STATE OF MICHIGAN

COURT OF APPEALS

PHARMACEUTICAL RESEARCH & MANUFACTURERS OF AMERICA,

Plaintiff-Appellee,

and

T.G., P.C. by her guardian and next friend, H.C., D.H., ALLIANCE FOR MENTALLY ILL OF MICHIGAN, MENTAL HEALTH ASSOCIATION OF MICHIGAN, MICHIGAN ASSOCIATION FOR CHILDREN WITH EMOTIONAL DISORDERS, and MICHIGAN PROTECTION AND ADVOCACY SERVICES, INC.,

Intervening Plaintiffs-Appellees,

v

DEPARTMENT OF COMMUNITY HEALTH,

Defendant-Appellant,

and

AARP, THE SENIORS COALITION, WASHINGTON LEGAL FOUNDATION, and ALLIED EDUCATIONAL FOUNDATION,

Amici Curiae.

FOR PUBLICATION
December 13, 2002
9:05 a.m.

No. 238862
Ingham Circuit Court
LC No. 01-094627-AZ

Updated Copy
February 14, 2003

Before: Markey, P.J., and Cavanagh and R.P. Griffin*, JJ.

PER CURIAM.

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* Former Supreme Court justice, sitting on the Court of Appeals by assignment.

Defendant, the Michigan Department of Community Health (DCH), appeals by leave granted the trial court's issuance of a preliminary injunction against implementation of a prescription drug rebate and preauthorization policy. We reverse.

The DCH administers Medicaid and non-Medicaid programs that provide prescription drug coverage for eligible Michigan residents. Under the Medicaid program, the federal government and the state share responsibility for reimbursing pharmacists the costs of covered drugs. See 42 USC 1396r-8. The manufacturer of the drug then rebates a portion of that cost to the state. The state's payments for medications dispensed under a non-Medicaid program were not rebated by drug manufacturers.

On October 9, 2001, the DCH announced its intention to implement a policy expanding the rebate requirement to "[p]rograms funded in all or in part by State dollars," which included, at least, the Medicaid Fee for Service Program (non-HMO recipients), the Children's Special Health Care Services Basic Health Plan (CSHCS), the Refugee Assistance Program,[1] and the State Medical Program (SMP). The new policy requires that prior authorization be obtained by the prescribing physician before the cost of certain identified medications would be reimbursed by the state under the affected programs. However, the prior authorization requirement would be waived if the drug manufacturer agreed to pay the State a "supplemental" rebate in addition to the "basic," or Medicaid-level, rebate already required under federal law as a condition of participation in the Medicaid program. The combined supplemental and basic rebate payments would reduce the state's cost for the identified drug to the level of that of an equivalent or "preferred" drug, thereby drastically reducing the state's prescription drug expenses.

On November 30, 2001, plaintiff, Pharmaceutical Research and Manufacturers of America (PhRMA),[2] brought this action seeking declaratory and injunctive relief alleging, in pertinent part, that (1) the basic and supplemental drug rebates and prior authorization requirements with regard to drugs dispensed under non-Medicaid programs were not statutorily authorized, (2) the supplemental rebate policy with regard to drugs dispensed under the Medicaid (non-HMO) program was not statutorily authorized, and (3) the alleged authority under which defendant sought to implement the proposed policy, 2001 PA 60, § 2204, is unconstitutional because it violates the separation of powers doctrine by retaining "veto" authority.

On December 28, 2001, motions to intervene and for preliminary injunction were filed by the intervening plaintiffs, mental health care consumers. With the filing of its complaint, PhRMA had also filed a motion for preliminary injunction. On the date set for hearing, the trial court granted the motion to intervene, but declined to hear the intervening plaintiffs' motion for preliminary injunction because the DCH had not been afforded sufficient time to file a response to the same. However, the trial court granted PhRMA's motion for preliminary injunction, barring the implementation of "the prescription drug rebate and prior authorization program

[1] The Refugee Assistance Program is federally funded, as provided by 8 USC 1522(e), entitling eligible persons to the same services as provided under the state's Medicaid program, 45 CFR 400.105, pursuant to the Social Welfare Act, MCL 400.10(3).

[2] PhRMA is an organization whose members are the suppliers of more than seventy-five percent of the sales of brand name prescription drugs in the United States.

requirements developed under 2001 PA 60." Relying on *Blank v Dep't of Corrections*, 462 Mich 103; 611 NW2d 530 (2000), the trial court held that plaintiff was likely to prevail on the merits of its case because 2001 PA 60, § 2204 violated the separation of powers doctrine in that it included a "veto provision," and, in addition, the DCH did not have the requisite statutory authority to implement the new policy. Further, after taking "judicial notice of at least some of the Intervening Plaintiffs' needs and characteristics," the trial court concluded that irreparable harm would result to the intervening plaintiffs if the injunction was not issued. The court held, "[i]t is indisputable that disadvantaged persons who are in need of continuing medical services which involve prescription drugs will be affected by these programs" as a consequence of the alleged delay in the dispensing of medically necessary medications. The DCH's application for leave to appeal was granted.

On appeal, the DCH argued that the preliminary injunction was improperly issued because PhRMA did not establish the requirements for such extraordinary relief. We agree. This Court reviews for an abuse of discretion the trial court's decision to grant or deny a preliminary injunction. *Alliance for Mentally Ill of Michigan v Dep't of Community Health*, 231 Mich App 647, 661; 588 NW2d 133 (1998). A trial court's findings of fact will be sustained unless they are clearly erroneous or we are convinced that we would have reached a different result. *Cipri v Bellingham Frozen Foods, Inc*, 235 Mich App 1, 9; 596 NW2d 620 (1999).

Injunctive relief is an extraordinary remedy. *Fancy v Egrin*, 177 Mich App 714, 719; 442 NW2d 765 (1989). A preliminary injunction serves to preserve the status quo pending a final hearing, enabling the rights of the parties to be determined without injury to either party. *Id*. To determine whether this equitable relief should be granted, the issuing court must consider "(1) the likelihood that the party seeking the injunction will prevail on the merits, (2) the danger that the party seeking the injunction will suffer irreparable harm if the injunction is not issued, (3) the risk that the party seeking the injunction would be harmed more by the absence of an injunction than the opposing party would be by the granting of the relief, and (4) the harm to the public interest if the injunction is issued." *Alliance for Mentally Ill of Michigan*, *supra* at 660-661. All these prerequisites must be met before a preliminary injunction may be granted. See *Michigan Coalition of State Employee Unions v Civil Service Comm*, 465 Mich 212, 226, 228; 634 NW2d 692 (2001).

First, we consider the trial court's conclusion that PhRMA was likely to prevail on the merits of its case because the DCH did not have the authority to implement the drug rebate and preauthorization policies with regard to Medicaid and non-Medicaid, state-funded, health care programs. On appeal, PhRMA, the intervening plaintiffs, and amici curiae[3] argue that the DCH was not so empowered because no specific statute directed the DCH to implement the policies, and, the only purported authority to impose the requirements with regard to the Medicaid program was 2001 PA 60, § 2204, which was unconstitutional.

In considering this issue, we must examine general principles of administrative law. The DCH is a principal department in the executive branch. MCL 330.3101. The functions, powers, and duties of the DCH, as an executive agency, are allocated by law, i.e., by executive order or

[3] The Seniors Coalition, Washington Legal Foundation, Allied Educational Foundation.

legislation. See Const 1963, art 5, § 2; *Straus v Governor*, 459 Mich 526, 534; 592 NW2d 53 (1999). Statutes are the primary source of administrative power; thus, whether an administrative agency has a particular power is typically a matter of statutory construction. *Alcona Co v Wolverine Environmental Production, Inc*, 233 Mich App 238, 247-248; 590 NW2d 586 (1998). Consistent with the goal of effectuating legislative intent, the power conferred includes that which is expressly granted and that which is granted by necessary or fair implication, i.e., "powers necessary to a full effectuation of authority expressly granted." *In re Quality of Service Standards for Regulated Telecommunication Services*, 204 Mich App 607, 613; 516 NW2d 142 (1994). However, to comport with the delegation doctrine, Const 1963, art 4, § 1, and the separation of powers doctrine, Const 1963, art 3, § 2, the legislative grant of authority must include standards that sufficiently check the exercise of delegated power—that are as precise as the subject matter permits considering its complexity—yet allow the Legislature to "avail itself of the resources and expertise of agencies and individuals to assist the formulation and execution of legislative policy." *Taylor v Gate Pharmaceuticals*, 248 Mich App 472, 478; 639 NW2d 45 (2001), quoting *Blue Cross & Blue Shield of Michigan v Governor*, 422 Mich 1, 51; 367 NW2d 1 (1985).

Pursuant to the Social Welfare Act (SWA), MCL 400.1 *et seq.* the DCH is responsible for establishing and administering medical assistance programs in the state, including the Medicaid program. See MCL 330.3101. Consistently with separation of powers principles, and in light of the complex nature of the endeavor, the Legislature has delegated broad authority to the DCH to enable it to accomplish its statutory responsibilities. For example, MCL 400.105(1) provides that the DCH "shall establish a program for medical assistance for the medically indigent under title XIX [42 USC 1396 *et seq.*]." However, consonant with the delegation doctrine, such authority is circumscribed by the addition of substantive standards, including, for example, eligibility requirements, types of services provided, and the directive to develop policies and procedures regarding the participation of, and reimbursement to, health care service providers. See MCL 400.106, 400.109, 400.111a. In a similar manner, 2001 PA 60, § 1690, MCL 333.5805 *et seq*., and MCL 550.2001 *et seq*. mandate that the DCH develop programs to provide health care services to indigent persons, i.e., the SMP, and children with special health care needs, i.e., the CSHCS, and to provide prescription drug insurance coverage to the elderly, i.e., the Elder Prescription Insurance Coverage (EPIC) program, respectively. Generally, then, the DCH has been delegated the responsibility of establishing and administering health care programs, including pharmaceutical programs, that most effectively meet the needs of those persons eligible for Medicaid and state-funded services, using the state's limited resources in the most efficient manner possible. In the absence of a specific legislative directive that modifies its authority, the DCH is obligated to fulfill its statutory duties to establish, administer, and maintain the integrity of such programs.

At issue here, first, is whether the DCH had the authority to implement a supplemental rebate and preauthorization policy with regard to drugs dispensed under the Medicaid program. PhRMA argues that the Legislature did not authorize the imposition of such rebate and preauthorization requirements. We disagree. Pursuant to MCL 400.109(1)(d), eligible persons "may receive pharmaceutical services from a licensed pharmacist of the person's choice as prescribed by a licensed physician or dentist and approved by the department of community health." Further, MCL 400.111a provides for the establishment of appropriate policies and procedures relating to the participation of health care service providers and the reimbursement of

costs.[4] Specifically, policies and procedures are mandated to assure that "reimbursement is not made to those providers whose services, supplies, or equipment cost the program in excess of the reasonable value received" and that "the state is a prudent buyer." MCL 400.111a(3)(d) and (e). Consequently, by the plain language of the statutes, the Legislature granted the DCH the authority to require preauthorization and required the DCH to implement appropriate payment and reimbursement policies. See *Danse Corp v Madison Heights*, 466 Mich 175, 182; 644 NW2d 721 (2002). Further, title XIX of the Social Security Act, particularly 42 USC 1396r-8(d)(1)(A) and 1396r-8(d)(5), authorizes states to implement prior authorization programs for drugs covered by Medicaid and, as discussed below, does not prohibit state supplemental drug rebate requirements. See, also, 42 USC 1396r-8(c).

PhRMA, the intervening plaintiffs, and their supportive amici curiae claim that if the Legislature intended to permit the DCH to implement such policies, it would have given an express grant of authority in its annual appropriation acts. We disagree. Although the Legislature effectively retains the power to limit and modify the delegated authority through annual appropriation acts or other subsequent legislation, its failure to do so is not construed as negating the authority already granted to the DCH. See MCL 400.1b; 2001 PA 60.

Here, the Legislature, in its annual appropriations act, did include a directive to the DCH to "submit changes to pharmacy policies for Medicaid recipients not enrolled in Medicaid HMOs to the chairpersons." See 2001 PA 60, § 2204. However, again, and consistently with the Legislature's clear intent to delegate such discretionary administrative decisions to the DCH, the Legislature gave limited guidance with respect to the type of changes to be instituted, stating "[t]hese changes may reflect a composite of pharmacy best practices in use by HMOs under contract to provide managed medical care services to nonexempt Medicaid recipients." *Id*.; see, also, *Grand Traverse Co v Michigan*, 450 Mich 457, 463-464; 538 NW2d 1 (1995). Accordingly, it was within the DCH's discretion, which is necessarily influenced by its superior knowledge and expertise, to determine what "changes" would be submitted for review, including its proposed preauthorization and supplemental rebate policies with regard to drugs dispensed under the Medicaid program. Consequently, whether 2001 PA 60, § 2204 is unconstitutional, as the trial court held, is not a dispositive issue. Pursuant to the SWA, the DCH was authorized and required to establish, administer, and maintain a Medicaid program that included prescription drug coverage. In the absence of a specific directive limiting the DCH's discretion with regard to the precise manner in which to accomplish its duty, the DCH is, and must be, permitted to formulate policies that promote the program's continued viability, including instituting preauthorization and drug rebate requirements.

Next, we consider whether the preauthorization and drug rebate policies are authorized with regard to prescription drugs dispensed through the non-Medicaid health care programs. Similar to the delegation of authority granted to the DCH by the SWA, the DCH has been granted broad authority to establish and develop several health care programs to assist our disadvantaged citizens. Under the SMP, 2001 PA 60, § 1690, the DCH is mandated to "establish a program that provides for the basic health care needs of indigent persons," including the

[4] Pursuant to MCL 24.207(q), such policies are not "rules" within the contemplation of the Administrative Procedures Act, MCL 24.201 *et seq.*

provision of pharmaceutical services. Pursuant to MCL 333.5805 *et seq*., the CSHCS program, the DCH is required to "develop, extend, and improve" a program and services for the "purposes of providing medical and physical care for crippled children." Similarly, with regard to the EPIC program, MCL 550.2001 *et seq*., the DCH must establish a program that provides prescription drug coverage to eligible persons. See, also, 2001 PA 60, § 1629(1).

The DCH has been provided specific directives, primarily through appropriations legislation, regarding preauthorization and rebate policies applicable to these programs. In particular, with regard to the SMP and CSHCS programs, 2001 PA 60, § 1627 provides as follows:

> (1) The department shall use procedures and rebates [sic] amounts specified under section 1927 of title XIX of the social security act, 42 U.S.C. 1396r-8, to secure quarterly rebates from pharmaceutical manufacturers for outpatient drugs dispensed to participants in state medical program and children's special health care services.
>
> (2) For products distributed by pharmaceutical manufacturers not providing quarterly rebates as listed in subsection (1), the department may require preauthorization.

With regard to the EPIC program, MCL 550.2006 provides that the DCH may:

> (b) Use procedures and rebate amounts specified under section 1927 of title XIX of the social security act, 42 U.S.C. 1396r-8, to secure quarterly rebates from pharmaceutical manufacturers for outpatient drugs dispensed to participants in EPIC.
>
> (c) For products distributed by the pharmaceutical manufacturers not providing quarterly rebates as listed in subdivision (b), require preauthorization.

Further, 2001 PA 60, § 1629(3) provides:

> The department shall immediately establish a pharmaceutical rebate recovery initiative for the EPIC program. This initiative shall be based on, and be no more restrictive than, the existing Medicaid pharmaceutical rebate program.

Accordingly, both a preauthorization policy and a rebate policy that is consistent with 42 USC 1396r-8 are expressly mandated. The Medicaid pharmaceutical rebate program does not establish a maximum rebate amount. See 42 USC 1396r-8(c). Further, state-imposed supplemental rebate policies are not prohibited by title XIX of the Social Security Act. In fact, the United States Department of Health and Human Services (HHS), the administrator of the federal component of the Medicaid program, released guidelines dated November 15, 2000, entitled "Medicaid Drug Rebate Program Release No. 102," which detail the process of obtaining federal approval for, and the effect of, such supplemental rebate agreements. The evidence of record reflects that, in conformity with these guidelines, the state of Florida submitted to the HHS an amended Medicaid plan that provided for state supplemental rebates [pursuant to Fla

Stat 409.912] and, on September 18, 2001, received approval to implement the policy. See, also, *Pharmaceutical Research & Mfrs of America v Medows*, 184 F Supp 2d 1186 (2001).

In sum, the DCH is statutorily authorized to implement preauthorization and drug rebate policies with regard to medications dispensed through Medicaid and non-Medicaid programs, including SMP, CSHCS, and EPIC. In the absence of a specifically defined legislative limitation, when the DCH is delegated the responsibility of establishing and administering health care programs, it must also be accorded concomitant powers to implement policies that promote that endeavor, including preauthorization and drug rebate policies. On the record before the trial court, PhRMA was not likely to prevail on the merits; therefore, the preliminary injunction was improperly issued and must be vacated. In consideration of our holding, we decline to address the issues whether 2001 PA 60, § 2204 is unconstitutional as violating the separation of powers doctrine and whether the irreparable harm requirement was met. See *Michigan Coalition of State Employee Unions*, *supra*.

Reversed and remanded for proceedings consistent with this opinion. We do not retain jurisdiction.

/s/ Jane E. Markey
/s/ Mark J. Cavanagh
/s/ Robert P. Griffin