of need based on a needs assessment. In response to that decision, the department sought to impose a moratorium on the granting of licenses. However, before the moratorium became effective, the department reversed its earlier denial of Dr. John's application based only on the assumed lack of authority, not a new finding of need. Dr. John's application to establish a clinic in Opelousas, without a needs certificate, was approved in June, 2001. The moratorium went into effect on July 1st.

On November 2, 2001, ORTC sued for injunctive relief. It challenged the department's finding that the "needs" regulation and protocol exceeded statutory authority. By a supplemental and amending petition, ORTC converted the proceeding to one for declaratory judgment. It re-affirmed its allegation that the "needs" regulation was valid and asked that the approval of Dr. John's application be declared null and void for failure to meet the regulatory standard. Dr. John intervened.

After trial, the trial court found that the department had the authority to obtain a "needs assessment," and to require a certification of need before approval to operate a clinic or facility could be given. Based on those findings, the court ruled that the department's approval to operate a treatment facility, without a certification of need, was an abuse of discretion. Therefore, the approval of Dr. John's application was declared to be null and void. The matter was then remanded to the department for further proceedings.

The department and Dr. John appealed. Although the constitutionality of the applicable statutes or regulations was not directly attacked at trial, appellants essentially argue that: (1) the department did not have legislative authority to promulgate a regulation requiring a needs assessment or to deny approval based on a finding of “no need”; (2) without specific quantitative and qualitative criteria for the needs determination, the process is too subjective and the department’s regulation could not be implemented; and (3) without a valid needs assessment requirement, the department’s decision to grant was within its discretion and not arbitrary or capricious.

The following legal precepts, in pertinent part, are applicable to the issues:

La. R.S. 40:1058.2

A. The Department of Health and Hospitals shall promulgate rules, regulations, and standards governing providers of substance abuse/addiction treatment services. The rules, regulations, and standards shall be promulgated in accordance with the Administrative Procedure Act and shall include at a minimum the following:

(1) Procedures to ensure the health, safety, and well-being of clients.

(2) Procedures to ensure that clients receive optimum treatment in order to achieve recovery.

(3) Procedures which allow the department to monitor facilities.

(4) Strategies to determine treatment priorities, as well as inpatient and outpatient criteria.

(5) Criteria to assure access of care without overutilization of services.

(6) Protocols to assure uniform and quality assessment, diagnosis, evaluation, and referral to appropriate level of care.

(7) Procedures to assure operational capability and compliance.

(8) Procedures for the application process.

(9) Procedures for annual on-site surveys and complaint investigations.

(10) Procedures to assure that only qualified personnel are providing care.

(11) Procedures to assure that delivery of services shall be cost-effective and in conformity with current standards of practice.

(12) Procedures to assure confidentiality of clients' records.

La. R.S. 40:1058.3

A. (1) Application to operate a substance abuse/addiction treatment facility shall be made to the department on application forms furnished by it and shall contain such information as is reasonable for the agency to require. The application shall be accompanied by a license fee.

La. R.S. 40:1058.5

A. An application for a license may be denied for any of the following reasons:

(1) Violation of any of the minimum standards prescribed by this Part and by the department.

The traditional practice of the department, which was mirrored in the department's published standards to operate a methadone program, required "[e]vidence of need/community support for the methadone maintenance program . . . ." LAC 48:VII.501B(2).

If the direction is clear and minimum standards are outlined, the legislature may certainly delegate authority to an administrative agency to determine facts and carry out the terms of the legislation. **Schwegmann Bros. Giant Super Mkts. v. McCrory**, 237 La. 768, 788, 112 So.2d 606, 613 (1959); **State v. All Pro Paint & Body Shop, Inc.**, 93-1316, pp. 6-7 (La. 7/5/94), 639 So.2d 707, 711-12. The minimum standards need not be express if they may be reasonably inferred from the statutory scheme. **All Pro Paint & Body Shop, Inc.**, 93-1316 at p. 13, 639 So.2d at 716. The requirements of clear intention and minimum standards ensure the regulatory scheme constitutes a valid exercise of the state's imperative to

protect the health, welfare, and safety of the public. **All Pro Paint and Body Shop, Inc.**, 93-1316 at p. 12, 639 So.2d at 715; see La. Const. Preamble & art. 1.

In interpreting the meaning of legislative provisions, the “words of a law must be given their generally prevailing meaning.” La. C.C. art. 11. If the law is clear and does not lead to absurd results, “the law shall be applied as written . . . .” La. C.C. art. 9. If the meaning is not clear, the law should be interpreted to fulfill the goal of the legislation. La. C.C. art. 10. If the words used in the law are ambiguous, “the meaning must be sought by examining” all the provisions of the law and in the context of the statutory scheme. La. C.C. art. 12.

The criteria for judicial review of an agency decision on the validity or applicability of a rule is found in La. R.S. 49:964G. See La. R.S. 49:962. Generally, the manifest error test is applied to the findings of fact by the agency or department and the arbitrary and capricious test is applied to the department’s conclusions and exercise of its discretion. See La. R.S. 49:964G. The same standard of appellate review is used by both the trial and appellate courts, without the traditional deference to the factual determinations made by the trial court. **Blair v. Stalder**, 99-1860, p. 9 (La.App. 1 Cir. 1/31/01), 798 So.2d 132, 139. However, if the trial court takes additional evidence beyond that submitted at the agency level, deference to its determinations of fact would be appropriate. See La. R.S. 49:963B.<sup>1</sup>

### LEGISLATIVE AUTHORITY

Louisiana R.S. 40:1058.2 provides the minimum “[s]tandards for substance abuse/addiction care” to be governed by departmental regulations and rules. One of the legislative directives to the department is to insure “access of care without

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<sup>1</sup> The department reviewed its regulation and found that it exceeded statutory authority. We are satisfied from our review of the record that no remedy would be forthcoming from a contested, adjudicated case, and that a minimal showing of irreparable harm was made. In addition, neither party disputed that such harm would occur if the rule was improperly applied. See La. R.S. 49:963D; **Bueto v. Video Gaming Division, Office of State Police, Department of Public Safety**, 94-0334, p. 4 (La.App. 1 Cir. 3/4/94), 637 So.2d 544, 546.

overutilization of services.” La. R.S. 40:1058.2A(5). Additionally, the legislature directed the department to “ensure the health, safety, and well-being of clients, . . . monitor facilities,” provide for an “application process,” and “assure that delivery of services shall be cost-effective and in conformity with current standards of practice.” La. R.S. 40:1058.2A(1), (3), (8) & (11). The department was also given the authority to obtain information it reasonably required for the application process and to conduct an “on-site survey” to insure that “minimum standards” were met before issuance of a license. La. R.S. 40:1058.3A(1); R.S. 40:1058.2A(9); R.S. 40:1058.4A. If the “minimum standards” set by the department are not met, the department may deny an application for a license. La. R.S. 40:1058.5A(1).

Considering the provisions of La. R.S. 40:1058.2A within the context of the statutory scheme, and using the common meanings of the words of the provisions, we find that the overall legislative goal is to offer safe, reasonable, adequate access of care, without overuse or abuse of the services. We interpret these multiple requirements as a mandate for a balanced approach to the opening of treatment facilities. To implement these goals, the legislature bestowed on the department the authority to set minimum standards based on the directives found in La. R.S. 40:1085.2, including the requirement that services must be “cost-effective and in conformity with current standards of practice.” La. R.S. 40:1058.2A(11). According to the un rebutted testimony at trial, the then current national standards of practice for offering services to addicts, and the state standards since 1980, included a finding of need and consideration of the impact of the facility on the community. The ultimate goal of all legislation must be to provide for the common good, and the safety and general welfare of the people of this state. See La. Const. Preamble & art. 1. By providing not only for adequate, cost-effective services, without overutilization or abuse, but also for the health and safety of the

clients and that of the community, the needs assessment and certification are instrumental in fulfilling both the legislative will and the overriding constitutional imperative. We agree with the trial court that the safety of the public is a particularly important consideration when administering methadone, a highly addictive schedule II controlled substance, in a community setting. Unlike a pharmacy, these treatment facilities provide an alternative drug, but a still addictive one, exclusively to former opiate addicts. The importance of obtaining and reviewing community needs information in the licensing process is emphasized by the trial court's finding that saturation of services could lead to overutilization and abuse of services by patients and create a danger to public safety. For example, un rebutted evidence was submitted to show that abuse or overuse of the services by the patients could result in unnecessary addiction to methadone. See La. R.S. 40:964, Schedule II, B(11). The testimony also showed that dual registrations, by the same patient at different treatment facilities, are made to obtain extra methadone for illegal sale to the public. By promulgating the regulation found in LAC 48:VII.501B(2), which included the department's traditional practice of requiring evidence of need and community support, the department sought to insure the statutory mandates. The regulation and protocol also provided for the common good - an obligation often forgotten in the fragmented society of today. The practical implementation of the regulation is through submission of the needs assessment by the applicant, review by the department, and the requisite issuance of a certification of need before the applicant receives approval to establish a facility and proceed toward licensure. Such procedures also protect the safety and welfare of the people of this state.

This record supports the finding that the department's regulation and protocol, requiring a showing of need before approval of an application, did not exceed the statutory authority granted to the department. From our review, we find



no evidence of overreaching or departmental requirements beyond the legislative authorization. We also agree that the department's conclusion, that the regulation was invalid and would not be applied to Dr. John's application, affected substantial rights of ORTC, was an abuse of discretion, and was not sustainable under the record. See La. R.S. 49:964G(5) & (6). Essentially, the department breached its obligation to provide for the common good and protect the health and welfare of the public.

### **GUIDELINES**

The "standard" letter to applicants requesting a needs assessment required the general number of patients in need of treatment and identification of established treatment programs in the state and surrounding areas. The needs assessments in the record included evidence of potential clients; the location, capacity, and occupancy rates of established service programs; and the location and number of clients that could be treated at the proposed facility. The submitted information was reviewed by a department employee for a determination of whether the community to be served actually needed the services.

From our review of the record, and notwithstanding the absence of more definitive written guidelines, we agree with the trial court's finding that the "needs" requirement should have been applied to Dr. John. In this particular case, the letter and protocol were minimally sufficient. In addition, the department's initial determination, that the information submitted by Dr. John did not show a need for another facility in the community, was a reasonable one and supported by the information contained in the needs assessment.

Obviously, different communities, whether urban or suburban, have varying numbers of residents, potential clients, and established clinics or treatment facilities. No set number of clinics would serve the needs of all types of communities. While more extensive and objective written procedures than a

“standard” letter may be prudent, the absence of more definitive qualitative or quantitative guidelines did not render the requirements of LAC 48:VII.501B(2) invalid. And certainly, the lack of more extensive guidelines did not invalidate the department’s legislative mandate to insure the services offered by the facilities met minimum standards based on current practices and did not lead to overutilization or abuse of services. Even assuming appellants’ allegation of inadequate guidelines or an overly subjective review process had merit, such weaknesses support a moratorium or a denial of the application, not a grant in derogation of the statutory mandates. See La. R.S. 40:1058.5A. From our review, we find that the argument based on inadequate guidelines does not provide a reasonable or sufficient basis for the department’s failure to apply its “needs” regulation and protocol.

Finally, we do not agree with appellants’ arguments that the record here contains sufficient evidence to prove that commerce and competition were unreasonably or improperly curtailed by the needs requirement. Nor do we agree that the use of the word “may,” in connection with the denial of applications for licenses under La. R.S. 40:1085.5A, allows the department to ignore its own important requirement of a needs assessment in the application process or those of the state legislature.

For these reasons, we affirm the judgment of the trial court. The costs of the appeal, \$831.35, are assessed equally to defendant-appellants, Louisiana Department of Health and Hospitals and Dr. Alex John, Jr.

**AFFIRMED.**