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**

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

Harold E. Pizzetta, III
MS Bar [redacted]
Special Assistant Attorney General
Chief, Civil Litigation Division
Office of the Attorney General
Post Office Box 220
Jackson, Mississippi 39205
Telephone: (601) 359-3816
Facsimile: (601) 359-2003
Attorney for Appellants

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STATEMENT OF THE ISSUE

In light of the great deference afforded the Division of Medicaid in interpreting its governing statutes in the complex and legislatively delegated area of rate setting, is the Division's administrative rule AP2008-23 which utilizes the lower of the State Maximum Allowable Cost or Average Wholesale Price as a basis for calculating a drug's Estimated Acquisition Cost an impermissible interpretation of Section 43-13-117(9)(b) when the legislature has deleted the statutory requirement that Estimated Acquisition Cost be calculated solely by reference to Average Wholesale Price and delegated the duty to determine Estimated Acquisition Cost to the Division?

STATEMENT OF THE CASE

This is an appeal from the Division of Medicaid's administrative rule AP2008-23 establishing the method for calculating a drug's "Estimated Acquisition Costs" (EAC) for the purpose of setting a reimbursement rate for pharmacists who voluntarily choose to enroll as Medicaid providers. The inherently legislative and complicated act of setting a Medicaid reimbursement rate has been delegated by statute to the Division. For years, an integral part of the reimbursement rate for pharmacists has been the determination of a drug's EAC along with other variables. Prior to 2005, the legislature defined EAC by statute as "twelve percent (12%) less than the average wholesale price" of a drug. Miss. Code Ann. 43-13-117(9)(b) (2004). However, it has become widely known that pharmaceutical companies have wildly and illegally manipulated the reported average wholesale price (AWP) of drugs in order to fraudulently increase Medicaid reimbursement. *See In re Pharmaceutical Industry Average Wholesale Price Litigation*, 520 F.Supp.2d 267, 270 (D.Mass. 2007) (finding drug manufacturers illegally inflated reported AWP by as much as 1,000% to defraud Medicaid and Medicare).

In 2005, the legislature amended the Division's governing statute to delete the requirement that EAC be determined solely by reference to AWP. In fact, the amendment deleted any reference as to how EAC must be calculated except that the legislature expressly delegated to the Division the authority and duty to determine the method by which EAC should be determined. *See* Miss. Code Ann. § 43-13-117(9)(b) (EAC shall be "determined by the division").

The Division has adopted a final version of rule AP2008-23 which calculates a drug's EAC as the lesser of: (1) AWP minus 25% or (2) the State Maximum Allowable Cost (S-MAC or MAC).[1] Aggrieved pharmacists appealed the final rule, arguing that the Division acted in contravention of its governing statutes because Section 43-13-117(9)(b) does not explicitly authorize the Division to utilize S-MAC to calculate EAC. The Division submits that calculating EAC as the lower of AWP or S-MAC is permissible under federal law, consistent with how other states calculate EAC, and is so well accepted as to be included in the hornbook on Medicaid reimbursement. *See* Jorge Lopez, Jr., *The ABC's of Public and Private*

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S-MAC is an effort by states to more equitably reimburse multi-source drugs that are of the same chemical content, dosage, and form and to participate in drug market efficiencies by establishing Medicaid rates based upon the average price pharmacies pay to purchase drugs, as evidenced by information obtained from pharmacies. S-MAC rates are annually adjusted and based on the average actual acquisition cost per drug, adjusted by a multiplier of at least 1.2, which ensures that each rate is sufficient to allow reasonable access by providers to the drug. *See* Notice, R.E. 5, R.6, R.Vol. 5. As the director of the federal agency that regulates Medicaid explained,

> Maximum Allowable Cost (MAC) programs are designed to ensure Medicaid programs pay appropriate prices for generic and multi-source brand drugs. Typically, States administering the MAC programs will publish lists of selected multi-source and generic drugs with the maximum price at which Medicaid will reimburse for those medications. Pharmacies generally will not receive payments that are higher than the MAC price. These programs differ from the FUL [federal upper limits] list, as states have more discretion in determining what drugs to include on the MAC list.

See Testimony of Dennis Smith, Centers for Medicare & Medicaid Services, before the House Energy and Commerce Subcommittee on Oversight and Investigations, December 7, 2004. (http://www.cms.hhs.gov/apps/media/press/testimony.asp?Counter=1278).

Reimbursement, 878 PLI/Pat 635, 643 (Oct. 2006). More importantly, though, is the great deference afforded the Division's interpretation of its governing statute. The legislature's deletion of the statutory requirement that EAC be calculated exclusively by reference to AWP, coupled with its express delegation of the determination of EAC to the Division, provides ample support that the Division's use of the lesser of AWP or S-MAC to calculate EAC is a permissible construction of its governing statute which cannot be judicially supplanted by even an equally permissible construction advanced by self-interested regulated entities.

Course of Proceedings

On April 1, 2008, the Division published the Notice of Proposed Rule Adoption AP2008-23. *See* Notice, R.E. 5, R. Vol. 5.[2] An oral hearing on the rule was conducted, and the rule became effective on May 1, 2008. *Id.* On April 30, selected pharmacists filed an appeal of the rule with the Chancery Court for the First Judicial District of Hinds County. *See* Complaint, R.Vol. 1, R.1.[3] The Division

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2 The record on appeal consists of 15 volumes. The pleadings, memoranda, and orders are in volumes 1 through 4, with pages numbered from 1 through 493. The administrative record complied by the Division is set forth in volumes 5 through 14 and numbered as pages 1 through 1424. A transcript of an oral argument regarding a protective order is contained in volume 15.

3 Although the notice of appeal was incorrectly styled as a complaint, the chancery court correctly determined that the matter was actually an appeal of an administrative rule. "After close examination of the Plaintiff's complaint, this Court has determined that this matter is, in fact, an appeal of an administrative agency action instead of a suit for injunctive relief." June 11, 2008, Protective Order, R.Vol. 2, R. 237. The pharmacists did not appeal the chancery court's decision regarding the nature of this legal action.

subsequently filed its administrative record. *See* Record Vols. 5-14.

The Fifth Chancery District adjudicates a very large proportion of the appeals from administrative agencies and has adopted Local Rule 25 to standardize and govern the appellate process. Rule 25, which was approved by this Court, provides that all parties are entitled to file an appellate brief and the matter shall be set on the trial docket before a final decision on the merits is rendered. *See* Local Rule 25 (appeal "must be set on the trial docket, even though oral argument is not desired, to be considered by the Court"; appeal cannot be set on the trial docket until "after all briefs have been filed"). Consistent with Local Rule 25, the chancery court entered a briefing schedule requiring the pharmacists to file their brief on June 27 and directing the Division to file its brief in opposition on July 7. Scheduling Order, R.E. 2, R.Vol. 2. However, on June 24 and prior to the submission of the Division's brief on the merits, the chancery court entered its written opinion concluding that the Division did not have the statutory authority to use both S-MAC and AWP to calculate EAC. *See* Opinion, R.E.3, R.Vol.2. The decision required the Division to return to the previous method of calculating EAC exclusively by reference to the fraudulently inflated AWP. *See In re Pharmaceutical Industry Average Wholesale Price Litigation*, 520 F.Supp.2d at 270.

Although the chancery court was required to defer to the Division's interpretation of its governing statutes, the court ruled before being apprised of the Division's basis for its interpretation. Further, although Local Rule 25 and the court's scheduling order provided the Division with the right to submit a brief in

opposition, the court decided this complex matter of statutory interpretation and Medicaid reimbursement policy without allowing the Division to submit a brief on the merits but clearly having read the pleadings of the pharmacists. Opinion, R.E. 3, R. 243, R.Vol.2.

Statement of Facts

The Division of Medicaid was created by the legislature and placed directly within the Office of the Governor. Miss. Code Ann. § 43-13-101. The Division has been tasked to administer Mississippi's complex Medicaid laws and, as a part of that responsibility, has been delegated the legislative authority to set reimbursement rates for providers. Miss. Code Ann. §§ 43-13-107(1), 43-13-117(9)(b), 43-13-121(1). While federal Medicaid law does not require a state to offer pharmacy benefits, Mississippi has chosen to undertake this exceptionally expensive and worthwhile benefit. *See* 42 U.S.C. §§ 1396a(a)(10), 1396d(a)(12). As part of implementing the complex state and federal cooperative program that is modern Medicaid,[4] the legislature has delegated to the Division the legislative authority to establish the reimbursement rates for drugs sold by pharmacists who voluntarily enroll as Medicaid providers. The current version of Section 43-13-117(9)(b) provides:

> 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) **as determined by the**

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4 Medicaid is a jointly financed federal and state health care program administered by the State according to Federal guidelines. 42 U.S.C. § 1396 *et al.*

> **division**, plus a dispensing fee, or the providers' usual and customary charge to the general public.
>
> Payment for other covered drugs, other than multisource drugs with CMS upper limits, shall not exceed the lower of the estimated acquisition costs **as determined by the division**, plus a dispensing fee or the providers usual and customary charge to the general public.

Miss. Code Ann. § 43-13-117(9)(b) (emphasis supplied).

Of critical importance to this appeal is the legislature's amendment to the statute in 2005. In 2004, Section 43-13-117(9)(b) did not contain the highlighted language "estimated acquisition cost (EAC) **as determined by the division.**" Instead, the 2004 statute provided that "[a]s used in 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) (2004). In 2005, the legislature deleted the requirement that EAC must be calculated exclusively by reference to AWP, deleted all references to AWP in Section (9)(b), and explicitly instructed that EAC shall be "determined by the division." The 2005 amendment did not merely authorize the Division to set its own percentage discount below AWP to calculate EAC, but deleted all references to AWP as a means to calculate EAC. Accordingly, the Division adopted administrative rule AP2008-23 which utilized the lesser of AWP or S-MAC to calculate EAC; this appeal followed.

SUMMARY OF ARGUMENT

The Division of Medicaid's fulfillment of its express legislative mandate and delegated authority to determine "Estimated Acquisition Cost" has led to a most unusual judicial procedure, a usurpation of the agency's legislative authority by the

chancery court, and fundamentally incorrect lower court decision. The Division, as the agency with unique expertise in the legal, medical, and fiscal requirements of the federal/state Medicaid program, is entitled to "great deference" when interpreting its governing statutes. Such deference is especially warranted when the agency acts in its legislative capacity of setting reimbursement rates.

The Division's interpretation of Section 43-13-117(9)(b) as permitting the calculation of EAC as the lesser of AWP or S-MAC should be affirmed on appeal. First, it is clear that the Division's decision to utilize both AWP and S-MAC to calculate EAC does not conflict with the plain language of Section 43-13-117(9)(b) as the legislature has deleted by amendment the requirement that EAC be calculated exclusively by reference to AWP.

Second, if the statute is determined to be "ambiguous or silent," it is nonetheless clear that the Division's actions are based on a "permissible construction" of the statute. Respecting the separation of powers doctrine, to be affirmed by the judiciary, an agency's interpretation need not be the "only" permissible interpretation or the interpretation that would have been chosen by the court. The Division's interpretation of Section 43-13-117(9)(b) to permit the use of S-MAC and AWP to calculate EAC is a permissible construction supported by the 2005 amendments to the statute, the definition of EAC in federal Medicaid law, the use of S-MAC to calculate EAC by other states, the conclusively established fraudulent reporting of AWP, and the hornbook guide to Medicaid reimbursement.

ARGUMENT

I. The Division's Interpretation of Its Governing Statute, Especially in the Inherently Legislative Area of Rate Setting, is Entitled to Great Deference.

While matters of law are reviewed *de novo*, "great deference [is] afforded an administrative agency'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) (quoting *Miss. State Tax Comm'n v. Mask*, 667 So.2d 1313, 1314 (Miss.1995)). The Division of Medicaid, as an administrative agency within the Office of the Governor, is afforded great deference in interpreting Section 43-13-117(9)(b), and a heavy burden is imposed on a party challenging the Division's interpretation. *See Electronic Data Systems Corp. v. Mississippi Div. of Medicaid*, 853 So.2d 1192, 1204 (Miss. 2003).

As a general matter, when reviewing an agency's statutory interpretation, Courts determine whether the statute is "ambiguous or silent" on the precise question, and, if so, 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) (quoting

Chevron, 467 U.S. at 843 n.11).

Although firmly grounded in the separation of powers doctrine, the great deference afforded administrative agencies reflects the complexity of legal, policy, and fiscal concerns with which agencies like the Division of Medicaid are intimately familiar with and which are the basis of their administrative expertise. As this Court has noted in similar circumstances,

> We have today a matter of statutory interpretation, committed initially to an agency within the executive department of the government, here the State Personnel Board and its alter ego, the Employees Appeal Board. Notwithstanding our ordinarily *de novo* review of questions of law, we have accepted an obligation of deference to agency interpretation and practice in areas of administration by law committed to their responsibility. 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. In today's context, that duty of deference is as well a function of EAB's unique administrative charge to blend and pursue pragmatically and at once fact finding, legal interpretation and promotion of legislatively established public policy.

Gill v. Mississippi Dept. of Wildlife Conservation, 574 So.2d 586, 593 (Miss. 1990) (citations omitted).

In addition to the traditional level of deference, this Court has specifically acknowledged that when acting in a legislative function, agencies as the designee of legislative authority, are entitled to special deference based on the principle of separation of powers. This Court "refrains from interfering with duly delegated authority to an administrative agency, *particularly where the rule making power of the agency is involved due to its legislative function.*" *Mississippi Public Service Comm'n v. Mississippi Power & Light Co.*, 593 So.2d 997, 1000 (Miss. 1991)

(emphasis supplied). This Court has explained the distinction between the different roles of administrative agencies and the requirements of, and basis for, judicial non-intervention as follows:

> In carrying out its legislative mandated function, the Board exercises two very different types of power. First, it carries out a quasi-judicial or "adjudicative" function as a delegation of power from the judicial branch of government. In exercising that power, 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. *The Board also carries out legislative or "rulemaking" functions as a delegation of power from the legislative branch of government. It does this function when, as is true in the case of the Board's adoption of rule 69, the Legislature directs the Board to enact rules or regulations on a particular subject within the Board's regulatory jurisdiction.* The Legislature mandated that the Board promulgate rules and regulations governing oilfield NORM. Miss. Code Ann. § 53-1-17(7); Miss.Code Ann. § 53-1-3(t)(I).
>
> This Court, as well as other courts, have recognized the distinction between adjudicatory and rulemaking functions of an administrative agency. In *Mississippi Pub. Serv. Comm'n v. Mississippi Power & Light Co.*, 593 So.2d 997, 1000 (Miss.1991), this Court held, *"the court refrains from interfering with duly delegated authority to an administrative agency, particularly where the rule making power of an agency is involved due to its legislative function." (emphasis added). In so ruling, this Court explained that the rule against interfering with duly delegated legislative authority is based upon separation of power considerations. Id.* at 999-1000. This Court recognized that the creation of administrative agencies resulted in a combination of powers from all three branches of government. *In 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. . . .*
>
> Here, the Board was clearly engaged in policy rulemaking pursuant to a specific delegation from the Mississippi Legislature. It was not adjudicating competing claims to a specific valuable right such as a permit to drill a well on a certain piece of property. . . . [I]t is a well-settled proposition that this Court refrains from interfering with the rulemaking function of an administrative agency.

Boyles v. Mississippi State Oil & Gas Bd., 794 So.2d 149, 157-58 (Miss. 2001) (emphasis supplied).

The proceeding before the lower court illustrates the constitutional and practical errors that arise when a chancery court usurps the authority of the Division and fails to defer to the Division's "everyday experience" that has provided the agency "familiarity with the particularities and nuances of the problems committed to its care which no court can hope to replicate." *Gill*, 574 So.2d at 593. The learned chancellor rushed headlong into an area of complex legal, medical, and fiscal policy without so much as a merits brief from the Division. As a practical matter, there was no way for the chancellor to defer to the Division's interpretation of its statute when he ruled before knowing the Division's basis for interpretation. The chancellor's unusual and hasty action impermissibly supplanted the Division's expertise regarding EAC, AWP, and S-MAC developed through years of planning, research, legislative consultation, consultation with independent experts, and work with the University of Mississippi's School of Pharmacy. *See, e.g.*, R.Vol. 6, R.285-300; R.Vol. 7, R.301-328.

II. The Pharmacists Cannot Establish that the Division's Interpretation of its Governing Statute is Either in Conflict with the Statute's Plain Language or an Impermissible Construction of the Statute.

As an initial matter, it is clear that the Division's decision to utilize both AWP and S-MAC to calculate EAC does not conflict with the plain language of Section 43-13-117(9)(b) as the legislature has deleted by amendment the requirement that EAC be calculated exclusively by reference to AWP. When

determining whether a statute is "ambiguous or silent" on the precise question, a court is seeking to determine whether the legislature has expressed its intent on the issue. *See Barbour*, 974 So.2d at 240. In this matter, the Division is not acting in the absence of a legislative directive, but is acting in accordance with the legislature's intent expressed directly through a deleting amendment. Indeed, the legislature's removal of the statutory restriction limiting the calculation of EAC to AWP, along with its explicit delegating to the Division of the duty to determine EAC, is a very clear declaration of legislative intent that the Division may use AWP or other reasonable means to calculate EAC. The legislature could have been no clearer if they had added the statutorily superfluous language: "By these amendments the Division is no longer required to calculate EAC by exclusive reference to AWP but is entrusted to calculate EAC using any reasonable method." The Division has acted in direct accordance with the legislature's intent as expressed through its amendment, and the pharmacists quarrel lies with the legislature and not the Division.

In the alternative, if the statute is determined to be "ambiguous or silent," it is nonetheless clear that the Division's actions are based on "a permissible construction of the statute." *Barbour*, 974 So.2d at 240; *Boyles*, 751 So.2d at 1029 (an agency's interpretation need not be the "only " permissible interpretation or the interpretation that would have been chosen by the court). The Division's interpretation of Section 43-13-117(9)(b) to permit the use of S-MAC and AWP to calculate EAC is a permissible construction supported by the 2005 amendments to

the statute, the definition of EAC in federal Medicaid law, the use of S-MAC to calculate EAC by other states, the conclusively established fraudulent reporting of AWP, and the hornbook guide to Medicaid reimbursement.

The everyday experience of the Division has given it great "familiarity with the particularities and nuances" of calculating EAC. *See Gill,*, 574 So.2d at 593. The federal agency which administers the Medicaid program[5] has defined "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 drug most frequently purchased by providers." 42 C.F.R. § 447.502. A drug's EAC is not a number reported on a website or data base, but is an "estimate" calculated by the Division and which varies from state to state. Federal law does not explicitly dictate what calculations or methods a state may use to arrive at a drug's EAC, but many states use the lesser of AWP or S-MAC to calculate EAC. *See e.g., Failor's Pharmacy 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

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Medicaid was established under Title XIX of the Social Security Act as a cooperative program between the federal government and the states. 42 U.S.C. § 1396 *et seq.*; *Arkansas Dept. of Health and Human Services v. Ahlborn*, 547 U.S. 268, 275 (2006). States that choose to participate in the Medicaid program must abide by federal statutes and regulations regarding eligibility determinations, the provision of services, and reimbursement to providers. 547 U.S. at 275. Medicaid is administered at the federal level by the Secretary of Health and Human Services, who in turn exercises his authority through the Centers for Medicare and Medicaid Services (CMS). *Id.*

acquisition costs (EAC) system, and began to reimburse ingredient costs *at the lower of the MAC or a percentage of AWP.*") (emphasis supplied). In fact, the use of S-MAC to determine a drug's EAC is so commonplace among states and courts that its use is documented in the Practicing Law Institute's hornbook on Medicaid law entitled "The ABC's of Public and Private Reimbursement." According to the hornbook,

> 1. States reimburse prescription drugs based upon Estimated Acquisition Cost (EAC) which is the state'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 the drug most frequently purchased by providers.
>
> 2. For brand-name drugs, most states currently rely on a standard, statutorily fixed formula based on a percentage discount from Average Wholesale Price (AWP), though some use a mark-up from Wholesale Acquisition Cost (WAC).
>
> 3. For generic drugs, many states use a reimbursement system based on Federal Upper Limit (FUL) prices and state-set Maximum Allowable Cost (MAC) prices.

Jorge Lopez, Jr., *The ABC's of Public and Private Reimbursement*, 878 PLI/Pat 635, 643 (Oct. 2006).

It is against this backdrop of federal law and the commonplace usage by other states that the 2005 amendments to Section 43-13-117(9)(b) become clear. Prior to 2005, Section 43-13-117(9)(b) stated that "[a]s 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) (2004). In 2005, the statute was amended and the entire provision linking EAC to AWP was deleted. Miss. Code Ann. § 43-13-117(9)(b) (2005). Further, the legislature added explicit

language providing that EAC shall be "determined by the division." Miss. Code Ann. § 43-13-117(9)(b) (2005). Had the legislature intended to require the Division to continue to calculate EAC based on AWP but desired to have the Division determine the percentage discount, the legislature could have easily amended the 2004 language to provide that EAC "means the average wholesale price for a drug discounted by a percentage determined by the division." Instead, because the amendment deleted all references to AWP, permissible constructions of the statute include that the legislature intended to allow the Division to calculate EAC based on AWP, on AWP and S-MAC, by S-MAC alone, or by some other reasonable method. The Division's clearly permissible interpretation, supported by the experience of other states, is that the statute authorized it to calculate EAC as the lesser of AWP or S-MAC. *See* Notice, R.E.5, R.Vol.5.

Also, the Division's practical understanding of the problems associated with relying exclusively on AWP to calculate EAC further supports the reasonableness of its interpretation. Unlike EAC, drug manufacturers report a drug's average wholesale price (AWP). It has become widely known that pharmaceutical companies have wildly and illegally manipulated their reported AWP in order to fraudulently increase Medicaid reimbursement. *See In re Pharmaceutical Industry Average Wholesale Price Litigation*, 520 F.Supp.2d 267, 270 (D.Mass. 2007). The extent of the fraud and the harm to state Medicaid agencies has been described in language one would consider unusually harsh for a federal court.

> 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].

* * *

> I find that the defendants unfairly and deceptively caused to be published false AWPs (or their formulaic counterparts: false [wholesale acquisition costs] or [wholesale list prices]) knowing that TPPs [third-party payers] and the government did not understand the extent of the mega-spreads between published prices and true average provider acquisition costs. Moreover, defendants knew that neither the government nor the TPPs could do much to change the AWP reimbursement benchmark because they were locked into the nationwide reimbursement scheme established by statute or contract.
>
> 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 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%.

520 F.Supp.2d at 270. The State of Mississippi and numerous other states have brought suits against pharmaceutical companies for defrauding their Medicaid programs through purposefully overstating the AWP of drugs.[6] Thus, in light of the legislature's amendment deleting the requirement that EAC be calculated

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The States of Arizona, Connecticut, Iowa, New York, Massachusetts, Minnesota, Montana, Nevada, Ohio, Pennsylvania, and New Jersey brought their respective actions in the multidistrict litigation in U.S. District Court in Massachusetts, while the Attorneys General and Medicaid Fraud Control Units of Alabama, Alaska, Arkansas, Hawaii, Idaho, Illinois, Kentucky, Missouri, South Carolina, West Virginia and Wisconsin have all filed suits in their respective state courts. On January 7, 2008, the State of Mississippi reached a $3.7 million settlement with just one of the several defendant pharmaceutical companies sued for defrauding Medicaid by reporting inflated AWP's. *See* www.ago.state.ms.us /index.php/press/releases/mississippi_settles_with_dey_labs/

exclusively by reference to AWP, and now that the fraudulent reporting of AWP has been judicially confirmed, the Division's interpretation of Section 43-13-117(9)(b) to permit the calculation of EAC to be based on the lesser of AWP or S-MAC is a permissible and reasonable interpretation given the Division's knowledge of the nuances and problems associated with relying exclusively on AWP.

Therefore, taking into account the history of Section 43-13-117(9)(b), the contours of federal law, the commonplace usage by other states of both AWP and S-MAC to calculate EAC, and the now confirmed fraudulent inflation of AWP by manufacturers, the pharmacists insistence that the Division must continue to use the inflated AWP as the exclusive means to calculate EAC because, even though the statute deleted this requirement, it did not explicitly give the Division authority to utilize any "new" or "different" method to calculate EAC is seen as a monetarily self-interested and unstudied assertion divorced from reality and at odds with the Division's expertise and Medicaid law. That the legislature delegated the calculation of EAC to the Division is a classic example of policy "intentionally left to be resolved by the agency charged with the administration of the statute in light of everyday realities." *Barbour*, 974 So.2d at 243 (citing *Chevron*, 467 U.S. at 865-866).

By way of example, the chancellor's conclusion that the use of S-MAC is prohibited by Section 43-13-121(1)(a)(iii) illustrates why the Division's expertise and familiarity with the legal and policy issues are deferred to by courts who cannot hope to "replicate" the agency's vast experience. *Gill*, 574 So.2d at 593. The

chancellor reasoned that because Section 43-13-121(1)(a)(iii) states that the Division "shall not change any . . . rates except as may be authorized in Section 43-13-117," the Division could not utilize the "newly proposed" S-MAC formula to calculate EAC and must revert back to the inflated AWP. *See* Opinion, R.E. 3, R.246-247. However, having ruled prior to the submission of the Division's brief, the chancellor was unaware of amendments to Section 43-13-117(9)(b) which changed the calculation of EAC by deleting the requirement that EAC be calculated exclusively by reference to AWP and delegated the duty of determining EAC to the Division. Further, the chancellor concluded that because S-MAC is also a "'cost containment measure' to be implemented by DOM seeking to reduce annual expenditures for certain drugs by $7.8 million in state funds," it was not a proper method of reimbursement. *See* Opinion, R.E. 3, R.249. The chancellor failed to appreciate that every method of calculating reimbursement is a "cost containment measure" with the possible exception of merely paying pharmacists whatever reimbursement they desire. Moreover, Section 43-13-121(1)(a)(iii) specifically directs that Medicaid must set rates at the "minimum levels absolutely necessary to provide the medical assistance." Devising a reimbursement calculation that is cost-efficient is not contrary to Medicaid's statutes, but is in fact required by those statutes. Balancing the fiscal concerns of the State with the expensive and optional pharmacy program through the calculation of EAC is the type of policy "intentionally left to be resolved by the agency charged with the administration of the statute in light of everyday realities." *Barbour*, 974 So.2d at 243.

As other courts have recognized, Medicaid statutes are a "'complex and highly technical regulatory program' benefitting from expert administration, which makes deference particularly warranted." *West Virginia v. Thompson*, 475 F.3d 204, 212 (4th Cir. 2007) (quoting *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994)). The legislature's decision not to statutorily define EAC is telling and purposeful.

> In the absence of any definitions for the terms "annual review" and "definitive findings" in the legislation or regulations and given the complexity of the Medicaid hospital reimbursement program and DOH's experience in implementing that program, we should defer to the interpretation of those terms by DOH, the agency empowered to administer the program.

St. Joseph's Hosp. Health Center v. Department of Health of State of New York., 247 A.D.2d 136, 151 (N.Y.A.D. 4 Dept.,1998); *see also M.D. Medical Supplies, Inc. v. Division of Medical Assistance and Health Services*, 2005 WL 3938317, *2 (N.J.Super.A.D. Mar. 29, 2006) ("In a case such as this, when we are asked to select one of two competing interpretations of a regulatory scheme, we will defer to the interpretation given by the Department of Human Services, the State agency responsible for the administration of the Medicaid program."). The Division properly exercised its expertise in selecting a permissible, if not the most reasonable, interpretation of Section 43-13-117(9)(b), and that interpretation, once afforded its great deference, should be affirmed.

CONCLUSION

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

Respectfully submitted,

MISSISSIPPI DIVISION OF MEDICAID,
OFFICE OF THE GOVERNOR, and
DR. ROBERT L. ROBINSON, Appellants

BY: JIM HOOD, ATTORNEY GENERAL

BY: /Harold E. Pizzetta III/
HAROLD E. PIZZETTA III, MSB [redacted]
SPECIAL ASSISTANT ATTORNEY GENERAL

Office of the Attorney General
Post Office Box 220
Jackson, Mississippi 39205
Telephone No. (601) 359-3860
Facsimile No. (601) 359-2003

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 ***Brief of Appellants*** to the following:

Lowry M. Lomax, Esq.
Lomax Law Firm, P.A.
1100 Tyler Avenue, Suite 102
Oxford, Mississippi 38655

J. Price Coleman, Esq.
Coleman Law Firm
1100 Tyler Avenue, Suite 101
Oxford, Mississippi 38655

Barry K. Cockrell, Esq.
Baker, Donelson, Bearman, Caldwell & Berkowitz, PC
Post Office Box 14167
Jackson, Mississippi 39236

Honorable William H. Singletary
Hinds County Chancery Court Judge
Post Office Box 686
Jackson, Mississippi 39205-0686

This the 17th day of February, 2009.

/Harold E. Pizzetta/
Harold E. Pizzetta, III