UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

COMMUNITY PHARMACIES OF INDIANA, INC., WILLIAMS BROTHERS HEALTH CARE PHARMACY, INC., and INDIANA PHARMACISTS ALLIANCE, INC. Plaintiffs, vs. INDIANA FAMILY AND SOCIAL SERVICES ADMINISTRATION and Its Subdivision, THE OFFICE OF MEDICAID POLICY AND PLANNING, By and Through PATRICIA CASANOVA, Director, MICHAEL A. GARGANO, Secretary, and DAVID TESTERMAN, Director of Medicaid Pharmacy Program, in their Official Capacities, not Individually, Defendants.	)	Case No. 1:11-cv-0893-TWP-DKL

ENTRY ON MOTION FOR PRELIMINARY INJUNCTION

This matter is before the Court on Plaintiffs' Motion for a Preliminary Injunction. There are three Plaintiffs in this matter: Community Pharmacies of Indiana, Inc., a non-profit trade association that represents over 170 pharmacies in Indiana; Williams Brothers Health Care Pharmacy, Inc., an independently-owned and operated pharmacy based in Washington, Indiana; and Indiana Pharmacists Alliance, Inc., a non-profit corporation representing Indiana individual pharmacists (collectively, "Plaintiffs"). For ease of reference, the multitude of Defendants in this matter, all of whom are agents or agencies of the State of Indiana, will be referred to collectively as the State ("State").

Recently, the State used an emergency rulemaking procedure to lower the Medicaid

"dispensing fee" reimbursed to pharmacies for filling prescriptions from $4.90 to $3.00 – a 38% decrease (the "Fee Reduction"). The impetus for the Fee Reduction was budgetary; the State simply needed to tighten its belt. The Fee Reduction went into effect on July 1, 2011. This lawsuit immediately followed, and, on July 8, 2011, the Court granted a temporary restraining order ("TRO") in favor of Plaintiffs. The parties have now re-briefed the issues in a more comprehensive fashion, and the Court held oral arguments on August 24, 2011.

Since the inception of this case, Plaintiffs' overarching argument has remained the same: The Fee Reduction is in violation of state and federal law and will cause irreparable harm. Plaintiffs maintain that even before the Fee Reduction, the dispensing fee was borderline inadequate for Indiana pharmacies. Thus, the Fee Reduction will make a bad situation worse and will force many pharmacies to seriously reevaluate whether the provision of Medicaid services is compatible with a viable business model. So, not only will the Fee Reduction hurt Plaintiffs financially, it could drive many pharmacies out of Medicaid altogether, thus harming certain Medicaid patients by restricting their geographic access to pharmacy services. The State counters that these apocalyptic scenarios are purely speculative, and, in any event, the Fee Reduction complies with state and federal law.

While the Court certainly sympathizes with Plaintiffs, the State's position best aligns with the law at this stage of the proceedings. For the reasons set forth below, the Court must reverse its decision on the TRO and **DENY** Plaintiffs' Motion for a Preliminary Injunction (Dkt. 12).

Legal Standard

A preliminary injunction is "an exercise of a very far-reaching power, never to be indulged in except in a case clearly demanding it." *Roland Mach. Co. v. Dresser Industries, Inc.,* 749 F.2d 380, 389 (7th Cir. 1984) (citation and internal quotations omitted). When a court is presented with a request for preliminary injunction, it considers multiple factors. As the Seventh Circuit Court of Appeals ("Seventh Circuit") has recognized, a party seeking to obtain a preliminary injunction must demonstrate: (1) "a likelihood of success on the merits," (2) "a lack of an adequate remedy at law," and (3) "a future irreparable harm if the injunction is not granted." *Reid L. v. Ill. State Bd. of Educ.*, 289 F.3d 1009, 1020-21 (7th Cir. 2002). The court must then balance, on a sliding scale, the irreparable harm to the moving party with the harm an injunction would cause to the opposing party. *See Girl Scouts of Manitou Council, Inc. v. Girl Scouts of U.S. of America, Inc*., 549 F.3d 1079, 1086 (7th Cir. 2008). The greater the likelihood of success, the less harm the moving party needs to show to obtain an injunction, and vice versa. *Id*. Finally, the court must consider the public interest in determining whether the injunction is to be granted or denied. *See Storck USA, L.P. v. Farley Candy Co.*, 14 F.3d 311, 314 (7th Cir. 1994).

The decision to grant or deny a request for injunctive relief is not governed by a rigid, unbending formula. As the Seventh Circuit has recognized, a court must "exercise its discretion to arrive at a decision based on a subjective evaluation of the import of the various factors and a personal, intuitive sense about the nature of the case." *Girl Scouts of Manitou*, 549 F.3d at 1086 (citation and internal quotations omitted).

Background

A. Medicaid in Indiana

Medicaid is jointly funded by the states and the federal government and pays for medical services to low-income persons – including the elderly, the disabled, and families with children – pursuant to state plans approved by the Secretary of the Department of Health and Human Services (hereinafter, "HHS"). *See* 42 U.S.C. § 1396a(a)-(b). As the Supreme Court has noted, Medicaid is a federal-state program that is "designed to advance cooperative federalism." *Wisconsin Dep't of Health & Family Services v. Blumer*, 534 U.S. 473, 495 (2002).

State participation in Medicaid is voluntary. But if a state opts to participate, and thus receive federal assistance, it must conform its Medicaid program to federal law. *See Blanchard v. Forrest*, 71 F.3d 1163, 1166 (5th Cir. 1996). A state electing to participate in Medicaid must submit a "plan" detailing how it will expend its funds. *Community Health Center v. Wilson-Coker*, 311 F.3d 132, 134 (2d Cir. 2002). The Secretary of HHS delegates power to review and approve plans to Regional Administrators of the Centers for Medicare and Medicaid Services ("CMS"). *See Wilson-Coker*, 311 F.3d at 134 (citing 42 C.F.R. § 430.15(b)). CMS reviews each plan to ensure that it complies with a long list of federal statutory and regulatory requirements. *See* 42 C.F.R. § 430.15(a)-(b). If the state plan satisfies these criteria, it is approved and the state receives "federal funding participation." 42 C.F.R. § 430.10.

CMS must also approve any proposed amendments to a state's plan. *See* 42 C.F.R. § 430.12; 42 C.F.R. § 430.20. Specifically, when a state plan amendment is proposed, CMS has 90 days to make a determination whether the amendment complies with the Medicaid Act. 42 U.S.C. § 1396n(f)(2). If CMS does not respond in a timely manner, the amendment is approved.

Id. If CMS asks for more information, the clock stops running until CMS receives the requested information. *Id*. From there, CMS has another 90 days to make a decision. *Id*. If CMS disapproves the amendment, the state may seek reconsideration and, ultimately, judicial review. 42 U.S.C. § 1316(a)(2)-(5).

Indiana participates in the Medicaid program and is therefore bound by its requirements. Ind. Code § 12-15-1-1, *et seq*. Specifically, the Office of Medicaid Policy and Planning ("OMPP"), a subdivision of the Indiana Family and Social Services Administration ("FSSA"), is the state agency responsible for administering Indiana's Medicaid program. *Id*.

B. Medicaid Reimbursements to Indiana Pharmacies

The State must reimburse pharmacies for services rendered to Medicaid recipients. 405 IAC 5-24, *et seq*. Specifically, the State reimburses Indiana pharmacies participating in the Medicaid program for the physical cost of the prescription drug ("ingredient cost"), plus a dispensing fee for each prescription filled ("dispensing fee"). From a pharmacy's standpoint, the sum – the ingredient cost plus the dispensing fee – is the figure that matters most. Stated differently, a pharmacy doesn't care if it receives a paltry dispensing fee, as long as it receives a correspondingly sufficient ingredient cost.

In Indiana, pharmacy participation in Medicaid is apparently robust. Of the 1,395 licensed pharmacies in Indiana, 1,391 participate in Medicaid.[1] Moreover, there are over 400

[1]Larry Sage, Executive Vice President of Indiana Pharmacists Alliance, testified by way of affidavit that "[m]any pharmacists" do not work with Indiana Medicaid recipients "because the dispensing fee (and physical cost) reimbursement rate is too low." (Dkt. 12-7 at 2). The sworn affidavit of Nathan Gabhart, Vice-President of Williams Brothers, echoes this statement. (Dkt. 12-5 at 6). These statements are curious, given that well over 99% of Indiana pharmacies participate in Medicaid. See Testerman affidavit (Dkt.49-5 at 5).

out-of-state pharmacies enrolled as Indiana Medicaid providers. Given this abundance of Medicaid-servicing pharmacies, most Indiana Medicaid patients have numerous options for their prescription drug needs. Specifically, 97.1% of all Indiana Medicaid patients have three or more pharmacies – not including mail order options or out-of-state providers – within their county of residence.

Finally, Indiana law requires the State, on a biannual basis, to conduct a survey of pharmacy providers to assess the "appropriate level of dispensing fees to be paid to providers for prescribed drugs." Ind. Code § 12-15-31.1-1. Recently, the State has used Myers & Stauffer, a certified public accounting firm that provides accounting and financial services to government health care officials, to complete these surveys. Meyers & Stauffer completed surveys in both 2009 and 2011.

C. The Fee Reduction

To reiterate, due to budgetary directives, the State has attempted to lower the dispensing fee paid to pharmacies for Medicaid prescriptions by 38% – from $4.90 to $3.00. Specifically, on May 10, 2011, House Enrolled Act 1001 (the "budget bill") was signed into law. The budget bill contained appropriations to all state agencies for fiscal years 2012 and 2013. Once enacted, the budget bill capped an agency's spending authority to the amount appropriated for the purposes listed in the budget bill. Medicaid assistance was appropriated $1,716,500,000 in state general funds for fiscal year 2012 and $1,882,500,000 for fiscal year 2013. These figures reflected FSSA's need to save $212 million, partially because federal assistance stemming from the "American Recovery and Reinvestment Act" (i.e. the stimulus package) expired on June 30,

2011.[2] Worse still, Indiana's Medicaid enrollment is projected to increase year to year. Obviously, increased Medicaid rolls coupled with decreased federal assistance is a bad combination for the fiscal health of the State's Medicaid program.

To hit the $212 million savings target demanded by the budget bill, FSSA made difficult choices and implemented numerous changes to its Medicaid program – such as the Fee Reduction. The Fee Reduction is expected to generate over $44 million in savings over the 2012 and 2013 fiscal years. Without the Fee Reduction, FSSA will invariably have to find $44 million in savings elsewhere, presumably through either Medicaid cuts or some other form of reimbursement reductions. The Fee Reduction was implemented by emergency rule with an effective date of July 1, 2011. Notice was first posted in the Indiana Register on May 4, 2011, and again on June 29, 2011. The rule will remain in effect for two years until it sunsets on June 30, 2013. Moreover, the plan amendment was submitted to CMS on April 7, 2011.

In making the Fee Reduction decision, the State worked with Myers & Stauffer to analyze the impact the Fee Reduction would have on pharmacy access for recipients. To that end, the State analyzed the following variables:

> marketplace conditions, dispensing reimbursement rates for other state Medicaid programs, dispensing reimbursement rates accepted by retail pharmacies from other third-party payors like commercial insurance companies and managed care organizations, the biannual dispensing reimbursement fee survey prepared for the State by Myers & Stauffer, the previous dispensing reimbursement fee rates accepted by retail pharmacies from managed care entities prior to 2010, and the access to pharmacy care available to Medicaid recipients in Indiana.

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[2]As Plaintiff's have asserted, the "need" for this savings target is somewhat questionable, given that the State recently trumpeted its *$1.18 billion surplus*. Nonetheless, the budget bill reflects the judgments and priorities of the legislature, which of course are not at issue.

Along similar lines, the State considered historical context. Specifically, prior to January 1, 2010, managed care entities ("MCE's") were responsible for processing Medicaid pharmacy claims. The MCE's paid retail pharmacies an average dispensing fee of $2.19 and an ingredient cost of anywhere from average wholesale price ("AWP") minus 14% to AWP minus 15%. According to the State, this amount is comparable to the ingredient cost reimbursement Medicaid currently pays for brand name drugs (i.e. AWP minus 16%).[3] On this point, David Testerman – the Director of Pharmacy for the OMPP – testified by way of affidavit as follows:

> The combination of the lower dispensing fee of $2.19 and comparable ingredient cost reimbursement means that for a period of years retail pharmacies willingly accepted total reimbursement at rates lower than the proposed Medicaid rate with the dispensing fee reduction – AWP minus 16% for the ingredient and $3.00 for the dispensing fee. In spite of lower reimbursement rates, OMPP maintained an extremely high participation rate for eligible pharmacy providers.

In other words, Indiana pharmacies like Plaintiffs have previously received reimbursement rates that were comparable to what they would receive after the Fee Reduction.

Here, the size of the Fee Reduction clearly blindsided Indiana pharmacists. On November 15, 2010, representatives of the pharmacy community met with the State to discuss a potential

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[3] "AWP" is a reference point in the pharmacy world used to facilitate prescription drug transactions. More precisely, AWP "is the published price a pharmacy is supposed to pay when it acquires a drug from a wholesaler. The actual prices pharmacies pay are typically lower than AWP, which has been characterized as a suggested retail price and likened to a 'sticker price' on a new car." *Omnicare, Inc. v. UnitedHealth Group, Inc.*, 629 F.3d 697, 700 n. 1 (7th Cir. 2011) (citation and internal quotations omitted). To use an analogy that resonates with baseball card aficionados, AWP is similar to the now-defunct *Beckett Baseball Card Monthly*, a magazine that listed the value of almost any conceivable baseball card, thus "greasing the wheels" of all well-informed baseball card transactions. That said, only a novice collector paid the full *Beckett* listing price. Akin to seasoned card collectors, pharmacies typically only pay AWP minus some percentage.

decrease in the dispensing fee reimbursement. During the meeting, a representative from the State suggested a relatively modest cut – from $4.90 to $4.20. Subsequently, on May 23, 2011, the State informed the pharmacy that it intended to reduce the dispensing fee far more drastically – all the way down to the comparatively draconian $3.00. Moreover, the State informed the pharmaceutical representatives that it would do so via emergency rule without a public hearing. Not surprisingly, this news generated an onslaught of responses and inquiries (76 in total) from the pharmaceutical community, all opposing the Fee Reduction. But, in the end, these exhortations proved futile and the Fee Reduction went forward. This lawsuit quickly followed.

To be sure, the Fee Reduction will harm pharmacies' bottom lines. According to Mr. Testerman, "[w]hen the [Fee Reduction] is implemented, the revenue decrease to each individual pharmacy will be between $12,000 and $18,000 on average," thus leading to an "average net lost profit per pharmacy [of] $2,500 to $5,000 per year." At first blush, this sum may not sound like a game-changer. However, many pharmacists already operate on thin margins. As Plaintiffs' evidence shows, Indiana pharmacies already receive an ingredient reimbursement rate in the bottom 13% for brand name drugs (and even lower, as a percentage of AWP, for generic drugs). (Dkt. 57 at 10). Thus, Plaintiffs' evidence establishes that, after the Fee Reduction, "Indiana will have one of the lowest Medicaid reimbursement rates in the country." (Dkt. 57 at 12).

In other words, the Fee Reduction could be the proverbial "straw that breaks the camel's back." for many pharmacies in small and rural counties. Some pharmacies may cease providing Medicaid services, while others may close altogether. Additional facts are added below as needed.

Reasonable Likelihood of Success on the Merits

Plaintiffs make three basic arguments challenging the legality of the Fee Reduction: (1) the State's attempt to enforce the Fee Reduction without prior CMS approval violates federal law; (2) the Fee Reduction violates Section 30(A) of the Medicaid Act; and (3) through the Fee Reduction, the State violated state and federal notice requirements. The Court will address each argument in turn.

Do Plaintiffs have standing under the Supremacy Clause?

Because Plaintiffs' claims primarily arise under the Supremacy Clause, the Court must, as a threshold matter, determine if Plaintiffs have a viable private right of action. This issue raises difficult questions, with sound arguments on both sides.[4] At the TRO stage, the Court sided with Plaintiffs, relying on a long line of authority from both the Supreme Court and circuit courts throughout the country. Having reviewed this issue again, the Court reaffirms its previous ruling. *See, e.g., Green v. Mansour*, 474 U.S. 64, 68 (1985) ("the availability of prospective relief . . . gives life to the Supremacy Clause"); *Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85, 96 n. 14 (1983) ("A plaintiff who seeks injunctive relief from state regulation, on the ground that such regulation is pre-empted by a federal statute which, by virtue of the Supremacy Clause of the Constitution, must prevail, thus presents a federal question which the federal courts have jurisdiction under 28 U.S.C. § 1331 to resolve."); *Verizon Maryland, Inc. v. Pub. Serv. Commission of Maryland*, 535

[4]The Supreme Court is set to resolve this issue once and for all during its upcoming October 2011 term. In *Maxwell-Jolly v. Independent Living Center of Southern California, Inc.*, 131 S. Ct. 992 (2011) (granting certiorari), the Supreme Court will determine whether Medicaid recipients and providers may maintain a cause of action under the Supremacy Clause to enforce 42 U.S.C. § 1396a(a)(30)(A) by asserting that the provision preempts a state law. Petition for Writ of Certiorari at ii, *Maxwell-Jolly*, 2010 WL 599171 (Feb. 16, 2010) (No. 09-958).

U.S. 635, 642 (2002) (same); *Arkansas Dep't of Health & Human Services v. Ahlborn*, 547 U.S. 268 (2006) (Arkansas statute automatically imposing lien on tort settlement proceeds was not authorized by federal Medicaid law); *ILCSC, Inc. v. Shewry*, 543 F.3d 1050, 1055 (9th Cir. 2008) ("The Supreme Court has repeatedly entertained claims for injunctive relief based on federal preemption, without requiring that the standards for bringing suit under § 1983 be met"); *Lankford v. Sherman*, 451 F.3d 496, 509 (8th Cir. 2006) ("preemption claims are analyzed under a different test than section 1983 claims, affording plaintiffs an alternative theory for relief when state law conflicts with a federal statute or regulation."); *Illinois Association of Mortgage Brokers v. Office of Banks & Real Estate*, 308 F.3d 762 (7th Cir. 2002) (recognizing the availability of injunctive relief to enjoin state officers from implementing a rule or regulation that is preempted under the Supremacy Clause).

In the Court's view, not only would a contrary ruling represent a significant departure from a substantial body of jurisprudence, it would also curtail an avenue of relief that has long been available: A cause of action for equitable relief against preempted state laws. In that same vein, the Court is not persuaded by the State's invitation to conflate Supremacy Clause claims with Section 1983 claims. So, until the Supreme Court says otherwise, Plaintiffs can pursue their claims under the Supremacy Clause.

2. Is CMS approval required before the State can implement the Fee Reduction?

The State submitted the Fee Reduction to CMS on April 7, 2011, and it has not yet been approved. In fact, on July 6, 2011, CMS requested additional information from the State, thus delaying its decision. (Dkt. 23). The State responded to this request on July 26, 2011. To date, the parties are waiting on CMS's response.

Undeterred by CMS's obvious concerns, the State wants to march forward with implementation of the Fee Reduction. The question arises: Can the State do this? Plaintiffs argue "No": That is, "[f]ederal courts have previously held that when state plan amendments have been submitted, but not approved, a state Medicaid agency may not implement the amendment until federal approval is obtained." (Dkt. 43 at 37) (emphasis in original). To be sure, there is some support for this position. *See, e.g., Exeter v. Memorial Hosp. Association v. Belshe*, 145 F.3d 1106, 1108 (9th Cir. 1998) ("approval is required before implementation of amendments to the Plan"); *AGI-Bluff Manor, Inc. v. Reagen*, 713 F. Supp. 1535, 1552 (W.D. Mo. 1989) ("The Medicaid Act and HHS regulations require that a state Medicaid plan or an amendment to the plan receive federal approval from HCFA prior to implementation.").

Unfortunately for Plaintiffs, this is not the law in the Seventh Circuit. In *Wisconsin Hosp. Association v. Reivitz*, 733 F.2d 1226 (7th Cir. 1984), the Seventh Circuit recognized that the available authority "suggests that proposed amendments may be implemented before approval is received from HHS." *Id*. at 1237 (emphasis added). It is true, as Plaintiffs emphasize, that *Reivitz* dealt with the now-repealed Boren Amendment – not Section 30(A). Nonetheless, with respect to the issue of whether CMS approval is required before a plan amendment can be implemented, this is a distinction without a difference. Here, there is no compelling reason to depart from the Seventh Circuit's holding in *Reivitz*.

The Court's ruling is reinforced by the regulations governing Medicaid. Specifically, 42 C.F.R. § 430.18(e)(2) explains that if the Medicaid administrator reviews CMS's initial decision and determines that it was incorrect, then "CMS pays the State a lump sum equal to any funds incorrectly denied." Obviously, this regulation presupposes that a state will go ahead and

implement the unapproved plan amendment. Otherwise, CMS wouldn't need to reimburse the state. In other words, the operative regulations implicitly (yet unmistakably) give states the ability to implement amendments at the pre-approval stage.

Plaintiffs do not specifically address the meaning of § 430.18, but instead counter that 42 C.F.R. § 447.256 precludes rate reductions from taking effect until CMS gives its imprimatur. The Court is not persuaded. Specifically, § 447.256(c) states that "[a] State plan amendment that is approved will become effective not earlier than the first day of the calendar quarter in which an approvable amendment is submitted . . .". Simply stated, this rule relates to the effective date for *approval*, not *implementation*. Moreover, if Plaintiffs' position were adopted, § 430.18(e)(2) would be rendered completely meaningless. Thus, the regulations do not bar a state from unilaterally implementing a rate reduction.

Finally, Plaintiffs highlight that on October 1, 2010, the Director of CMS's Center for Medicaid wrote a letter to all State Medicaid Directors stating, in relevant part: "Federal statute and regulations require CMS to review and approve [plan amendments] . . .before a State may implement Medicaid program modifications." (emphasis added). Plaintiffs argue that "considerable weight" should be given to an executive department's interpretation of a statutory scheme that it is entrusted to administer. *See Chevron, U.S.A., Inc. v. Natural Resources Defense Council*, 467 U.S. 837, 844 (1984).

This argument is well-taken, but the Court is not persuaded. First, CMS has not exactly been a model of consistency on this issue. In a more recent letter, dated June 24, 2011, CMS wrote "please be advised that we will defer FFP for State payments made in accordance with this amendment until it is approved. Upon approval, FFP will be available for the period beginning

with the effective date through the date of actual approval." As the State notes, "CMS's statement that it will defer federal funding participation ("FFP") until approval necessarily contemplates that the State may implement rules prior to approval." (Dkt. 59 at 4). Second, and perhaps more importantly, real world experience shows that a state is permitted to implement amendments prior to approval. For instance, OMPP recently implemented a 5% Medicaid rate reduction for podiatrists and chiropractors. Specifically, the proposed rate reduction was submitted to CMS on December 17, 2010, and the reduction was implemented on January 1, 2011. CMS did not actually approve the rate reduction until March 17, 2011. From there, the State received FFP dating back to the effective date of January 1, 2010. This example shows that, when the rubber meets the road, CMS has approved Indiana's decision to implement a reduction prior to federal approval. And, as the State's evidence also shows, this instance is not an aberration; OMPP apparently implements policy changes prior to CMS approval with some regularity. (Dkt. 59-1 at 2). Moreover, according to the State, CMS has never voiced criticism or concern "regarding OMPP's practice of implementing policy changes prior to [plan amendment] approval." (Dkt. 59-1 at 3).

In the end, Plaintiffs only have a letter from CMS and cases from the Ninth Circuit to support their position. Given the Seventh Circuit's decision in *Reivitz*, the operative regulations, and real world practice, Plaintiffs' authority simply isn't enough to show a reasonable likelihood of success on the merits with the facts currently before the Court.[5] Accordingly, Plaintiffs' first argument fails to carry the day.

[5]As of today's date, CMS approval has not been granted or denied. If in fact CMS disapproves, the strength of Plaintiffs case for success on the merits would be greatly improved.

3. Does the Fee Reduction violate Section 30(A) of the Medicaid Act?

To answer this question, the Court begins its analysis with the language of the statute. Specifically, 42 U.S.C. § 1396a(a)(30)(A) provides that a state plan must:

> provide such methods and procedures relating to the utilization of, and the payment for, care and services available under the plan . . . as may be necessary to safeguard against unnecessary utilization of such care and services and to assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area . . .

(emphasis added). In essence, this statute requires that the reimbursement amount be sufficient to attract enough providers so that services are available to Medicaid patients like they are to the general population of that geographic area. This provision, while certainly noble, also illustrates the inherent difficulty with setting price controls in government programs: If the price is too low, not enough providers will offer the service; too high, and the budget is impacted. This leads to an economically rational tug of war between the government (who wants to pay as little as possible) and the provider (who wants to earn a profit).[6] Stated differently, in the absence of market forces, it is very difficult, if not impossible, for the State to ascertain where supply and demand would naturally meet at an equilibrium to dictate price and quantity.

In any event, the main thrust of Plaintiffs' argument is that a State "may not adopt Medicaid rates based solely on budgetary considerations." (Dkt. 43 at 42). Indeed, some circuits

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[6]In no way is this statement meant to impugn the motives of pharmacies. By angling for the highest reimbursement rate possible, they are just behaving rationally. As the Northern District of Illinois colorfully noted, "This is not to suggest that the providers have no concern for the patients they serve, and are interested only in looting the state treasury." *American Society of Consultant Pharmacists v. Garner*, 180 F. Supp. 2d 953, 972 (N.D. Ill. 2001).

have adopted the general rule that budgetary considerations cannot be the paramount factor in Medicaid decisions. *See, e.g., Arkansas Medical Soc., Inc. v. Reynolds*, 6 F.3d 519, 531 (8th Cir. 1993) ("Abundant persuasive precedent supports the proposition that budgetary considerations cannot be the conclusive factor in decisions regarding Medicaid."); *Rite Aid of Pennsylvania, Inc. v. Houstoun*, 171 F.3d 842, 856 (3d Cir. 1999) ("budgetary considerations may not be the sole basis for a rate revision"). That said, even these courts generally recognize that budget factors may be taken "into consideration when setting its reimbursement methodology." *Arkansas Medical*, 6 F.3d at 531.[7]

Contrary to Plaintiffs' position, the Seventh Circuit has ruled that, in the context of Section 30(A), pre-implementation motivations, processes, and predictions are not of particular importance. Instead, the Seventh Circuit single-mindedly focuses on *post-implementation results*. This point was unequivocally driven home in *Methodist Hospitals, Inc. v. Sullivan*, 91 F.3d 1026 (7th Cir. 1996).

In *Methodist*, a group of hospitals and physicians sued FSSA after Indiana changed its formula used to pay Medicaid providers for outpatient services. *Id*. at 1027. The new reimbursement formula was tethered to a median cost of the particular service in Indiana. *Id*. at 1028. Therefore, if a hospital had a higher than average cost for a given service, its corresponding reimbursement rate took a hit. *Id*. The plaintiffs, who consisted of hospitals with higher than average costs, brought suit alleging that they had been damaged by the new reimbursement formula. *Id*.

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[7]As a practical matter, budget considerations usually must play *some* role in determining reimbursement reductions. After all, if not for budgetary reasons, why else would a State reduce reimbursements, and thus incur the wrath of Medicaid providers?

After ruling that the plaintiffs had a private right of action to enforce Section 30(A) using § 1983,[8] the Seventh Circuit addressed the plaintiffs' substantive arguments. *Id*. at 1029. In doing so, *Methodist* expressly rejected the notion that Section 30(A) requires "comprehensive studies prior to any change in a state's plan of reimbursement." *Id*. On this point, the court expressed deep skepticism about the efficacy of such studies, recognizing that "it is exceptionally difficult to determine demand and supply schedules for a single product." *Id*. at 1030.[9] Along those lines, the court highlighted that Section 30(A) "requires each state to produce a *result*, not to employ any particular methodology for getting there." *Id*. (emphasis in original). Further, "states may behave like other buyers of goods and services in the marketplace: they may say what they are willing to pay and see whether this brings forth an adequate supply. If not, the state may (and under § 1396a(a)(30), must) raise the price until the market clears." *Id*. (emphasis added).

Applying these principles, *Methodist* highlighted that Indiana had reduced its reimbursement rate; launched studies to determine if the new prices attracted sufficient providers; and then, based on the studies, modified the reimbursement formula for inpatient services but left the outpatient services formula intact. *Id*. The Seventh Circuit noted that "Indiana used 1994 [the year the challenged reimbursement formula was in place] to check predictions against reality.

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[8]Presumably, this ruling is no longer good law in the wake of subsequent Supreme Court decisions. *See, e.g., Gonzaga University v. Doe*, 536 U.S. 273, 283, 87 (2002) (to have a right of action under § 1983, the statute must have "individually focused terminology" that "unambiguously confer[s]" a right).

[9]This reasoning makes sense. After all, before a transaction is consummated, a shrewd seller will not divulge the lowest price at which he'll sell, just as a shrewd buyer will not divulge the highest price at which he'll buy. Indeed, "[p]eople often do not *know* their reservation prices" and "they do not willingly reveal them." *Methodist Hospitals*, 91 F.3d at 1030 (emphasis in original).

This approach seems to us sound. Whether or not a better way could be devised, it was a lawful way to proceed." *Id*. (emphasis added). Finally, the court emphasized that during the year the new reimbursement formula was in place, no provider actually withdrew from the Medicaid program, despite the dire pre-implementation predictions to the contrary. *Id*.

Tracking *Methodist*, the Northern District of Illinois denied a motion for a preliminary injunction in a case that bears a strong resemblance to the present one. In *American Society of Consultant Pharmacists v. Garner*, 180 F. Supp. 2d 953 (N.D. Ill. 2001), Illinois changed its reimbursement formula for pharmacies that provide prescription drug services to Medicaid recipients. *Id*. at 955-56. Specifically, to stave off a budgetary shortfall for Medicaid prescription drugs, the Illinois Department of Public Aid ("IDPA"), through emergency rule, lowered reimbursement rates for prescription drugs in order to reduce annual Medicaid expenditures by between $52 million and $70 million. *Id*. at 961-62. Anticipating the change, a trade association of Illinois pharmacies filed a motion for preliminary injunction against the Director of the IDPA, alleging that the new formula violated Section 30(A). *Id*. at 956.

Right off the bat, *Garner* noted that the plaintiffs' doomsday predictions, while troubling, were "just that" and did not show that "closures or reductions in service have occurred or are imminent." *Id*. 964. Turning to the Seventh Circuit's binding decision in *Methodist*, the *Garner* court observed:

> [T]he balance of the opinion makes clear that a provider may not prove a Section 30(A) violation merely by criticizing a state's procedure in implementing a revised rate, or by predicting a diminished level of access and quality of care. The Seventh Circuit made clear that a claim under Section 30(A) will stand or fall based on proof of the actual results of a reimbursement plan.

Id. at 969 (emphasis added). In the end, the court found that *Methodist* was fatal to the plaintiffs'

request for injunctive relief. *Id*. Similarly, in *Molina Healthcare of Ind. v. Henderson*, 2006 WL 3518269 (S.D. Ind. Dec. 4, 2006), Judge Tinder recognized as follows:

> Plaintiffs here are asking the court to oversee the State's methodology. They allege, but cannot show, that the State awards will not achieve sufficient access for providers. Although they point to geographical "holes" in one of the three new provider networks, this does not mean that recipients in those areas will lack access to a provider through one of the other networks or that the alleged deficiencies will not be corrected by the time that the contracts take effect. Their complaint is solely with the methods that the State employed. This is not an (a)(30) concern.

Id. at *12 (emphasis added).

To reiterate, in the Seventh Circuit, actual *post-implementation results* are paramount for purposes of a Section 30(A) analysis. Conversely, pre-implementation processes, methods, and predictions (where providers have every incentive to overstate the effect of the cut) are of little importance. *Garner*, 180 F. Supp. 2d at 972-73 ("And what *Methodist Hospitals* teaches is that in deciding among the conflicting claims about whether the reimbursement rate is sufficient to satisfy that standard, the test is not what is predicted but rather what happens – which is nothing more than the application of the adage that actions speak louder than words.") (emphasis added). Here, the State has not been given a meaningful opportunity to test *results* to determine whether the new dispensing fee will actually attract sufficient pharmacy services. While it may seem harsh, the *Methodist* and *Garner* decisions clearly establish that the State should be given the opportunity to implement the Fee Reduction, police the situation, and adjust the formula as necessary to ensure an adequate supply of services. *See id*. at 974.

Plaintiffs respond that this simply cannot be the state of the law. Otherwise, the State is effectively immunized from injunctive relief in the context of Section 30(A): "Such [a] conclusion

would be illogical because a party who is irreparably harmed by [the] State's illegal conduct would have no recourse in federal court." (Dkt. 57 at 7). However, Plaintiffs' argument demonstrates the very essence of *Methodist Hospitals*. That is, dire predictions notwithstanding, the State *must* be given the opportunity to test the *results* of rate reductions because it is nearly impossible to accurately predict the economic effect of such reductions. That said, it also stands to reason that if a State acted in a patently absurd fashion, then injunctive relief could still be available. The *Garner* case acknowledged this possibility, stating that perhaps "one would not need to await the marketplace's answer to the adequacy of a rate that was so unreasonable on its face (for example, zero) that it inevitably would fail to attract sufficient supply." *Garner*, 180 F. Supp. 2d at 976.

But that is not the case here. On this point, the Court's ruling is strongly reinforced by the fact that the State has some evidence indicating that even with the Fee Reduction, the dispensing fee will in fact be adequate to keep Medicaid providers in the pharmacy services market. As discussed in detail in the background section above, the State has completed various studies and looked to recent history in devising the scale of the Fee Reduction. While the percentage of the reduction feels extreme, the Court simply cannot find that the Fee Reduction selected by the State was arbitrary, capricious, or, worse still, unreasonable on its face.

This is certainly not to say that Plaintiffs are crying wolf. Indeed, their dire predictions may, but hopefully will not, morph into reality. Regardless, at this stage, the Court simply has more questions than answers when it comes to the Fee Reduction's future impact on the availability of Medicaid services. For instance, will a meaningful number of pharmacies actually close shop or reduce Medicaid services? And even assuming a mass exodus of pharmacies from certain markets, will new providers enter these markets? Or, more likely given the high barriers of

entry into the pharmacy market, will existing providers expand into these markets? Finally, how would closures affect access for Medicaid patients as compared to non-Medicaid patients? After all, "to show a violation of equal access under Section 30(A), the plaintiffs must provide evidence of the *recipients*' access and how it compares to the non-Medicaid population in the same geographic area." *Id*. at 973 (emphasis in original; citation and internal quotations omitted). Without the aid of crystal ball, neither the Court nor the parties knows the answers to these difficult questions with any reasonable certitude. For these reasons, the Court finds Plaintiffs' Section 30(A) argument is unlikely to succeed on the merits.

Finally, Indiana law mirrors Section 30(A). *See* Ind. Code § 12-15-13-2(a). In fact, Plaintiffs concede that "this state statute reiterates the federal Medicaid statutes . . .". (Dkt. 43 at 13). Accordingly, Plaintiffs' state claim involving "equal access" suffers the same fate as their Section 30(A) claim. *See Indiana Family & Social Services Admin. v. Walgreen Co.*, 769 N.E.2d 158 (Ind. 2002) (reversing preliminary injunction after Indiana used emergency rulemaking procedure to reduce drug reimbursement rates and decrease the dispensing fee paid to pharmacies, despite the plaintiff's argument that a reduction in the dispensing fee would cause a handful of pharmacies to close).

4. Did the Fee Reduction violate state and federal notice requirements?

Finally, Plaintiffs argue that, through the Fee Reduction, the State violated state and federal notice requirements. To put it charitably, the State's implementation of the Fee Reduction was less than transparent. It was not, however, legally deficient. Under Ind. Code § 4-22-2-37.1, the Secretary of FSSA and OMPP can enact emergency rules regarding Medicaid reimbursement rates by following proper protocol. Ind. Code § 4-22-2-37.1(a)(37). The rule takes effect on the later of:

(1) "the effective date of the statute delegating authority to the agency to adopt the rule"; (2) "the date and time that the rule is accepted for filing under subsection (e)"; (3) "the effective date stated by the adopting agency in the rule"; or (4) "the date of compliance with every requirement established by law as a prerequisite to the adoption or effectiveness of the rule." § 4-22-2-37.1(f). Here, FSSA published notice of the emergency in the Indiana Register on May 4, 2011, and again on June 29, 2011. No notice or comment period was required by law. At bottom, the State complied with Indiana law notice requirements.

Similarly, Plaintiffs argue that the State failed to comply with 42 C.F.R. § 447.205. To the contrary, the State fully complied with this regulation. The notice was published in May, almost two months prior to the effective date of the rule; it gave an estimate of any expected increase or decrease in annual aggregate expenditures; it explained the motivation behind the reimbursement reduction; it provided that copies were available from the local offices for public review; it gave an address where written comments could be sent; and it made clear that no public hearings would be held. 42 C.F.R. § 447.205(c)-(d).

Finally, Plaintiffs claim that the State violated the notice requirements of 42 U.S.C. § 1396a(a)(13)(A). This argument is unavailing, as Section 13(A) does not apply to pharmacy services. Instead, it only applies to "hospital services, nursing facility services, and services of intermediate care facilities for the mentally retarded." Moreover, courts have rejected the argument that pharmacy reimbursement rates are covered by Section 13(A) because pharmacies provide services to nursing homes. *See Long Term Care Pharmacy Alliance v. Ferguson*, 362 F.3d 50 (1st Cir. 2004). In *Ferguson*, the First Circuit used microeconomic principles to explain why Section 13(A) was well-suited for care facilities, but not pharmacies:

> [I]t is easy to imagine why Congress wanted special protection for care facilities. Their sunk-cost structure makes them especially vulnerable to slow destruction by long-term underfunding; by contrast, the market reaction is likely to be quick and decisive if the Commonwealth seeks to underpay for drugs, whether provided by ordinary retailers or closed pharmacies. If WAC plus 5% is not enough to elicit an adequate supply, the Division will simply be forced to pay more and promptly so.

Id. at 56. For this reason, coupled with Congress' failure to explicitly include pharmacy services in Section 13(A), the *Ferguson* court held that pharmacies are outside the scope of Section 13(A). *Id*.; *see also American Soc. of Consultant Pharmacists v. Concannon*, 214 F. Supp. 2d 23, 31 (D. Me. 2002). For these reasons, Plaintiffs' notice-based arguments do not have a reasonable likelihood of success on the merits.

Conclusion

Because it is dispositive, the Court's preliminary injunction analysis begins and ends with the "reasonable likelihood of success on the merits" prong. For the reasons set forth above, Plaintiffs' Motion for a Preliminary Injunction (Dkt. 12) is **DENIED**. The State is free to implement and enforce the Fee Reduction.

SO ORDERED: 09/14/2011

Hon. Tanya Walton Pratt, Judge
United States District Court
Southern District of Indiana

Distribution attached.

Copies to:

Mark W. Bina
KRIEG DEVAULT LLP
mbina@kdlegal.com

Randall R. Fearnow
KRIEG DEVAULT LLP
rfearnow@kdlegal.com

Wade Dunlap Fulford
Indiana Attorney General
wade.fulford@atg.in.gov,emily.davis@atg.in.gov

Ryan Michael Hurley
BAKER & DANIELS - Indianapolis
ryan.hurley@bakerd.com,deb.lee@bakerd.com,kris.hagan@bakerd.com

Harmony A. Mappes
BAKER & DANIELS - Indianapolis
harmony.mappes@bakerd.com,betsy.smith@bakerd.com

Debra Ann Mastrian
KRIEG DEVAULT LLP
dmastrian@kdlegal.com

Scott Stuart Morrisson
KRIEG DEVAULT LLP
smorrisson@kdlegal.com,csmith@kdlegal.com

Kate E. Shelby
INDIANA ATTORNEY GENERAL
kate.shelby@atg.in.gov,nick.femyer@atg.in.gov