STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS

PROVIDENCE, SC	**Filed: May 28, 2003**	**SUPERIOR COURT**
CHRISTOPHER CHAPPELL **Appellant**	: :	
V.	:	**C.A. No. PC 02-4586**
RHODE ISLAND DEPARTMENT OF HUMAN SERVICES **Appellee**	: :	

DECISION

KRAUSE, J. This is an appeal from a decision of the Rhode Island Department of Human Services ("DHS," the "Agency," or "appellee"), denying Mr. Christopher Chappell's (the "appellant" or "Chappell") request that the Agency reimburse him, pursuant to the Agency's Medical Assistance Program (the "MA Program") for costs related to his use of the drug, Provigil. Jurisdiction is pursuant to G.L 1956 § 42-35-15.

FACTS/TRAVEL

The appellant was a participant in DHS's MA Program. The appellant principally suffered from a medical condition known as fibromyalgia, that caused relatively widespread pain throughout his body. As a result, the appellant had difficulty sleeping at night, and was groggy during the daytime. The appellant's physician, Dr. Edward Reardon ("Reardon"), prescribed the medication Provigil to treat the appellant's "chronic fatigue." Subsequently, DHS, via the MA Program, refused to cover the payment of this drug because the only Federal Food and Drug Administration (the "FDA") - approved use for it is narcolepsy – a condition from which the appellant apparently does not suffer.

On June 14, 2002 the appellant, pursuant to G.L. 1956 § 40-8-7, 1 Code of Rhode Island Regulations (CRIR) 19, Rule 15020 007 at 151, requested a hearing to appeal DHS's decision denying coverage for Provigil, and on July 9, 2002, DHS held a public hearing on the matter. At the hearing the appellant argued that because Reardon had prescribed Provigil for his chronic fatigue, DHS should have covered the payment of the drug. In support of his contention, the appellant presented the hearing officer with independent research that he (the appellant) had conducted on the internet regarding alternative uses for Provigil. DHS's pharmacist, Mr. Frank Morelli ("Morelli"), however, testified that since Provigil was not approved for the treatment of chronic fatigue, he could not approve its coverage pursuant to the MA Program. Morelli testified that, pursuant to federal guidelines, DHS may only cover the cost of Provigil for uses specifically approved by the FDA, or for uses that are supported by certain medically recognized journals. Since Provigil is approved only for the treatment of narcolepsy, and since the appellant's treating physician did not otherwise indicate his reasons for prescribing Provigil for the appellant's chronic fatigue, Morelli testified, he could only approve the coverage of Provigil for the treatment of narcolepsy. Nevertheless, the hearing officer reserved final judgment on the matter pending the receipt of a letter from Reardon specifically addressing why he had prescribed Provigil to treat the appellant's conditions.

On July 19, 2002, DHS received a letter dated July 19, 2002 from Reardon, simply stating that he (Reardon) felt that the appellant might "benefit from ... Provigil ... to aid in his chronic fatigue associated with [other conditions]." Letter of Dr. Edward Reardon of July 18, 2002 at 1. On July 23, 2002, the hearing officer issued a final,

written decision affirming DHS's denial of coverage for Provigil, from which the instant appeal was taken.

STANDARD OF REVIEW

Aggrieved parties may appeal a final decision of DHS to this Court pursuant to G.L. 1956 § 42-35-15, which provides in pertinent part:

> "(g) The court shall not substitute its judgment for that of the agency as to the weight of the evidence on questions of fact. The court may affirm the decision of the agency or remand the case for further proceedings, or it may reverse or modify the decision if substantial rights of the appellant have been prejudiced because the administrative findings, inferences, conclusions, or decisions are:
> (1) in violation of constitutional or statutory provisions;
> (2) in excess of the statutory authority of the agency;
> (3) made upon unlawful procedure;
> (4) affected by other error of law;
> (5) clearly erroneous in view of the reliable, probative and substantial evidence of the whole record; or
> (6) arbitrary or capricious or characterized by an abuse of discretion or clearly unwarranted exercise of discretion." G.L. 1956 § 42-35-15.

It is settled that this Court may not substitute its judgment for that of the agency under review as to the credibility of witnesses and/or the weight of the evidence concerning issues of fact. Costa v. Registrar of Motor Vehicles, 543 A.2d 1307, 1309 (R.I. 1988). Additionally, this Court generally gives deference to an agency's interpretation of its own regulations and governing statutes. Bureau of Alcohol, Tobacco & Firearms v. Federal Labor Relations Authority, 464 U.S. 89, 97, 78 L.Ed. 2d 195, 203, 104 S. Ct. 439, 445 (1983); Citizens Savings Bank v. Bell, 605 F. Supp. 1033, 1042 (D.R.I. 1983). The Court must confine its review to the record of the administrative hearing to determine if any "legally competent evidence" exists to support the agency's decision. Arnold v. R.I. Dept. of Labor and Training, No. 01-237 MP., slip op. (R.I. filed March 26, 2003) (defining legally competent evidence as "such relevant evidence that a

reasonable mind might accept as adequate to support a conclusion, and means an amount more than a scintilla but less than a preponderance"). Thus, the Superior Court must uphold the agency's findings if they are supported by competent evidence. R.I. Public Telecommunications Authority, et al. v. R.I. Labor Relations Bd, et al., 650 A.2d 479, 485 (R.I. 1994). Nevertheless, the Court may vacate a decision of the Agency if it is "clearly erroneous in view of the reliable, probative, and substantial evidence contained in the whole record." Costa, 543 A.2d at 1309.

* * * * * *

The appellant argues that DHS's decision and underlying rule denying coverage for Provigil contravened established federal and state laws because, he claims, whether or not a specific drug may be covered for a particular use does not depend exclusively on whether the FDA has expressly approved the drug for that use. The appellant also maintains that the DHS decision considered only the schedule of FDA approved uses for Provigil and did not consider whether its use in the treatment of the appellant's other conditions was supported by medically recognized compendia.

Pursuant to Title XIX of the federal Social Security Act, 42 U.S.C. §§ 1396 - 1396v (1992) (also known as the "Medicaid Act"), the State of Rhode Island, through the DHS, has established the MA Program, G.L. 1956 § 40-8-1 et seq., to aid low income individuals with the increasing costs of medical care. Although Rhode Island's participation in the Medicaid Act is optional, once the state opts to participate, it must fully comply with the "federal statutory and regulatory requirements." Ohlson v. Weil, 953 P.2d 939, 943 (Colo. App. 1997). According to the provisions of the Medicaid Act, Rhode Island, through DHS, must provide certain mandatory services to recipients. See

42 U.S.C. §§ 1396(a)(10)(A); 1396d(a)(1) to (5); 1396a(a)(17); 1396a(a)(21); and 42 C.F.R. §§ 440.210 and 440.220 (1996). Similarly, Rhode Island provides as an additional, optional service to recipients coverage of prescription drugs. 42 U.S.C. §§ 1396a(a)(10)(A) and 1396d(a)(12); G.L. 1956 § 40-8-1 et seq. With respect to the coverage of prescription drugs pursuant to these guidelines, 42 U.S.C. § 1396r-8(d)(1)(B) provides in pertinent part that a state may "exclude or otherwise restrict coverage of a covered outpatient drug if – (i) the prescribed use is not for a medically accepted indication . . . ." 42 U.S.C. § 1396r-8(d)(1)(B). 42 United States Code, section 1396r-8(k)(2) provides in relevant part that covered outpatient drugs are

> "(A) of those drugs which are treated as prescribed drugs for purposes of section 1396d(a)(12) of this title, a drug which may be dispensed only upon prescription . . . , and – (i) which is approved for safety and effectiveness as a prescription drug under section 505 or 507 of the Federal Food, Drug, and Cosmetic Act . . . or which is approved under section 505(j) of such act . . . ." 42 U.S.C. § 1396r-8(k)(2)(A).

Title 42 United States Code, section 1396r-8(k)(6) provides in pertinent part that

> "[t]he term 'medically accepted indication' means any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act . . . or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in subsection (g)(1)(B)(i) of this section." 42 U.S.C. § 1396r-8(k)(6).

Title 42 United States Code, section 1396r-8(g)(1)(B)(i) indicates that the compendia referred to in 42 U.S.C. § 1396r-8(k)(6) are comprised of the "(I) American Hospital Formulary Service Drug Information; (II) United States Pharmocopeia-Drug Information; (III) the DRUGDEX Information System; and (IV) American Medical Association Drug Evaluations," while 42 U.S.C. § 1396r-8(g)(1)(B)(ii) provides that "peer-reviewed medical literature" may also be used to demonstrate a medically accepted indication for a covered outpatient drug. 42 U.S.C. §§ 1396r-8(g)(1)(B)(i) and (ii).

General Laws 1956 , section 40-8-2(4) describes a drug, for the purposes of the MA Program, as including "only such drugs and biologicals prescribed by a licensed . . . physician as are either included in the United States pharmacopoeia, national formulary, or are new and nonofficial drugs and remedies." G.L. 1956 § 40-8-2(4).

Appellant argues that DHS's authority to limit coverage of Provigil, pursuant to 42 U.S.C. § 1396r-8(d)(1)(B), is not strictly limited to the schedule of approved uses for particular prescription drugs as promulgated by the FDA; in this case, the only FDA approved use for Provigil is for the treatment of narcolepsy, a condition from which the appellant does not suffer. Title 42 United States Code, section 1396r-8(d)(1)(B)(i) permits states to "exclude or otherwise restrict coverage" of outpatient drugs only when such drugs are not for "medically accepted indications," the latter term meaning "any use for a covered outpatient drug" which is either FDA approved or listed in certain recognized medical compendia. 42 U.S.C. §§ 1396r-8(k)(6) and 1396r-8(g)(1)(B)(i). Appellant claims that DHS has misinterpreted the definition of the term "medically accepted indication" as it was Congress' intent that the term should apply to all off-label uses for FDA approved drugs, not just the listed schedule of approved uses as indicated by the FDA. In other words, the appellant contends that simply because the FDA has only approved Provigil for the specific treatment of narcolepsy does not mean that DHS cannot cover its prescription for chronic fatigue if a treating physician believes that such a use is a medically accepted indication for the drug.

It has been said that "a golden rule of statutory interpretation [is] that, when one of several possible interpretations produces an unreasonable result, that is a reason for rejecting that interpretation in favor of another which would produce a reasonable result."

2A Norman J. Singer, Statutes and Statutory Construction § 45:12 at 81-82 (6th ed. 2000); see also Dart Industries v. Clark, 657 A.2d 1062, 1067 (R.I. 1995) (noting that courts will not interpret a statute so as to lead to an absurd result). It has also been noted that, "a statutory subsection may not be considered in a vacuum, but must be considered in reference to the statute as a whole . . . [and], all parts must be construed together without according undue importance to a single or isolated portion." Id. § 46:05 at 165-166; see also Warwick Mall Trust v. State, 684 A.2d 252, 257 (R.I. 1996) (interpreting individual provisions of a statute in light of the "act as a whole"). It is, therefore, axiomatic that "effect must be given, if possible, to every word, clause and sentence of a statute . . . [so that] no part will be inoperative or superfluous, void or insignificant . . . ." Id. § 46:06 at 181-186; see also Roberts v. City of Cranston Zoning Bd. of Review, 448 A.2d 779, 781 (R.I. 1982) (recognizing, as a "cardinal rule" of statutory interpretation, that "if possible, every word, clause, and sentence of a statute must be given effect . . . [and] [n]o sentence, clause or word should be construed as unmeaning and surplusage, if a construction can be legitimately found which will give force to and preserve all the words of the statute").

Presently, the appellant maintains that within the definition of "medically accepted indication," 42 U.S.C. § 1396r-8(k)(6), the word, "approved," modifies the word "drug," not the word "use." The resulting grammatical effect, it is argued, is that all conceivable medical uses for an FDA-approved drug warrant state Medicaid coverage. Appellant's Brief, at 5; see discussion supra at 5-6. If, however, such a construction were to be accorded to this half of the sentence, then the ultimate effect would be to render the following half of the sentence, which indicates that certain medical compendia may be used to demonstrate a medically accepted indication for a drug, "inoperative or

superfluous." Singer, Statutes and Statutory Construction, § 46:06 at 181-186; see Roberts, 448 A.2d at 781. The more reasonable construction of 42 U.S.C. § 1396r-8(k)(6) is that Congress intended the first half of the sentence to mean that all FDA approved *uses* for a particular covered outpatient drug equal a medically accepted indication, while the second half of the sentence indicates an alternative procedure for reaching the same result. See Singer, Statutes and Statutory Construction, §§ 46:05 at 165-166 and 46:06 at 181-186; Warwick Mall Trust, 684 A.2d 257; Roberts, 448 A.2d at 781. Specifically, an off-label use for a drug will equal a medically accepted indication if it is "supported by one or more citations included or improved for inclusion in any of the compendia described in subsection (g)(1)(B)(i) of this section." 42 U.S.C. § 1396r-8(k)(6).

The appellant's contention that DHS's rules and, specifically the instant DHS decision, improperly only considered the specific schedule of FDA-approved uses for Provigil and not the accepted medical compendia available, is not supported by the reliable, probative, and substantial evidence of record. The record reflects that Morelli based his decision to deny coverage on MA Program Regulation § 300-10-2, which addresses prior authorizations. That section reads in pertinent part that

> "[p]rior authorization is required for all drugs not included within the scope of the Medical Assistance Program . . . . Approval will be granted on the basis of the required information that was supplied." MA Program Regulation § 300-60-7.[1]

[1] At the time of the hearing, MA Program Regulation § 300-10-2 actually referred to long term care services - a subject with no relation to the present matter. Under the October 1993 enactment of DHS's regulations, § 300-10-2 did refer to prior authorizations under the pharmacy services section of the MA Program. However, pursuant to the September 1997 enactment, the section covering prior authorizations was changed to § 300-60-7.

The record indicates that Morelli denied the prior authorization because "the diagnosis of chronic fatigue by the physician [was] not an approved indication for [Provigil]." Tr. at 2. Morelli explained that "[i]n general . . . , I look at the diagnosis [of the prescribing physician] . . . [and] if [the prescribing physician] puts down a use of the medication which is not approved, or . . . even experimental in nature, I would deny it . . . ." Id. at 3. The following exchange between the Hearing Officer and Morelli, outlined Morelli's rationale for denying coverage: "Hearing Officer: So basically you denied [the appellant's] request to use Provigil because it's not approved for the treatment of chronic fatigue? Mr. Morelli: Right . . . if it's not an approved indicated use for any particular drug, the State has . . . the right to deny that service." Tr. at 3. Indeed, Morelli initially explained to the Hearing Officer that in the instant case, because Provigil was not FDA-approved for the treatment of chronic fatigue, and because Reardon, the treating physician, did not point to any recognized medical compendia supporting such a use, Morelli "could never approve it." Tr. at 6. However, Morelli continued: "we need something from the physician to support [his prescription] . . . we're willing to go further if the doctor wants to document – with any further information – [his prescription]." Id. Ultimately, there is no evidence of record that the appellant or Reardon cited, or otherwise made reference to, any of the accepted compendia enumerated in either 42 U.S.C. § 1396r-8(g)(1)(B)(i) or G.L. 1956 § 40-8-2(4), indicating that Provigil is medically recognized as a treatment for chronic fatigue. See generally Tr; see also Letter of Dr. Edward Reardon of July 18, 2002, at 1. Likewise, the appellant did not indicate which specific DHS rule or set of rules limits Agency approval of outpatient drugs to only FDA approved uses.

Even if the Hearing Officer's written decision may offer some inaccurate interpretations of law, there is no evidence that any such mistake seriously affected the propriety of his ruling or prejudiced any substantial rights of the appellant. See Belcher v. Director, 895 F.2d 244 (6th Cir. 1989) (where an Administrative Law Judge's application of the incorrect regulation in an action for disability benefits under the federal Black Lung Benefits Act was harmless error since the petitioner could not have met the requirements necessary for recovery under the proper regulation); see also Branniff Airways, Inc. v. Civil Aeronautics Bd., 379 F.2d 453 (D.C. Cir. 1967) (holding that "[r]eversal is not required by the fact that an agency made an error if it is shown that the error was not prejudicial"). Specifically, the Hearing Officer, in his decision, mistakenly states that "[t]he policies of the [MA Program] are clear, the agency cannot grant prior authorization for drugs prescribed for a use other than those approved by the . . . [FDA]." Decision at 3. This statement is inaccurate though, as DHS could properly approve a drug for an off label use if such use were supported by certain accepted medical compendia. See Bureau of Alcohol, Tobacco & Firearms, 464 U.S. at 97 (courts must give deference to an agency interpretation of its own regulations and enabling statutes; however, such deference should not rise to the level of blind allegiance); see also Citizens Savings Bank, 605 F. Supp. at 1042. Also, this Court can only speculate as to why the Hearing Officer indicated in his decision that "agency policies prohibit the authorization of medical procedures, including drugs, of an investigational or experimental nature." Decision at 3. While this statement is, ostensibly, true, it nevertheless suggests that the Hearing Officer's decision to uphold the Agency's denial was based, at least in part, on Provigil being an experimental drug. Despite this,

however, the record is bereft of any evidence that either Morelli or the Hearing Officer based his decision to deny coverage on whether Provigil was or was not experimental. Thus, while the Hearing Officer's written decision is somewhat unclear as to why he affirmed the Agency's denial, the record more clearly points to his rationale, and such a lack of clarity in the written decision constitutes harmless error. See Korpel v. Heckler, 797 F.2d 858, 866 n.4 (10th Cir. 1986) (even though district court "should have elaborated on the facts which formed the basis for its conclusions . . . such an omission is, however, harmless error because the record supports such findings"). Accordingly, since the treatment of chronic fatigue is not an FDA approved use for Provigil, and since the appellant did not provide the hearing officer with any evidence that the use of Provigil for the treatment of chronic fatigue is a medically accepted indication pursuant to the medical compendia listed in 42 U.S.C. § 1396r-8(g)(1)(B)(i), or G.L. 1956 § 40-8-2(4), the hearing officer's decision upholding DHS's decision to deny coverage for Provigil, with respect to this issue, was not erroneous.

The appellant further contends that by limiting its coverage of prescription drugs to ones, the uses of which are expressly FDA-approved, DHS's decision and underlying rule are unreasonable and inconsistent with federal and state law, and ultimately have the effect of excluding medically necessary drugs from coverage. However, since neither the July 23, 2002 decision, nor any underlying DHS rule limited the coverage of Provigil as the appellant avers, this argument must fail.

The appellant also claims that DHS's decision denying him prescription drug coverage constituted an arbitrary denial or reduction in "the amount, scope, or duration of a covered service solely because of diagnosis." The appellant has referred this Court to

42 C.F.R. § 440.230, which defines the sufficiency of amount, duration, and scope of certain compliant state Medicaid services. Title 42 Code of Federal Regulations, section 440.230 (2002) provides in pertinent part that

> "(b) [e]ach service must be sufficient in amount, duration, and scope to reasonably achieve its purpose. (c) The Medicaid agency may not arbitrarily deny or reduce the amount, duration, or scope of a *required service* under §§ 440.210 and 440.220 to an otherwise eligible recipient solely because of the diagnosis, type of illness, or condition." 42 C.F.R. § 440.230. (Emphasis added).

Presently, the appellant maintains that because DHS's decision to deny his request for coverage was based on his diagnosis of chronic fatigue, this constituted an impermissible denial of coverage pursuant to 42 C.F.R. § 440.230. In support of this contention, the appellant cites to Weaver v. Reagen, 886 F.2d 194 (8th Cir. 1989) (holding, inter alia, that the state's denial of the prescription drug AZT to certain applicants with Acquired Imuno-Deficiency Syndrome (AIDS), based on their particular diagnoses, contravened the requirements of 42 C.F.R. § 440.230). The appellant's reliance on Weaver, however, is misplaced. In Ohlson that Court addressed the applicability of 42 C.F.R. § 440.230 to situations where state Medicaid plans have denied coverage for optional services. Ohlson, 953 P.2d 939, 943 (holding that a state Medicaid plan's denial of coverage for the optional service of prosthetic devices did not contravene the provisions of 42 C.F.R. § 440.230.) The Ohlson court, criticizing Weaver, noted that "despite the clear language of [42 C.F.R. § 440.230] limiting its applicability to 'required services,' [some courts] nonetheless have applied this regulation to optional services." In the present case, since the provision of prescription drugs is clearly an optional service per 42 U.S.C. § 1396d(a)(12), the requirements of 42 C.F.R. § 440.230 are not

applicable. Accordingly, the Hearing Officer's decision upholding DHS's decision to deny coverage for Provigil, with respect to this additional issue was not erroneous.

Finally, the appellant suggests that DHS impermissibly based its denial of the appellant's request for coverage, in part, on the perceived experimental nature of Provigil. The appellant contends that the drug is not experimental. However, the record indicates that neither Morelli nor the Hearing Officer based his decision solely or principally upon whether or not Provigil was an experimental drug. Accordingly, that contention is without merit.

CONCLUSION

For all of the foregoing reasons this Court affirms the decision of the Hearing Officer and denies the within appeal therefrom.

Counsel shall submit the appropriate judgment for entry.