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

In the Matter of	)	
	)	OAH No. 12-0217-MDS
F C	)	Agency No.
	)	

DECISION

I. Introduction

F C is a minor, represented throughout this proceeding by his father, U C. F is a Medicaid recipient who challenged the division's denial of his request for prior authorization and direct reimbursement of two name brand drugs: Risperdal 1 mg and Depakote ER 500 mg. Coverage was denied because F's request was not accompanied by evidence of two prior "trial/failure of preferred generic for a multisource drug."[1] Through his father, F challenged the denial and requested a hearing. Eventually the division agreed that prior authorization of the medications for one year was appropriate, but would not agree to directly reimburse Mr. C's family for the prescriptions paid out-of-pocket.

The dispute between the parties has been narrowed to a single question of law: whether F's family is entitled to direct reimbursement for prescriptions out of pocket after the division's denial of prior authorization. This decision concludes that F's family is eligible, and direct reimbursement is granted for those requests that meet the criteria under § 6320 of the State Medicaid Manual.

II. Procedural Background and Material Facts

On June 22, 2012, F's physician applied for prior authorization for prescriptions of Risperdal 1 mg and Depakote ER 500 mg. The treating physician gave his opinion that these medications were medically necessary, stating that F had not responded to generic versions in the past and had been on the name brand in varying doses for years with good success.[2]

Unknown to the physician or F's family, there had been a change in the division's approach to granting prior authorization for these drugs. The recipient was now required to provide documentation of adverse drug reaction or treatment failure of at least two generic

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[1] Exh. D. at 2.

[2] *Id.*, C Exh. 1 at 13, 15 (For example at 13 - Depakote ER 250 mg was prescribed as early as October 2007).

versions from two different manufacturers before the division would grant prior authorization. On June 26, 2012, because F's request was not accompanied by documentation of "[i]nadequate trial/failure of preferred generic for a multisource drug," the division denied his request.[3]

Despite the denial, F's family purchased the drugs as prescribed and requested a hearing. The hearing occurred on several different dates due to the evolving nature of the dispute. The first session, on August 14, 2012, focused on the evidence, or lack thereof, of adverse events. However, a review of the regulations revealed that the controlling regulation for determining whether prior authorization would be approved was 7 AAC 105.130(c). This subsection provides that the likelihood of adverse effects is but *one* of several factors to be considered, not the only factor.[4]

A supplemental hearing was scheduled for August 30, 2012 to provide the parties with an opportunity to address all relevant factors. The parties were informed that, based on the evidence and arguments presented at the August 14, 2012 hearing, it appeared that the division failed to balance all of the relevant factors and disregarded the provider's statement of medical necessity.[5] The parties were also informed that absent additional evidence, the following facts were established on a more likely than not basis:

- F has been on the name brands of these medications for over four years and is doing well.
- F's providers believe that it is medically necessary that he remain on the name brand to avoid a medical crisis.
- The division's witness testified that the generic and name brands are identical.
- Mr. C testified that F has had adverse reactions when placed on the generic version of these two drugs.
- The medical providers could not identify an instance of adverse effect associated with the generic version.

[3] Exh. D. at 2.

[4] The division is required to consider, including but not limited to: "the service's medical necessity, clinical effectiveness, cost effectiveness, and likelihood of adverse effects…." 7 AAC 105.103(c).

[5] *See generally* Exh. E; Order Setting Supplemental Hearing (August 21, 2012).

- The medications at issue were recently placed on the list of brand name medications requiring prior authorization.[6]

On August 23, 2012 the division informed Mr. C that it would provide prior authorization of the name brand drugs for one year because, upon further review, it believed that there was "reasonable evidence to suggest that the documentation was not submitted because the physicians failed to maintain this important information in F C's medical record."[7]

The division's prior authorization did not resolve the matter for Mr. C. He had purchased the medications as prescribed from pharmacies in Ohio and Alaska. Mr. C wanted reimbursement for those expenses. He also sought a ruling that the prior authorization was for dosages different from those requested by the treating physician, and asked that the division stipulate that any name brand dosage of either drug will not require additional proof of adverse events.

At Mr. C's request, the supplemental hearing was continued to September 6, 2012. In the interim, the division resolved the issue regarding reimbursement for payment made to Alaska pharmacies. The division had arranged for the Alaska pharmacy to reimburse Mr. C and submit the billing to Medicaid. It took no steps to remedy the Ohio payments because the Ohio pharmacy was not an Alaska Medicaid program provider.

When it came to the Ohio pharmacies, the division took the position that it could not reimburse a non-Alaska Medicaid program provider (Ohio) and that it could not provide direct payment to Mr. C without violating the vendor payment principle.

The general rule is that Medicaid may only reimburse a program provider, referred to as the vendor payment principle. The division argued that it could not pay Mr. C because he is not a program provider. By having the Alaska pharmacies reimburse Mr. C, Medicaid was not directly reimbursing a non-program provider.

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[6] The parties were advised of these tentative findings in the Order Setting Supplemental Hearing (August 21, 2012).

[7] Letter from Chad Hope, Pharm.D., Pharmacy Program Manger to Mr. C, dated August 23, 2012.

This left the five Ohio prescriptions unresolved.[8] These are shown here:

Date	Total Cost	Amount Paid By Mr. C	Amount Paid By Insurance
6/28/12	$46.46	$46.46	$0.00
6/29/12	$46.46	$46.46	$0.00
6/29/12	$46.46	$39.97	$0.00
7/10/12	$92.62	$70.08	$22.54
7/11/12	$75.32	$64.87	$10.45[9]

The division was asked to reconcile its position with the State Medicaid Manual § 6320, which provides an exception to the vendor payment principle when there has been an erroneous denial of Medicaid. It was agreed that the matter should be briefed. A briefing schedule was established and two issues were identified:

1) Whether Mr. C can seek prior authorization for dosages that were not part of the prior authorization request, and
2) Whether the division can directly reimburse Mr. C for prescriptions purchased in Ohio after the division denied his request for prior authorization and subsequently changed its position.

The parties' post hearing briefs went beyond these two issues. For example, the division asserted that is not required to give equal weight to all factors identified at 7 AAC 105.130(c) when considering whether to grant a request for prior authorization. Arguments that do not address the two issues identified will not be addressed.

III. Discussion

A. *Mr. C may not expand the scope of prior authorization beyond that requested by his provider, Depakote ER 500 mg and Risperdal 1mg.*

The division is correct that the C family may not expand the scope of prior authorization beyond the request. The goal of the prior authorization program "must be to ensure appropriate drug therapy, while permitting sufficient professional prerogatives to allow for

[8] C Exh. 1 at 7 – 12.
[9] Sheet 1, November 26, 2012 Update.

individualized drug therapy."[10] To meet this goal, the Department's regulation, 7 AAC 105.130(c), requires a balancing of factors. These include, but are not limited to[11]

> medical necessity, clinical effectiveness, cost-effectiveness, and likelihood of adverse effects, as well as service-specific requirements in 7 AAC 105 – 7 AAC 160. The department may place minimum or maximum quantities allowed of a specific service, may require other services before the recipient receives the requested service, or may require prior authorization for other services, as necessary. . . .[12]

For the division to fulfill its obligation to balance all factors it must know what it is being asked to authorize. If F's providers believe a prior authorization of differing dosage is medically appropriate, then prior authorization for differing doses should be requested. No such request has been filed.

B. *Future requests for non-generic versions of Depakote and Risperdal.*

As recognized by the division, because F had been on these name brand medications for a number of years, his providers had no reason to document prior adverse events on generic equivalents. Now that the division has authorized the name brand medications, there will be no future events to document. While it may seem that for these two medications the division has accepted that the name brand is medically necessary, it is not an acceptance that extends beyond the period of prior authorization.

Prior authorization today is not a guarantee of prior authorization in the future. Medicine is dynamic. It is not unreasonable for the division to require F's providers to request prior authorization again in 12 months. However, absent a change in circumstance or the law, it would be difficult for the division to support a denial of a request for prior authorization based solely on the lack of documented adverse events while on generic medication when, because of prior authorization, F was not taking the generic version of these two drugs. Unless he disregards his doctor's advice and uses a generic version of these drugs, there will be no adverse events to document.

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[10] 7 CFR § 456.703(a). This section is incorporated by reference at 7 AAC 120.120(h).

[11] The regulation reads "[f]or prior authorization, factors that the department will consider include. . . ." By statute the words "includes" or "including" are to be construed as if followed by the phrase "but not limited to." AS 01.10.040.

[12] 7 AAC 105.130(c).

C. *Direct reimbursement*

The division retroactively approved the prescriptions authorizing all Alaska Medicaid enrolled providers to refund Mr. C and bill it for the cost.[13] As a result, the only reimbursement issue left is whether the division can provide direct reimbursement to Mr. C for the prescriptions he purchased in Ohio. The division argues that it is not required to provide direct reimbursement to Mr. C for the Ohio prescriptions under § 6320 of the State Medicaid Manual (SMM) because 1) the SMM is a policy statement and not legal authority; 2) SMM § 6320 only applies to a decision rendered after a hearing and holding that the agency denial was in error, not a division decision to cover a previously denied service; 3) the provider was a non-Alaska Medicaid enrolled provider; and 4) there is no evidence that Mr. C's insurance was billed as the primary.

1. <u>The State Medicaid Manual § 6320's exception to the vendor payment principal is applicable to the State Medicaid Plan.</u>

The State Medicaid Manual (SMM) provides instructions, citations, and information for implementing title XIX of the Social Security Act.[14] When the SMM contains an "instruction" it is an "official interpretation of the law and regulation, and, as such, [is] binding on Medicaid State agencies."[15]

SMM § 6320, Direct Reimbursement by States to Medicaid Recipients to Correct Erroneous Denials, provides:

> This *instruction* implements and clarifies longstanding [Health Care Financing Administration] policy which makes direct reimbursement available to all individuals who pay for medical services between the date of an erroneous determination of ineligibility for Medicaid and the date that determination is reversed.[16]

Because § 6320 is an instruction, the division is required to comply with that section.

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[13] Letter from Chad Hope, Pharm. D., Pharmacy Program Manger to Mr. C dated August 23, 2012.

[14] State Medicaid Manual, Forward §B(1). The entirety of this document is available at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021927.html.

[15] *Id.* Additionally, in OHA Case # 08-FH-382 (2009) Director Ellie Fitzjarrald treated the SMM as authoritative when she affirmed the Hearing Authority's decision. The legal analysis relied upon the SMM as authority "directing the conclusion" that the agency decision be upheld. *Id.* This decision may be found on line at http://aws.state.ak.us/officeofadminhearings/Documents/HSS/08-FH-382.pdf.

[16] (emphasis added).

2. Section 6320 does not require a fully adjudicated finding that the division's decision was erroneous.

Section 6320.2, Payment for Services, provides that:

> States may make direct reimbursement to individuals who paid for covered services after an erroneous determination of ineligibility which is reversed on appeal. The purpose of this exception to the vendor payment principle is to correct the inequitable situation that results from an erroneous determination made by the agency.

Neither the plain language of, nor the reason for, this exception supports the division's position.

If the division's argument were accepted, the division could deny a covered service and then the day before a judge issues a written decision it could agree that the service was denied in error but not have to remedy the inequity. Certainly, this is not the result intended. Rather, all that is required is that a state plan denies a covered service and the division corrects or changes its position.

3. Requirements for direct reimbursement.

Six criteria that must be met before direct payment reimbursement may be made:[17]

(a.) Services must have been covered under the state plan at the time the services were provided and paid for during the period between a denial of eligibility and successful appeal.

All Ohio prescriptions were paid for during the period from June 26, 2012 through the date the division changed its position. As demonstrated by the agreement to cover the Alaska prescriptions, the services were covered.

(b.) No third party reimbursement available for the service.

Mr. C explained that the Ohio pharmacy did submit two of the five Ohio purchases for third party payment and payment was received from the third party. Therefore it is established that no third party reimbursement was available for the out of pocket expense. Accordingly, the out of pocket expense for these two Ohio purchases is eligible for reimbursement under this criteria.

As to the remaining three Ohio purchases, it is unknown why the pharmacy did not submit the remaining three Ohio purchases for third party reimbursement. These three

[17] SMM § 6320.3.

purchases are not eligible for direct reimbursement under this criterion because it has not been established that third party reimbursement was not available for the expense.

For these three unsubmitted purchases, Mr. C proposes that the two submitted prescriptions demonstrate what would have been covered if submitted and the percentage of coverage should be applied to the three unsubmitted prescriptions.[18] While this approach is intuitively attractive, SMM § 6320 requires proof that third party reimbursement is not available for the service. F has third party coverage. Therefore, his representative must establish that third party reimbursement was not available for these prescriptions. He has not done so. Therefore, only the prescriptions filled on July 10 and 11 for which third party reimbursement was sought are eligible for direct reimbursement under § 6320.

(c.) Proof of payment.

The division does not dispute that Mr. C paid for these prescriptions.

(d.) Vendor payments would otherwise have been appropriate, but the provider does not have to be an Alaska Medicaid enrolled provider.

Section 6320.3 specifically includes nonparticipating providers. Therefore, whether the Ohio pharmacy is or is not an Alaska Medicaid enrolled provider is not a bar to direct reimbursement. The division's action in paying the Alaska providers shows that vendor payments would have been appropriate.

(e.) Services were medically necessary when provided but prior approval was erroneously denied.

The Department's regulation 7 AAC 105.130(c) includes a finding of medical necessity as a prerequisite to prior authorization. Therefore, implicit in the division's prior authorization is a finding of medical necessity. This finding is supported by the treating physician.[19]

[18] For example, on July 10, 2012, Mr. C's insurance did not cover 75.66% of the total cost of the Depakote prescription. Sheet 1, November 26, 2012 update. He proposes that for the three unsubmitted prescriptions, Medicaid accept that 75.66% of the total cost would not have been covered had third party payment been sought.

[19] Exh. D.

(f.) Payment is at the level of fee schedule or the upper limit as specified in the State plan even though Mr. C may have paid more.

This is not so much a criterion as a statement on the maximum amount of direct reimbursement.

In sum, that portion of the two submitted prescriptions that was not reimbursed by a third party, the prescriptions filled on July 10 and 11, are eligible for direct reimbursement under § 6320, in an amount not to exceed the fee schedule or upper limit of the State Plan.

IV. Conclusion

F C's family is eligible for direct reimbursement under State Medicaid Manual § 6320 for unreimbursed out of pocket expenses paid in Ohio for Depakote ER 500 mg on July 10, 2012 and Risperdal 1 mg on July 11, 2012 at up to the level of the fee schedule or the upper limit as specified in the State plan. The denial of reimbursement is otherwise affirmed.

Dated this 12th day of December, 2012.

Signed
Rebecca Pauli
Administrative Law Judge

Adoption

The undersigned adopts this decision as final under the authority of AS 44.64.060(e)(1). 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 27th day of December, 2012.

By: *Signed*
Signature
Rebecca L. Pauli
Name
Administrative Law Judge
Title

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