ORIGINAL

STATE OF MICHIGAN
IN THE SUPREME COURT
APPEAL FROM THE COURT OF APPEALS
Hons. M.J. Kelly, P.J., and Hoekstra and Stephens, J.J.

STATE OF MICHIGAN ex rel. MARCIA GURGANUS,

Docket No 146791

Plaintiff-Appellee,

v.

CVS CAREMARK CORPORATION; CVS PHARMACY, INC.; CAREMARK, LLC; CAREMARK MICHIGAN SPECIALTY PHARMACY, LLC; CAREMARK MICHIGAN SPECIALTY PHARMACY HOLDING, LLC; CVS MICHIGAN, LLC; WOODWARD DETROIT CVS, LLC; REVCO DISCOUNT DRUG CENTERS, INC.; KMART HOLDING CORPORATION; SEARS HOLDING CORPORATION; SEARS HOLDINGS MANAGEMENT CORPORATION; SEARS ROEBUCK & CO.; RITE AID OF MICHIGAN, INC.; PERRY DRUG STORES, INC.; TARGET CORPORATION; KROGER COMPANY OF MICHIGAN; KROGER COMPANY; WALGREEN COMPANY; AND WAL-MART STORES, INC.;

Defendants-Appellants.

/

CITY OF LANSING and DICKINSON PRESS, INC.,

Docket No. 146792

Plaintiffs-Appellees/Cross-Appeallants,

v.

RITE AID OF MICHIGAN, INC. and PERRY DRUG STORES, INC.,

Defendants-Appellants/Cross-Appellees.

/

CITY OF LANSING, DICKINSON PRESS, INC., and SCOTT MURPHY, individually and On behalf of all others similarly situated,

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CVS CAREMARK CORPORATION; CVS PHARMACY, INC.; CAREMARK, LLC; CAREMARK MICHIGAN SPECIALTY PHARMACY, LLC; CAREMARK MICHIGAN SPECIALTY PHARMACY HOLDING, LLC; CVS MICHIGAN LLC; WOODWARD DETROIT CVS, LLC; REVCO DISCOUNT DRUG CENTERS, INC.; KMART HOLDING CORPORATION; SEARS HOLDINGS CORPORATION; SEARS HOLDINGS MANAGEMENT CORPORATION; SEARS ROEBUCK & COMPANY; TARGET CORPORATION; KROGER COMPANY OF MICHIGAN; KROGER COMPANY; WALGREEN COMPANY; and WAL-MART STORES, INC.,

Defendants-Appellants/Cross-Appellees.

AMICUS CURIAE BRIEF OF THE SMALL BUSINESS ASSOCIATION OF MICHIGAN

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INTEREST OF AMICI CURIAE

The Small Business Association of Michigan (SBAM) supports Defendants-Appellants' Brief on Appeal. SBAM is the only statewide and state-based association that focuses solely on serving the needs of Michigan's small business community. Its membership includes more than 21,000 small and medium size Michigan-based businesses, the vast majority of which are privately and family owned. SBAM recognizes the unique challenges of running a successful small business, and all of SBAM's programs and services exist to improve the business climate and conditions in which small businesses operate.

Small businesses do not possess the economic wherewithal to adapt quickly and seamlessly to rapid changes in regulatory requirements. Thus, they rely on state policies and practices regarding the manner and scope of regulatory enforcement. Businesses, in particular small businesses, rely on long-standing state non-enforcement of outmoded regulatory requirements. SBAM's members have a keen interest in the disposition of this litigation, where plaintiffs have almost literally dusted off a statute that has never been enforced and provided it with an interpretive gloss that no branch of government has endorsed in its 35-year history. Even worse, plaintiffs' interpretation is so alien that it is difficult to reconcile with the State of Michigan's own mandatory Medicaid reimbursement calculation method. SBAM's members would be greatly harmed by a precedent that allows private plaintiffs to interfere with state choices about regulatory non-enforcement.

STATEMENT OF QUESTIONS INVOLVED

SBAM will address the following question, as framed by the Court in its September 18, 2013 Order:

Question 2: What is meant by the requirement that a pharmacist shall "pass on the savings in cost" when the pharmacist dispenses a generically equivalent drug product and what constitutes a violation of that requirement?

SBAM: It is unclear what the legislature intended when it enacted MCL 333.17755(2) (the "Substitution Statute") in 1978, but the State of Michigan has abandoned it by participating in the market for generic drugs without regard to any effect of the statute, by failing to ever investigate or enforce alignment of generic drug pricing with open market practice, and by declining to intervene in this case. Whatever regulatory infraction might have been contemplated by the Substitution Statute in 1978, enforcement of that statute or any claim premised on a purported violation of the statute would violate Due Process.

STATEMENT OF FACTS

SBAM adopts Defendants' statement of facts, with the following additions.

In the 35 years since MCL 333.17755(2) was enacted, the pharmaceutical supply chain and the market forces influencing the price of prescription drugs has fundamentally changed.[1] A law drafted in 1978 to regulate the supply chain for generic prescription drugs is the equivalent of a law drafted in 1978 to regulate mobile phone service. Neither the agency tasked with enforcing the Substitution Statute, the state Pharmacy Board, nor the Attorney General have ever attempted to enforce its vague mandate, including in the present *qui tam* action. The State of Michigan has adopted Maximum Allowable Cost ("MAC") pricing for Medicaid reimbursement that ignores the Substitution Statute.[2] As the long list of defendants illustrates, no one in the pharmaceutical supply chain, including the State of Michigan, treats this vague and theoretical directive as a viable market regulation.

ARGUMENT

I. Question 2: What is meant by the requirement that a pharmacist shall "pass on the savings in cost" when the pharmacist dispenses a generically equivalent drug product and what constitutes a violation of that requirement?

A. It would violate Due Process to enforce the Substitution Statute regardless of how it is interpreted.

SBAM's members operating in regulated industries are very concerned about a private lawsuit that would seek to enforce—either directly or indirectly through a purported "false claims" action—an outmoded statute that the State has openly abandoned. Because the

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[1] **Exhibit A**, *Declaratory Ruling of the West Virginia Board of Pharmacy* (Oct. 23, 2012) at 8 (Finding that a similar substitution statute "was enacted in 1978 at a time when the pharmacy market in the United States was vastly different than it is today.").

[2] **Exhibit B**, materials from Michigan Department of Community Health Medicaid Program website, at 3 (Maximum Allowable Cost (MAC) Pricing Frequently Asked Questions).

Substitution Statute is vague, quickly became obsolete and has only become more so over the decades, has never been enforced since its enactment in 1978, and is ignored by the State when it acts as a market participant, it would violate Due Process to now allow private plaintiffs to attempt to enforce that statute or base other civil suits on purported violation of the statute. The fair notice required by Due Process shields defendants from such abuses.

Thirty-six years ago the Michigan legislature guessed at how prescription generic drugs might be priced as the market developed. It decided to regulate pricing practices that did not yet exist and drafted a vague mandate that never fit the practices that the market, and the government as the largest market participant, developed in the following years. No arm of the state has ever tried to reconcile MCL 333.17755(2) with the complex pricing practices that keep generic drugs available and affordable for Michigan consumers. Neither the Board of Pharmacy nor the Attorney General has ever sought to enforce MCL 333.17755(2), even declining to intervene in the *qui tam* action filed by Marcia Gurganus. The trial court was rightly troubled that Michigan businesses and consumers should, more than three decades later, pay the price for failed political prognostication. The result plaintiffs advocate will not result in any sure change in prices, but rather a proliferation of confused lawsuits.

How then must this Court interpret a statute drafted in the context of an outdated market for prescription drugs, and in anticipation of a set of imagined future market forces that were long ago displaced by something else with the blessing of the State? Due Process requires that statutory interpretation stops short of guessing. Undoubtedly, the Court is duty bound to give meaning to a statute where it can and to presume its constitutionality, *Stone v Williamson*, 482 Mich 144, 209; 753 NW2d 106 (2008) (Markman, J. concurring in result), but it is also duty

bound to recognize those rare but significant circumstances where a statute is so infirm on its face or as applied that the legislature must reexamine it.

Due Process demands fair notice of what a statute prohibits. A law that is so vague that a reasonable person cannot determine what conduct is required or prohibited violates this fair notice requirement.[3] Likewise, enforcement of a law under circumstances which would cause a reasonable citizen to believe the statute has been abandoned by the State would violate the fair notice requirement.[4] The principles underlying the latter Due Process challenge are not unlike a promissory estoppel defense: when the state, through deliberate action or inaction, causes citizens to believe that an obsolete statute has been abandoned, Due Process prohibits the statute's enforcement. The deliberateness of the State's action or inaction is judged by the duration and continuousness of its position, actions that are inconsistent with the statute, and the extent to which conduct that allegedly violates the statute is open and prevalent. The obsoleteness of the statute is relevant to the conclusion that reasonable citizens would interpret the state's action or inaction as a green light to conduct their affairs without regard to that statute.

In some jurisdictions, a "doctrine of desuetude" is used as short-hand for the rare circumstances under which an obsolete statute may become constitutionally void by long and continued non-enforcement. Like a vague law, a desuetudinal one fails to provide the fair notice required by Due Process. *Committee on the Legal Ethics of the West Virginia State Bar v Printz*, 416 SE 2d 720, 724 (W Va 1992). By declaring such a law constitutionally void, the Court

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[3] *Dep't of State Compliance and Rules Division v Michigan Ed Ass'n–NEA*, 251 Mich App 110, 116; 650 NW2d 120 (2002) ("A statute may qualify as void for vagueness if . . . it does not provide fair notice of the conduct it regulates.").

[4] *See e.g., Raley v Ohio*, 360 US 423; 79 S Ct 1257; 3 L Ed 1344 (1959) (Recognizing the defense of estoppel by entrapment grounded in the Due Process Clause of the Fifth Amendment).

honors the legislative responsibility to "reexamine the statute." *Franklin v Hill*, 264 Ga 302, 306; 444 SE2d 778 (1994) (holding that "in this case, where the constitutionality of the statute is doubtful, where the statute is woefully out of step with current legal and societal standards, and where the statute has been rarely used, the court should not hesitate to reexamine the statute in its entirety."); *See also*, R. Bork, The Tempting of America, 96 (1990); G. Calabresi, A Common Law for the Age of Statutes, 120–45 (1982).

In their opposition to SBAM's motion for leave to file this brief, plaintiffs argue that "Michigan courts have specifically and repeatedly rejected the doctrine of desuetude." Answer to Motion at 1. To be sure, this rare species of Due Process challenge is not liberally invoked in Michigan because our courts presume the constitutionality of statutes and do not ignore laws merely because of age or disuse. *Washtenaw Cnty Rd Comm'rs v Pub Serv Comm'n*, 349 Mich 663, 682; 85 NW2d 134 (1957). But Michigan courts do not "reject" Due Process concerns. Whether described as "fair notice" or "desuetude," the Due Process challenge SBAM asks the Court to consider is premised on much more than disuse. The United States Supreme Court recognized the necessary place of such a Due Process challenge in *Poe v Ullman*, 367 US 497; 81 S Ct 1752; 6 L Ed 2d 989 (1961), where the court was asked to consider the constitutionality of a Connecticut law prohibiting the use of contraceptives. Because the law had never been enforced in the "three-quarters of a century since its enactment," despite "common[] and notorious[]" violation of the law, the court suggested that it may have been "nullif[ied]" by the state. *Poe*, *supra* at 502. Citing *Poe v Ullman*, Justice Levin once explained the necessary applicability of this Due Process doctrine to Michigan statutes:

> This change in the character of a device cannot, of course, create an exception to a valid statute. Where, however, the device takes on a character unlike that of the devices prohibited so that a citizen might doubt that his device is of the

> kind the statute intended to prohibit, and where that doubt is reinforced, or indeed caused, by lack of prosecution in the face of the open and common sale and possession of the device, the doubt a reasonable citizen might feel as to whether his device is actually one which the statute prohibits may be such that the citizen is deprived of the clear warning that due process requires. A criminal statute must give fair notice to an ordinary citizen * * * *
>
> "A penal enactment which is linguistically clear, but has been notoriously ignored by both its administrators and the community for an unduly extended period, imparts no more fair notice of its proscriptions than a statute which is phrased in vague terms. Though the language of a desuetudinal act may be clear, 'the hardened gloss life has written upon it' will seem to the individual a 'tougher and truer law than the dead words of the written text.' In this situation, a rational choice between statute and the 'living law' of both community and state becomes insuperably difficult and dangerous for the spectator."
>
> I do not suggest that prosecutorial non-use, changed circumstances or pervasive public disobedience may operate to repeal or modify a valid enactment. Repeal or modification is the province of the Legislature. If circumstances and public opinion have changed so as to make it now appropriate that citizens be allowed to carry gas-ejecting weapons for self-defense, it is for the Legislature to so declare, as it recently has in limited fashion. The question suggested here is not whether nonenforcement can cause a statute to lapse into desuetude and thereby become constitutionally unenforceable, but rather whether a combination of the circumstances described can operate to deprive a person of the requisite clarity of notice that his conduct is forbidden.

People v Lynch, 410 Mich 343, 359–60; 301 NW2d 796 (1981) (Levin, J. concurring) (*quoting Bonfield, The Abrogation of Penal Statutes by Nonenforcement*, 49 Iowa L Rev 389, 416 (1964)) (addressing a 1929 statute prohibiting carrying "gas-ejecting weapons," which would apply on its face to products such as pepper spray). The Due Process limitation on statutory enforcement described in Justice Levin's concurrence applies with equal force to civil statutes. Indeed, the risk that fair notice is lacking when a law has become desuetudinal is greater with a regulatory infraction like MCL 333.17755(2).

Those courts that have expressly considered a Due Process challenge grounded in desuetude usually require proof of three elements to establish that fair notice has been undermined. First, the court must consider whether the prohibited conduct is *malum in se* or *malum prohibitum*. *Printz, supra* at 726; *United States v Elliott*, 266 F Supp 318, 326 (SDNY 1967). Long non-enforcement of a law does not raise any fair notice concerns if the conduct prohibited is the sort that reasonable people would know was wrong regardless of the statute. Regulatory infractions like alleged violation of the Substitution Statute, however, are susceptible to desuetude.

Second, "there must be an open, notorious, and pervasive violation of the statute for a long period before desuetude will take hold." *Printz, supra* at 726. In *Poe v Ullman*, the Supreme Court noted the fact that the banned contraceptives were openly and notoriously sold throughout the state. *Poe, supra* at 502. In *People v Lynch, supra*, Justice Levin noted that the State had regulated the sale of products that would technically violate the gas-ejecting weapons statute—how can the citizen reconcile the apparent legal sale of products that are illegal to possess? Here, the State of Michigan has accepted for decades Medicaid claims made without regard to the alleged Substitution Statute ceiling. The State of Michigan knows very well that pharmacies make claims to Medicaid based on the MAC price list that the State has adopted. The State cannot claim ignorance of pharmacy pricing practices or the fact that no one in the industry has ever calculated "savings in cost" under MCL 333.17755(2).

Third, the State must have demonstrated "a conspicuous policy of nonenforcement." *Printz, supra* at 726; *See also, Stegenga v Department of Treasury*, 179 Mich App 307, 312; 445 NW 2d 495 (1989)(expressing the related principle that the State should be estopped from enforcing a law where by its own actions it has induced citizens to rely on a contrary rule). Here,

the State of Michigan has conspicuously abandoned whatever pricing mandate MCL 333.17755(2) may have attempted to impose. The State has never enforced the statute or even endeavored to illuminate its requirement through regulation or other guidance. The state adopted MAC pricing for its Medicaid program. The Department of Community Health's Medicaid website explains MAC pricing in detail, but never mentions MCL 333.17755(2). And what better evidence of the State's policy of nonenforcement than the Attorney General's decision not to intervene in the *qui tam* action? Since that decision, neither the Attorney General nor the Pharmacy Board has taken any action to enforce MCL 333.17755(2).

The State has been a major player in the supply chain for generic prescription drugs continuously since the statute was enacted 36 years ago. MCL 333.17755(2) has never been enforced because it was ill-conceived and quickly became obsolete. Through its market participation and non-enforcement of the Substitution Statute, the State has deprived Michigan pharmacists of fair notice of whether, when, and how this statute might apply to their conduct. Enforcement of the Substitution Statute, including allowing a purported violation of the statute to serve as the basis of a "false claim" lawsuit, would violate Due Process.

RELIEF REQUESTED

For the foregoing reasons, the SBAM request that the Court REVERSE the ruling of the Court of Appeals.

January 7, 2014

Respectfully submitted,

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APPENDIX

EXHIBIT A — *Declaratory Ruling of the West Virginia Board of Pharmacy* (Oct. 23, 2012).

EXHIBIT B — materials from Michigan Department of Community Health Medicaid Program website.

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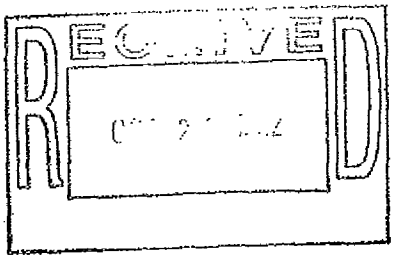

October 23, 2012

Tyler N. Williams
Dinsmore & Shohl
Huntington Square
900 Lee Street, Suite 600
Charleston, WV 25301

Re: Declaratory Ruling in the Matter of Walgreen Co. & The Kroger Co.

Dear Mr. Williams,

Please find enclosed the Declaratory Ruling in the Matter of Walgreen Co. and The Kroger Co. Thank you for your attention to this matter. Should you have any questions or concerns please feel free to contact me.

Sincerely,

David E. Potters

David E. Potters
Executive Director & General Counsel

cc: Frances A. Hughes
Michael B. Hissam

A

BEFORE THE WEST VIRGINIA BOARD OF PHARMACY

WALGREEN CO. and
THE KROGER CO.

DECLARATORY RULING IN THE MATTER OF
WALGREEN CO. AND THE KROGER CO.

Pending before the Board is a Petition for Declaratory Ruling filed by Walgreen Co. and The Kroger Co.[1] The Petition was filed pursuant to the West Virginia Administrative Procedures Act,[2] W. Va. Code § 29A-4-1. It seeks a declaration regarding the applicability of W. Va. Code § 30-5-12b,[3] part of the West Virginia Pharmacy Act,[4] to pharmacy reimbursement contracts entered into between Petitioners and third-party reimbursement sources such as pharmacy, medical and prescription benefit plans.[5]

1. PUBLIC HEARINGS

After having given the necessary public notice, Board President Lydia Main brought the Petition up for consideration at the Board's regularly scheduled meeting in Huntington, West Virginia on September 7, 2012. Before hearing arguments and taking evidence, Board Members Carl K. Hedrick, Jr. and Rebekah E. Hott recused themselves from the proceedings based upon their association with one or more of the Petitioners or other pharmacies that may be similarly situated. The remaining Board Members then proceeded to hear testimony from Dan Luce on behalf of Walgreen Co.[6] and arguments by counsel for both of the Petitioners.

Mr. Luce described the history of changes in the market for prescription medications over the more than three decades since Section 12b was adopted and the increased use of generic prescription medications over that period. This history is set forth in some detail below. Perhaps most notable among the factors and marketplace changes contributing to the increased use of generic drugs has been the growth in the number of Benefit Plans providing coverage for prescription medications. Mr. Luce also discussed the impact such expanded coverage afforded by Benefit Plans has had on

[1] Hereinafter referred to as "Petitioners."
[2] Hereinafter referred to as the "APA."
[3] Hereinafter referred to as "Section 12."
[4] Hereinafter referred to as the "Pharmacy Act."
[5] Hereinafter referred to collectively as "Benefit Plans."
[6] Also present at the hearing were Tracy McDaniel and Christopher Koon from The Kroger Co. Both were prepared to offer testimony supportive of that presented by Mr. Luce. Because their testimony would have been largely duplicative, it was deemed unnecessary.

reimbursement rates that pharmacies receive for dispensing such medications. All of this is set forth in greater detail below.

In addition to the foregoing, the Board had the benefit of written submissions filed by the Petitioners prior to the hearing. Those submissions, as well as the arguments heard on September 7, addressed not only the merits of the Petition but also the Board's legal authority to hear and decide the questions presented.[7] The Petitioners addressed the latter issue in response to an Opinion issued by the Attorney General after the Petition was filed.[8] In that Opinion, the Attorney General took the position that the Board not only should not but could not address the questions presented.

Following the taking of evidence and arguments of counsel, the Board considered the issues, including whether it had the legal authority to proceed. Whereupon Board Member Charles Woodcock moved that the Board issue a ruling in favor of Petitioners, which motion was seconded by Board Member Samuel Kapourales. After further discussion, the Board, based upon the record before it and considering itself otherwise sufficiently advised, unanimously approved that motion. It thereupon directed the Board's General Counsel to prepare a written ruling consistent with Mr. Woodcock's motion for presentation at the next Board meeting.

On October 9, 2012, after giving the requisite public notice, the Board reconvened to consider the draft ruling prepared by its General Counsel. Before doing so, Mr. Hedrick and Ms. Hott again recused themselves from those deliberations. That draft, appearing to fully and accurately reflect the prior motion, was thereupon approved and adopted and is hereby entered. In so doing, the Board formally approves and adopts the findings and ruling set forth herein. This ruling is binding only as between Petitioners and the Board in accordance with the provisions of the APA. It may, however, serve as guidance to others similarly situated with respect to the Board's position regarding Section 12b.

2. THE BOARD'S RULING

a. The Legislature, through the adoption of the Pharmacy Act, specifically delegated to the Board of Pharmacy the exclusive

[7] Those submissions were made a part of the record in this matter.

[8] W. Va. Code § 5-3-1 provides that they shall give written opinions and advice upon questions of law "whenever required to do so, in writing, by . . . any . . . board . . . ." The Board made no written request for the Attorney General's Opinion as to its authority, having available to it its own General Counsel who is fully conversant with the statutory authority pursuant to which it operates. The Board is also unaware of any such written request for that Opinion having been requested by the Governor or any other executive branch officer. As such, the Board questions the basis upon which the Attorney General presumed to issue that Opinion. That said, the Board has given the substance of the Attorney General's Opinion due consideration in rendering its ruling in this matter.

authority to regulate the practice of pharmacy in the State of West Virginia;

b. By virtue of the specific authority granted it under the Pharmacy Act, the Board is authorized under the APA to issue a declaratory ruling in response to the Petition before it;

c. The Petition raises important questions regarding the scope and application of Section 12b that the Board should address;

d. At the time Section 12b was adopted, generic drugs were not in widespread use and the vast majority of prescriptions were filled by means of direct consumer purchases from individual pharmacists without the involvement of Benefit Plans, the vast majority of which did not provide coverage for prescription medication;

e. In order to encourage the use of lower cost, but therapeutically equivalent generic medications, Section 12b expressly provides that, when presented with a prescription for a brand name medication, a pharmacist shall substitute a lower cost, therapeutically equivalent generic and all savings in the retail price shall be passed on to the purchaser;

f. Concepts such as prescription drug benefit plans, Pharmacy Benefit Managers, third-party payors, and pharmacy reimbursement contracts that prevail today were largely unknown at the time Section 12b was enacted;

g. For this reason, Section 12b speaks in terms of the type of retail sales that predominated in 1978 and makes no reference to third-party transactions involving pharmacy reimbursement contracts such as predominate today;

h. Prior to the adoption of Section 12b, Congress enacted ERISA. ERISA's provisions govern pharmacy benefit plans provided by non-governmental, non-church employers or employee

organizations such as unions, a fact which the Legislature presumptively knew at the time it enacted Section 12b.

i. ERISA would preempt application of Section 12b to pharmacy reimbursement contracts entered into by such plans, a fact which the Legislature presumptively knew at the time it enacted Section 12b. *See, PCMA v. Dist. Of Columbia*, 613 F.3d 179 (D.C. Cir. 2010);

j. Extension of Section 12b to pharmacy reimbursement contracts negotiated by agencies of the State of West Virginia such as the Public Employees Insurance Agency would create the specter of pharmacies being subjected to penalties imposed by one arm of the state for complying with contracts deemed by another arm of the state to be in the best interest of those it represents;

k. Attempting to apply Section 12b to pharmacy reimbursement contracts would materially increase the administrative costs associated with the practice of pharmacy in West Virginia when compared to those of other states. Those costs would likely be passed along to Benefit Plans and, ultimately, their beneficiaries. The imposition of these added costs is contrary to the intended purpose behind Section 12b and would be contrary to the public interest and welfare the Pharmacy Act is intended to protect;

l. The Legislature has not appropriated the substantial resources that would be required to the Board to enforce the provisions of Section 12b if the Legislature truly deemed it applicable to pharmacy reimbursement contracts;

m. Since its adoption in 1978, no complaint has ever been filed with the Board pursuant to Section 12b(q) by any person, including the Attorney General of West Virginia, claiming that pharmacies in West Virginia were violating the provisions of Section 12b by complying with freely negotiated pharmacy reimbursement contracts;

n. In interpreting and applying the provisions of the Pharmacy Act, the primary goal of the Board is to ascertain and give effect to the intent of the Legislature. *See Raines Imps. v. Am. Honda Motors Co.*, 674 S.E.2d 9 (W.Va. 2009). In so doing, the Board must consider the plain language of the statute itself. *See Pilgrim's Pride Corp.* v. *Morris*, 723 S.E.2d 642 (W.Va. 2011). However, where a literal reading of a statutory enactment would compel a result at odds with its intended purpose, the Board may consider the historical context in which statute was enacted. *Public Citizens* v. *United States Dep't of Justice*, 491 U.S. 440, 455 (1989); *State ex rel. Holmes* v. *Gainer*, 447 S.E.2d 887 (W.Va. 1994). Finally, a statute should be read to afford it practical application in carrying out the purpose for which it was enacted. *Thomas* v. *South Charleston*, 148 W.Va. 577; 136 S.E.2d 788 (1964).

o. With these principles in mind and based upon all of the foregoing factors, whether considered individually or collectively, the Board is of the opinion and accordingly rules that:

(i) the provisions of Section 12b apply only to retail transactions involving the substitution of a lower cost, therapeutically equivalent, generic medication for the medication prescribed by a physician; and

(ii) they do not apply to transactions subject to pharmacy reimbursement contracts involving third-party payors as described herein; and

p. The Board is further of the opinion that should its ruling regarding the scope and application of Section 12b as reflected herein be deemed erroneous by a reviewing authority, until and unless the Legislature appropriates the resources necessary to apply Section 12b to pharmacy reimbursement contracts, the Board will exercise its prosecutorial discretion to devote such resources as it has available to it toward the pursuit of other

matters arising under the Pharmacy Act that have a true adverse impact the public health and welfare.

3. DISCUSSION

a. The Board's Authority

Because the Attorney General's Opinion raises questions regarding its legal authority to issue the requested declaratory ruling, the Board believes it necessary and appropriate to first address that question. The Petition was filed in accordance with the APA. In § 29A-4-1, the APA provides that:

> On petition of any interested person, an agency may issue a declaratory ruling with respect to the applicability to any person . . . or state of facts of any . . . statute enforceable by it.

Here, Petitioners seek a declaratory ruling with respect to the applicability of Section 12b to certain stated facts detailed in the Petition. Given that they operate pharmacies in West Virginia, Petitioners are clearly subject to the provisions of Section 12b and are, therefore, "interested parties" under the APA and entitled to seek the requested declaratory ruling. The only remaining question then is whether the Pharmacy Act is enforceable by the Board. Notwithstanding the Attorney General's assertions to the contrary, the Board's authority to enforce the Pharmacy Act is incontrovertible.

The State Legislature is vested with the authority to regulate the pharmacy profession, among other professions, in order to ensure the health, safety and welfare of the general public. *See, e.g., State ex rel. Barker* v. *Manchin,* 167 W.Va. 155, 279 S.E.2d 622 (W. Va. 1981). Absent a specific delegation of that authority to the executive branch, it is a matter of "fundamental law" that neither the Governor (through his executive agencies and boards) nor the Attorney General may impinge upon that power. *Id.* at 630. *See also, State ex rel. State Bldg. Cmm'n* v. *Bailey,* 151 W.Va. 79, 150 S.E.2d 449 (W. Va. 1966).

The Legislature, through the Pharmacy Act, delegated its authority to regulate pharmacists and pharmacies to this Board exclusively. *See,* W. Va. Code § 30-5-2(e)(1). It granted no other agency, board or executive branch officer, including the Attorney General, any such regulatory authority. Because of the Legislature's exclusive delegation of authority, this Board – and this Board alone – is charged with determining who may engage in the practice of pharmacy and operate pharmacies within our borders, as well as whether the privilege of practicing pharmacy should be revoked or suspended as a result of a failure to abide by the provisions of the Act. W. Va. Code §§ 30-5-5, 30-5-7, and 30-5-19. *See also, Barker* 279 S.E.2d at 630; *Coll* v. *Cline,* Syl Pt. 2, 320 W. Va. 599, 505 S.E.2d 662 (W. Va. 1988), *Mountaineer Disposal* v. *Dryer,* Syl Pt. 3, 156 W.Va. 766, 197 S.E.2d 111 (W. Va. 1973).

More specifically, the Legislature expressly authorized this Board to investigate and adjudicate complaints filed against pharmacists and pharmacies for alleged violations of Section 12b and to impose such penalties and take such other actions as are appropriate when it finds that Section 12b has been violated. No other agency or executive branch office is vested with any similar authority. W. Va. Code §§ 30-5-12b(q), 30-5-12b(r). In order to properly discharge this responsibility, the Board is implicitly, if not explicitly, authorized to interpret and apply Section 12b. The Attorney General's arguments to the contrary defy common sense and, if adopted, would frustrate the very purpose of the Act itself.

Given the Legislature's specific and exclusive delegation to the Board of the authority to regulate the practice of pharmacy in West Virginia, the Board finds that it has the legal authority – indeed the legal duty – to issue a declaratory ruling as to the scope and applicability of Section 12b of the Pharmacy Act. W. Va. Code § 29A-4-1. Because the Petition raises important questions regarding Section 12b, the answers to which may have significant impacts upon the manner in which the practice of pharmacy is conducted in West Virginia, the Board is of the opinion that those questions should be answered through the issuance of a declaratory ruling.

In so ruling, the Board rejects the Attorney General's assertion that declaratory rulings issued pursuant to W. Va. Code § 29A-4-1 are limited to factual situations unique to the person requesting that ruling. The plain language of W. Va. Code § 29A-4-1 requires only that the declaratory ruling go to the question of the applicability of the statute to a state of facts, nothing more. To adopt the Attorney General's reading of W. Va. Code § 29A-4-1 would require the Board to rewrite the statute by inserting requirements that do not appear within its text. This is something that the Attorney General himself acknowledges is improper under the rules governing statutory construction.

The Board also rejects the Attorney General's contention that the Board should stay its hand with respect to the Petition in light of civil actions the Attorney General previously filed against Petitioners (and others) in Boone County, West Virginia.[9] In those actions, the Attorney General has sought to enforce Section 12b as he interprets its provisions.[10] In urging the Board to stay its hand pending the outcome of those actions, the Attorney General presupposes that the Legislature vested

[9] The Board has been advised that the Circuit Court dismissed the Attorney General's claims against Walgreen and various other defendants on the grounds that venue was improper in Boone County. His claims against the Kroger Co. and Rite Aid remain pending, however.

[10] He has done so based upon the provisions of W. Va. Code § 30-5-23 which provide that "the Board of Pharmacy or any person . . . may apply to a court having competent jurisdiction over the parties and the subject matter for a writ of injunction to restrain repetitious violations of the provisions of this article." An application for injunctive relief under this section necessarily presupposes that there has been a prior finding by the Board of "repetitious violations" of the Pharmacy Act. *See* W. Va. Code § 30-5-12b(r). It does not and cannot mean that any "person" is entitled to apply for injunctive relief whenever, in their individual judgment, the Pharmacy Act has been violated on a repetitious basis. To so interpret § 30-5-23 would destroy the uniform regulation of the practice of pharmacy in West Virginia that the Pharmacy Act was intended to accomplish.

him with concurrent authority to enforce the provisions of the Pharmacy Act in general and Section 12b specifically. With all due deference, the Attorney General's presupposition is incorrect.

As previously noted, the Pharmacy Act is not enforceable by the Attorney General. The Legislature delegated no such authority to him and he is not vested with any such authority by virtue of the common law. *State ex rel. Manchin* v. *Browning*, 120 W. Va. 779, 296 S.E.2d 909 (W. Va. 1982). *See, e.g., State ex rel. Barker* v. *Manchin,* 167 W.Va. 155, 279 S.E.2d 622 (W. Va. 1981); *see also, State ex rel. State Bldg Comm'n* v. *Bailey* 151, W.Va. 79, 150 S.E.2d 449 (W. Va. 1966).[11] Moreover, the Attorney General did not initiate his civil suits in Boone County at the Board's request or in his capacity as the Board's legal counsel. The Attorney General neither consulted with the Board regarding the advisability of such action nor solicited the Board's view as to the proper scope and application of Section 12b. Instead, he chose to act unilaterally and, in so doing, impinge upon the authority delegated to the Board. Given this, the Board is not required to and should not, as a matter of policy, stay its hand in deference to the Attorney General's civil litigation.[12]

Being mindful of the responsibilities vested in this Board by the Legislature regarding the regulation of the practice of pharmacy in West Virginia as well as the applicable rules of statutory construction, the Board now turns to Section 12b and the specific questions presented by the Petition.

b. <u>History of Section 12b</u>

Consistent with the testimony of Mr. Luce and the submissions of the Petitioners, it is clear that Section 12b was enacted in 1978 at a time when the pharmacy market in the United States was vastly different than it is today. Generic drugs had only recently been introduced to the market and were not in widespread use. Pharmacies and pharmacists had considerably more flexibility in setting the retail prices for prescription medications than they do now. Most people for whom prescription medications

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[11] *See also, Securities Investor Protection Corp.* v. *Barbour,* 421 U.S. 412 (1975). That case involved the question of whether an entity other than the Securities and Exchange Commission was entitled to institute certain proceedings under SIPA. In concluding that it could not, the Supreme Court noted that Congress created the SEC to solve a public problem and provided it with substantial supervisory and enforcement powers to do so. This statutory scheme "ordinarily implies that no other means of enforcement was intended by the Legislature." That would yield only to "clear contrary evidence of legislative intent." *Id. at* 419, quoting *Passenger Corp.* v. *Passenger Assn.*, 414 U.S. 453, 458 (1974).

[12] The Board recognizes that its authority to issue declaratory rulings is not without boundaries. In issuing such rulings, it must, for example, do so in accordance with established rules governing the construction of statutes. In order to ensure that it has done so, moreover, its rulings are subject to review by the Circuit Court of Kanawha County. W. Va. Code § 29A-4-1; W. Va. Code § 29A-5-2. As the West Virginia Supreme Court has made clear, however, the reviewing court is not to address the question *de novo*. Rather, it must defer to the Board's reading of the statute, even if it might have construed it statute differently, so long as the Board has reached its decision in accordance with the applicable rules of construction. *West Virginia Health Care Cost Review Auth. v. Boone Mem'l Hosp.*, 196 W. Va. 326, 472 S.E.2d 411 (1996). This deference reflects the judicial branch's recognition of the proper role of the executive branch and the fact that the resolution of questions such as those presented here often encompass not just questions of law, but also questions of public policy that executive agencies, as opposed to the Courts, are best equipped to address. *Pauley v. Beth Energy Mines*, 561 U.S. 680 (1991); *Wyeth* v. *Levin*, 129 S.Ct. 1187, 173 L. Ed.2d 51, 2009 LEXIS 1774, 2009 WL 529172 at 11 (Mar. 4, 2009).

were prescribed paid 100% of the cost of their prescription medications out of their own pockets. And, people were generally unaware of the availability of less expensive, generic drugs or their ability to request that their physicians prescribe such medications in lieu of more costly brand name drugs.

Faced with this reality and the pressures that increasing costs were having upon individual consumers of prescription drugs, the Legislature enacted Section 12b. It was clearly intended to encourage the substitution of less expensive, therapeutically equivalent generic medications for more expensive, brand name drugs whenever such an equivalent was available. It did so by authorizing pharmacists to exercise their professional judgment to make such substitutions and requiring that the cost savings resulting from that substitution be passed along to the consumer/patient.

After the enactment of Section 12b, the pharmacy market underwent a dramatic and fundamental change. Employers began offering pharmacy benefit plans to their employees in ever increasing numbers. As a result, the vast majority of prescription medications today are covered by such plans. As the number of such plans grew, they began using the services of pharmacy benefit managers (PBMs) to negotiate contracts for pharmacy services with independent pharmacy groups, chains, and individual pharmacists. Today, those contracts are often multi-state or nationwide in scope. Moreover, it is now common for PBMs to represent multiple plans. As a consequence, they bring to their negotiations the aggregated purchasing power of those plans and all of the individual participants in those plans.

Pharmacy benefit plans are, and have been from the outset, under pressure to manage their expenses and hold down costs passed along to employers and beneficiaries. In order to do so, they increasingly rely on PBMs. PBMs, in turn, compete for the business of these plans based upon their ability to negotiate contracts that provide for pharmacy services at the lowest possible cost. This has resulted in contracts with Petitioners and other pharmacies throughout West Virginia and the nation that require the substitution of lower cost and therapeutically equivalent generic drugs for prescribed name brand medications and for the reimbursement of the pharmacies dispensing those medications at rates substantially below what would otherwise be charged at retail. Those requirements and reimbursement rates govern the entire spectrum of medications covered by these plans. Pharmacies agree to those requirements because of the anticipated number of prescriptions they will fill over the life of the contract, numbers that could not necessarily be achieved in the absence of such a contract

Thus, market forces that were not present (and could not reasonably have been anticipated) in 1978 are, today, causing generic medications to be dispensed in far greater numbers and at lower costs than was the case when Section 12b was enacted. The contractual arrangements between pharmacies and Benefit Plans are far different from the direct-to-consumer transactions that predominated in 1978. They are also far more complex, involve parties with relatively equal bargaining power, and result in agreements that serve the interests of the beneficiaries of these plans. It is against this background that the Board must determine whether Section 12b is applicable to prescriptions

dispensed pursuant to these types of contracts and, if so, how it is to be applied as a practical matter in order to advance the purposes of the statute.

c. Employee Retirement Income Security Act ("ERISA")

In assessing the scope and application of Section 12b, the Board has also been mindful of ERISA. ERISA was enacted to, among other things, "avoid a multiplicity of [State] regulation[s] [and] . . .permit the nationally uniform administration of employee benefit plans." *N.Y. State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 657 (1995). In order to achieve this uniformity, ERISA expressly preempts "State laws insofar as they . . . relate to employee benefit plans." 29 U.S.C. § 1144(a). "A law 'relates to' an employee benefit plan, in the normal sense of the phrase, if it has a connection with or reference to such a plan." *Shaw v. Delta Air Lines*, 463 U.S. 85, 96-97 (1983).

ERISA plans are defined to include both pension or welfare plans provided to employees by employers (other than church or governmental employers) and employee organizations. A "welfare plan" is a plan, fund, or program which is established or maintained by an employer (or by an employee organization, or by both) to provide medical or related benefits. ERISA §3(1). This would include pharmacy benefit plans provided by non-governmental, non-church employers as well as unions and other employee organizations in West Virginia.

Thus, ERISA covers virtually all Benefit Plans offered by private, non-church employers and employee organizations throughout the state. It does so in order to ensure that such plans can be administered in uniform manner on a multi-state or nationwide basis without having to be tailored to meet differing state laws and regulations. Nominally, Section 12b would require plans operating in West Virginia to price generic drugs in the particular manner set forth therein and, as a consequence, preclude those plans from entering into pharmacy service contracts on a uniform nationwide or multi-state basis to the extent those contracts did not incorporate the provisions of Section 12b. That is antithetical to the stated goal of ERISA.

ERISA was enacted in 1974, well before Section 12b. As such, the Legislature was presumptively aware of the scope and preemptive nature of the federal law when it adopted Section 12b. It is unlikely, therefore, that the Legislature intended Section 12b to apply in a way that would clearly be preempted by ERISA. Regardless, it is clear that, if Section 12b were deemed to apply to plans governed by ERISA, Section 12b would be preempted and have no force or effect as to such plans.

The United States District Court for the District of Columbia reached that exact same conclusion in *PCMA v. Dist. Of Columbia*, 613 F.3d 179 (D.C. Cir. 2010). There, the District of Columbia sought to compel compliance with the provisions of a local statute that, like Section 12b, required pharmacies within the District to substitute lower-priced, therapeutically equivalent generics for high-priced brand

named drugs and pass along the financial savings occasioned by that substitution. The court found that the statute in that case ran afoul of ERISA and the "free hand" it was intended to afford plan administrators to "structure their plans in [the District] precisely as they would elsewhere." *Id.* at 80 (quoting *Pharm. Care Mgmt. Ass'n v. Rowe,* 429 F.3d 294, 303 (1st Cir. 2005)). The statute did so by "improperly inject[ing] state regulation into an area exclusively controlled by ERISA." *Id.* at 85. As such, the court enjoined enforcement of the District's statute.

Accordingly, the Board finds that Section 12b, even if it were deemed to apply to third party payor contracts, would not be enforceable with respect to any contract entered into by Petitioners that relates to a plan covered by ERISA.[13]

d. Government-Employer Benefit Plans

That then leaves government and church sponsored Benefit Plans if Section 12b was deemed to cover pharmacy reimbursement contracts. Such government sponsored plans would include the welfare plans offered state workers through the Public Employee Insurance Agency ("PEIA"). The question, then, becomes: If Section 12b cannot apply to non-governmental plans because of the preemptive effect of ERISA, did the Legislature nevertheless intend Section 12b to apply to pharmacy reimbursement contracts negotiated by or on behalf of PEIA and other similar governmental organizations for the benefit of state workers, retirees and their beneficiaries?

PEIA, for example, utilizes the services of a PBM in the same way as private employers. That PBM negotiates pharmacy reimbursement contracts on PEIA's behalf with pharmacy groups and chains using the substantial bargaining power that PEIA has because it represents such a large pool of state workers and beneficiaries. Given its bargaining power, PEIA, through its PBM, is able to negotiate not only which generic drugs will be substituted for which name brand prescriptions but also the reimbursement rates for those medications. Only when PEIA is satisfied with the agreed upon medications to be dispensed and the reimbursement rates it will pay pharmacies for that service are those pharmacies permitted access to its beneficiaries.

If Section 12b applies to those contracts, and if the reimbursement rates negotiated by PEIA do not comport with the requirements of Section 12b *with respect to every single drug covered by PEIA's contract,* that contract would likely be deemed void. Moreover, any pharmacy group or chain that, in good faith, agreed to the terms of such contracts and accepted reimbursements in accordance with its terms, would find itself subject to potential fines and enforcement actions – actions instituted by one arm of the State for accepting the reimbursements agreed to and paid by another arm of the State.

[13] Section 12b does not apply to prescription medications dispensed under the Medicare or Medicaid programs. In this regard, the Board notes that even the Attorney General in his civil actions does not allege violations of Section 12b with respect to these programs and seeks no relief for substituted prescription transactions under these programs.

The absurdity of this scenario is self-evident. In essence, a pharmacy or pharmacist would be punished for simply honoring its contract with a state agency or department – a contract that the state agency or department determined to be in the best interest of workers and retirees to whom it provides prescription drug coverage. It is difficult for the Board to see how application of Section 12b in such a manner would serve the interests the Legislature intended to advance when it enacted the statute in 1978. This is particularly true where the agency or department charged with providing benefits of this type is not compelled to agree to the contractual terms it did and has not complained to the Board about that contractual arrangement.

e. The Practical Application of Section 12b

Added to the foregoing is the question of how Section 12b can, as a practical matter, be applied as the Attorney General interprets it to pharmacy benefit contracts that set reimbursement rates to be paid pharmacies for medications dispensed pursuant to that contract. Gone are the days when drug manufactures sold generic drugs to wholesalers and wholesalers sold them to pharmacies at standard mark-ups. The nature of today's market is such that prescription medications are often purchased in bulk by large pharmacy chains or groups pursuant to a variety of contractual arrangements involving discounts and retroactive rebates. PBMs themselves negotiate with generic drug manufactures in order to secure rates for medications included in their formularies that are lower than might otherwise be the case.

Thus, determining what, for example, a pharmacy's cost is for a particular branded medication and the generic drug substituted for it on the particular day when a prescription was filled is something that is not easily determined. Moreover, those cost figures, once determined, would then have to be compared to the negotiated reimbursement rates agreed to by the pharmacy and applicable third party payor for other generic substitutes to determine whether the medication required to be dispensed was the lowest retail cost, effective brand that was in stock. This, in turn, would require data regarding the medications that each pharmacy had *in stock* on the particular day and time each and every substituted generic drug was dispensed. And then, in order to determine whether the cost savings on any given generic substitution transaction was passed on to a given patient on a given prescription on that given day would require creation, for each generic substitution transaction, a non-existent "shadow" transaction, in which the same patient with the same pharmacy benefit coverage on the same day received the prescribed brand name drug instead of the substituted generic drug. Absent that shadow transaction, it would be impossible to determine the true cost savings on any generic transaction because there would be no benchmark brand drug transaction against which to measure the "savings."[14]

[14] Given the discounts and associated rebates that are a part of this pricing, that determination alone would take resources well beyond those provided the Board by the Legislature.

Requiring pharmacies located in West Virginia to compile and maintain such data would impose an obvious and significant burden upon them with all the attendant costs. Those costs would either have to be absorbed by the pharmacies, making the practice of pharmacy in West Virginia less attractive when compared to our sister states, or, in the alternative, passed on in the form of higher reimbursement rates for prescription medications paid by Benefit Plans operating in West Virginia. Neither outcome serves to promote the public welfare and health of West Virginia residents or advance the goal of providing affordable prescription drugs for all residents of West Virginia.

Beyond this, the simple fact is that Board does not have the administrative resources that would be required to gather and analyze the data necessary to determine compliance with Section 12b if it were deemed applicable to pharmacy reimbursement contracts. It would take a veritable army of inspectors and auditors to review the myriad of real and shadow transactions involved and the data related to each such transaction. Data would have to be reviewed first to determine whether the medication in question was dispensed in substitution for a brand name drug. If so, given that Section 12b speaks in terms of retail prices, it would then be necessary to determine whether that generic carried the lowest retail price of the therapeutically equivalent generic in stock at the pharmacy when the prescription was filled. Then, the actual generic substitution transaction would have to be compared to the shadow brand name drug transaction in order to determine whether or to what extent the cost savings resulting from the generic drug transaction were passed on to the patient.

Even if the focus were not on retail prices, but instead were limited to the reimbursement rates to which the pharmacy was contractually entitled for dispensing a generic in substitution for a higher priced, brand name medication, the task becomes no easier. The Board's auditors would have to determine what the reimbursement rate was under the particular contract involved. It would then have to determine whether the formulary for that plan recognized other generics as appropriate, alternative (or even preferred) substitutes for that branded product, and, if so, what the reimbursement rate for each alternative was. Each of these determinations would have to be replicated every time a generic drug was dispensed in substitution of a branded product, as would a new "shadow" brand drug transaction, since plan formularies frequently change in terms of approved and preferred generics.

In the more than 30 years that Section 12b has been the law, the Board has not received a single complaint from any source, including the Attorney General, that pharmacies are violating Section 12b by dispensing generic medications pursuant to negotiated pharmacy reimbursement contracts. The Board interprets this to mean that there is not a problem that demands a solution, and particularly not a solution that would undermine the Legislature's objectives of the Pharmacy Act. The Board also interprets the absence of such complaints to mean that the resources that would be needed to enforce Section 12b, if it were deemed applicable to pharmacy reimbursement contracts, could and

should be better allocated toward pressing concerns that are having a negative impact on the public health and welfare.

Accordingly, even if Section 12b can be read to apply to pharmacy reimbursement contracts, which the Board concludes it should not, the Board will, in the exercise of its prosecutorial discretion, elect not to enforce Section 12b in this manner unless and until the Legislature indicates its disagreement with the Board's determination and appropriates the funds necessary to extend the ambit of Section 12b to such contracts. To do so would divert scarce and valuable resources from more pressing concerns while at the same time driving up the administrative costs associated with the practice of pharmacy with no discernable benefit to the residents of West Virginia.

f. The Plain Language of Section 12b

The backdrop against which Section 12b was adopted, ERISA's preemptive effect, the specter of pharmacies being held in violation of state law for accepting reimbursements for medications dispensed pursuant to contracts negotiated by state entities, the vast resources that would be required to enforce Section 12b were it deemed applicable to such contracts, and the total absence of any suggestion that the high cost of prescription medications today is the product of pharmacy reimbursement contracts negotiated by or on behalf of Benefit Plans, all suggest that Section 12b was never intended to be applied to such contracts. The plain meaning of the language of Section 12b confirms that.

First, lest there be any doubt, Section 12b is, by its express terms, limited to transactions involving the substitution of a therapeutically equivalent generic drug for a higher priced medication prescribed by a treating physician. It does not apply where there is no such substitution. To conclude otherwise would require the Board ignore the language of statute itself.

Second, Section 12b speaks in terms of "retail" prices paid by "purchasers" of prescription medications. "Retail" prices are commonly defined as prices established in connection with the sale of goods in small batches directly to the consumers of those goods. That Section 12b speaks in such terms is not surprising given the fact that the market for prescription medications in 1978 involved precisely that type of direct retail transaction between the pharmacists and patients.

Conversely, Section 12b makes no reference to "reimbursement rates," "PBMs," "Third Party Payors," "Prescription Benefit Plans," or "Plan Beneficiaries." This, too, is not surprising given that these were largely unknown concepts at the time the Legislature adopted Section 12b. As a result of the emergence of Benefit Plans, PBMs, and third-party payors, pharmacies today are reimbursed for prescription medications in the vast majority of transactions, not on the basis of "retail" prices, but instead on the basis of contractually negotiated reimbursement rates predicated upon volume dispensing.

Accordingly, the Board concludes that Section 12b was not enacted and does not apply to prescriptions dispensed pursuant to contracts negotiated with Benefit Plans, third-party payors, state or other such entities.

Trying to twist the language of Section 12b to fit situations involving pharmacy reimbursement contracts with third party payors would, in the view of the Board, be inconsistent with accepted rules governing statutory construction. Moreover, doing so would not further the goals of Section 12b, but, instead, frustrate them. It would disrupt the provision of pharmacy services in West Virginia by voiding most if not all existing reimbursement contracts to the extent doing so was not preempted by ERISA. This, in turn, would serve to distinguish West Virginia as an outlier in terms of the manner in which the practice of pharmacy is regulated. None of this would serve to aid the orderly regulation of the practice of pharmacy in this state, or the operation of pharmacies, Benefit Plans or, most importantly, their beneficiaries.

IT IS SO RULED This 9th day of October, 2012.

THE WEST VIRGINIA BOARD OF PHARMACY

Monday • March 25, 2013 • 03:08 PM

Michigan Department of Community Health Medicaid program

You will need Adobe® Reader to view any printable PDF document (s).
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Note: Information about manuals or documents not provided on this Web site, may be obtained by calling the Michigan Medicaid state office at 517-335-5161.

MPPL Drug List

MPPL Drug List	Last Modified
MPPL Introduction	04/09/2008
MPPL and Coverage Information	02/28/2013
Michigan Preferred Drug List – Summary Document (Effective 02/05/2013)	01/11/2013
MPPL and PDL Changes (Effective 07/20/2011)	06/30/2011
MPPL Drug List	Last Modified

Other Drug Information

Other Drug Information	Last Modified
Quantity Limitation Information	11/10/2011
Copay Information	11/01/2010
ABW County Plan Carveout	10/16/2012
Health Plan Carveout	10/16/2012
Anti-ulcer Medication Policy – Definition of High Dose	01/10/2008
NOTICE on fluoxetine 40 mg coverage	01/10/2008
Maintenance Drug List	01/10/2008
Part D covered and excluded drugs 04/19/2006	08/12/2009
Other Drug Information	Last Modified

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Other Drug Information	Last Modified
Quantity Limits on Acetominophen Products	07/16/2010
Drug coverage for PlanFirst! can be viewed at: www.michigan.gov/medicaidproviders Under >> Billing and Reimbursement >> Provider Specific Information >> Family Planning	not available
Compound Exclusion List	05/10/2007
Drug Classes and Products Covered for the MOMS Program	10/18/2012
FAQ's for Drug Manufacturers	07/16/2010
Additional Information on Billing Medicare/Medicaid COB Claims	08/04/2005
Dose Optimization Program	03/31/2010
Clinical Alerts	not available
Other Drug Information	**Last Modified**

Secure Personnel

MAGELLAN MEDICAID ADMINISTRATION

Maximum Allowable Cost (MAC) Pricing Frequently Asked Questions

What is a State Maximum Allowable Cost program?

State MAC programs are modeled after the Centers for Medicare & Medicaid Services (CMS) Federal Upper Limit (FUL) program. The intent is to provide a maximum price the state will pay for a given generic pharmaceutical irrespective of its package size or manufacturer. The Michigan MAC program is designed to promote the efficient purchasing of generic pharmaceuticals within the Department of Community Health's pharmacy provider network to ensure that the Medicaid program is a prudent payer of prescription drugs.

How are the drugs selected for inclusion on the MAC list?

"AB" rated generic drugs that have more than one generic manufacturer are selected for inclusion on the Department's MAC list. Other considerations are included such as market availability, drug shortages, obsolete or terminated status, CMS rebate status, and the clinical practicality of generic interchange.

How are market prices researched?

Prices are researched using wholesaler information (prices and availability). At least two wholesalers conducting business within the State of Michigan are included in this analysis. In addition, industry data, such as published pricing information, and information provided by Michigan pharmacies is used to review and assess the MAC program and to ensure that established MAC prices reflect current pharmaceutical market conditions.

How are MAC prices set?

The State of Michigan uses a vendor to set the MAC prices. The vendor uses a proprietary algorithm that computes the MAC price.

Where are the MAC list and prices located?

All information is posted at the vendor's Michigan Medicaid website:
https://michigan.fhsc.com/MAC/MacInfo.asp

This includes

- Monthly MAC List
- Weekly MAC Price Update List
- MAC Price Research Request Form
- MAC Pricing Request Form

How do providers request a MAC pricing review?

Providers may request a MAC price review by filling out the *MAC Price Research Request Form* and submitting it to the vendor. All inquiries must be accompanied by actual invoices from the providers wholesaler for consideration. All efforts will be made to respond to requests within two business days.

What should I do if I'm unsatisfied with the initial MAC pricing review response and believe the price is incorrect?

Providers should submit a second price review request with documentation supporting why they believe the price is incorrect and warrants re-review. Providers can also contact the State MAC Department (see contact information below) to request additional assistance including a more detailed explanation of the review determination.

Whom should I contact if I have questions?

The State of Michigan welcomes providers' questions, comments, and input regarding the Medicaid MAC program. Providers are encouraged to contact the State's vendor, Magellan Medicaid Administration, regarding

- Changes in product availability
- Questions or concerns regarding MAC prices
- Questions concerning drugs included on the MAC list
- How to obtain a copy of the MAC list

Magellan Medicaid Administration, Inc.
Attn: State MAC Department
Mail: 4300 Cox Road, Glen Allen, VA 23060
Fax: (888) 656-1951
E-mail: StateMACProgram@MagellanHealth.com

Michigan Department of Community Health
MDCH
Jennifer M. Granholm, Governor
Janet Olszewski, Director

MICHIGAN PHARMACEUTICAL PRODUCT LIST (MPPL)

INTRODUCTION

Michigan Pharmaceutical Product List (MPPL) provides specific pharmacy coverage information for billing the Michigan Department of Community Health (MDCH) fee-for-service programs: Medicaid, Children's Special Health Care Services (CSHCS), Maternity Outpatient Medical Services (MOMS), Adult Benefits Waiver (ABW) [formerly State Medical Program (SMP)] and Plan First! It applies to drug products billed by retail and long-term care (LTC) pharmacies that are enrolled as Medicaid Provider Types 50. The MPPL is to assist you in the pre-point of sale (POS) decision making only. POS is your most reliable source of information regarding coverage parameters. The drug products listed are not necessarily covered for all programs. The presence of a particular drug product in this file **does not guarantee payment.** Changes to drug product coverage may occur between postings of this document.

The MPPL lists drug products alphabetically and specifies coverage parameters such as prior authorization, age, and sex requirements. Covered drug products include both prescription and prescribed over-the-counter (OTC) drugs where applicable. Every effort is made to list a drug product under its generic name with a reference to the brand name.

Drug products listed on the MPPL are reimbursable based on the parameters listed and if they are manufactured by a Centers for Medicare Medicaid Services (CMS) approved labeler or medically necessary. **Note: If the MDCH is informed that a drug product availability prevents the use a rebatable national drug code (NDC), the MDCH will consider the coverage of the most cost effective alternative.**

The MPPL does not apply to drug products used:

- *In an Inpatient Hospital Setting*
- *In an Outpatient Hospital Emergency Room or Clinic Setting*
- *In a Physician's Office or a Clinic Setting*
- *For Persons enrolled in Medicaid Health Plans (MHPs) or County Health Plans (CHPs)*
- *In Mental Health Hospital LTC Units and Medical Care Facilities with In-house Pharmacies*

Drug product coverage not individually listed within the MPPL are:

- *X1B – Diaphragms*
- *X1B - Artificial Tears Ophthalmic. Solution [Maximum Allowable Cost (MAC) = 0.41650/ml]*

DRUG LIST ABBREVIATIONS AND REMARKS:

The following drug list abbreviations and remarks indicate conditions of coverage for a specific drug product.

Abbreviation	Meaning of Abbreviation
#	Prior Authorization (PA) Required. (Refer to prior approval instructions)
CC	Covered only for CSHCS Program
EFFECTIVE DATE	First Date the Drug Product Is Covered or Recent MAC Price Change.
EQ	MAC Price Established. (Override must be obtained for reimbursement above the MAC rate.)
HIV	HIV Drug Products that are part of MHP and CHP Carve-Out
INJ	Injectable Drug Products Covered for Home Infusion and LTC Beneficiaries
P1st	Drug Products that are payable under Plan First! Program
NCC	Drug Products Not Covered for CSHCS Program
NOSMP	Drug Products Not Covered for ABW Program (formerly SMP)
NOLTC	Drug Products Not Reimbursed to Pharmacies for LTC beneficiaries.
PSY	Drug Products that are part of MHP and CHP Psychotropic Carve-Outs.
REMARKS	Examples: 1) For 10 Years of Age and Under Only (The drug product will not be reimbursed for beneficiaries 11 years old and over). 2) No PA for 6-17 Years of Age (PA is required for beneficiaries 5 years old and under as well as 18 years old and over). 3) PA for 30 Years of Age & Over (PA is not needed for beneficiaries 29 years old and under). 4) Reproductive Females Only (Prenatal vitamins are covered during the ante and postpartum term and not as a daily multiple vitamin).
UNIT	Units Are Either EACH, ML OR GM. (The billing quantity listed on the invoice must be based on the unit listed for the drug. **Note: When the unit is each, bill the quantity based on the dosage form. An exception is an antihemophilic drug, which must be billed per Antihemophilic Factor Unit (AHF). Humate has a unit of each, the dosage form is vial, but the remarks state use AHF units.)**

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Michigan Department of Community Health

Benefit Plan Co-pay Information

Group ID	Description	Coverage	Co-pay
INCARCE	Incarcerated Medicaid patients	No coverage	No coverage
SHPDUAL	Health Plan with Medicaid and CSHCS	Standard	No Co-pay
CSHCSCAID	Children's Special HealthCare Services with Medicaid	Standard with Children's special health	No Co-pay
SHP5ONLY	Health Plan with CSHCS	Select mental health and antiviral	No Co-pay
CSHCS5ONLY	Children's Special HealthCare Services	Standard with Children's special health	No Co-pay
HPHKFULLCAID	Health Plan with Medicaid	Select mental health and antiviral	$3.00 Brand $1.00 Generic
HKFULLCAID	Healthy Kids Medicaid	Standard	$3.00 Brand $1.00 Generic
FULLREFCAID	Full Refugee Medicaid	Standard	$3.00 Brand $1.00 Generic
HPFULLCAID	Health Plan Full Medicaid	Select mental health and antiviral	$3.00 Brand $1.00 Generic
FULLCAID	Full Medicaid	Standard	$3.00 Brand $1.00 Generic
MOMS	Maternity Outpatient Medical Services	Pregnancy related medications	No Co-pay
EMERREFCAID	Emergency Refugee Medicaid	Standard	$3.00 Brand $1.00 Generic
HKEMERGCAID	Healthy Kids Emergency Medicaid	Standard	$3.00 Brand $1.00 Generic
EMERGCAID	Emergency Medicaid	Standard	$3.00 Brand $1.00 Generic
SMPCOP	Adult Benefit Waiver-County Plan Coverage	Select mental health and antiviral	$1.00
SMPFULL	Adult Benefit Waiver	Standard	$1.00

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Benefit Plan Co-pay Information

?	Description	Coverage	Co-pay
SMPEMERG	Adult Benefit Waiver - Emergency	Standard	$1.00
HPTMACAID	Health Plan Full Medicaid	Select mental health and antiviral	$3.00 Brand $1.00 Generic
HPTMAPLUS	Health Plan Full Medicaid	Select mental health and Antiviral	$3.00 Brand $1.00 Generic
TMAPLUSFULL	Full Medicaid	Standard	$3.00 Brand $1.00 Generic
TMACAID	Full Medicaid	Standard	$3.00 Brand $1.00 Generic
TMAEMERG	Emergency Medicaid	Standard	$3.00 Brand $1.00 Generic
TMAPLUSEMERG	Emergency Medicaid	Standard	$3.00 Brand $1.00 Generic
FAMILYPLAN	Family Planning Waiver	Pregnancy prevention and related medications	No Co-pay
QMB	Qualified Medicare beneficiary	Medicare Part B covered drugs	No Co-pay