IN THE SUPREME COURT OF THE STATE OF MISSISSIPPI

CASE NO. 2008-SA-01245

DIVISION OF MEDICAID, OFFICE OF THE GOVERNOR, STATE of MISSISSIPPI; and DR. ROBERT L. ROBINSON, in his Official Capacity as Executive Director of the Division of Medicaid.	**APPELLANTS**
V.	
MISSISSIPPI INDEPENDENT PHARMACIES ASSOCIATION, INC, et al.	**APPELLEES**

REPLY BRIEF OF APPELLANTS MISSISSIPPI DIVISION OF MEDICAID, OFFICE OF THE GOVERNOR, and DR. ROBERT L. ROBINSON

On Appeal from the Chancery Court of the First Judicial District of Hinds County, the Honorable William Hale Singletary

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ORAL ARGUMENT NOT REQUESTED

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

FEDERAL CASES

STATE CASES

STATE STATUTES

FEDERAL REGULATIONS

OTHER AUTHORITIES

Summary of Argument and Statement on Oral Argument

The independent pharmacists are correct in their statement on page 1 of their brief that this appeal raises "complex and important public policy issues." It is axiomatic that the more complex the matter of public policy entrusted by law to the judgment of an agency, the more the judicial review becomes uncomplicated and deferential. Agencies have the "unique administrative charge to blend and pursue pragmatically and at once fact finding, legal interpretation and promotion of legislatively established public policy" and deference is rooted in the judiciary's "realization that the everyday experience of the administrative agency gives it familiarity with the particularities and nuances of the problems committed to its care which no court can hope to replicate."[1] Thus, while the issues are complex, the resolution of this appeal is uncomplicated.

The universal truth of the modern Medicaid program is at play in this appeal. When Medicaid changes a reimbursement rate, providers, whose participation in the program is voluntary, file suit and allege financial ruin. In light of the arguments raised by the pharmacists, the narrative is clear. With no negative connotation intended, it is in the rational self-interest of the pharmacists to seek, through litigation or other means, the highest level of Medicaid payment possible. In contrast, the Division's interest, and that of the Legislature, is rooted in a broader social and financial policy. Medicaid is a program to provide healthcare to Mississippi's neediest citizens. Medicaid is not a financial lifeline to pharmacies whose costs exceeds those of 95% of the other pharmacies in this state. Every dollar in excess reimbursement spent in the pharmacy program is a dollar that is unavailable to provide additional pharmacy benefits or other Medicaid

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[1] *Gill v. Mississippi Dept. of Wildlife Conservation*, 574 So.2d 586, 593 (Miss. 1990).

benefits to individuals. For example, because of the cost of the pharmacy benefit, the Division generally limits the number of prescription drugs it will provide a beneficiary per month. Simply stated, the Division and pharmacists approach the issue from decidedly different viewpoints.

The Division values the services provided by its pharmacy providers and carefully considered their comments when setting the two reasonable rates at issue in this appeal. In light of the comments received regarding the S-MAC rate, the Division's final rule increased the drug acquisition S-MAC rate to ensure that the average pharmacist will receive a payment that exceeds its costs by 30%. The S-MAC rate covers 838 drug groups. The proposed S-MAC rate is set so high that every pharmacy in the state can purchase drugs in 420 of the groups at or below the rate, and 9 out of 10 pharmacists can purchase drugs in the remaining 418 groups at or below the rate. By rough approximation, the S-MAC rate exceeds the drug cost for 95% of the state's pharmacies. Indeed, if a pharmacy's purchasing practices are as efficient as the average Mississippi pharmacy, a pharmacy will not only be reimbursed for the costs of the drugs, but will also receive a healthy 30% profit. Further, with respect to the dispensing fee, the Division's current dispensing fee of $4.91 is the 13th highest in the nation. The new dispensing fee of $5.50 proposed by the Division – challenged as unreasonably low by the pharmacists – will be the 6th highest Medicaid dispensing fee in the nation. Further, the average pharmacy in Mississippi has only 15% of their prescriptions covered by Medicaid, 85% are from other sources. Thus, 85% of the average pharmacy's profits should be unrelated to the rates at issue. Oral argument is unnecessary as it is abundantly clear from the record that the rates set by the Division in administrative rule AP2008-23 are reasonable and consistent with state law.

Argument

I. Courts Refrain from Interfering in an Agency's Exercise of its Duly Delegated Legislative Rule-Making Authority.

While the traditional administrative deference is discussed below, the pharmacists have lost sight of the fact that under the separation of powers doctrine a review of an agency's legislative act of rule-making is fundamentally different and more deferential than a review of an agency's quasi-judicial adjudicative function.[2] This appeal is of rate setting through rule-making, not an adjudicative decision. In addition to the traditional great deference, this Court has found it a "well-settled proposition" that "[i]n order to maintain the appropriate checks and balances, the judicial branch of government must refrain from interfering with the portion of administrative agency's function that has been delegated by the legislative branch." *Boyles v. Mississippi State Oil & Gas Bd.*, 794 So.2d 149, 157-58 (Miss. 2001); *see Mississippi Pub. Service Comm'n v. Mississippi Power & Light Co.*, 593 So.2d 997, 1000 (Miss. 1991).

The pharmacists unrepentantly ask this Court to override the Division's legislative rule regarding what the pharmacists rightly categorize as "complex and important public policy issues"[3]; a task which this Court is prohibited from undertaking because the judiciary does not substitute its "policy" judgment for that of an administrative agency. Because agencies like the

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[2] The Division exercises its "quasi-judicial or 'adjudicative' function as a delegation of power from the judicial branch of government [. . . when . . .] it decides disputes between competing parties to a controversy specific to the parties' interests and in which neither the Board nor other parties have a stake." *Boyles v. Mississippi State Oil & Gas Bd.*, 794 So.2d 149, 157-58 (Miss. 2001). The Division exercises its "legislative or 'rulemaking' functions as a delegation of power from the legislative branch of government [. . . when . . .] the Legislature directs the Board to enact rules or regulations on a particular subject within the Board's regulatory jurisdiction." *Id.*

[3] *See* Miss. Indep. Pharm Br. at 1.

Division have the "unique administrative charge to blend and pursue pragmatically and at once fact finding, legal interpretation and promotion of legislatively established public policy," this Court has established "an obligation of deference to agency interpretation and practice in areas of administration by law committed to their responsibility." *Gill v. Mississippi Dept. of Wildlife Conservation*, 574 So.2d 586, 593 (Miss. 1990). "This duty of deference derives from our realization that the everyday experience of the administrative agency gives it familiarity with the particularities and nuances of the problems committed to its care which no court can hope to replicate." *Id.* Never has such constitutional respect for an agency's expertise been more appropriate than in the "particularities and nuances" of complex "public policy issues" that comprise the modern Medicaid rate setting. *See* Division's Initial Br. at 20.

II. The Division's Interpretation of its Statute to Allow Utilization of S-MAC to Calculate EAC is a Permissible Interpretation.

The pharmacists contend that Section 43-13-117(9)(b) prohibits the Division from using the State Maximum Allowable Cost method (S-MAC) as a method to calculate a drug's "estimated acquisition cost" (EAC)[4], and, therefore, they ask this Court to override the Division's interpretation of its governing statute. The pharmacists raise two specific arguments. First, they contend that the "average wholesale price" method (AWP), and not S-MAC, is the only method used in Medicaid practice to calculate EAC. Second, the pharmacists argue that S-MAC determines "actual," and not "estimated", acquisition costs, and is, therefore, prohibited by Section 43-13-117(9)(b). Both arguments implicate the Division's interpretation of its complex governing statutes and are unquestionably wrong. The Division's interpretation of Section

[4] This brief uses the acronym "EAC" and the phrase "estimated acquisition cost" interchangeably depending on whether the context is sufficiently clear. The same is also the practice regarding the use of AWP and "average wholesale price."

43-13-117(9)(b) to permit the use of S-MAC is a permissible construction supported by the amendments to the statute, by the statutory definition of EAC under state and federal Medicaid law, and by the use of S-MAC by other states.

A. Pharmacists Cannot Overcome the Great Deference Afforded the Division's Interpretation of its Governing Statutes.

As an initial matter, the pharmacists functionally ignore that "great deference" is afforded the Division's "construction of its own rules and regulations and the statutes under which it operates." *McDerment v. Miss. Real Estate Comm'n*, 748 So.2d 114, 118 (Miss.1999); *see Electronic Data Sys. Corp. v. Mississippi Div. of Medicaid*, 853 So.2d 1192, 1204 (Miss. 2003). If the statute is either "ambiguous or silent" on the precise matter, the agency's interpretation must be upheld if it is "based on a permissible construction of the statute." *Barbour v. State ex rel. Hood*, 974 So.2d 232, 240 (Miss. 2008)(citing *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 865-866 (1984)). Further, "[t]he court need not conclude that the agency construction was the only one it permissibly could have adopted to uphold the construction, or even the reading the court would have reached if the question initially had arisen in a judicial proceeding." *Mississippi Gaming Comm'n v. Imperial Palace of Mississippi, Inc.*, 751 So.2d 1025, 1029 (Miss. 1999) (emphasis supplied).

B. By Statute, the Legislature has Delegated to the Division the Authority to Determine the Method of Calculating a Drug's EAC, With or Without Utilizing AWP.

As set forth in the Division's initial brief, the pharmacists are wrong in their assertion that the Division's adoption of S-MAC as a method to calculate EAC lacked the necessary legislative authorization. The pharmacists note that an unnumbered paragraph at the end of Section 43-13-117 provides that "rates of reimbursement" may not be "increased, decreased or otherwise

changed from the levels in effect on July 1, 1999, unless they are authorized by an amendment to this section by the Legislature." The relevant inquiry is whether the Legislature amended Section 43-13-117 after 1999 so as to authorize the Division to change the method by which EAC is determined. The Legislature made just such an amendment in 2004. In 2003, Section 43-13-117(9)(b) provided that:

> (b) Payment by the division for covered multiple source drugs shall be limited to the lower of the upper limits established and published by the Centers for Medicare and Medicaid Services (CMS) plus a dispensing fee, **or the estimated acquisition cost (EAC) plus a dispensing fee**, or the providers' usual and customary charge to the general public.
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> * * *
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> As used in this paragraph (9), "estimated acquisition cost" means twelve percent (12%) less than the average wholesale price for a drug.

Miss. Code Ann. 43-13-117(9)(b) (Rev. 2003) (emphasis supplied). During the 2004 legislative session, Section 43-13-117(9)(b) was amended to read:

> (b) Payment by the division for covered multisource drugs shall be limited to the lower of the upper limits established and published by the Centers for Medicare and Medicaid Services (CMS) plus a dispensing fee, **or the estimated acquisition cost (EAC) <u>as determined by the division</u>**, plus a dispensing fee, or the providers' usual and customary charge to the general public.

Miss. Code Ann. 43-13-117(9)(b) (Rev. 2004) (emphasis supplied). This same 2004 amendment deleted in its entirety the requirement that "estimated acquisition cost" be set at "average wholesale price" minus 12%. *See id.* Thus, by adding the requirement that the Division determine a drug's EAC, while at the same time deleting the requirement that EAC be calculated by reference to AWP, the legislature unmistakably authorized the Division to develop a new method to calculate a drug's "estimated acquisition cost" that may, or may not, utilize AWP. *See*

Division's Initial Br. at 6-7, 12-14.[5]

Statutory amendments have meaning and purpose. *Cf State ex rel. Pair v. Burroughs*, 487 So.2d 220, 226 (Miss. 1986) ("A construction which will render any part of a statute inoperative, superfluous, or meaningless is to be avoided.") That the Legislature undertook the effort to amend that statutory language, and that the Governor signed that amendment into law, must be given effect.[6] The pharmacists' efforts to judicially re-engraft AWP into Section 43-13-117(9)(b) against the will of the Legislature is contrary to law and bad policy. The Legislature's delegation of broad discretion to the Division in 2004 was a prescient act. It has now been conclusively determined by a federal district court that pharmaceutical companies were fraudulently reporting their drug's AWP and thereby costing state and federal programs like Medicaid and Medicare hundreds of millions of dollars each year in excessive and fraudulent reimbursements. As one federal court found,

> The overwhelming evidence at trial established that AWPs are fictitious and are rarely, if ever, prices paid by doctors for PADs or by pharmacies for [self-administered drugs or SADs].
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> * * *
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> Unscrupulously taking advantage of the flawed AWP system for Medicare reimbursement by establishing secret mega-spreads far beyond the standard industry markup was unethical and oppressive. It caused real injuries to the

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[5] The Miss. Indep. Pharm. Brief spends multiple pages arguing that the unnumbered paragraph in Section 43-13-117(9)(b) "froze" rate methodology in 1999 without ever mentioning the 2004 statutory amendments that authorize the Division to develop new methods to calculate EAC. *See* Miss. Indep. Pham. Br. at 15-19.

[6] The Legislature could have adopted a much more limited amendment to Section 43-13-117(9)(b) by requiring the Division to use AWP to establish EAC but delegated to the Division the responsibility to establish the percentage deduction from AWP, e.g., AWP minus 12%, 20% or 1,000%. Instead, the Legislature deleted <u>any</u> reference to AWP and tasked the Division to "determine" the best manner in which to calculate a drug's "estimated acquisition costs."

> insurers and the patients who were paying grossly inflated prices for critically important, often life-sustaining, drugs. Defendants caused these injuries by not reporting a true average wholesale price, that approximated provider actual acquisition costs or was within well established industry expectations (i.e., the Hartman 30 percent "speed limit"). Instead, the spreads were as high as 1,000%.

In re Pharm. Indus. Average Wholesale Price Litig. ("*AWP II*"), 520 F.Supp.2d 267, 270 (D.Mass. 2007) (emphasis supplied). The federal court further found that government programs like Medicaid and Medicare lost hundreds of millions of dollars because they were locked into reimbursement methods using AWP "by statute or contract." *Id.* Thus, the Legislature's delegation of discretion to the Division to devise and actively manage the calculation of EAC is sound public policy and an act designed to decrease the opportunity for fraud. The pharmacists' argument that AWP is the only method to calculate EAC was untrue before 2007 and is certainly untrue after 2007 given the revelation of fraud and the changing nature of pharmacy reimbursement. The federal Medicare program has long since stopped using the fraudulently reported AWP as a basis for calculating pharmacist reimbursement, and, by virtue of a court approved settlement in the AWP litigation, the entire AWP reporting system will soon no longer exist. *In re Pharm. Indus. Average Wholesale Price Litig.* ("*AWP I*"), 491 F.Supp.2d 20, 44 (D. Mass. 2007) (federal government has stopped using AWP); Myers and Stauffer Proposal, R. Vol. 5, R. 148 ("We recently provided issue briefs and analysis for our State MAC clients regarding the impending discontinuation of AWP's").

C. The Use of S-MAC is a "Permissible Interpretation" of Section 43-13-117(9)(b)'s Requirement that the Division Determine a Drug's EAC.

The pharmacists contend that S-MAC is an "impermissible fourth method of reimbursement" rather than a manner to calculate a drug's estimated acquisition costs. The pharmacists argue that S-MAC violates Section 43-13-117(9)(b)'s requirement that

reimbursement be determined by "estimated" acquisition costs because – the pharmacists believe – that S-MAC determines a drug's "actual" acquisition costs. Thus, the pharmacists believe S-MAC to be a foreign and unprecedented method that can only be categorized as a completely new "fourth" method of reimbursement wholly unrelated to "estimated acquisition costs." The pharmacists are wrong.

As set forth below, the express terms of Section 43-13-117(9)(b) delegate to the Division the authority to determine a drug's "estimated acquisition cost." The federal agency that administers Medicaid (the Centers for Medicare & Medicaid Studies (CMS)) defines "estimated acquisition cost" as a state agency's "best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size of drugs most frequently purchased by providers." 42 C.F.R. § 447.502. CMS does not dictate to states what method should be used to calculate EAC. S-MAC provides the Division with the "best estimate" of the "price generally and currently paid" by pharmacists by reviewing drug invoices from Medicaid pharmacies in Mississippi and using that information to determine the "average" cost to a pharmacist for each drug. *See* Rule Explanation, R. Vol. 13, R. 1239. In other words, the Division uses the average price paid by pharmacists as the "best estimate" of the "price generally and currently paid" by pharmacists. *Id.* Once the "average price" is determined for a particular drug, the Division then increases that number by 30% (a multiplier of 1.3)[7] to the benefit the pharmacists and to ensure the "reasonableness" of the rate as required by statute. *See* Rule Explanation, R. Vol. 13, R. 1239; 43-13-177(9)(b) (limiting reimbursement to those costs

[7] The original proposed rule used a multiplier of 1.2 (or 20%). *See* Proposed Rule, R. Vol. 5, R. 6. Taking into account the comments of the pharmacists during the rule making process, the Division increased the multiplier to 1.3 (or 30%). *See* Rule Explanation, R. Vol. 13, R. 1239; R. Vol. 13, R. 1280.

that are "reasonable"). The use of S-MAC is consistent with state and federal law, the history of Section 43-13-117(9)(b), and the practice in other states.

1. S-MAC is Used in Other States to Calculate a Drug's Estimated Acquisition Cost for Pharmacy Reimbursement.

Courts have previously noted the use of S-MAC to calculate EAC by other state Medicaid programs. *See Failor's Pharm. v. Dept. of Social and Health Services*, 886 P.2d 147, 150 (Wash. 1994) ("Based on field audits of pharmacies and the 1980 survey, DSHS changed in 1982 to the current estimated acquisition costs (EAC) system, and began to reimburse ingredient costs at the lower of the MAC or a percentage of AWP."). In fact, the use of S-MAC to determine a drug's EAC is so commonplace among states that its use is documented in the Practicing Law Institute's hornbook on Medicaid law entitled "The ABC's of Public and Private Reimbursement." *See* Jorge Lopez, Jr., The ABC's of Public and Private Reimbursement, 878 PLI/Pat 635, 643 (Oct. 2006) (quoted *verbatim* in the Division's initial brief at 15). In fact, Mississippi is one of only three states that does not currently use S-MAC as part of its reimbursement methodology. *See* Division Memorandum, R. Vol. 13, R. 1278.

The pharmacists' effort to contradict the "ABC's Reimbursement" with the conclusory affidavit of its consultant does not satisfy the heavy burden to overturn the Division's interpretation of its statute.[8] Similarly, the pharmacists mistakenly tell the Court that CMS has provided a "universally accepted definition of EAC" that excludes the use of S-MAC. *See* Miss.

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[8] Pharmacists rely on an affidavit containing the legal opinion of Brian Resisetter of "Medical Marketing Economics." The affidavit was filed as part of the pharmacists' chancery court complaint and not provided as part of the administrative record. According to its website, MME specializes in assisting "pharmaceutical and biotech companies, payers, specialty pharmacies, law firms, investment houses, and advertising agencies" in such items as strategic planning and litigation. *See* http://www.m2econ.com/services.htm.

Indep. Pharm. Br. at 20 (citing R. Vol. 7, R. 325). First, the document cited by the pharmacists is undated and not attributed to CMS. Second, the pharmacists quote only the footnote without quoting the main text. The main text recites that "states currently have options as to how they will establish EAC and dispensing fees. In some states they are set by state legislation. In other states, studies are done as to what the amounts should be." *See* Unidentified Document, R. Vol. 7, R. 325. Moreover, the footnote quoted by the pharmacists merely recited that states "generally used published compendia prices" and provides AWP as an example. *See id.* at note 6. This undated and unattributed generalized statement provides no support for the pharmacists' claim that S-MAC cannot be used to determine EAC.[9] When compared to Lopez's published hornbook on Medicaid reimbursement and the statement in cases like *Failor's Pharm.*, the pharmacists' self-serving, conclusory affidavit and the undated, generalized footnote are unpersuasive.

2. S-MAC is an "Estimate" Consistent With the Legislative History of Section 43-13-117(9)(b).

The clearest indication of what the Legislature intended by the phrase "estimated acquisition cost" is provided by recalling that prior to 2004 the Legislature defined "estimated acquisition cost" as twelve percent (12%) less than the average wholesale price. Miss. Code Ann. 43-13-117(9)(b) (Rev. 2003) (repealed in 2004). Thus, according to the Legislature (and the pharmacists), AWP was a permissible method to "estimate" a drug's acquisition costs. **The S-MAC method is no less an estimate of a drug's acquisition cost than is the AWP method.** In fact, S-MAC utilizes the same basic components as AWP, but in a more accurate manner,

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[9] Subsequent to the filing of the pharmacists' brief in this Court, CMS approved the State Plan amendment submitted by the Division regarding S-MAC and EAC. Of course, the trial court's determination that the rule violated state law prevents the Division from putting the rule and plan amendment into effect.

thereby providing the "best estimate" required by federal law.

The AWP Method: The Division, Medicaid divisions in other states, and the federal Medicare program previously used a drug's reported "average wholesale price" to calculate the "estimated acquisition cost" for pharmacy reimbursement. *See generally, AWP Litigation I*, 491 F.Supp.2d at 32. Under the AWP method, pharmaceutical manufacturers self-reported the national average wholesale price at which they were (allegedly) selling their drugs to pharmacists. However, the Department of Justice and federal court decisions have now documented that the "price reported by the pharmaceutical industry [was] without any oversight. Many pharmaceutical companies unscrupulously took advantage of that flawed AWP system by establishing secret mega-spreads between the fictitious reimbursement price they reported and the actual acquisition costs of doctors and pharmacies." *Id.* at 31, 41-44. Manufacturers were fraudulently inflating their reported average wholesale price by as much as 1,000% on certain drugs and by at least 30% on most drugs. *AWP Litigation II,* 520 F.Supp.2d at 270. Thus, a reimbursement methodology based on AWP resulted in a windfall for pharmacists.[10]

As the University of Mississippi School of Pharmacy documented regarding the fraudulently reported AWP and EAC, the Division is "[u]nder increasing pressure from policy makers and CMS to revise the reimbursement formula for medications to outpatient pharmacies" to provide reimbursement "that more closely resemble[s] the Estimated Acquisition Costs" of drugs. *See* Sch of Pharm Proposal, R. Vol. 6, R. 299. In light of the Legislature's explicit

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[10] The pharmacists categorize the new rate as a "cut" in comparison to the windfall that pharmacists reaped by virtue of the fraudulent reimbursement scheme devised by drug manufacturers. When the Legislature tied pharmacy payments to a drug's "average wholesale price" paid by pharmacists minus 12%, the pharmacists became the financial beneficiary of the fact that manufacturers were inflating their reported average wholesale price by between 30 to 1,000%.

delegation to the Division of the task to determine a drug's EAC, the Division retained the services of a national professional firm – Myers and Stauffer, LC – that has extensive experience in Medicaid pharmacy programs, included experience devising Medicaid S-MAC plans and rates in Iowa, Illinois, Indiana, Idaho, and Wyoming. *See* Proposal, R. Vol. 6, R. 153. Myers and Stauffer conducted an extensive survey of Mississippi Medicaid pharmacies as part of the process of devising the S-MAC rate. *See* R. Vol. 13, R. 1283-1284; R. Vol. 8, R.479-600.

The S-MAC Method: S-MAC and AWP share the same general method of calculating EAC with the three notable differences being that S-MAC more accurately reflects EAC; is less susceptible to fraudulent manipulation; and, because it is not set by statute, can be more proactive in adjusting reimbursement to reflect market changes in acquisition costs. Like AWP, the basis of a drug's S-MAC rate is the cost at which the pharmacies are on average purchasing the drug. The AWP method begins by determining the national average wholesale price of the drug paid by pharmacists as reported by the drug's manufacturer. The S-MAC method begins by determining a Mississippi pharmacy's average acquisition cost of the drug as reported by the pharmacists. *See* R. Vol. 13, R. 1239, 1283-1284. In sum, AWP focuses on the (1) national average (2) of a drug's wholesale price paid by pharmacists (3) as reported by the manufacturer. S-MAC focuses on the (1) Mississippi average (2) of the price paid by the Medicaid participating pharmacists (3) as reported by the pharmacists themselves. *See id.*; Myers and Stauffer Work Plan, R. Vol. 6, R. 287-288. Both AWP and S-MAC utilize an average of price paid by pharmacists for a particular drug, but gather that information from different sources.

The next step in the AWP and S-MAC process is different – and beneficial to the pharmacists. Under the AWP methodology, the Legislature required the Division to pay the pharmacists a drug's AWP minus 12%. *See* Miss. Code Ann. 43-13-117(9)(b) (Rev. 2003)

("'estimated acquisition cost' means twelve percent (12%) less than the average wholesale price for a drug"). Under the S-MAC model, once a drug's average cost to the pharmacist is determined, the Division sets the reimbursement rate as the average plus 30%. *See* Division Memorandum R. Vol. 13, R. 1239, 1279 (noting that the S-MAC rate is then multiplied by a factor of 1.3). Had AWP been accurately reported by manufacturers, the AWP minus 12% rate would have likely provided a lower actual reimbursement than S-MAC plus 30%.

Thus, both S-MAC and AWP first determine the "average" of costs to pharmacists for a specific drug. Both methodologies modify the reported average – AWP to the detriment of pharmacies and S-MAC to the benefit of pharmacies. Given that the Legislature previously endorsed AWP as an "estimate" of acquisition costs, and given that the S-MAC method is no less an estimate of a drug's "estimated acquisition cost" than is the AWP method, the Division's use of S-MAC is certainly a "permissible interpretation of its statute."

3. S-MAC is a More Accurate Estimate, but it Does Not Impermissibly Reimburse Pharmacists for Actual Costs.

Although the pharmacists spend much of their brief arguing that S-MAC's failure to reimburse every pharmacy their actual costs renders S-MAC "unreasonable" (the 10% will lose money argument), the pharmacists first argue that S-MAC does reimburse pharmacists for their "actual" costs and is, therefore, not an "estimate" authorized by state or federal Medicaid law. This inconsistent argument is without merit. Federal law requires the Division to use its "best estimate of the price generally and currently paid by providers" for the drug. *See* 42 C.F.R. § 447.502 (emphasis supplied). S-MAC is a "better" estimate than AWP because S-MAC is

premised on more accurate, empirical data.[11] Best estimates are based on accurate empirical data; estimates not based on empirical data are either wild guesses or, as was the case with AWP reimbursement, based on falsified data.[12] That S-MAC is a more accurate estimate because it is based on the average drug cost as reported by Mississippi pharmacists does not change S-MAC from an estimate to an actual reimbursement method.[13]

III. The S-MAC and Dispensing Rates Established by the Division Are Reasonable.[14]

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[11] S-MAC more accurately estimates the drug costs of Mississippi pharmacies because, unlike AWP, S-MAC is based on the drug costs of Mississippi pharmacies participating in the Medicaid program. Because S-MAC is derived from information provided under the direct oversight by the Division and by pharmacists who are enrolled as Medicaid providers, S-MAC is less susceptible to the fraudulent manipulation experienced under AWP. *See* 491 F.Supp.2d at 31, 40-44 (noting that the AWP method's reliance on self-reporting "without any oversight"). Finally, because it is not set by statute, S-MAC can be more proactive in adjusting reimbursement to reflect market changes in acquisition costs. If a drug become unavailable at the S-MAC rate set by the Division, "the Division can be proactive . . . [and] can adjust SMAC rates for drugs with FULs that are truly below actual acquisition cost." *See* Division's Written Response to MME, R. Vol. 12, R. 1118; *see also* "State MAC Update Procedures" R. Vol. 6, R. 294-295.

[12] For example, the "best estimate" of the driving time from Jackson to Hattiesburg would be calculated by reviewing such empirical data as the distance in miles and the "average" driving time in a series of trips. An "estimate" is not, as the pharmacists suggest, a "guess" devoid of supporting information.

[13] In truth, the pharmacists' argument regarding statutory authorization is a throw-away contention. The pharmacists acknowledged in a moment of candor during the rule making process that the S-MAC method itself is not bad policy. *See* Stmt of MS Indep. Pharm. Ass'n. and MS Pharm. Ass'n. at R. Vol. 12 at R. 1131 ("It's not that it's a bad idea and the pharmacists who are here aren't really opposed to a state MAC").

[14] The pharmacists have raised a number of what they believe to be alternative grounds to affirm the chancellor's opinion. Those arguments are addressed in Sections III through V below. The Division believes that these issues are properly reviewed and rejected by this Court without the necessity of considering whether to remand this matter to the chancellor. In an administrative appeal, this Court defers to the agency's determination but reviews a chancellor's opinion *de novo*. *OXY USA, Inc. v. Mississippi State Tax Comm'n*, 757 So.2d 271, 274 (Miss. 2000). Thus, remanding the matter to the chancellor would serve little purpose while significantly delaying resolution.

A. The Division's Rule-Making Factual Determination Regarding Reasonableness is Entitled to Deferential Review.

The pharmacists assail the "reasonableness" of the Division's S-MAC rates (regarding a drug's acquisition cost) and dispensing fees (regarding the cost of filling the prescription). The Division's factual conclusions regarding reasonableness are entitled to considerable deference. There is a rebuttable presumption in favor of an agency's decisions; the burden of proving to the contrary is on the challenging party. *His Way Homes, Inc. v. Mississippi Gaming Com'n*, 733 So.2d 764, 767 (Miss. 1999). An agency's decision is supported by "substantial evidence" and must be upheld on appeal when there is "an adequate basis of fact from which the fact in issue can be reasonably inferred." *Stevison v. Public Employees' Retirement Sys. of Mississippi*, 966 So.2d 874, 878 -879 (Miss.App. 2007). Where there is substantial evidence, "an agency's fact finding must be allowed to stand 'even though there might be room for disagreement on that issue.'" *Miss. Public Serv. Comm'n v. Merchants Truck Line, Inc.*, 598 So.2d 778, 782 (Miss.1992)

The Division's legislative act of setting rates involves considerations not present in most administrative appeals. Rule-making involves "legislative facts" regarding public policy, as opposed to objective "adjudicative" or judicial facts pertaining to who did what and when. A greater level of deference is afforded such policy judgments because "legislative facts combine empirical observation with application of administrative expertise to reach generalized conclusions." *Association of Nat. Advertisers, Inc. v. F.T.C.*, 627 F.2d 1151, 1162 (D.C. Cir. 1979); *cf. Gill*, 574 So.2d at 593 (Miss. 1990) (deference derived from agency's "unique administrative charge to blend and pursue pragmatically and at once fact finding, legal

interpretation and promotion of legislatively established public policy"). "In the context of administrative law, legislative facts are those that affect an industry as a whole. An agency may resolve legislative questions through rule-making, relying on generalized data concerning an industry, the agency's special expertise, and policy considerations." *Patagonia Corp. v. Board of Governors of Fed. Reserve Sys.*, 517 F.2d 803, 816 (9th Cir. 1975).

Further, "reasonableness" in rate setting is a uniquely legislative act afforded great deference. Federal courts reviewing challenges to the "reasonableness" of Medicaid rates have adopted a "range of reasonableness" doctrine "whenever courts evaluate administrative rate-making against a statutory reasonableness standard." *Folden v. Washington State Dept. of Social and Health Services*, 744 F.Supp. 1507, 1529 -1530 (W.D.Wash. 1990). In general, rates required to meet a standard of reasonableness may fall within a zone of reasonableness; the establishment of one rate as "reasonable" does not necessarily render every other rate "unreasonable." In *Federal Power Comm'n v. Conway Corp.*, 426 U.S. 271, 278 (1976), the Supreme Court, although in another context, opined that rate-making is not "an exact science." "Statutory reasonableness is an abstract quality represented by an area rather than a pinpoint. It allows a substantial spread between what is unreasonable because too low and what is unreasonable because too high." *Id* (emphasis supplied). When the rate is within the zone of reasonableness, courts will not "impose upon" an agency its "view of what constitutes wise economic or social policy." *Madison v. Mississippi Medicaid Comm'n*, 86 F.R.D. 178, 184 (N.D.Miss., 1980).[15]

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[15] By comparison, "reasonableness," even in an adjudicative proceeding, is a factual determination entrusted to civil and criminal juries. *See North Biloxi Dev. Co., L.L.C. v. Mississippi Transp. Comm'n*, 912 So.2d 1118, 1125 (Miss.App. 2005); *Johnson v. State*, 908 So.2d 758, 764 (Miss. 2005). On review, a court will only override a jury's determination of

Finally, although the pharmacists exaggerated financial claims are unsupported in the record and rebutted below, it is important to note that a pharmacy's participation in the Medicaid program is voluntary. Participation in the Medicaid program may not be financially feasible for all pharmacies, especially those more expensive or inefficient than the average. As a federal court noted about the Mississippi Medicaid program,

> Providers of services are not required to participate in a state's Medicaid program, but if they do choose to participate, they must agree to accept payment in accordance with the state plan provisions. . . . The Medicaid program is not designed to protect providers from the consequences of their business decisions or from business risks. The Medicaid Act and implementing regulations grant the states a wide discretion in determining fee structures.

Madison, 86 F.R.D. at 184.

B. By Statute, the Division Must Pay the "Absolute Minimum" that is Reasonable and is not Authorized to Provide a Profit to Pharmacists.

Section 43-13-117(9)(b) limits the amount the Division may pay a participating pharmacist for the cost of a covered drug to the lowest of one of three calculations: (1) the upper limit set by the federal agency, plus a dispensing fee; (2) the pharmacist's "usual and customary charge to the general public"; or (3) "the estimated acquisition cost (EAC) as determined by the division, plus a dispensing fee." The Legislature further requires the Division to reimburse pharmacists for only the "reasonable costs of filling and dispensing" prescriptions. *Id.* Importantly, the Legislature directs the Division to "fix all of those fees, charges and rates at the minimum levels absolutely necessary to provide the medical assistance authorized by this article." *See* Miss. Code Ann.§ 43-13-121(1)(a)(iii) (emphasis supplied). The directive from the

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reasonableness if it is "so contrary to the overwhelming weight of the evidence that to allow it to stand would sanction an unconscionable injustice." *Thames v. State,* 5 So.3d 1178, 1183 (Miss.App. 2009).

legislature is clear: pay the absolute minimum that is reasonable. By paying the absolute minimum necessary, the Division is able to provide more services to more beneficiaries with the Division's limited resources. That the Division seeks to set reimbursement rates at the minimum absolutely necessary is good social and economic policy and not the result of evil motives by the Legislature or the Governor's office. In a point lost to the pharmacists, state Medicaid law limits the Division's reimbursement to the absolute minimum "costs" and does not require or authorize the Division to ensure that pharmacists make a "profit" on any Medicaid prescriptions.

C. The Division's Determination of a Reasonable S-MAC Rate is Entitled to Great Deference.

The Division's S-MAC rate is presumed to be valid and is supported by substantial evidence. When a Medicaid agency is tasked to reimburse a pharmacy based on an "estimate of the acquisition cost," "the purpose of these regulations is clear: state agencies are not to pay more for prescribed drugs than the prevailing retail market price." *Madison*, 86 F.R.D. at 184. Such a regulation "does not guarantee any minimum payment to pharmacists, nor does it prescribe the method by which the states should estimate costs below the maximum ceiling." *Id.* The S-MAC rate far exceeds the "prevailing retail market price" paid by the pharmacist for drugs. Indeed, the S-MAC rate is calculated by taking the average pharmacist's cost of acquisition of a drug and increasing the average cost by 30%. *See* Rule Explanation R. Vol. 13, R. 1239, 1279-1280.

The S-MAC program and rate were devised by Myers and Stauffer. Myers and Stauffer has extensive experience in Medicaid pharmacy programs, including experience devising Medicaid S-MAC plans and rates in other states. *See* Proposal, R. Vol. 6, R. 153. In designing the S-MAC method and rate, Myers and Stauffer surveyed Mississippi Medicaid pharmacists. R. Vol. 13, R. 1283-1284; R. Vol. 8, R.479-600. Of the 838 drug groups covered by the S-MAC

rate, two facts are uncontested:

> • For 420 of the 838 drug groups, the survey revealed that every pharmacy in the state was able to purchase the drug at or below[16] the S-MAC rate.
>
> • For the remaining 418 drug groups, 9 out of every 10 pharmacies in the state were able to purchase the drug at or below the S-MAC rate.[17]

See "Cost Coverage Analysis," R. Vol. 8, R. 558. Nonetheless, pharmacists contend that a rate is not "reasonable" unless it reimburses the actual costs[18] of every pharmacist, including the pharmacists whose actual acquisition costs exceeds the cost incurred by over 90% of the other pharmacies. No sensible interpretation of the word "reasonable" would require Medicaid to pay the "actual costs" of the few most expensive and inefficient pharmacies in the state. *See Pennsylvania Pharm. Ass'n v. Casey*, 800 F.Supp. 173, 177 (M.D.Pa. 1992) (noting "reasonable costs" are not "actual costs").

The Division has determined that a "reasonable cost" set at a "minimum level absolutely necessary to provide the medical assistance" is a rate in which every pharmacy could purchase drugs from 420 groups at or below the S-MAC rate and at which 9 out of 10 pharmacists could purchase drugs from 418 groups at or below this rate. When almost every pharmacy in the state is

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[16] When a pharmacy is able to purchase the drug for a price that is less than the S-MAC rate, the pharmacy retains the difference as profit.

[17] Importantly, these calculations were made before the Division agreed to increase the S-MAC multiplier from 1.2 to 1.3. *See* R. Vol. 13, R. 1279. Thus, under the final rule adopted by the Division, there would be fewer than 418 drugs in group two and fewer than 10% of the pharmacies who would be unable to purchase these drugs at or below the S-MAC rate.

[18] Of course, the pharmacists previously argued that the Division cannot utilize S-MAC because it determines actual, and not estimated, acquisition costs. The indefensible implication of the pharmacists' argument is that the Division must set the estimate at a rate so high as to meet the actual costs of the most expensive pharmacists and that the Division must then consider the significant overpayments to more reasonably priced pharmacists as the financial price to be paid for an "estimate."

able to buy the prescription drug at or below the S-MAC rate, there is no legal (or policy) definition of "reasonableness" that would require the Division to increase its rate to reward the one-in-ten pharmacies who, for some reason or another, is not buying the drug at or below the rate of the other 9 pharmacies. *See Massachusetts State Pharm. Ass'n v. Rate Setting Comm'n* 438 N.E.2d 1072, 1081 (Mass. 1982) ("The fact that the rate to be paid under the regulation is shown to be inadequate for an individual pharmacy cannot support a successful attack on a general rate regulation.") Indeed, the rate provides a necessary incentive for the most expensive and inefficient 10% to lower their acquisition costs to those of the other 90% of pharmacies. *See Mississippi Hosp. Ass'n, Inc. v. Heckler*, 701 F.2d 511, 517 (5th Cir.1983) ("Since the rates are prospective, every (long term care facility) has an opportunity to recover its full costs as long as it can bring them below the eighty percent ceiling established" by looking at the previous year's cost reports and audits."); *cf. Idaho County Nursing Home v. Idaho Dept. of Health and Welfare*, 821 P.2d 988, 991 - 992 (Idaho,1991) ("Use of a percentile cap has been held to be an effective tool in promoting efficiency and economy in the Medicaid program of providing long term care to nursing home residents.") Medicaid does not "protect providers from the consequences of their business decisions or from business risks" or support inefficient business models. *See Madison*, 86 F.R.D. at 184. If the Division is required to reimburse the most inefficient and expensive pharmacies who voluntarily chose to participate in Medicaid, there will be no incentive for pharmacies to control costs or to act "reasonably" incurring expenses. Moreover, every excess dollar of reimbursement provided to a pharmacist is a dollar that cannot be used to provide the pharmacy benefit or other services to Medicaid beneficiaries. In short, a rate that exceeds the cost at which over 90% of the pharmacies can purchase a drug is, by common sense, "reasonable."

pharmacy, both of which numbers are below the dispensing fee set by the Division. Finally, the pharmacists do not inform the court that the average pharmacy in Mississippi has only 15% of their prescriptions covered by Medicaid, 85% are from other sources. R. Vol. 7, R. 313. Thus, 85% of the average pharmacy's profits should be unrelated to the rates at issue.

Finally, the pharmacists find no legal support for their argument that the Division impermissibly considered the reality of its own budget constraints in setting rates. Medicaid law "should not be read to mean that states cannot consider cost efficiency in adopting reimbursement plans, or that courts should engage in some type of motivation analysis. It means only that budgetary constraints cannot excuse a failure to comply with federal standards." *Heckler*, 701 F.2d at 518. The Division's rate should not be overturned when the "reimbursement rate is not based 'solely on ... budgetary appropriations,' but represents considered judgments of what rates will both reflect the actual costs incurred and also allow the state to comply with its constitutional obligation to balance its budget. *Coalition of Michigan Nursing Homes, Inc. v. Dempsey*, 537 F.Supp. 451, 463 (D.C.Mich.1982). When, as here, the Division's rates reimburse a provider for "reasonable costs" – "costs incurred by an efficiently operated facility," those rates are reasonable. *Madrid Home for the Aging v. Iowa Dept. of Human Services, Division of Medical Services*, 557 N.W.2d 507, 514 (Iowa 1996). The overall reasonableness and thoroughness of the Division's actions is seen in the agency's written decision at the close of the rule-making proceedings.

> The Division of Medicaid values the services provided by our pharmacy providers. Having carefully considered the comments received from the pharmacy provider community, the Division of Medicaid agrees to increase the [S-MAC] multiplier from 1.2 to 1.3 to allow for increased reimbursement. The Division of Medicaid will constantly monitor the FUL along with acquisition costs to ensure that ingredient costs are reasonable. If provider purchasing practices are efficient, providers should not only be reimbursed for the costs of the

> drugs, but should also receive a healthy profit. Purchasing drugs at the SMAC price will result in reimbursement with a 30% profit on the cost of the drug. Based upon the Division's fiscal resources, the increase in the dispensing fee from $4.91 to $5.50 is reasonable. DOM's current dispensing fee is approximately the 13th highest in the country. At $5.50, we believe DOM's dispensing fee will be the 6th highest in the nation.

R. Vol. 13, R. 1279-1280.

IV. Pharmacists' Allegations Regarding the Economic Impact Statement do not Justify Reversing the Division's Adopted Rule.

The pharmacists contend that the Division's rule should be reversed because of a failure to provide an Economic Impact Statement (EIS) as contemplated by Section 25-43-3.105. The pharmacists are wrong on several levels.

First, the requirements of Section 25-43-3.105 do not apply to the adopted rule. Section 25-43-3.105(7) exempts an agency from providing an EIS if: (a) the "rule is required by the federal government pursuant to a state/federal program delegation agreement or contract" or (b) the rule "is expressly required by state law." *See* Miss. Code Ann. § 25-43-3.105(7)(a) &(b). In other words, if the Legislature has directed the agency to undertake a particular rule making act, that same Legislature has exempted the agency from providing an EIS. Similarly, the Legislature has exempted an agency from providing an EIS when the rule is required by federal law. While in such instances an EIS **may be voluntarily provided** by the agency, it is not required by the Administrative Procedures Act.

In this instance, both exemptions individually apply as both state and federal law mandate the Division to promulgate a rule setting forth these reimbursement rates. State law expressly requires that a drug's "estimated acquisition costs" shall be "determined by the Division." Miss. Code Ann. § 43-13-117(9)(b). Regarding federal law, Medicaid is a "state/federal program" as that term is used in Section 25-43-3.015(7)(a). *See Jones v. Howell*, 827 So.2d 691, 693 (Miss.

2002). 42 C.F.R. § 447.518(a) requires the Division's Medicaid "State Plan" to "describe comprehensively the agency's payment methodology for prescription drugs." This adopted rule is the method by which the Division amends the State Plan. *See* Rule, Vol. 5, R. 4 ("This administrative policy amendment is being filed to reflect changes (SPA2008-01) that are being made to the Mississippi State Plan regarding pharmacy reimbursement.") Because the Division is required by both federal and state law to adopt a rule setting for pharmacy reimbursement rates, there are two separate statutory provisions exempting this rule from the EIS requirement.

Second, before a party can assert that a deficient EIS warrants reversal, that party must identify its "specific concerns regarding the statement" during the administrative proceedings so as to afford the agency an opportunity to provide the missing information. Miss. Code Ann. § 25-43-3.105(3). The pharmacists' brief provides no citation to the record for their alleged notice, and for good reason. The "specific concerns regarding the statement" that were actually raised by these pharmacists were addressed by the Division. Specifically, the only concerns raised were that the voluntarily provided EIS did not include "an estimate of the costs or economic benefit to all persons affected by the proposed rule, nor does it provide an analysis of the impact on small businesses, i.e. the pharmacists." *See* R. Vol. 5, R. 49. In fact, the Division provided just such information specifically to the pharmacists in the form of the in-depth and lengthy reports prepared by Myers and Stauffer, LC, and the University of Mississippi School of Pharmacy. The Myers and Stauffer's report documented the "costs" to all pharmacies of the proposed S-MAC rate. Myers and Stauffer's survey of Mississippi Medicaid pharmacists documented that every pharmacy could purchase 420 drug groups and 9 out of 10 pharmacists could purchase 418 drug groups at or below the proposed S-MAC rate. *See* R. Vol. 13, R. 1283-1284; R. Vol. 8, R.479-600. A copy of the Myers and Stauffer report was provided to the pharmacists, at their request,

on April 3, 2008 (a month before the public hearing). *See* R. Vol. 7, R. 349. Similarly, with respect to dispensing fees, the Division enlisted the University of Mississippi School of Pharmacy to conduct a survey of Mississippi pharmacies' dispensing costs. *See* R. Vol 7, R. 306-318. The School of Pharmacy identified two statistically sound and generally accepted methods of determining a pharmacy's dispensing cost. R. 309-311. Under the second method of calculation, the School of Pharmacy concluded that the average cost of dispensing was found to be $5.21 per prescription. The median cost was $4.02 per prescription. R. 315. The Division set the reasonable cost of dispensing rate as $5.50 – in excess of both the average cost and the median cost. *See* Rule R. Vol. 5, R. 5. A copy of the University of Mississippi's study was also provided to the pharmacists, at their request, on April 3, 2008. *See* R. Vol. 5, R. 51. Thus, the Division had quantified in an exceptionally detailed manner how the proposed rates would impact pharmacists by virtue of two extensive surveys of Mississippi pharmacists. This information answered the "specific concerns" raised by the pharmacists.[21] Having answered the specific concerns raised by the pharmacists regarding the EIS, the Division satisfied its obligation under 25-13-3.105(3).

Further, even if the EIS was technically deficient, and had the pharmacists indicated their "specific concerns" to the Division, a rule may be invalidated only "if that failure substantially impairs the fairness of the rule-making proceeding." Miss Code Ann. § 25-43-3.105(3). The pharmacists do not even allege, let alone establish, that any deficiency in the EIS substantially impaired the proceeding's fairness. In fact, all the information required in an EIS was given

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[21] Although the pharmacists do not raise this issue, a finding that these detailed statistical studies do not satisfy the requirement of considering a rule's economic impact would set a procedural bar that no agency could ever expect to meet when undertaking their rate setting function.

directly to the pharmacists prior to the public hearing.[22] The pharmacists have not identified any information they believed to be required under an EIS that they were not provided prior to the public hearing. Indeed, unlike other types of rules, each pharmacist knew the direct economic impact of the rule on their business without needing to await the Division's analysis. For example, when the pharmacies were informed that the S-MAC rate for drug X was $2.25, the pharmacies knew immediately whether they were one of the 95% who were already purchasing the drug at or below $2.25.[23]

Finally, Section 25-43-3.105(6) provides that a rule may not be invalidated for an agency's failure to comply with EIS requirements "[i]f the agency has made a good faith effort to comply." In light of the fact that the Division provided to the pharmacists information answering their "specific " concerns regarding the EIS, and in light of the fact that all of the required information in an EIS was provided directly to the pharmacists prior to the public hearing, the

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[22] The information required in the eight categories under Section 25-43-3.105(2)(a)–(h) was given to the pharmacists prior to the public hearing. The rule itself, the EIS, the Myers and Stauffer study, and the University of Mississippi study described the need for, and benefits of, the rule. *See* Vol. 5, R. 4,8, 307 ("introduction"), R. Vol. 13, R. 1283-1284; R. Vol. 8, R.479-600. The Division explained the need for the rule directly to the pharmacists. *See* R. Vol. 12, R. 1111-1118. The estimated costs of the rule to the agency were set forth in the EIS. R. Vol. 5, R. 8. The estimate of the financial impact on pharmacies is set forth in the studies of Myers and Stauffer and the University of Mississippi. A comparison of the costs of adopting the rule and the alternatives considered were set forth in the above documents and specifically discussed in writing with pharmacists. *See* R. Vol. 13, R. 1278-1280; R. Vol. 12, R. 1111-1118. A detailed statement of the data and methodology used by the Division is set forth in the Myers and Stauffer and University of Mississippi surveys.

[23] There are undoubtably other types of general rules, such as limits on pollution, where the financial impact of the rule on the regulated entity would not be immediately apparent. When the rule establishes a reimbursement rate, the regulated entity immediately understands how that rate will impact its business. In this instance, the appealing pharmacists have quantified for themselves the "cost" of the rule and argued such a cost to this Court. The rule is transparent; everyone is fully aware of the financial impact.

Division attempted in "good faith" to provide, and did in fact provide, all of the required and relevant information to the pharmacists.

V. The Division's Notice and Comment Rule Making Procedures More Than Satisfied the Requirements of the Mississippi Administrative Procedure Statutes and Provided the Due Process Required in Rule Making.

The pharmacists' argument regarding the rule making procedures wanders vaguely amongst statutory and constitutional provisions in the hopes of convincing this Court to find that agencies are required, by statute or constitutional provision, to adopt rule-making procedures providing for "sworn testimony, cross-examination, subpoena power, [and] discovery." *See* Miss. Indep. Pharm Br. at 37. To be clear, the pharmacists believe that any person who will be impacted by a rule should have the constitutional right to subpoena agency officials to provide testimony under oath and subject to cross-examination as part of the notice and comment rule-making proceeding. No court has ever found such trial-like procedures to be constitutionally mandated in the rule-making setting, and for good reason. Rule-making is a legislative and not an adjudicative, judicial function. Engrafting trial procedures into rule-making would bring the machinery to a halt and turn the public hearings into month-long trials. More specifically, an examination of the pharmacists' constitutional and statutory arguments shows no legal or logical support for their contentions.

As required by the Mississippi Administrative Procedures Law, the Division gave public notice of the proposed rule and conducted a public hearing to solicit input from pharmacists and others. *See* Miss. Code Ann. § 25-43-3.101; 25-43-3.103; 25-43-3.104. Prior to the hearing, the Division responded to the pharmacists' multiple letter requests for documents by providing pharmacists with all of the documents utilized in devising the rule, including the two detailed studies conducted by Myers and Stauffer and the University of Mississippi. *See* R. Vol. 7, R.

349; R. Vol. 5, R. 51. During the rule making process, the pharmacists met directly with policy advisors in the Governor's office (the Division of Medicaid is within the Office of the Governor) and attorneys for the Division. *See* R. Vol. 7, R. 343 (letter to Governor's office from pharmacists stating "as promised in our meeting of March 21"); R. Vol. 13, R. 1307; Miss. Code Ann. § 43-13-101. Throughout the process, the pharmacists and the Division exchanged a series of letters and memoranda debating the merits of the rule and discussing alternatives. *See e.g.*, R. Vol. 7, R. 343; R. Vol. 12, R. 1111-1118; R. Vol. 5, R. 48-50; R. Vol. 13, R. 1285. A public hearing was held in which pharmacists were permitted to speak and to submit additional materials, in writing, after the hearing. At the conclusion of the rule making process, the Division issued a written memorandum in which it adopted the findings in the Myers and Stauffer and University of Mississippi surveys, raised the S-MAC rate in response to comments by the pharmacists,[24] and addressed other contentions raised by the pharmacists. R. Vol. 13, R. 1278-1280.

With respect to the pharmacists' constitutional argument, it is clear that in the context of rule making, constitutional due process does not require a hearing at all, and certainly not a formal, evidentiary, trial-like hearing. *See e.g.*, *Kinkaid School, Inc. v. McCarthy*, 833 S.W.2d 226, 231 (Tex.App.-Hous. 1992) ("In legislation, or rule-making, there is no constitutional right to any hearing whatsoever ..."); *R.L. Polk and Co. v. Ryan*, 694 N.E.2d 1027, 1035 (Ill.App. 4 Dist. 1998) ("Due process does not require a hearing in the context of administrative rule

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[24] The record is replete with letters from pharmacists and others to the Division. The pharmacists' assertion that certain information was provided during the process but not included in the record is unproven. The pharmacists do not identify what those documents were, prove that they were actually provided to the agency, establish that the information was not redundant of information already in the record, or even argue how consideration of this unidentified information should have altered the Division's analysis.

making."); *Sima Products Corp. v. McLucas*, 460 F.Supp.128, 133-134 (D.C.Ill. 1978) (rejecting challenge to lack of evidentiary hearing in rule making, "the constitutional sufficiency of informal administrative procedures has long been recognized."); *East Texas Guidance & Achievement Center, Inc. v. Brockette*, 431 F.Supp. 231, 234 (D.C.Tex. 1977) ("this determination constitutes an exercise by a governmental agency of its rule-making function, and there is no constitutional requirement for public hearings before a government agency exercises its rule-making authority"); *Kupferman v. New York State Bd. of Social Welfare*, 60 A.D.2d 674, 674 (N.Y.A.D. 1977) ("We reject the constitutional argument. It is clear that due process does not require a hearing prior to the adoption of regulations which are of general application and are promulgated pursuant to an agency's rule-making authority"); *National Dairy Products Corp. v. Louisiana Milk Comm'n*, 236 So.2d 596, 600 (La.App., 1970) ("Courts have held that no hearing whatsoever is required where administrative agencies are dealing with rule-making matters, unless a hearing is required by Statute.").

The requirements for hearings in rule making proceedings are creatures statute, not the Constitution. *See e.g.*, Miss. Code Ann. § 25-43-3.104. Courts are "particularly reticent" to find that the Constitution requires additional rule making procedures above those set by statute, especially when the legislature has "considered and deliberately rejected a cross-examination requirement." *Kennecott Corp. v. E.P.A.* 684 F.2d 1007, 1020 (D.C. Cir. 1982) (rejecting constitutional requirement of cross-examination in rule making).[25] Here, Mississippi's

[25] As the pharmacists note, the Legislature has provided for more rigorous, trial-like proceedings in adjudicative, rather than rule-making, situations. *See* Miss. Code Ann. § 43-13-116 (providing for witness testimony in hearings determining the eligibility of a medicaid applicant). Importantly, the Legislature has not instituted such onerous requirements in rule-making.

Administrative Procedures Law requires only an "oral proceeding" and does not require a trial-like proceeding. Miss. Code Ann. § 25-43-3.104(d). Interestingly, the pharmacists refer the Court to the Secretary of State's model rules for "oral proceedings." *See* Miss. Indep. Pharm. Record Excerpts, Ex. J at 106.00–107.04.[26] The model rules adopted by the Secretary of State do not require or even permit "sworn testimony, cross-examination, subpoena power, [and] discovery" in connection with the oral proceeding. *See* Model Rule 107.01 (Pharm. Record Excerpts at Ex. J). Neither Section 25-43-3.104, the Secretary of State's model rules, nor the oral proceeding conducted by the Division violate the constitutional requirement of due process. *See Association of Nat. Advertisers, Inc. v. F.T.C.*, 627 F.2d 1151, 1165-1166 (D.C. Cir. 1979) ("Congress is under no requirement to hold an evidentiary hearing prior to its adoption of legislation, and Congress need not make that requirement when it delegates the task to an administrative agency."(internal quotation omitted)).

The inapplicability of trial proceedings to rule-making has been recognized by this Court when it previously rejected a similar due process claim in *Boyles v. Mississippi State Oil & Gas Bd.*, 794 So.2d 149, 159 (Miss. 2001).

> *Morgan* is clearly distinguishable from the fact situation before this Court as *Morgan* concerned adjudication, while the facts before this Court concern administrative rulemaking procedure. As discussed above, the procedures for rulemaking and adjudication differ.
>
> Nothing in the procedures employed in the promulgation of Rule 69 violated the appellants' due process rights. The appellants' arguments arise from their misinterpretation of the nature of the proceedings as adjudicatory proceedings, the fact that certain procedural rulings were not to their liking, and the fact that the Rule, as eventually adopted, was not as stringent as they would have preferred.

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[26] The Secretary of State's model rules are improperly contained in the pharmacists' "record excerpts." "Record excerpts" should be items contained in the record. The model rules are not part of the record before the agency, trial court, or this Court.

None of that amounts to a due process violation.

In sum, the pharmacists' extensive participation and input into the rule making process is a testament to the thoroughness of the Division's review and its due regard for the perspective of the pharmacists.

Conclusion

The Division's administrative rule AP2008-23 should be affirmed. The decision of the chancery court should be reversed and rendered.

Respectfully submitted,

MISSISSIPPI DIVISION OF MEDICAID,
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DR. ROBERT L. ROBINSON, Appellants

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CERTIFICATE OF SERVICE

This is to certify that I, Harold E. Pizzetta, III, Special Assistant Attorney General for the State of Mississippi, have this date mailed via United States mail, postage fully prepaid, a true and correct copy of the foregoing ***Reply Brief of Appellants*** to the following:

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This the 8th day of July, 2009.

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