BEFORE THE ALASKA OFFICE OF ADMINISTRATIVE HEARINGS ON REFERRAL BY THE COMMISSIONER OF HEALTH AND SOCIAL SERVICES

In the Matter of:	)	
	)	
ACCREDO HEALTH GROUP, INC.	)	OAH No. 13-0622-MDA
	)	

DECISION

I. Introduction

Accredo Health Group, Inc. (Accredo) is a specialty pharmacy that provides pharmacy services to Alaska Medicaid recipients. A Medicaid audit for calendar year 2009 resulted in a claim that Accredo had been overpaid a total of $63,192.50 for the pharmaceutical services it provided during 2009. Accredo disputed $57,957.50 of that amount and requested a hearing.

The Office of Administrative Hearings conducted a formal hearing on January 9, 2014. T. Allen Hansen, a principal with Myers and Stauffer, LC, and Chad Hope, a licensed pharmacist employed by the Alaska Department of Health and Social Services (Department), testified on behalf of the Department. Nikki Hudak-Ink, a licensed pharmacist, who is the director of pharmacy operations for Accredo, testified on Accredo's behalf. All were qualified as experts in their respective fields.

The undisputed evidence in this case demonstrates that Accredo dispensed and was paid for medications for an Alaska Medicaid patient that exceeded the amount specified in that patient's prescription, without receiving medical authorization for the change. Accredo was paid a total of $57,957.50 for those unauthorized medication disbursements. Accredo must repay the Department for those unauthorized medication disbursements.

II. Facts

Adam[1] is an Alaska Medicaid recipient with pulmonary arterial hypertension (PAH). He is treated for this condition with a medication by the name of Remodulin. Remodulin has a very limited distributorship and is not dispensed by any pharmacies or hospitals within Alaska. Accredo is one of the only three pharmacies that distribute Remodulin nationally. It is based in Pennsylvania.

Remodulin is administered intravenously. Its use cannot be stopped suddenly, nor can its dose be decreased suddenly. Stoppage or dosage decrease can result in immediate life threatening side effects.

[1] "Adam" is a pseudonym used to protect the privacy of the patient.

In 2009, Adam was being prescribed Remodulin, along with sodium chloride which is necessary for its administration. His April 14, 2009 Remodulin prescription reads: "[d]ispense one month of medication, needles, syringes, ancillary supplies and HME to administer medication." The prescription form contains the language "[r]efill X 1 year (unless notated otherwise) or ___ times." The blank between "or" and "times" is filled in with the handwritten number "1."[2] Thus, the April 14, 2009 prescription was for a one month supply of Remodulin, with one one month refill. The subsequent July 2, 2009 prescription called for two refills.[3]

A 28 day supply of the drugs consists of 100 ml (five 20 ml vials) of Remodulin and 1600 ml (32 50 ml packets) of sodium chloride.[4] During April through July 2009, Accredo dispensed the following prescriptions to Adam:

April 15, 2009:	Nine vials of Remodulin (180 ml)
	3300 ml sodium chloride
May 18, 2009:	Nine vials of Remodulin (180 ml)
	3300 ml sodium chloride
July 29, 2009:	Seven vials of Remodulin (140 ml)

The Department paid Accredo in full for the Remodulin and sodium chloride prescriptions. The Department had Accredo's 2009 Medicaid billings audited. The audit found that April 15, 2009, May 18, 2009, and July 29, 2009 shipments exceeded the prescribed one month supply (100 ml Remodulin, 1600 ml sodium chloride). The audit found as a result that Accredo had received the following payments to which it was not entitled:

April 15, 2009:	Remodulin	$23,130.00[5]
	Sodium Chloride	$ 59.35[6]
May 18, 2009:	Remodulin	$23,137.90[7]
	Sodium Chloride	$ 67.25[8]
July 29, 2009	Remodulin	$11,563.00[9]
		$57,957.50

[2] Agency Record at 652.
[3] Ex. C.
[4] The parties agree on these amounts. *See* Department Brief at p. 2; Accredo Brief at p. 3.
[5] Claim D335026; Agency Record at 18.
[6] Claim D335027; Agency Record at 18.
[7] Claim D335030; Agency Record at 19.
[8] Claim D335031; Agency Record at 19.
[9] Claim D335036; Agency Record at 20.

Accredo did not dispute that the amount dispensed upon each of the three dates (April 15, May 18, and July 29, 2009) exceeded the amount prescribed to be dispensed monthly. Nor does it dispute the audit's findings regarding the payment amounts. Accredo, however, dispensed the larger than prescribed amounts because of its concerns that Adam lives in Alaska where the drug was unavailable and it wanted him to have a 30 day backup supply.[10]

The original prescriptions did not prescribe a backup supply. There are no prescribing doctor's notes indicating that Accredo was authorized to dispense a backup supply. Four years later, on May 3, 2013, Adam's prescribing physician wrote on the two relevant prescriptions (April 14, 2009 and July 2, 2009) to "please issue a 4 week supply as back up."[11]

Nikki Hudak-Ink is a licensed pharmacist in Pennsylvania and several other states. She is the director of pharmacy operations for Accredo. She testified that it was Accredo's standard of care to "provide back up for all patients," and that there was no call made to the prescriber to vary the script:

> The particular pharmacist, if they do have an issue with the prescription, it is their duty to call and contact the prescriber and talk to them about what the proper thing to prescribe is. Because this is our standard of care to provide backup for all patients, there was no call made to the physician that's documented because they did not have any problem with this prescription.
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> We did believe that this was the intent of the prescriber. This particular prescriber is a expert in PAH patients and treating them. And since I've been in practice, this has always been the standard with these types of drugs to have the backup. So, it's never that this physician did not ever believe, that this physician didn't think that we would be providing a backup supply for this patient.[12]

She further testified that there was no need to consult the prescriber if the pharmacist felt comfortable with what he or she was dispensing, based upon the pharmacist's experience and knowledge.[13]

Chad Hope is a licensed pharmacist in Alaska and is the pharmacy program manager for the Department. He testified that a pharmacist may not vary the amount specified on a prescription, and that in the event the pharmacist felt a change was necessary, it was the pharmacist's obligation to obtain a new prescription from the physician.

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10 *See* Exs. E, F.

11 Exs. B, C.

12 Ms. Hudak-Ink Testimony at 1:49:20 - 1:50:33.

13 *Id.* at 1:50:53 – 1:51:41

III. Discussion

The Department seeks to collect funds allegedly overpaid by the Medicaid program to Accredo for Adam's Remodulin and sodium chloride prescriptions. The Department agrees that it has the burden of proof by a preponderance of the evidence.

Adam's prescriptions provide that he was to be dispensed one month of medications at a time. Accredo dispensed Adam's medications on three occasions (April 15, May 18, and July 29, 2009) in an amount that exceeded the monthly dosage for those drugs. The amount attributable to those over-dispensed drugs comes to a total of $57,957.50. The Department has not argued that Adam did not receive those drugs. Instead, the Department argued that Accredo should not be compensated for having dispensed the Remodulin and sodium chloride in larger quantities than prescribed.

Accredo argued that the circumstances of Adam's care made the over dispensing medically necessary. Adam lives in Alaska. Accredo is located in Pennsylvania. Remodulin is a drug that is only distributed by three pharmacies, and is not available in Alaska. If Adam was to run out of Remodulin, it could have potentially fatal effects. Accredo therefore maintains that Adam having a month's backup supply of his medication was medically necessary. Accredo did not obtain physician authorization to provide Adam with a backup supply in 2009, and did not feel it was necessary to do so.

Chad Hope, the Department's expert, testified that a pharmacist could not vary a prescription amount without consulting with and obtaining authorization from the prescriber. His testimony is consistent with the Alaska pharmacy regulations which require that a pharmacist obtain a prescription that lists the name, strength, and quantity of the drug prescribed.[14] The Alaska regulation regarding refills of prescriptions mandate that a "[a] pharmacist may dispense a refill of a prescription only in accordance with the prescribing practitioner's authorization as indicated on the prescription drug order."[15] Failure to comply with these regulations could result in disciplinary sanctions.[16]

Ms. Hudak-Ink, Accredo's expert, testified to a looser standard that provided a pharmacist with some discretion, allowing the pharmacist to deviate from the explicit terms of a prescription based on experience and knowledge. Her testimony is not consistent with either the

[14] 12 AAC 52.460(a)(4) – (6). All references to regulations are to those in effect during the relevant time period, April to July 2009.
[15] 12 AAC 52.470(a).
[16] 12 AAC 52.910(a).

Alaska pharmacy regulations or the Pennsylvania pharmacy licensing statutes, the jurisdiction where she is licensed and where Accredo operates. The Pennsylvania pharmacy statutes are clear that a pharmacist is subject to having his or her license suspended or revoked if he or she varies the terms of a prescription.[17] In addition, the Pennsylvania Court has explicitly stated, referring to pharmacy licensing regulations, that a pharmacist may not refill a script "prior to a reasonable time when the previous dosage should have been consumed according to the physician's orders."[18] Doubling up a prescription is not comparable with a refill within a "reasonable time when the previous dosage should have been consumed according to the physician's orders." Mr. Hope was therefore more credible than Ms. Hudak-Ink on the issue of pharmacist discretion. His testimony established that Accredo could not, without consulting with and obtaining authorization from the prescribing physician, dispense more than one month supply of Remodulin at a time.

Although Accredo argued that variation of the prescription was medically necessary, a determination of medical necessity is one that would be reserved for the physician, not a pharmacist. No evidence indicates that the backup supply was discussed and authorized by the physician. The 2013 physician's directive to issue a backup supply, written on the April 14 and July 2, 2009 prescriptions, has no probative effect on the question of medical necessity for prescriptions dispensed in 2009.[19]

Under the Medicaid regulations in effect as of 2009, when the drugs were dispensed and paid for, payments were not allowed "for an item or service not properly prescribed or determined necessary by a health care practitioner."[20] As discussed above, Accredo's dispensing did not comply with the prescription, nor was there any authorization from the prescriber for the deviation. The Department has therefore established by a preponderance of the evidence that

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[17] The statute reads that a license may be refused, revoked, or suspended if a pharmacist "[h]as .. dispensed, sold or caused the .. dispensing or sale of any drug .. which contains more or less than the proportionate quantity of ingredient or ingredients specified by the person who prescribed such drug, unless the consent of the prescriber is first obtain to each such specific prescription." 62 P.S. §390.5(a)(8).

[18] *Goldberg v. Commonwealth, State Board of Pharmacy*, 410 A.2d 413, 416 (PA 1980) (construing 49 Pa. Code 27.18(t)).

[19] The handwritten directive, dated May 3, 2013, contained on the April 14 and July 2, 2009 prescriptions is not contemporaneous with those scripts. *See* Exs. B and C. At best, it is prospective as of May 3, 2013: "Please issue 4 week back up supply." It therefore does nothing to establish or support an inference that the prescriber intended or directed that there be a backup supply in place when the 2009 prescriptions were written. The handwritten directive would also be hearsay under Evidence Rule 802, and not admissible under the business record exception (ER 803(6)) due to its lack of contemporaneity and the fact it was written as a post-hoc justification for the purposes of this litigation, *i.e.*, it was not generated in the normal course of business. Under the Alaska APA, if the Department had objected, this could not be used to support a factual finding. *See* AS 44.62.460(d).

[20] 7 AAC 43.010(2).

Accredo's excess dispensing of Remodulin and sodium chloride was neither properly prescribed nor deemed necessary by the prescriber. The Department may recover payments that were made "incorrectly for services that do not meet standards established for reimbursement of services."[21] The Department has met its burden of proof and established that it is entitled to recover the amount paid for the excess dispensing of Remodulin and sodium chloride. That amount is $57,957.50.

IV. Conclusion

The Department compensated Accredo for dispensing more Remodulin and sodium chloride in amounts than was prescribed. Because Accredo may compensated by Medicaid only for authorized prescriptions, it is required to reimburse the Department for the amount that it received for the over-dispensed amounts: $57,957.50.

DATED this 27th day of January, 2014.

By: *Signed*
Lawrence A. Pederson
Administrative Law Judge

Adoption

The undersigned adopts this Decision, under the authority of AS 44.64.060(e)(1), as the final administrative determination in this matter.

Judicial review of this decision may be obtained by filing an appeal in the Alaska Superior Court in accordance with Alaska R. App. P. 602(a)(2) within 30 days after the date of this decision.

DATED this 25th day of March, 2014.

By: *Signed*
William Streur, Commissioner
Department of Health and Social Services

[This document has been modified to conform to the technical standards for publication.]

[21] 7 AAC 43.081(a)(8).