STATE OF FLORIDA
DIVISION OF ADMINISTRATIVE HEARINGS

DISNEY MEDICAL EQUIPMENT, INC., d/b/a DISNEY PHARMACY DISCOUNT,	)	
Petitioner,	)	
vs.	)	Case No. 05-2277MPI
AGENCY FOR HEALTH CARE ADMINISTRATION,	)	
Respondent.	)	

RECOMMENDED ORDER

This case came before Administrative Law Judge John G. Van Laningham for final hearing on January 11, 2006, in Tallahassee, Florida.

APPEARANCES

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For Respondent: Jeffries H. Duvall, Esquire
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STATEMENT OF THE ISSUE

The issue for determination is whether Petitioner must reimburse Respondent an amount up to $1,676,390.45, which sum Petitioner received from the Florida Medicaid Program in payment

of claims arising from Petitioner's dispensing of pharmaceuticals between July 3, 2000 and March 28, 2002. Respondent alleges that the amount in controversy represents an overpayment related to Petitioner's failure to demonstrate the availability of sufficient quantities of drugs to support its billings to the Medicaid program.

PRELIMINARY STATEMENT

Respondent Agency for Health Care Administration is the agency responsible for administering the Florida Medicaid Program. Petitioner Disney Medical Equipment, Inc., d/b/a Disney Pharmacy Discount, is a Medicaid provider.

After auditing Petitioner's claims-payment history, purchase invoices, and other records, Respondent issued a Final Agency Audit Report on December 29, 2004, wherein it alleged that Petitioner had been overpaid $1,676,390.45 for Medicaid claims arising from Petitioner's dispensing of drugs to Medicaid recipients. In a Petition for Hearing dated January 6, 2005, Petitioner requested an administrative hearing on the overpayment assessment. Respondent referred this pleading to the Division of Administrative Hearings on June 22, 2005.

At the final hearing, which took place as scheduled on January 11, 2006, with both parties present, Respondent presented two witnesses, namely its employees Kenneth Yon and Kathryn Holland. Respondent also offered 13 exhibits,

identified as Respondent's Exhibits 1-13, which were admitted into evidence.

Petitioner called Sara Padron as its only witnesses and offered Petitioner's Exhibits 1-22, 25-32, which were received into evidence.

The undersigned agreed to take official recognition of all applicable Florida Statutes, Florida Administrative Code Rules, and Medicaid handbooks.

The final hearing transcript was filed on January 25, 2006. The parties timely filed proposed recommended orders on the established deadline, which (after enlargements) was March 13, 2006. These papers were carefully considered in the preparation of this Recommended Order.

Unless otherwise indicated, citations to the Florida Statutes refer to the 2005 Florida Statutes.

FINDINGS OF FACT

1. Respondent Agency for Health Care Administration ("AHCA" or the "Agency") is the state agency responsible for administering the Florida Medicaid Program ("Medicaid").

2. Petitioner Disney Medical Equipment, Inc., d/b/a Disney Pharmacy Discount ("Disney Pharmacy"), was, at all relevant times, a Medicaid provider authorized, pursuant to contracts it had entered into with the Agency known as Provider Agreements,

to receive reimbursement for covered services rendered to Medicaid beneficiaries.

3. Exercising its statutory authority to oversee the integrity of Medicaid, the Agency directed its agent, Heritage Information Systems, Inc. ("Heritage"), to conduct an audit of Disney Pharmacy's records to verify that claims paid by Medicaid during the period from July 3, 2000 to March 28, 2002 (the "Audit Period") had not exceeded authorized amounts.

4. Over the course of four days in May 2002, three of Heritage's auditors reviewed records on-site at Disney Pharmacy's drugstore in Hialeah, Florida; they also interviewed some of the store's personnel. Thereafter, Heritage analyzed the data it had collected using several different approaches. Each approach pointed to the conclusion that Medicaid had paid too much on claims submitted by Disney Pharmacy during the Audit Period. The total amount of the alleged overpayment differed substantially, however, depending on the analytical approach taken.

5. The approach that yielded the largest apparent overpayment was the "prorated purchase invoice" analysis. Generally speaking, under this approach, the volume of pharmaceuticals that the provider maintained in its inventory during the Audit Period is compared to the provider's contemporaneous Medicaid claims to determine whether the

provider possessed enough of the relevant pharmaceuticals to support the Medicaid claims presented. If the total amount purportedly dispensed, according to the claims made in connection with a particular drug, exceeds the amount of that drug available at the time for dispensing, then an inference of impropriety arises with regard to those claims for which product was apparently unavailable; the Agency considers amounts paid on such claims to be overpayments.

6. To determine the quantities of certain drugs that Disney Pharmacy had kept on hand during the Audit Period, Heritage tallied up the total number of "units" of selected drugs that Disney Pharmacy had acquired, using as a database the invoices reflecting Disney Pharmacy's purchases of the drugs under review. Heritage then ascertained——again using Disney Pharmacy's records——the utilization rate of Medicaid beneficiaries for each of the pharmaceuticals under consideration. In other words, Heritage determined, for each drug at issue, the relative demand——expressed as a percentage of the total number of units of that drug dispensed to all customers during the Audit Period——attributable to Medicaid beneficiaries. Heritage found, for example, that Medicaid recipients accounted for 55.13% of Disney Pharmacy's total sales of the drug Acetylcysteine-10% solution ("Acetylcysteine") during the Audit Period.

7. Having calculated the total amount of each drug at issue that Disney Pharmacy had acquired during the Audit Period, and having further determined for each such drug the Medicaid utilization rate, Heritage multiplied the total number of available units of each drug by the applicable utilization rate, prorating the entire supply of each drug to reflect the approximate number of units available for dispensing to Medicaid recipients specifically. For example, Disney Pharmacy's records showed that it had purchased a total of 121,440 units of Acetylcysteine during the Audit Period. Disney Pharmacy's records showed, additionally, that this drug was dispensed to Medicaid beneficiaries 55.13% of the time. Thus, the prorated quantity of Acetylcysteine available for Medicaid recipients was approximately 66,950 units (121,440 x 0.5513).

8. The prorated number of available units of each subject drug was compared to the total number of units for which Medicaid had reimbursed Disney Pharmacy during the Audit Period. For Acetylcysteine, these figures were 66,950 and 1,076,070, respectively. If the total number of units for which Medicaid had paid on claims for a particular drug were found to exceed the amount of that drug which Disney Pharmacy apparently had on hand——as it did for Acetylcysteine——then the inventory shortfall——1,009,120 units in the case of Acetylcysteine——was multiplied by the drug's average per-unit cost to Medicaid,

producing a drug-specific apparent overcharge. Thus, for example, because the average cost of Acetylcysteine was $0.65 per unit, the apparent overcharge with respect to this drug was $655,928.00.

9. Using the foregoing approach, Heritage identified apparent overcharges in connection with 13 drugs. The sum of these drug-specific overcharges is $1,676,390.45. Two drugs——Acetylcysteine and Ipratropium Solution ("Ipratropium")——account for nearly 93% of this grand total. Two other drugs——Albuterol-0.83% ("Albuterol") and Metaproterenol-0.4% ("Metaproterenol")——account for another 7.0% of the total alleged overcharge. These four drugs——whose individual overcharges, taken together, comprise approximately 99.8% of the total alleged overcharge of $1,676,390.45——are used for treating breathing disorders and typically are inhaled by the patients who use them.[i]

10. There is no genuine dispute regarding the reason why Disney Pharmacy was unable to document its acquisition of Acetylcysteine, Ipratropium, Albuterol, and Metaproterenol (collectively the "Inhalation Therapy Drugs") in quantities sufficient to support its claims to Medicaid for these pharmaceuticals. During the Audit Period, Disney Pharmacy generally filled prescriptions for the Inhalation Therapy Drugs by "compounding" the prescribed medications. (Compounding is a process whereby the pharmacist mixes or combines ingredients to

fashion a tailor-made medication for the patient.) Thus, Disney Pharmacy (for the most part) did not purchase the commercially available versions of the Inhalation Therapy Drugs; rather, it created its own "generic copies" of these medications, purchasing only the raw materials needed to make finished products.

11. Medicaid reimburses for compound drugs under certain conditions, which will be spelled out below. But first: it is undisputed that Disney Pharmacy did not submit claims for compound drugs. Instead, in presenting claims to Medicaid for the Inhalation Therapy Drugs, Disney Pharmacy billed the medications under their respective National Drug Code ("NDC") numbers, as though commercially manufactured drug products had been dispensed. (An NDC is an 11-digit number, unique to each commercially available pharmaceutical, which identifies the manufacturer, product, and package size.) As a result, Medicaid paid Disney Pharmacy for mass produced products when, in fact, the pharmacy actually had dispensed its own homemade copies thereof.

12. According to the Prescribed Drug Coverage, Limitations and Reimbursement Handbook ("Medicaid Handbook"), which authoritatively sets forth the terms and conditions under which Medicaid reimburses providers for dispensing pharmaceuticals,

Medicaid may pay for a compound drug if the following criteria are met:

> - At least one pharmaceutical is a reimbursable legend drug;
> - The finished product is not otherwise commercially available; and
> - The finished product is being prepared to treat a specific recipient's condition.

Medicaid Handbook at 9-16.[ii] To present a claim for a compound drug, the provider must adhere to the following instructions:

> Compound drug codes must be submitted on paper Pharmacy 061 claim forms, because they are reviewed and manually priced by Medicaid.
>
> When billing for a compound drug, enter one of the following compound drug codes. More than one code is available so that more than one compound can be dispensed to a recipient on the same day without using the same number.
>
> 55555-5555-55 66666-6666-66
> 77777-7777-77 88888-8888-88

Id.

13. Disney Pharmacy attempts to defend its failure to follow the unambiguous instructions for billing compound drugs by explaining that, before commencing the practice of compounding, the provider's owner, Sara Padron, made a telephone call to AHCA to ask for guidance on submitting claims for drugs created on-site. Ms. Padron testified at hearing that the AHCA employee with whom she spoke had told her to present claims for

compound drugs by billing for the manufactured products that they most resembled, using the manufactured products' NDC numbers. Ms. Padron could not identify the person who purportedly gave her this plainly incorrect advice.

14. Ms. Padron's testimony in this regard was not contradicted——although in fairness to the Agency hers was the kind of testimony that resists direct evidential challenge, forcing an opponent to stress the implausibility of the claim as a means of discrediting it. Ms. Padron's account cannot simply be dismissed as incredible, for an AHCA employee undoubtedly could give an incorrect answer to a provider's question. But even assuming that Ms. Padron reached a person whom one reasonably could suppose to be knowledgeable about Medicaid billing procedures, and further assuming Ms. Padron asked a clear question which fairly and accurately described the situation, neither of which was proved or should be taken for granted, the undersigned remains skeptical that Ms. Padron was instructed to bill for compound drugs as if billing for their commercially available counterparts: the advice is just too obviously wrong.

15. It is not necessary, however, to accept or reject Ms. Padron's testimony concerning the "official" answer she says she received because even if Ms. Padron were told to bill for compound drugs as though manufactured products had been

dispensed, no reasonable provider could have relied upon such a dubious oral representation. The statement, for starters, is an invitation to commit fraud. Common sense should inform any reasonable provider that a claim for something other than what was actually delivered will, if discovered, almost certainly be viewed as deceptive (or worse) by the payor. Additionally, the alleged statement attributed to AHCA's employee contradicts the plain instructions in the Medicaid Handbook on that very subject. No provider can reasonably rely upon verbal advice, given anonymously (or functionally so, since the advisor's name, if given, was evidently easily forgotten) over the telephone, which contravenes the clear language of the Medicaid Handbook.

16. Disney Pharmacy's other defenses are likewise unpersuasive. Disney Pharmacy maintains that compounding the drugs in question substantially benefited the patients who received them, which is probably true——but certainly beside the point. The problem here is not with the practice of compounding per se; the problem is that Disney Pharmacy sought and received reimbursement from Medicaid for mass produced, commercially available drugs that had not actually been dispensed. For the same reason, it is irrelevant, even if likely true, that the Board of Pharmacy, which periodically inspects Disney Pharmacy, never objected to the compounding that was occurring at the premises. Again, to be clear, the problem is not that the

compounding was improper, but that the Medicaid billing was improper.

CONCLUSIONS OF LAW

17. The Division of Administrative Hearings has personal and subject matter jurisdiction in this proceeding pursuant to Sections 120.569 and 120.57(1), Florida Statutes.

18. The specific charge against Disney Pharmacy is that it failed "to demonstrate that it had available during a specific audit or review period sufficient quantities of goods . . . to support the provider's billings to the Medicaid program." § 409.913(15)(n), Fla. Stat. It is found and concluded that AHCA proved this charge; indeed, Disney Pharmacy admitted that it had not purchased the Inhalation Therapy Drugs, in their commercially available forms, in quantities sufficient to support its billings for such goods. What Disney Pharmacy bought——but did not bill for——were the ingredients needed to make the Inhalation Therapy Drugs.

19. A provider's failure to demonstrate that it possessed sufficient quantities of goods is punishable by "any remedy provided by law, including, but not limited to, the remedies provided in subsections (13) and (16) [of Section 409.913] and [in] s. 812.035." § 409.913(15).

20. The Agency has not sought any of the remedies provided in subsections (13) or (16) of Section 409.913, nor has it

sought relief under Section 812.035, Florida Statutes. Instead, the Agency is traveling under the theory that Disney Pharmacy received "overpayments."

21. The Agency is empowered to "recover overpayments . . . as appropriate." § 409.913, Fla. Stat. Thus, the recovery of overpayments is a "remedy provided by law."

22. An "overpayment" includes "any amount that is not authorized to be paid by the Medicaid program whether paid as a result of inaccurate or improper cost reporting, improper claiming, unacceptable practices, fraud, abuse, or mistake." § 409.913(1)(e), Fla. Stat.

23. The burden of establishing an alleged Medicaid overpayment by a preponderance of the evidence falls on the Agency. South Medical Services, Inc. v. Agency for Health Care Admin., 653 So. 2d 440, 441 (Fla. 3d DCA 1995); Southpointe Pharmacy v. Department of Health and Rehabilitative Services, 596 So. 2d 106, 109 (Fla. 1st DCA 1992).

24. Although the Agency bears the ultimate burden of persuasion and thus must present a prima facie case through the introduction of competent substantial evidence before the provider is required to respond, Section 409.913(22), Florida Statutes, provides that "[t]he audit report, supported by agency work papers, showing an overpayment to the provider constitutes evidence of the overpayment." Thus, the Agency can make a prima

facie case by proffering a properly supported audit report, which must be received in evidence. See Maz Pharmaceuticals, Inc. v. Agency for Health Care Administration, DOAH Case No. 97-3791, 1998 Fla. Div. Adm. Hear. LEXIS 6245, *6-*7 (Mar. 20, 1998); see also Full Health Care, Inc. v. Agency for Health Care Administration, DOAH Case No. 00-4441, 2001 WL 729127, *8-9 (Fla.Div.Admin.Hrgs. June 25, 2001)(adopted in toto, Sept. 28, 2001, AHCA Rendition No. 01-262-FOF-MDO).

25. In addition, Section 409.913(22), Florida Statutes, heightens the provider's duty of producing evidence to meet the Agency's prima facie case, by requiring that the provider come forward with written proof to rebut, impeach, or otherwise undermine the Agency's statutorily-authorized evidence; it cannot simply present witnesses to say that the Agency lacks evidence or is mistaken.

26. Section 409.913(7), Florida Statutes, describes the duties of providers who make claims under Medicaid as follows:

> (7) When presenting a claim for payment under the Medicaid program, a provider has an affirmative duty to supervise the provision of, and be responsible for, goods and services claimed to have been provided, to supervise and be responsible for preparation and submission of the claim, and to present a claim that is true and accurate and that is for goods and services that:
> (a) Have actually been furnished to the recipient by the provider prior to submitting the claim.

> (b) Are Medicaid-covered goods or services that are medically necessary.
> (c) Are of a quality comparable to those furnished to the general public by the provider's peers.
> (d) Have not been billed in whole or in part to a recipient or a recipient's responsible party, except for such copayments, coinsurance, or deductibles as are authorized by the agency.
> (e) Are provided in accord with applicable provisions of all Medicaid rules, regulations, handbooks, and policies and in accordance with federal, state, and local law.
> (f) Are documented by records made at the time the goods or services were provided, demonstrating the medical necessity for the goods or services rendered. Medicaid goods or services are excessive or not medically necessary unless both the medical basis and the specific need for them are fully and properly documented in the recipient's medical record.
>
> The agency may deny payment or require repayment for goods and services that are not presented as required in this subsection.

27. The pertinent statutes, administrative rules, and Medicaid Handbook that were in effect during the Audit Period govern this dispute. See Toma v. Agency for Health Care Administration, DOAH Case No. 95-2419, 1996 WL 1059900, *23 (Recommended Order issued July 26, 1996) (adopted in toto, Sept. 24, 1996, 18 F.A.L.R. 4735).

28. Disney Pharmacy argues AHCA's reliance on the audit report and supporting work papers to establish the overpayment is misplaced because the underlying data were not adequately

proved. Disney Pharmacy contends as well that the audit report should not be accepted uncritically as proof of the alleged overpayment.[iii]

29. On the latter point, the undersigned agrees with Disney Pharmacy that the statutory directive to receive the audit report and supporting papers as "evidence" should not be construed to require that such evidence be believed, no matter what. The statute does, however, put the onus on the provider to undermine the credibility of the audit report, by offering some evidence, argument, or both of sufficient logical force to cast doubt on the report's findings, assumptions, or conclusions. Here, Disney Pharmacy has not attempted directly to refute any of the audit report's particular findings, assumptions, or conclusions.

30. As for the absence of proof of the underlying data, it seems to the undersigned that one of the purposes of Section 409.913(22) is to obviate the need to fill the record with voluminous writings, many of which might not be the subject of genuine dispute. Indeed, the audit report and supporting papers here comprise a summary of records that would have been inconvenient to examine at hearing. (Such a summary, the undersigned notes, would be admissible in a civil proceeding pursuant to Section 90.956, Florida Statutes, provided certain prerequisites to admission were met.)

31. In this case, moreover, the information upon which the audit report was based came mostly from Disney Pharmacy's own records. To the extent other data were used, they were taken from materials in the Agency's files that Disney Pharmacy could have examined and copied (if it did not) well ahead of the final hearing.

32. Yet, Disney Pharmacy declined to offer evidence refuting the particular findings of the audit report or suggesting that the Agency had misapprehended some material information upon which the report was based. To the contrary, Disney Pharmacy conceded the material facts that establish its liability to Medicaid for overpayments, namely, that claims routinely were made for commercially available drugs when such drugs had not, in fact, been dispensed. By introducing the audit report in its case in chief, the Agency made a prima facie showing of the amount of the alleged overpayment——which was really the only genuine issue open to dispute once Disney Pharmacy tacitly admitted its liability. If Disney Pharmacy believed that AHCA had erred in calculating the overpayment, then it should have produced some evidence at hearing (which it could have done, if such proof exists) to substantiate its belief; it did not.

33. Based on the evidence presented, it is found and concluded that, in billing for commercially available

medications rather than the compound drugs which it had, in fact, dispensed, Disney Pharmacy violated the duty to present "true and accurate" claims for the goods that were "actually . . . furnished to" Medicaid recipients. See § 409.913(7)(a), Fla. Stat.

34. Moreover, it is found and concluded that, in making claims for commercially available medications instead of the compound drugs that were actually provided, Disney Pharmacy violated clear and unambiguous instructions, found in the Medicaid Handbook, for billing for compound drugs.

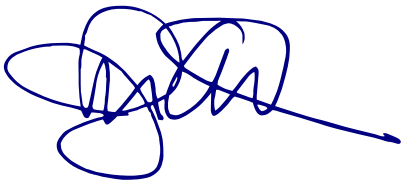
35. At a minimum, these violations constitute "improper claiming" as that term is used in Section 409.913(1)(e), Florida Statutes. Consequently, the undersigned finds and concludes that the amounts which Disney Pharmacy received as a result of its pattern and practice of improper claiming are, in fact and in law, overpayments. Id.

36. Based on the foregoing findings and conclusions, it is determined that Disney Pharmacy is liable to the Agency for an overpayment of $1,676,390.45.

RECOMMENDATION

Based on the foregoing Findings of Fact and Conclusions of Law, it is RECOMMENDED that the Agency enter a final order requiring Disney Pharmacy to repay the Agency the principal amount of $1,676,390.45.

DONE AND ENTERED this 11th day of April, 2006, in Tallahassee, Leon County, Florida.



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Filed with the Clerk of the
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this 11th day of April, 2006.

ENDNOTES

[i]/ The relatively insignificant alleged overcharges associated with the other nine drugs that were reviewed will not be discussed separately herein.

[ii]/ At hearing, the undersigned informed the parties that he would take official recognition of applicable administrative rules; neither party objected to this. AHCA has adopted the Medicaid Handbook as a rule, incorporating its contents by reference in Florida Administrative Code Rule 59G-4.250(2). As of this writing, the Medicaid Handbook is available online, and was accessed on April 8, 2005, at <http://floridamedicaid.acs-inc.com/XJContent/Prescribed_Drug_Services.pdf?id=000000000422> (Adobe Reader required).

[iii]/ Disney Pharmacy also hints that Section 409.913(22), Florida Statutes, might be unconstitutional. The undersigned will leave that issue alone. See, e.g., Fla. Marine Fisheries Comm'n v. Pringle, 736 So. 2d 17, 22 n.4 (Fla. 1st DCA 1999(administrative process cannot resolve constitutional attack upon a statute).

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NOTICE OF RIGHT TO SUBMIT EXCEPTIONS

All parties have the right to submit written exceptions within 15 days from the date of this recommended order. Any exceptions to this recommended order should be filed with the agency that will issue the final order in this case.