

COLORADO COURT OF APPEALS

Court of Appeals No.: 05CA2358
Colorado State Pharmacy Board
No. 3.00.21

Brighton Pharmacy, Inc., and Donald Coble, Pharm.D., CDE,

Appellants,

v.

Colorado State Pharmacy Board,

Appellee.

ORDER AFFIRMED

Division I

Opinion by: JUDGE ROY
Márquez and Furman, JJ., concur

Announced: April 5, 2007

Ducker, Montgomery, Aronstein & Bess, P.C., Joel W. Cantrick, Denver,
Colorado, for Appellants

John W. Suthers, Attorney General, Joanna Lee Kaye, Assistant Attorney
General, Denver, Colorado, for Appellee

Appellants, Brighton Pharmacy, Inc. (the pharmacy), and Donald Coble, Pharm.D., CDE (the pharmacist), seek review of the rulemaking action of the Colorado State Pharmacy Board (the Board) following which it promulgated Rule 3.00.21, 3 Code Colo. Regs. 719-1 (the Rule). We affirm.

On July 21, 2005, the Board held a rulemaking hearing to consider a rule prohibiting pharmacists from dispensing prescription drugs resulting from Internet-based questionnaires, Internet-based consultation, or a telephonic consultation without a valid preexisting patient-practitioner [patient-physician] relationship. As ultimately adopted, the Rule states:

A pharmacist shall make every reasonable effort to ensure that any order, regardless of the means of transmission, has been issued for a legitimate medical purpose by an authorized practitioner. A pharmacist shall not dispense a prescription drug if the pharmacist knows or should have known that the order for such drug was issued on the basis of an internet-based questionnaire, an internet-based consultation, or a telephonic consultation, all without a valid preexisting patient-practitioner relationship.

From our review of the record, it appears that a typical scenario addressed by this Rule involves websites to which a consumer can go and request a prescription for a particular pharmaceutical. Requests for Viagra (sexual enhancement) and hydrocodone (pain killer) constitute a significant portion of the business. The customer then answers a series of prepared questions unique to the pharmaceutical requested. The answers are submitted to a physician who issues an electronic prescription and transmits it to a participating pharmacy which fills it and sends the pharmaceutical to the customer. Frequently, the customer, physician, and pharmacist are all from different states and have never met. The charge for pharmaceuticals is considerably higher under this arrangement than with more traditional sources and no insurance is involved. While this record does not show who owns or operates the website and how the physician and pharmacy are paid, the pharmacy is normally paid considerably more in this arrangement than it would otherwise receive for the same pharmaceutical.

There are legitimate variations on this theme, which, from the pharmacies' perspective, have similar characteristics and may be

difficult to differentiate. The pharmacist testified that there were many legitimate instances of persons obtaining drugs over the Internet and expressed his concern that the proposed legislation would hinder persons with valid medical needs from obtaining their prescriptions in this manner. This appeal followed.

I.

Rules adopted by an administrative or regulatory agency are presumed valid, and the challenging party has a heavy burden to establish a rule's invalidity. Colo. Ground Water Comm'n v. Eagle Peak Farms, Ltd., 919 P.2d 212 (Colo. 1996). The invalidity of a rule may be established by demonstrating that a rulemaking body (1) acted in an unconstitutional manner; (2) exceeded its statutory authority; or (3) acted in a manner contrary to statutory rulemaking requirements. Section 24-4-106(7), C.R.S. 2006; Brown v. Colo. Ltd. Gaming Control Comm'n, 1 P.3d 175 (Colo. App. 1999).

The appropriate standard of review for a rulemaking proceeding is one of reasonableness. Brown v. Colo. Ltd. Gaming Control Comm'n, supra. A reviewing court may not substitute its judgment for that of the administrative agency on the merits of the

adopted rule. Citizens for Free Enter. v. Dep't of Revenue, 649 P.2d 1054 (Colo. 1982).

II.

Appellants assert that the agency did not substantially comply with the rulemaking procedures of the Colorado Administrative Procedure Act (APA), § 24-4-101, et seq., C.R.S. 2006. We disagree.

The statutory rulemaking requirements are set forth in § 24-4-103, C.R.S. 2006. The APA requires “substantial compliance” with the procedures, and an agency’s failure to meet that standard renders the rule invalid. Section 24-4-103(8.2)(a), C.R.S. 2006. Substantial compliance is more than minimal compliance, but less than strict or absolute compliance. Woodsmall v. Reg'l Transp. Dist., 800 P.2d 63 (Colo. 1990). To determine whether there has been substantial compliance, we look, inter alia, to the extent of the noncompliance and the purpose of the provision violated. Studor, Inc. v. Examining Bd. of Plumbers, 929 P.2d 46 (Colo. App. 1996).

A.

First, appellants assert that the Board did not provide a complying statement of basis and purpose as required by the APA. We disagree.

The APA requires a prehearing statement of basis and purpose, § 24-4-103(2.5)(a), C.R.S. 2006; and “[a]fter consideration of the relevant matter presented, the agency shall incorporate by reference on the rules adopted a written concise general statement of their basis, specific statutory authority, and purpose.” Section 24-4-103(4)(c), C.R.S. 2006. The reason for the former requirement is to provide public notice of what the agency is considering, and the latter requirement is to assist in appellate review. Citizens for Free Enter. v. Dep’t of Revenue, *supra*, 649 P.2d at 1062.

Here, the Board included the following statement of basis and purpose in its notice of rulemaking hearing and in its final publication of the rule:

Basis and Purpose: Proposed Rule regarding Dispensing of Orders resulting from Internet-based questionnaires, Internet-based consultation, or a telephonic consultation without a valid preexisting patient-practitioner relationship.

Appellate review of whether the basis and purpose of a rule has foundation in fact is not de novo and is tied to the administratively compiled record. Citizens for Free Enter. v. Dep’t

of Revenue, supra; see also Walter O. Boswell Mem'l Hosp. v. Heckler, 573 F. Supp. 884, 889 (D.D.C. 1983).

With respect to the second, post-hearing statement, the court in Citizens for Free Enterprise v. Department of Revenue, supra, stated:

Second, and perhaps of more importance, is the nature of the "factual" findings underlying the department's conclusion. In applying the "based on the record" requirement of section 24-4-103(4), courts should display sensitivity to the range and nature of determinations that must be made by an administrative agency. On the one end of the continuum, regulations may be based primarily upon policy considerations, with factual determinations playing a tangential or unimportant role. In that context, specific factual support for the regulation should not be required, although the reasoning process that leads to its adoption must be defensible. See Colorado Auto & Truck Wreckers Association v. Department of Revenue, [618 P.2d 646 (Colo. 1980)]; K. Davis, Administrative Law Treatise §§ 6:13, 14:28 (2d ed. 1978). On the other extreme, the necessity for the regulation may turn upon a discrete fact capable of demonstrable proof. In that case, the reasonableness of agency action will depend upon the presence of factual support for its determination. K. Davis, Administrative Law Treatise, §§ 6:13, 14:28 (2d ed. 1978). Often, the reasonableness of agency action will involve combined factual determinations and policy choices, and the nature and scope of

judicial review must be appropriately tailored depending upon which is predominant. In this respect, the United States Supreme Court has recently recognized that regulations may be based on "judgmental or predictive facts," which are primarily founded on policy choices rather than factual determinations and which are not capable of definitive proof. In evaluating the adequacy of the record to support such factual determinations, some deference to administrative expertise is appropriate. FCC v. National Citizens Committee for Broadcasting, 436 U.S. 775, 98 S.Ct. 2096, 56 L.Ed.2d 697 (1978); accord, National Small Shipments Traffic Conference, Inc. v. CAB, 618 F.2d 819 (D.C. Cir.1980); see generally K. Davis, Administrative Law Treatise § 29.00-1 (1982 Supp.).

Citizens for Free Enter. v. Dep't of Revenue, supra, 649 P.2d at 1064-65 (footnote omitted).

Here, the regulation was not based on findings of fact obtained from evidence presented at the hearing or otherwise. Instead, it was based almost entirely on policy considerations. Indeed, at the hearing the pharmacist and another practitioner acknowledged the problem raised by Internet prescriptions based on questionnaires and without any valid physician-patient relationship other than communication over the Internet or by telephone pursuant to the

patient's narrow request to have a prescription for a specific pharmaceutical.

In addition, the purpose of the regulation is self-explanatory. Cal-Almond, Inc. v. U.S. Dep't of Agric., 14 F.3d 429, 443 (9th Cir. 1993)(regulation without a basis and purpose statement was upheld because its basis and purpose were obvious).

Therefore, we conclude that the agency substantially complied with the APA requirement of providing a statement of basis and purpose.

B.

Appellants next assert that the Board has not maintained an adequate and appropriate record of the rulemaking hearing proceeding. We disagree.

The APA requires that the agency rulemaking record must contain "[a]ny official transcript of oral presentations made in the proceeding upon which the rule is based or, if not transcribed, any tape recording or stenographic record of those presentations and any memorandum prepared by a presiding official summarizing the contents of those presentations." Section 24-4-103(8.1)(b)(IV), C.R.S. 2006. Maintaining an adequate record provides a rationale

and support for agency decisions; allows for public inspection of the agency's actions; and establishes a record that an appellate court may use to evaluate the basis of an agency's conclusions. Citizens for Free Enter. v. Dep't of Revenue, supra; Studor, Inc. v. Examining Bd. of Plumbers, supra. Agency actions are to be reviewed based solely upon the record made before the agency. Studor, Inc. v. Examining Bd. of Plumbers, supra.

Here, the hearing was tape recorded and subsequently transcribed. The transcript contains numerous omissions because portions of the tape were inaudible and frequently failed to identify the speaker. Upon appellants' request, the representatives of the Board who were present at the hearing reviewed the transcript, filled in some of the missing statements, and identified many of the speakers.

However, following this effort there remained inaudible and unreconstructed portions of the tape recording. Appellants assert that these remaining instances render the transcript inadequate and, therefore, the transcript does not meet the APA's record requirement. However, the substance of and core testimony at the hearing appears to be intact and is sufficient, in our view, for public

inspection and appellate review. In addition, written comments were included in the record from, among others, the pharmacist that address many of the items discussed at the hearing.

Similarly, we are not persuaded by appellants' assertion that the lack of discussion by Board members renders the Rule invalid. While appellants are correct that much of the Board's discussion is inaudible, the comments and questions during the testimony are sufficient, in our view, to convey the Board's thought process and reasoning.

Finally, as to the record of the rulemaking hearing, appellants assert that the voice vote of the Board members renders it impossible to determine whether the rule was adopted by the majority of a quorum because the transcript does not reflect attendance or how those present voted. However, the record indicates that a quorum of the Board was present, and the vote in favor of the Rule was unanimous. Under these circumstances, the record sufficiently indicates that the majority of a quorum voted in favor of the Rule.

Therefore, we conclude that the Board substantially complied with APA rulemaking provisions.

III.

Appellants next assert that the agency exceeded its statutory authority in enacting the Rule. Specifically, appellants assert that a determination of whether there is a “valid preexisting patient-practitioner relationship” necessarily involves knowledge of the Medical Practice Act, § 12-36-101, et seq., C.R.S. 2006, and the rules promulgated by the Colorado State Board of Medical Examiners (BME); is beyond the expertise of individual pharmacists and the Board; and improperly injects the Board into areas which are properly regulated by the BME. We disagree.

As previously stated, an agency must operate within the boundaries of its legislative authorization. Section 24-4-106(7). We use traditional tools of statutory construction to determine the intent of the General Assembly as to whether an administrative regulation exceeds legislative authorization. If determining the intent is possible, then that interpretation must be given effect, and the administrative regulations at issue must be fully consistent with it. Barela v. Beye, 916 P.2d 668 (Colo. App. 1996). In addition, we give deference to the interpretation of a statute by the agency

charged with enforcement of that statute. Urbish v. Lamm, 761 P.2d 756 (Colo. 1988).

Here, § 12-22-101, C.R.S. 2006, of the Pharmacy Act (the Act), provides:

The practice of pharmacy is declared a professional practice affecting the public health, safety, and welfare and is subject to regulation and control in the public interest. It is a matter of public interest and concern that the practice of pharmacy . . . merits and receives the confidence of the public and that only qualified persons be permitted to practice pharmacy in this state. [The general provisions of the Act] shall be liberally construed to carry out these objects and purposes.

The Board has the responsibility of enforcing the Act, § 12-22-103, C.R.S. 2006, and may promulgate rules “as may be deemed necessary by the board for the proper administration and enforcement of the responsibilities and duties delegated to the board by this article.” Section 12-22-108, C.R.S. 2006. Those responsibilities include “[t]he regulation of the sale at retail and the dispensing of drugs.” Section 12-22-112(1)(a), C.R.S. 2006; see also Moore v. Dist. Court, 184 Colo. 63, 518 P.2d 948 (1974).

Here, the determination of whether a “valid preexisting patient-practitioner relationship” exists does not exceed a pharmacist’s or the Board’s scope of technical experience and expertise because the Rule provides that pharmacists shall not dispense a prescription when he or she “knows or should have known” of the lack of such a relationship. “Actual knowledge” is defined as “[d]irect and clear knowledge as distinguished from constructive knowledge.” Black’s Law Dictionary 888 (8th ed. 2004); see also Lombard v. Colo. Outdoor Educ. Ctr., Inc., ___ P.3d ___ (Colo. App. No. 05CA1781, Jan. 25, 2007). Therefore, any time a pharmacist actually knows about the lack of a valid patient-practitioner relationship, the rule prohibits dispensing the prescription.

Similarly, the phrase “should have known” does not create a need for specialized medical knowledge. The phrase “should have known” has historically been used in conjunction with “know” or “knowledge” to create an objective standard to avoid denial of apparent facts or intentionally induced ignorance. A division of this court in Sulca v. Allstate Insurance Co., 77 P.3d 897 (Colo. App. 2003), stated:

Dictionaries define “knowledge” as “an awareness or an understanding” and “actual knowledge” as “[an awareness or an understanding] of such information as would lead a reasonable person to inquire further.” E.g., Black’s Law Dictionary 876 (7th ed. 1999); Webster’s Third New International Dictionary 1252 (1986) (defining “knowledge” as “the act, fact, or state of knowing . . . awareness [or] understanding”).

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The requirement that a plaintiff use due diligence in discovering the relevant circumstance or event imposes an objective standard and does not reward denial or self-induced ignorance.

Sulca v. Allstate Ins. Co., supra, 77 P.3d at 900; see also Lombard v. Colo. Outdoor Educ. Ctr., Inc., supra. Therefore, an objectively reasonable person standard applies when determining if a pharmacist “should have known” whether there is a valid patient-practitioner relationship.

In addition, pharmacists already have a duty to exercise due diligence in examining a prescription to determine its legitimacy. See Rule 3.00.20 (prohibiting pharmacists from dispensing any drug to any person “in such quantity or in any situation where the licensee or registrant knows or reasonably should know said drug has no recognized medical utility or application”); see also § 12-22-

126(1)(h), C.R.S. 2006 (it is illegal “[t]o sell, compound, dispense, give, receive, or possess any drug or device unless it was sold, compounded, dispensed, given, or received in accordance with sections 12-22-121 to 12-22-124”). Rule 300.21 extends that duty to Internet prescription activity.

Finally, we do not perceive any conflict with the BME’s ability to regulate the practice of medicine because the BME already has rules establishing that it is unprofessional conduct to issue a prescription without a preexisting patient-practitioner relationship. Pharmacists should fill only those prescriptions issued by practitioners authorized to issue them. See § 12-22-102(27), C.R.S. 2006. BME Policy 40-9 provides guidelines for physicians issuing prescriptions to unknown patients prior to completing an appropriate exam. It states, in pertinent part:

[I]t is unprofessional conduct for a physician to provide treatment and consultation recommendations, including issuing a prescription, via electronic or other means, unless the physician has obtained a history and physical evaluation of the patient adequate to establish diagnoses and identify underlying conditions and/or contra-indications to the treatment recommended/provided. Issuing a prescription on the basis of a questionnaire,

Internet-based consultation, or a telephonic consultation, all without a valid pre-existing patient/practitioner relationship does not constitute an acceptable standard of care.

BME Policy 40-9 (emphasis added). The regulation then describes limited circumstances in which a physician may prescribe prescriptions for a patient whom the physician has not personally examined.

Therefore, we are satisfied that the Board's regulation of the sale and dispensing of drugs in this manner does not exceed its statutory authority.

IV.

Finally, appellants assert that the phrases "valid preexisting patient-practitioner relationship" and "internet-based questionnaire, an internet-based consultation, or a telephonic consultation" are impermissibly vague and overbroad. We disagree.

Regulations adopted by an administrative agency are presumed valid. Bd. of County Comm'rs v. Colo. Oil & Gas Conservation Comm'n, 81 P.3d 1119 (Colo. App. 2003).

The generally accepted test for vagueness is "whether the statute 'either forbids or requires the doing of an act in terms so

vague that people of common intelligence must necessarily guess as to its meaning and differ as to its application.” People v. Smith, 638 P.2d 1, 3 (Colo. 1981)(quoting Connally v. Gen. Constr. Co., 269 U.S. 385, 391, 46 S.Ct. 126, 127, 70 L.Ed. 322 (1926)). Here, however, we are not dealing with persons “of common intelligence.” Rather, we are dealing with the regulation of trained professionals who should reasonably be expected to be knowledgeable as to their profession and the environment in which it is practiced.

In addition, as to vagueness, the APA requires that no rule be adopted unless “[t]o the extent practicable, the regulation is clearly and simply stated so that its meaning will be understood by any party required to comply with the regulation.” Section 24-4-103(4)(b)(III), C.R.S. 2006. This is a due process standard.

In Regency Services Corp. v. Board of County Commissioners, 819 P.2d 1049 (Colo. 1991), our supreme court addressed overbreadth in the context of a county regulatory scheme for massage parlors. The court stated:

A regulatory scheme suffers from constitutional overbreadth if it threatens the existence of protected fundamental rights by encompassing those protected activities within its prohibition. . . . In light of the fundamental

nature of the rights implicated by the overbreadth doctrine, “a heightened level of scrutiny is involved in overbreadth analysis.” [People v. Becker, 759 P.2d 26, 29 (Colo. 1988)]. Where, however, fundamental freedoms are not implicated, a regulatory scheme will pass constitutional muster as long as it is reasonably related to a legitimate governmental interest. E.g., Village of Hoffman Estates v. Flipside, Hoffman Estates, Inc., 455 U.S. 489, 494-97, 102 S.Ct. 1186, 1191-92, 71 L.Ed.2d 362 (1982); Becker, 759 P.2d at 29.

Regency Servs. Corp. v. Bd. of County Comm’rs, supra, 819 P.2d at 1059-60.

Appellants have not identified, and we are not familiar with, a fundamental constitutional right that is violated or limited by any overbreadth of this regulation; nor do they argue that there is no legitimate governmental interest in the regulation of Internet pharmaceutical transactions. Appellants’ arguments sound in due process, and we will address them on that basis, utilizing the standard of Board of County Commissioners v. Colorado Oil & Gas Conservation Commission, supra.

A.

First, we conclude that the phrase “valid preexisting patient-practitioner relationship” is not impermissibly vague.

The term “practitioner” means “a person authorized by law to prescribe any drug or device, acting within the scope of such authority.” Section 12-22-102(27). While the phrase in question is neither defined in a dictionary nor defined by the agency, an agency need not define statutory terms with linguistic precision in order to withstand a vagueness challenge, nor does a statute have to specify every conceivable boundary of its application. Colo. State Bd. of Accountancy v. Paroske, 39 P.3d 1283 (Colo. App. 2001).

In addition, according to a witness from the Drug Enforcement Administration, that agency has the identical requirement in its regulations and the American Medical Association has a similar requirement. Moreover, an administrative hearing and judicial review are sufficient safeguards to ensure against an arbitrary or unbridled exercise of administrative discretion in applying the Rule. Colo. State Bd. of Accountancy v. Paroske, supra. Therefore, even if the phrase “valid preexisting patient-practitioner relationship” is not a term of general use, it is used by practitioners in the health care industry and should be well within the knowledge of a Colorado licensed pharmacist.

B.

Next, appellants argue that the phrases “Internet-based questionnaire,” “Internet-based consultation,” and “telephonic consultation” are vague. They assert that the Rule provides no guidance as to which transactions are covered by the Rule, with the result that legitimate Internet prescriptions practices as well as “rogue” Internet pharmacies will be prohibited. We conclude that that eventuality is remote, and therefore, disagree.

Appellants’ argument seems to be that while the terms “internet based” and “telephonic” are not vague and mean “electronic,” the terms “questionnaire” and “consultation” are vague. However, these phrases and terms are used in conjunction with the requirement that the prescribing physician have a “valid preexisting patient-practitioner relationship.”

To illustrate their argument, appellants pose the following scenario:

An example is a large New Jersey family on an extended vacation in Texas . . . that has an established relationship with its family doctor in New Jersey and that needs a variety of prescriptions filled or refilled, perhaps due to the loss of a prescription during the course of their travels. If the family seeks to obtain

prescription drugs via the Internet from a pharmacist in Colorado, no abuse is presented, and there is no rational basis to prohibit the transaction. Yet the broad language of the Rule would prohibit a Colorado pharmacist from filling the prescriptions because they are “numerous,” involve the same physician, and the patient, the physician, and the pharmacist are located in different states.

At the outset, this scenario ignores the existence of an established and valid New Jersey patient-practitioner relationship. It also ignores the more likely alternatives of calling the New Jersey physician or the New Jersey pharmacy, or both, and picking up the prescriptions at the nearest pharmacy in Texas. But, in the unlikely event the New Jersey family would choose to fill the prescriptions in this manner, the Colorado pharmacy would require a prescription, which would be obtained, probably electronically, from the New Jersey pharmacy or the New Jersey physician with an established patient-practitioner relationship that is easy to verify. There would be no need to retain the services of an Internet physician who would prescribe based on an Internet questionnaire, Internet consultation, or telephone consultation, and presumably cost a great deal more.

In our view, the terms and phrases to which appellants object are not vague or ambiguous.

The Board's order adopting the rule is affirmed.

JUDGE MÁRQUEZ and JUDGE FURMAN concur.