STATE OF FLORIDA
DIVISION OF ADMINISTRATIVE HEARINGS

THE FLORIDA RETAIL FEDERATION, INC.,	)	
Petitioner,	)	
vs.	)	Case No. 04-1828RX
AGENCY FOR HEALTH CARE ADMINISTRATION,	)	
Respondent.	)	

FINAL ORDER

This case came before Administrative Law Judge John G. Van Laningham for final hearing on June 17, 2004, in Tallahassee, Florida.

APPEARANCES

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STATEMENT OF THE ISSUE

The issue in this case is whether the methodology that Respondent uses to determine the amounts payable to pharmacies for prescription drugs dispensed to Medicaid beneficiaries constitutes an invalid exercise of delegated legislative authority on the ground that the methodology in question, which is incorporated by reference in Florida Administrative Code Rule 59G-4.250, enlarges, modifies, or contravenes the specific provisions of law implemented.

PRELIMINARY STATEMENT

Case History

On May 19, 2004, Petitioner, The Florida Retail Federation, Inc., filed its Petition For Invalidity of a Rule with the Division of Administrative Hearings ("DOAH"), initiating the instant proceeding. Petitioner alleged that Respondent Agency for Health Care Administration has been reimbursing pharmacies for prescription drugs covered under the Florida Medicaid Program pursuant to a methodology that contravenes the controlling statutes and hence is an invalid exercise of delegated legislative authority.

The undersigned conducted a formal hearing on June 17, 2004, within the time period specified in Section 120.56(1), Florida Statutes (2003). Both sides appeared through counsel.

Petitioner presented four witnesses who appeared in person at the hearing: Scott Dick, Vice President of Government Affairs and Member Services for the Florida Retail Federation; Sybil Richard, Bureau Chief, Medicaid Pharmacy Services; Jerry Wells, Pharmacy Program Manager for the Florida Medicaid Program; and David H. Kreling, Ph.D., who was accepted without objection as an expert in the area of Medicaid reimbursement and, more specifically, on the meaning of certain terms of art referenced in various Medicaid regulations. In addition, Petitioner offered seven exhibits, numbered 1 through 7, which were received in evidence. (Petitioner's Exhibits 2 and 3 are the depositions of Ms. Richard and Mr. Wells, respectively. This testimony was taken into evidence subject to specific objections that were subsequently overruled.)

Respondent called one witness, its Pharmacy Program Manager Mr. Wells. Respondent also asked that official recognition be taken of various state and federal statutes and regulations and some state session laws. This was done without objection.

The final hearing transcript was filed on June 23, 2004. Each party thereafter timely filed a Proposed Final Order.

<u>Pending Motions</u>

The following motions, which were filed after the final hearing, remain pending and require a ruling: Petitioner's Motion to Strike Respondent's Proposed Findings of Fact;

Respondent's Motion to Dismiss Petition; and Respondent's Motion to Correct Errors in Official Transcript. Having considered these matters, it is hereby ORDERED that:

1. Petitioner's Motion to Strike Respondent's Proposed Findings of Fact is denied.

2. Respondent's Motion to Dismiss is denied.

3. The Motion to Correct Errors in Official Transcript is granted, to the extent that a copy of the motion, which contains a list of errata, will be attached to the final hearing transcript.

Official Recognition

After the final hearing and before the deadline for filing proposed final orders, the undersigned determined sua sponte that it might be appropriate to take official recognition of the file in Sheraton Bal Harbour Association, Ltd. v. Florida Department of Revenue, DOAH Case No. 03-2441RX, as a means of shedding light on the brief, per curiam opinion issued in Department of Revenue v. Sheraton Bal Harbour Ass'n, Ltd., 864 So. 2d 454 (Fla. 1st DCA 2003), where the court held that DOAH does not have jurisdiction to entertain a rule challenge to a rule that no longer exists. At a telephone conference on July 2, 2004, the parties were informed that the undersigned was inclined officially to recognize the foregoing file, and that each party would have the opportunity to (a) present information relevant to the propriety

of taking official recognition; and (b) offer argument and supporting authorities for the purpose of showing that the matters recognized would be instructive or inapposite, as the case may be. The parties were directed to file their respective papers concerning these subjects no later than July 12, 2004, which they did.

It turned out that neither party believes the court's decision in Sheraton is pertinent to this case. The undersigned disagrees, for reasons that will be discussed elsewhere in this Final Order. That said, the undersigned ultimately did not base any findings of fact or conclusions of law herein on DOAH's file in Case No. 03-2441RX. Nevertheless, because the undersigned reviewed the file, it is hereby made a part of the record, via official recognition.

Statutory Citations

Unless otherwise indicated, citations to the Florida Statutes refer to the 2003 Florida Statutes. Notwithstanding, citations to the 2003 Florida Statutes will sometimes include the statute-year, for emphasis.

FINDINGS OF FACT

The Parties

1. Medicaid is a cooperative federal-state program in which Florida participates in partnership with the national government. Medicaid provides medically necessary health care——

including, relevantly, prescription drugs——to lower income persons. In addition to shouldering administrative and regulatory responsibilities, Florida partially funds the Florida Medicaid Program, contributing about 42 percent of the money budgeted for the program's operation in this state. Federal funds make up the balance.

2. Respondent Agency for Health Care Administration (the "Agency") is the state agency charged with administering the Medicaid Program in Florida. (At the federal level, the Centers for Medicare and Medicaid Services of the U.S. Department of Health and Human Services, known collectively as "CMS," is the agency authorized to administer Medicaid.)

3. Among other things, the Agency is responsible for reimbursing Medicaid providers in accordance with state and federal law, subject to specific appropriations. In this connection, the Agency is authorized and required to prescribe, by rule, reimbursement methodologies. The Agency is permitted to publish such methodologies in policy manuals and handbooks, provided the latter are incorporated by reference in duly promulgated rules.

4. Petitioner, The Florida Retail Federation, Inc. (the "Federation"), is a trade association whose members include all or most of the major drugstore chains doing business in Florida. These drugstore chains, which include Walgreen's, CVS, Eckerd's,

Albertson's, Publix, Winn-Dixie, Target, and Wal-Mart, participate in the Federation's Chain Drugstore Council, which is the only organization in this state representing the interests of drugstore chains.

5. Members of the Federation's Chain Drugstore Council operate more than 2,500 separate pharmacies, each of which is an enrolled Medicaid provider of prescription drugs. Given that there are approximately 4,000 pharmacy-providers participating in the Florida Medicaid Program, the Federation represents a significant percentage of the enrolled pharmacies.

6. The Federation advocates on behalf of its members before the Florida Legislature and the state regulatory agencies. Medicaid funding is one of the organization's top priorities. The Federation brought the instant proceeding because it believes that the Medicaid Program has been under-reimbursing its members based on a methodology that contravenes the applicable Florida statutes.

The Disputed Rule

7. The Medicaid reimbursement methodology for prescribed drugs is set forth in the Florida Medicaid Prescribed Drugs Services Coverage, Limitations, and Reimbursement Handbook, July 2001 (the "Handbook), which Handbook was incorporated by reference in, and hence adopted via Section 120.54(1)(i)1., Florida Statutes, as, Florida Administrative Code Rule 59G-

4.250. The methodology, which will be referred to hereafter as the "Reimbursement Rule," limits the amount that the Medicaid Program will pay for prescription drugs, as follows:

> Reimbursement for covered drugs dispensed by a licensed pharmacy that has been approved to be an eligible provider, or a physician filling his own prescriptions if there is no licensed pharmacy within a ten mile radius of his office, shall not exceed the lowest of:
>
> • Average Wholesale Price (AWP) minus 13.25 per cent of the drug, (also known as the Estimated Acquisition Cost or EAC) plus the dispensing fee;
>
> • Wholesaler Acquisition Cost (WAC) plus 7 per cent plus the dispensing fee;
>
> • Federal Upper Limit (FUL) price plus the dispensing fee;
>
> • The State Maximum Allowable Cost (SMAC) plus a dispensing fee established by the state on certain categories of drugs not reviewed by CMS (formerly HCFA); or
>
> • Amount billed by the pharmacy, which cannot exceed the pharmacy's average charge to the public (non-Medicaid) in any calendar quarter, for the same drug, quality, and strength. This average is known as the pharmacy's usual and customary charge for the prescription.

8. By its plain terms, the Reimbursement Rule (a) requires that five separate methods for determining reimbursement be applied with respect to each prescription and (b) mandates that the maximum allowable payment for each prescription be the lowest dollar amount resulting from the application of these

five methods to the claim at hand.[1] For ease of reference, the five separate methods enumerated in the Reimbursement Rule will be referred to collectively as the "Limits." Individually, the Limits will be called the "First Limit," "Second Limit," etc., with the numerical adjective corresponding to the order in which the Reimbursement Rule lists the respective Limits. (Thus, for example, the First Limit is the one based on average wholesale price; the Fourth Limit references the state maximum allowable cost.)[2]

9. The Reimbursement Rule was promulgated to implement two statutes in particular. One of these was Section 409.908, Florida Statutes, which provided in pertinent part as follows:

> A provider of prescribed drugs shall be reimbursed the least of the amount billed by the provider, the provider's usual and customary charge, or the Medicaid maximum allowable fee established by the agency, plus a dispensing fee.

§ 409.908(14), Fla. Stat. (2003). The other was Section 409.912, Florida Statute, which directed, in relevant part, that "[r]eimbursement to pharmacies for Medicaid prescribed drugs shall be set at the average wholesale price less 13.25 percent." § 409.912(40)(a)2., Fla. Stat. (2003).

The Challenge

10. The Federation filed its Petition for Invalidity of Rule ("Petition") on May 19, 2004, initiating the instant

proceeding. The Petition describes a straightforward objection to the Reimbursement Rule, namely that the prescribed Limits include methods for determining reimbursement <u>in addition to</u> "average wholesale cost less 13.25 percent," which latter, according to the Petition, constitutes the <u>exclusive</u> method for reimbursing pharmacies, pursuant to Section 409.912(40)(a)2., Florida Statutes (2003). Thus, the Federation alleged, only the First Limit is permissible; the rest are unauthorized, and the Reimbursement Rule enlarges, modifies, or contravenes Section 409.912(40)(a)2. for using them, making the Reimbursement Rule an invalid exercise of delegated legislative authority pursuant to Section 120.52(8)(c), Florida Statutes.

11. As this proceeding progressed, the Federation's position became a bit more complicated. Forced to deal with Section 409.908(14), Florida Statutes (2003), which was not mentioned in the Petition, the Federation effectively conceded (assuming it ever disputed) that "amount billed" and "usual and customary charge" are statutorily authorized methods for calculating reimbursement, in addition to discounted average wholesale price. Unable as a result to argue that the Fifth Limit should be rejected <u>in toto</u>, the Federation claimed instead that the Reimbursement Rule's <u>definition</u> of "usual and customary charge" enlarges, modifies, or contravenes the use of that term in Section 409.908(14), Florida Statutes (2003).

12. On this point, the Federation presented expert testimony at hearing that "usual and customary charge" is a term of art used in the industry to mean the amount a pharmacy charges cash paying customers who have no insurance coverage for the prescription in question. The Reimbursement Rule's definition, in contrast, does not restrict the scope of "usual and customary charge" to uninsured customers, but rather requires that charges to all non-Medicaid customers be taken into account in determining the average charge that equals "usual and customary charge." Because private insurers and HMOs typically negotiate discounts not available to uninsured consumers, the inclusion of amounts charged to insured customers in the equation for calculating "usual and customary charge," à la the Reimbursement Rule, is likely to produce, in most instances, a lower "usual and customary charge" than would obtain were charges to insured customers excluded from the calculation. The Federation argues that the legislature intended "usual and customary charge" to have the more generous technical meaning that the industry ascribes to it, and therefore that the Reimbursement Rule enlarges, modifies, or contravenes the specific law implemented by giving the term a different, more parsimonious meaning.

13. Confronting Section 409.908(14) also compelled the Federation to argue that, while the section imposes (and hence

enables the Agency to implement) limits on reimbursement in addition to discounted average wholesale price, the reference therein to "the Medicaid maximum allowable fee established by the agency" as an alternative reimbursement limit nevertheless cannot be construed as authority for the adoption of a methodology that would result in reimbursement at less than the least of (a) the amount billed by the provider, (b) the provider's "usual and customary charge" (as the Federation would define that term), or (c) average wholesale cost less 13.25 percent. In this regard, the Federation asserts that Section 409.908(14) and Section 409.912(40)(a)2.——which might at first blush appear to be inconsistent with one another——can easily be harmonized by construing "Medicaid maximum allowable fee established by the agency" to mean "average wholesale price less 13.25 percent."

The Agency's Defense of Reimbursement Rule

14. The Agency's arguments in support of the Reimbursement Rule can be reduced to two principal propositions. First, the Agency insists that if it were to reimburse pharmacies for all prescribed drugs at average wholesale price less 13.25 percent, the resulting payments, in the aggregate, would exceed federal limits on reimbursement, for reasons that need not detain us here. Exceeding federal limits, the Agency asserts, could cause CMS to take adverse action against the Florida Medicaid Program,

perhaps putting at risk Florida's continued receipt of federal matching funds.

15. Second, the Agency contends that Section 409.912(40)(a)2., Florida Statutes (2003), which requires that reimbursement be set at the average wholesale price less 13.25 percent, does not establish a floor (as the Federation maintains) but rather, when read in conjunction with Section 409.908(14), Florida Statutes (2003), prescribes another potential ceiling in addition to the pharmacy's actual charge, "usual and customary charge," and "the Medicaid maximum allowable fee established by the agency," which are the other potential ceilings pursuant to Section 409.908(14). Under this interpretation of the statutes, application of the Reimbursement Rule always produces the Medicaid maximum allowable fee established by the Agency——a statutorily authorized limit——and if that fee happens in a given situation to be less than the discounted average wholesale price, so be it.

The New Statutory Methodology

16. The 2004 Legislature amended Sections 409.908(14) and 409.912(40)(a)2., Florida Statutes (2003), enacting a bill (House Bill No. 1843) that was signed by the governor while this case was pending, on May 28, 2004. See Laws of Florida, Ch. 2004-270, §§ 12 and 17. The relevant statutory amendments took effect on July 1, 2004, id. at § 25, which was shortly after the

final hearing in this case——and prior to the date of this Final Order.

17. As amended, Section 409.908(14), Florida Statutes (2004), reads in relevant part as follows, with the recently added language underlined:

> A provider of prescribed drugs shall be reimbursed the least of the amount billed by the provider, the provider's usual and customary charge, or the Medicaid maximum allowable fee established by the agency, plus a dispensing fee. The Medicaid maximum allowable fee for ingredient cost will be based upon the lower of: average wholesale price (AWP) minus 15.4 percent, wholesaler acquisition cost (WAC) plus 5.75 percent, the federal upper limit (FUL), the state maximum allowable cost (SMAC), or the usual and customary (UAC) charge billed by the provider.

18. As amended, Section 409.912(40)(a)2., Florida Statutes (2004), provides in pertinent part as follows, with the newly added language underlined and recently deleted language stricken through:

> Reimbursement to pharmacies for Medicaid prescribed drugs shall be set at the lesser of: the average wholesale price (AWP) minus 15.4 percent, the wholesaler acquisition cost (WAC) plus 5.75 percent, the federal upper limit (FUL), the state maximum allowable cost (SMAC), or the usual and customary (UAC) charge billed by the provider ~~the average wholesale price less 13.25 percent~~.

19. Collectively, Sections 409.908(4) and 409.912(40)(a)2., Florida Statutes (2004), will be referred to hereafter as the "New Statutory Methodology."

CONCLUSIONS OF LAW

I. Jurisdiction

20. Before addressing the merits of the Federation's rule challenge, a pair of interrelated (perhaps indistinguishable) jurisdictional issues must be examined. The first of these issues is whether the Reimbursement Rule is still an "existing" rule for purposes of Section 120.56, Florida Statutes, given the recent enactment of the New Statutory Methodology. If the Reimbursement Rule is an existing rule, then the second question is whether this rule challenge was rendered moot on July 1, 2004, when the New Statutory Methodology took effect.

A. Is the Reimbursement Rule An "Existing" Rule?

21. As the First District Court of Appeal recently made clear, DOAH is without jurisdiction to entertain a challenge to a repealed rule, because "section 120.56, Florida Statutes[,] does not authorize a rule challenge to a rule that is no longer in existence." Department of Revenue v. Sheraton Bal Harbour Ass'n, Ltd., 864 So. 2d 454 (Fla. 1st DCA 2003). In the instant case, the Agency has not repealed the Reimbursement Rule, and so Sheraton is at least superficially distinguishable on that basis. This distinction might not make a difference, however,

if the general principle announced in Sheraton applies in rule challenges involving rules that no longer exist for reasons other than repeal.

22. In assessing Sheraton's reach, it is significant that formal administrative repeal via Section 120.54(3), Florida Statutes, is not the only way for a rule to cease to exist. A rule expires by operation of law, for example, upon the repeal of the statute that authorized the rule. See Christo v. State Dept. of Banking and Finance, 649 So. 2d 318, 321 (Fla. 1st DCA), rev. dismissed, 660 So. 2d 712 (Fla. 1995)(repeal of statute implemented by rule results in automatic expiration of rule); accord, Canal Ins. Co. v. Continental Cas. Co., 489 So. 2d 136, 138 (Fla. 2d DCA 1986). The undersigned concludes without hesitation that DOAH would not have jurisdiction, under the holding of Sheraton, to hear a rule challenge directed to a rule that had "expired" in consequence of the repeal of the rule's enabling statute, regardless whether the rule itself had been repealed by agency action. (Administrative repeal, in that situation, would be merely a formality.) For that reason, then, it is concluded that the general principle announced in Sheraton——that rules no longer in existence cannot be challenged——extends beyond Section 120.56 proceedings involving rules that have been formally repealed. Sheraton, in short,

cannot be dismissed as inapposite simply because the Reimbursement Rule has not been repealed administratively.

23. Here, though, the statutes authorizing the Reimbursement Rule, like the Reimbursement Rule itself, have not been repealed, and hence the Reimbursement Rule has not automatically expired by operation of law pursuant to the principle just mentioned. However, there is another legal principle whose operation causes a rule to become inoperative, namely:

> An administrative rule or regulation is operative and binding on those coming within its terms from its effective date until it is modified or superseded by subsequent legislation or by subsequent[ly adopted] regulations . . . .

Hulmes v. Division of Retirement, Dept. of Admin., 418 So. 2d 269, 270 (Fla. 1st DCA 1982), pet. rev. denied, 426 So. 2d 26 (Fla. 1983). When a rule is superseded by legislation enacted after the rule's effective date, the rule loses all force and effect immediately upon such legislation's becoming law. Florida Dept. of Revenue v. A. Duda & Sons, Inc., 608 So. 2d 881, 884 (Fla. 5th DCA 1992), rev. denied, 621 So. 2d 431 (Fla. 1993)(rule relied upon by taxpayer had been superseded by statutory amendment in 1987 and thus was without "force or effect" in 1988 at time of relevant transactions, despite fact that rule was not amended to conform to statute until 1989).

24. A rule that has no force or effect because it has been modified or superseded by statute is, like a repealed rule, no longer in existence in any meaningful sense. Thus, it is concluded, on the authority of Sheraton, that such a rule, to the extent of the statutory modification or supersession, cannot be challenged.

25. The next question, then, is whether the New Statutory Methodology has modified or superseded the Reimbursement Rule. Because the New Statutory Methodology employs the same five Limits as the Reimbursement Rule, albeit with some modifications (e.g. a higher discount on average wholesale price (15.4 percent vs. 13.25 percent) and a lower markup on wholesaler acquisition cost (5.75 vs. 7.0 percent)), the short and simple answer is "yes." To be more precise, the New Statutory Methodology supersedes the Reimbursement Rule (in all but perhaps one respect, which will be discussed anon), because the New Statutory Methodology is complete in itself, capable of implementation without reference to the Reimbursement Rule. As of July 1, 2004, the Agency need look no further than the New Statutory Methodology for authoritative direction regarding the reimbursement of Medicaid providers for prescription drugs.

26. The only aspect of the Reimbursement Rule that arguably has not been supplanted by the New Statutory Methodology is the definition of "usual and customary charge" as

set forth in the Reimbursement Rule. Recall that the New Statutory Methodology, like the Reimbursement Rule, establishes the provider's "usual and customary charge" as the Fifth Limit. Unlike the Reimbursement Rule, however, the New Statutory Methodology does not define "usual and customary charge" (just as Section 409.908(14), Florida Statutes (2003), also did not define "usual and customary charge"). The definition of "usual and customary charge" set forth in the Reimbursement Rule is not inconsistent with the New Statutory Methodology and could continue to be used by the Agency as the operative definition of that still-relevant (and as-yet not statutorily defined) term.

27. It is concluded, therefore, that the Reimbursement Rule's definition of "usual and customary charge" has not been superseded by, but rather subsists in the face of, the New Statutory Methodology. In all other respects, the New Statutory Methodology has superseded and replaced the Reimbursement Rule.

28. Consequently, as of July 1, 2004, the Reimbursement Rule has been without force or effect, with the exception of the definition of "usual and customary charge," which latter is, accordingly, the only part of the Reimbursement Rule that is still in existence and subject to challenge. The rest of the Reimbursement Rule, being "no longer in existence," is now outside DOAH's jurisdiction under Section 120.54, Florida Statutes. See Sheraton, 864 So. 2d at 454.

29. To the extent the instant rule challenge is based on objections unrelated to the Reimbursement Rule's definition of "usual and customary charge," it must be dismissed for want of jurisdiction.

B. Is This Rule Challenge Moot?

30. Let us assume for argument's sake that, contrary to the foregoing conclusion, DOAH was not largely divested of jurisdiction in this case, pursuant to the holding in Sheraton, when the New Statutory Methodology took effect on July 1, 2004. The question would yet remain whether the New Statutory Methodology has rendered this action moot, as the Agency maintains.

31. As an initial matter, it is immaterial to the question of mootness that the Reimbursement Rule has not been repealed and can still be found in the Handbook. The proposed rules under attack in NAACP, Inc. v. Florida Board of Regents, 29 Fla. L. Weekly D1461a, 2004 WL 1359507, ___ So. 2d ____ (Fla. 1st DCA June 18, 2004), likewise had not been repealed and could still be found in the Florida Administrative Code, and the court nevertheless dismissed the rule challenge as moot because intervening events had made it impossible for the court to grant "effectual relief" to the petitioners. 2004 WL 1359507, *5 (when newly created constitutional board invested with regulatory jurisdiction over state university system adopted, as

its own, rules originally proposed by state agency formerly having such jurisdiction, pending challenge to agency's proposed rules became moot, because constitutional board's rules——which cannot be challenged under the Administrative Procedure Act—— would remain in effect even if agency's rules were invalidated). The pertinent question is whether it is possible for the Federation to obtain effective relief in this Section 120.56 proceeding. If the answer is "no," then this cause is moot and must be dismissed.

32. The relief available in a rule challenge is a declaration by the administrative law judge that "all or part of a rule [is] invalid." § 120.56(3)(b), Fla. Stat. Such a declaration has the following effect: "The rule or part thereof declared invalid shall become void when the time for filing an appeal expires." Id. Note that the statute does not authorize the administrative law judge to declare the invalid rule void ab initio.

33. In State Bd. of Optometry v. Florida Soc. of Ophthalmology, 538 So. 2d 878 (Fla. 1st DCA 1989), the court examined Section 120.56(3), Florida Statutes (1988), the predecessor of the statute quoted above,[3] and pronounced that rules could be invalidated only on a prospective basis. Wrote the court:

> It is apparent that the statutory scheme in chapter 120 for invalidating agency rules contemplates that once a rule . . . has been issued and acted or relied upon by the agency or members of the public in conducting the business of the agency, the rule will be treated as presumptively valid, or merely voidable, and must be given legal effect until invalidated in a section 120.56 rule challenge proceeding. . . . The statutory scheme is obviously intended to avoid the chaotic uncertainty that would necessarily flow from retroactively invalidating agency action taken in reliance on the presumed validity of its rule prior to a proper rule challenge proceeding holding the rule invalid. Applying the theory underlying section 120.56(3) to this case, we hold that rule 21Q-10.001, which was held invalid by the hearing officer and our opinion, will become void and ineffective as of the date the decision of this court becomes final.

Id. at 889; see also City of Palm Bay v. State Dept. of Transp., 588 So. 2d 624, 628 (Fla. 1st DCA 1991).

34. Based on Section 120.56(3)(b) and State Bd. of Optometry, which make clear that an administrative decision invalidating a rule cannot be applied retroactively, the undersigned concludes that for a party to be granted effective relief in a rule challenge, that party must be in a position to benefit from prospective (future) agency or judicial action taken without resort to the disputed rule, which prospective action cannot include the reversal of past final agency action taken in compliance with the disputed, but presumptively valid, rule.[4]

35. Given that, it becomes necessary to decide whether the Federation's members could possibly benefit from the prospective (as opposed to the retroactive) application of a decision partially invalidating the Reimbursement Rule, as the Federation seeks. When questions involving the subject of retroactivity arise, as here, the analysis should focus initially on identifying the triggering event that "locks in" the applicable law. This is important to know because applying a law that did not exist on the date of the triggering event would constitute a retroactive application of such law, whereas applying a law that was in existence as of the triggering event would not be a retroactive application, even if the triggering event had its genesis in events transpiring before the existence of the law in question. In other words, one needs to know what the triggering event is to determine what would constitute a retroactive application of current law to a particular dispute.

36. In relation to this case, if there were a possibility that a relevant triggering event could occur after a partial invalidation of the Reimbursement Rule would become final, and if the law governing such event would be the partially invalidated Reimbursement Rule, then application of the partially invalidated Reimbursement Rule would be "prospective" from the standpoint of this proceeding——and the potential for granting effective relief herein would exist.

37. As for triggering events, several possibilities come to mind: (a) date of service; (b) submission of the claim; (c) payment of the claim; and (d) final agency or court action on a disputed claim. The undersigned believes that (a) is the proper trigger, because the Agency and the providers should know with certainty, at the time covered drugs are dispensed, the methodology for determining how much the Medicaid Program will reimburse the providers for those drugs. Of course, if date of service were the trigger, then the Federation could not possibly obtain effective relief in this proceeding (with one exception to be discussed). This is because, first, the partial invalidation of the Reimbursement Rule could not become final, if at all, until after the New Statutory Methodology began governing claims, which means that all post-invalidation dates of service necessarily would give rise to claims reimbursable under the New Statutory Methodology rather than the Reimbursement Rule (or a partially invalidated Reimbursement Rule). And second, it would be impermissible to apply a partially invalidated Reimbursement Rule to claims not controlled by the New Statutory Methodology (i.e. claims arising from dates of service occurring before July 1, 2004), for that plainly would constitute a retroactive invalidation of the challenged rule.

38. Even assuming, however, that the applicable methodology does not "lock in" on the date of service but instead attaches at some later point in time, then the trigger (however defined) can still only occur, for any given claim, either (a) before July 1, 2004; or (b) on or after July 1, 2004. No decision in this case can have any effect on the reimbursement of claims whose triggers occurred before July 1, 2004, because the Reimbursement Rule governed such claims, and agency action taken in reliance on the Reimbursement Rule cannot be undone retroactively (that is, after the triggering event) in consequence of a rule challenge. See State Bd. of Optometry, 538 So. 2d at 889. At the same time, however, no decision in this case can have any effect on the reimbursement of claims whose triggers occurred (or will occur) on or after July 1, 2004, because the New Statutory Methodology governed (or will govern) such claims.[5]

39. In sum, then, it is concluded that (with one small exception to be addressed) there is no possibility that a triggering event could occur after a partial invalidation of the Reimbursement Rule would become final, where the law governing such event would be the partially invalidated Reimbursement Rule. Hence there is but a very limited potential for granting effective relief in this case, which accordingly is moot except for that small possibility.

40. The one issue as to which effective relief might yet be granted concerns the Reimbursement Rule's definition of "usual and customary charge." As stated in the previous section, the definition of "usual and customary charge" set forth in the Reimbursement Rule is not inconsistent with the New Statutory Methodology and indeed could continue to be used by the Agency as the operative definition of that term, which is used (but not defined) in the New Statutory Methodology. Thus, the Federation's members are in a position to benefit from prospective agency or judicial action taken without resort to the Reimbursement Rule's "usual and customary charge" definition, should it be deemed invalid.

41. Consequently, to the extent that the Federation has challenged the Reimbursement Rule's definition of "usual and customary charge," this action still presents a live controversy, notwithstanding that the New Statutory Methodology became law pendente lite. All of the Federation's other objections to the Reimbursement Rule, however, were rendered moot when the New Statutory Methodology took effect on July 1, 2004.

II. Standing

42. Throughout this litigation, the Agency has insisted that the Federation lacks standing to maintain this rule challenge. The Federation, therefore, was required to prove

standing or face dismissal. See State Dept. of Health and Rehabilitative Services v. Alice P., 367 So. 2d 1045, 1052 (Fla. 1st DCA 1979)(burden is upon petitioner to prove standing, when standing is resisted).

43. Because the Administrative Procedure Act was designed in part to expand public access to the activities of agencies, it has long been recognized that a trade or professional association is entitled to bring a rule challenge in a purely representative capacity provided it demonstrates "that [1] a substantial number of its members, although not necessarily a majority, are substantially affected by the challenged rule, [2] that the subject matter of the rule is within the association's general scope of interest and activity, and [3] that the relief requested is of the type appropriate for a trade association to receive on behalf of its members." See NAACP, Inc. v. Florida Bd. of Regents, 863 So. 2d 294, 298 (Fla. 2003)(citing Florida Home Builders Ass'n v. Department of Labor & Employment Sec., 412 So. 2d 351, 352-53 (Fla. 1982))(emphasis removed; bracketed numbers added).

44. The Agency contends that only a small number (i.e. 33) of the Federation's 9,000 or so members are substantially affected by the Reimbursement Rule, and that 33 is not a "substantial number" relative to 9,000. While this sounds facially plausible, the Agency's argument plays down the fact

that the 33 members in question include all (or most) of the major drugstore chains in the state. This group of members, which includes Walgreen's, CVS, Eckerd's, Albertson's, Publix, Winn-Dixie, Target, and Wal-Mart, in turn operates more than 2,500 drugstores in Florida, each of which is an enrolled Medicaid provider. Considering that there are approximately 4,000 pharmacies participating in the Florida Medicaid Program, the Federation's members obviously are a key provider constituency. It is concluded that the Federation has met the "substantial number" test.

45. The Agency also contends that the Federation's affected members have not suffered real and immediate harm as a result of the Reimbursement Rule, because (the Agency argues) under the Reimbursement Rule's definition of "usual and customary charge," the Agency could have paid providers even less than they were actually reimbursed prior to July 1, 2004, had the Agency properly limited providers to usual and customary charges as the Reimbursement Rule requires. (The Agency, in other words, takes the position that it erroneously applied its own Reimbursement Rule.)

46. This argument is not persuasive. First, the Federation's position, which it attempted to prove at hearing, is that if "usual and customary charge" is a statutorily authorized limit (a point which the Federation initially

disputed but since seems to have conceded), then the Reimbursement Rule's definition of "usual and customary charge" is invalid. As the Agency's argument makes clear, there can be no question that the Federation's members are substantially affected by the Reimbursement Rule's definition of "usual and customary charge."

47. Second, the Federation satisfied the "substantially affected" test by demonstrating that its members are directly regulated by the Reimbursement Rule. See Coalition of Mental Health Professionals v. Department of Professional Regulation, 546 So. 2d 27, 28 (Fla. 1st DCA 1989).

48. Finally, as the Florida Supreme Court recently confirmed, the associational standing test does not require, in a rule challenge, a showing of "immediate and actual harm," but rather that the disputed rule has a "substantial effect" on a substantial number of the association's members. NAACP, Inc., 863 So. 2d at 300. The Federation has made the requisite showing of "substantial effect."

49. The Agency does not contest the Federation's satisfaction of the remaining elements of the associational standing test. It is concluded that the Federation does have standing to maintain this rule challenge on behalf of its members.

III. The Definition of "Usual and Customary Charge"

50. The Reimbursement Rule defines the term "usual and customary charge" to mean "the pharmacy's average charge to the public (non-Medicaid) in any calendar quarter, for the same drug, quality, and strength." The Agency understands the "non-Medicaid public" to include not only persons without insurance coverage who generally pay full price, but also private insurers and HMOs, which typically pay a discounted price reflecting their negotiating leverage.

51. The Federation maintains that the term "usual and customary charge," though ambiguous, has a technical meaning as used in the "industry" (apparently the insurance industry), namely the amount a pharmacy charges to a cash paying customer who has no coverage for the prescription. The Federation argues that the legislature intended for the term "usual and customary charge" to have this so-called technical meaning, and hence that the Reimbursement Rule enlarges, modifies, or contravenes, the laws being implemented.

52. The Federation has not persuaded the undersigned, however, that its preferred definition of the term is the only acceptable meaning of "usual and customary charge" as used in Section 409.908(14), Florida Statutes (2003), or in the New Statutory Methodology. Rather, the Federation has articulated _an_ acceptable, maybe even the most widely accepted, definition——

which is insufficient to show that the Reimbursement Rule enlarges, modifies, or contravenes the specific provisions of law implemented.

53. Further, because the purpose of Section 409.908(14) is to control Medicaid costs by imposing limits on reimbursement, it seems unlikely that the legislature intended "usual and customary charge" to mean, as the Federation would have it, the price customarily paid by those in the weakest bargaining position——essentially "sticker price." In contrast, the Reimbursement Rule's definition, as the Agency interprets it, takes account of negotiated discounts, and hence is likelier actually to result in a meaningful limit on reimbursement. It is concluded, therefore, that the Reimbursement Rule's definition of "usual and customary charge" comports with the intent and purposes of the statute.

54. While the foregoing conclusions should compel a decision in the Agency's favor, there is some evidence that gives the undersigned pause. At hearing, the Agency's Pharmacy Program Manager for the Medicaid Program opined that it would be "difficult for pharmacies to stay in business" if the Agency were to enforce the Reimbursement Rule's definition of "usual and customary charge." He even went so far as to characterize such enforcement as "punitive." The undersigned presumes that the legislature would not have intended to impose a limit so

onerous that it would threaten to put pharmacies out of business.

55. Upon reflection, though, the undersigned cannot believe that the Reimbursement Rule's definition of "usual and customary charge" would be so draconian in practice. For one thing, for any given drug, the disputed definition logically should produce a limit that is somewhat higher than the lowest price the pharmacy accepts for that drug. Unless pharmacies are using Medicaid to heavily subsidize the discounts given to private insurers (and there is no evidence here of that), it is hard to see (and there is no persuasive evidence showing) why pharmacies would be ruined if Medicaid reimbursed them at rates somewhat higher than those paid by private insurers.

56. For another, there is no evidence demonstrating that pharmacies must participate in the Medicaid Program to stay in business. Thus, the undersigned reasons that if the Agency were to set reimbursement levels so low that pharmacies could not make a profit, then, instead of going out of business, the pharmacies would simply stop participating in the Medicaid Program, until such time as increased reimbursement levels made participation economically feasible again.

57. Ultimately, then, despite some troubling testimony, the undersigned concludes that the Reimbursement Rule's definition of "usual and customary charge" is consistent with

the statute's use of that term and falls within the range of permissible interpretations of the statute. Accordingly, the definition does not enlarge, modify, or contravene the specific provisions of law implemented; it is, rather, a valid exercise of delegated legislative authority. See Board of Podiatric Medicine v. Florida Medical Ass'n, 779 So. 2d 658, 660 (Fla. 1st DCA 2001)(rule definition that was consistent with statute and within range of permissible interpretations did not enlarge, modify, or contravene statute and thus was valid exercise of delegated legislative authority); Florida Institutional Legal Services, Inc. v. Florida Dept. of Corrections, 579 So. 2d 267, 269 (Fla. 1st DCA), rev. denied, 592 So. 2d 680 (Fla. 1991) (rule definition that comported with intent and purposes of statute was not clearly erroneous and thus could not be declared invalid).

ORDER

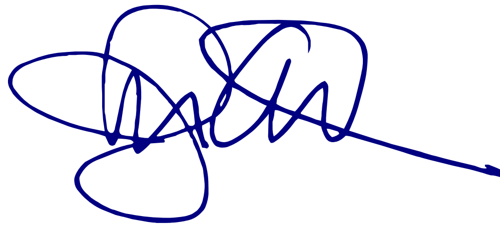
Based on the foregoing Findings of Fact and Conclusions of Law, it is ORDERED that:

1. To the extent this rule challenge is based on objections unrelated to the Reimbursement Rule's definition of "usual and customary charge," it is dismissed for lack of jurisdiction.

2. Alternatively, this action is dismissed as moot, except to the extent the challenge concerns the Reimbursement Rule's definition of "usual and customary charge."

3. The Reimbursement Rule's definition of "usual and customary charge" constitutes a valid exercise of delegated legislative authority.

DONE AND ORDERED this 19th day of July, 2004, in Tallahassee, Leon County, Florida.



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Filed with the Clerk of the
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this 19th day of July, 2004.

ENDNOTES

1/ Logically, to ensure that reimbursement is always equal to the lowest dollar amount calculable under the five prescribed methods requires that all five methods be applied to every claim.

2/ The Fifth Limit actually comprises two methods: amount billed and "usual and customary charge." For simplicity's sake,

however, and following the convention of the Reimbursement Rule, the undersigned will treat the Fifth Limit as a single limit.

[3]/ The wording of § 120.56(3), Fla. Stat. (1987), differed slightly, but not materially, from that of § 120.56(3)(b), Fla. Stat. (2003).

[4]/ There are, to be sure, some cases supporting a contrary conclusion. In Moultrie v. Florida Dept. of Corrections, 496 So. 2d 191 (Fla. 1st DCA 1986), for example, the court held that an inmate who had been assessed damages pursuant to a Department of Corrections rule as punishment for damaging state property had standing to challenge the rule, even though the damages had already been collected in full. The court observed: "If the inmate prevails on his rule challenge he may be entitled to a refund or restoration of the funds to his inmate account." Id. at 193.

In Austin v. Department of Health and Rehabilitative Services, 495 So. 2d 777 (Fla. 1st DCA 1986), the court affirmed an order upholding the validity of a rule that required applicants for public assistance to cooperate with the agency, on pain of sanctions, in identifying, locating, and establishing the paternity of parents of children for whom public assistance was sought. In its opinion, the court noted that while the appeal was pending, the legislature had passed a law codifying the disputed rule. The court found that this recent legislation had not rendered the case moot, however, because "if [the] court chose to invalidate the rule, the appellants and others affected by the rule could seek relief from the sanctions allowed by the rule for the six-month period between [the rule's effective date] and [the effective date of the newly enacted law]. Id. at 778 n.2.

Maybe it is possible to square Moultrie and Austin with the first district's later decisions in State Bd. of Optometry and City of Palm Bay, but to the undersigned the earlier cases appear to authorize the very retroactive invalidation of rules——and consequent chaotic uncertainty——that was deemed impermissible in State Bd. of Optometry. It is therefore concluded that, to the extent Moultrie and Austin conflict with State Bd. of Optometry, they are no longer good law.

[5]/ The undersigned takes for granted that any claim whose trigger falls on or after July 1, 2004, must be reimbursed in accordance with the New Statutory Methodology, even if the claim

had its genesis in events occurring before July 1, 2004. This is because once the New Statutory Methodology became effective, it began operating to the exclusion of any possibly conflicting rules or policies that might subsequently emerge. Cf., e.g., Broward Children's Center v. Hall, 859 So. 2d 623, 627 (Fla. 1st DCA 2003)(when rule and statute directly conflict, the latter controls); accord, Carver v. State Div. of Retirement, 848 So. 2d 1203, 1206 (Fla. 1st DCA 2003).

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NOTICE OF RIGHT TO JUDICIAL REVIEW

A party who is adversely affected by this Final Order is entitled to judicial review pursuant to Section 120.68, Florida Statutes. Review proceedings are governed by the Florida Rules of Appellate Procedure. Such proceedings are commenced by filing the original notice of appeal with the Clerk of the Division of Administrative Hearings and a copy, accompanied by filing fees prescribed by law, with the District Court of Appeal, First District, or with the District Court of Appeal in the Appellate District where the party resides. The notice of appeal must be filed within 30 days of rendition of the order to be reviewed.