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

In the Matter of	)		
	)		
FH	)	OAH No. 14-1197-MDX	
	)	Agency No.	

#### **DECISION AFTER REMAND**

## I. Introduction

This matter arises out of Medicaid recipient F H's claim that the Division of Health Care Services ("Division") improperly denied payment for her ferrous sulfate prescription. A proposed decision was issued, finding that the Division had failed to give Ms. H advance notice that it would no longer pay for the prescription. After the Division submitted a proposal for action raising new arguments, the Commissioner of Health and Social Services remanded the case to the undersigned to take additional evidence and make additional findings regarding the notice issue. The parties then submitted additional information and arguments in response to the remand order.

Based on the entire record, the Division's decision to not pay for Ms. H's prescription is hereby affirmed.

## II. Procedural Background

The question presented in Ms. H's appeal is whether the Division properly denied payment for her prescribed over-the-counter drug, ferrous sulfate. Ms. H argues that, notwithstanding the fact that the Division issued new regulations in 2014 that removed ferrous sulfate from the list of over-the-counter drugs that the Division will pay for under Medicaid, in this instance the Division must pay for the drug because it was prescribed by her physician and is "medically necessary." Ms. H also argues that the Division failed to provide her with proper notice that it would no longer cover her ferrous sulfate.

The hearing was held on August 7, 2014. Ms. H was represented at the hearing by her spouse, C J; the Division was represented by fair hearing representative Angela Ybarra. At the close of the hearing it was decided that Ms. H would be allowed additional time to submit supplemental evidence and/or written argument in support of her position, and the Division

Although ferrous sulfate is available over-the-counter without a prescription, Ms. H takes ferrous sulfate under a written prescription from her doctor.

would be given an opportunity to respond to any such supplemental filing. The Division was also given the opportunity to provide a response to Ms. H's argument during the hearing that the Division violated Medicaid hearing procedures by failing to give her advance written notice of the determination that payment would not be made for her ferrous sulfate prescription. A schedule was set for submission of these filings, and Ms. H timely submitted her supplemental filing. The Division opted to not submit a responsive filing, which would have been due on August 25, 2014. The record of the proceeding was then closed.

The proposed decision was issued on October 13, 2014. In response, the Division elected to file a proposal for action raising new arguments on the issue of advance written notice.<sup>2</sup> The record, including the proposal for action, was provided to the Commissioner of Health and Human Services as the final decisionmaker. The Commissioner then remanded the case for the undersigned to "take additional evidence about the need for and efficacy of advance notification" and "make additional findings about the length of time [Ms. H's] prescription will be covered."

The parties were directed to submit "evidence and arguments, in written form, addressing the issues stated in the Commissioner's [remand] order." Both sides submitted short post-remand briefs, <sup>5</sup> but neither side submitted any new evidence. This decision takes into consideration the parties' post-hearing filings, as well as all of the evidence and arguments presented at the hearing.

## III. Facts

Ms. H suffers from advanced diabetes and unspecified heart conditions, and she is prescribed numerous medications by her physician.<sup>7</sup> Her physician also prescribes ferrous sulfate, an over-the-counter iron supplement, to help remedy iron depletion caused by her other prescription medications. In the past the Division authorized payment for the ferrous sulfate prescription (estimated to cost approximately \$18 per refill). At that time ferrous sulfate was

In the proposal for action, the Division acknowledged that it had "overlooked" filing its post-hearing response to Ms. H's argument regarding advance notice.

<sup>&</sup>lt;sup>3</sup> See Scheduling Order, November 6, 2014.

<sup>&</sup>lt;sup>4</sup> Id

There was an approximate two-week delay in this last stage of the process, occasioned by the Division's failure to serve its post-remand brief on Ms. H.

The Division cited statistics in its brief regarding the number of prescriptions for which payment was denied in October 2014, but it did not submit actual evidence in the form of documents or affidavits in support of those numbers.

Very little documentation of the claimant's medical condition was entered into the record of this matter. The factual findings here are based on Mr. J's testimony concerning Ms. H's condition.

explicitly included in a Division regulation that provided that the Division would pay for "a drug that has been prescribed even if that drug may be sold without a prescription, as follows: ... ferrous sulfate and ferrous gluconate in nonsustained release forms...."

However, when the division amended its regulations effective May 18, 2014, ferrous sulfate was removed from the listing of drugs for which the Division will authorize payment when they have "been prescribed even if [they] may be sold without a prescription." Ms. H was unaware that her ferrous sulfate was no longer covered by Medicaid, until Mr. J was informed by Ms. H's pharmacist, in late May 2014, that the Division would no longer pay for the drug.

Mr. J attempted to verbally request a fair hearing on behalf of Ms. H on May 23, 2014, via a telephone call to the Division's "recipient help line." His request was denied because it was not made in writing. Mr. J then spoke with the Director of Health Care Services, Margaret Brodie, who told him that some form of a written document should have been provided to him by the pharmacy when the claim was denied. In fact, no such document was ever provided to Mr. J, even after he went back to the pharmacy and attempted to obtain one. Subsequently he asked his wife's physician to request prior authorization from the Division for the ferrous sulfate prescription, based on it being medically necessary due to the effects of her other medications. The physician's staffperson made the request via telephone, in Mr. J's presence, and she told him that the request had been denied by the Division because the drug was considered an over-the-counter drug. Mr. J testified that on June 23, 2014 he faxed a request for a fair hearing to the Division's contractor, Xerox, from the No Name Public Assistance office. For unknown reasons, Xerox's fair hearing referral indicates the date of the fair hearing request to be July 11, 2014.

The approximate \$18 cost of the ferrous sulfate prescription is significant to Ms. H, as she has very little income and subsists on social security, food stamps and public assistance. <sup>10</sup>

## IV. Discussion

## A. Ms. H's Medical Necessity Argument

Mr. J argues on his wife's behalf that Medicaid is required to pay for her ferrous sulfate prescription, notwithstanding the regulatory change deleting it from the list of over-the-counter medications for which the Division will authorize payment. The argument is simply that Medicaid must pay for medically necessary drugs, and that ferrous sulfate is medically necessary

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Former 7 AAC 120.110(a)(4)(G).

<sup>&</sup>lt;sup>9</sup> 7 AAC 120.110(a)(4).

J testimony.

for Ms. H's physical well-being due to the effects of the other prescription drugs that she takes (and that Medicaid pays for). Mr. J explains: "this prescribed medication satisfies the criteria for Covered Services provided in 7 AAC 105.00[sic]... and does not fall within the scope of Noncovered Services detailed in 7 AAC 105.110...."

We will assume for purposes of this decision that ferrous sulfate is "medically necessary" for Ms. H's health. <sup>12</sup> In fact, the Division did not dispute Ms. H's assertions on this point. Rather, it argues that because the drug is no longer listed Ms. H is not entitled to coverage for it, regardless of the medical necessity of the drug.

The question of whether someone in Ms. H's position is entitled to payment under this scenario, however, requires that we analyze the language of the regulations in question.

Relevant portions of these regulations are set forth below:

#### 7 AAC 105.100. Covered services

The department will pay for a service only if that service

(1) is identified as a covered service in accordance with AS 47.07 and 7 AAC 105 - 7 AAC 160;

. . . .

(3) is ordered or prescribed by a provider authorized to order or prescribe that service under applicable law;

. . .

(5) is medically necessary as determined by criteria established under 7 AAC 1057 AAC 160 or by the standards of practice applicable to the provider;

.... and

(7) is not specifically excluded as a noncovered service under 7 AAC 105 - 7 AAC 160.

### 7 AAC 105.110. Noncovered services

Unless otherwise provided in 7 AAC 105 - 7 AAC 160, the department will not pay for a service that is

(1) not reasonably necessary for the diagnosis and treatment of an illness or injury, or for the correction of an organic system, as determined upon review by the department;

Claimant's Supplement to Record, email from C. J, August 15, 2014; note that the first regulation reference within the quote contains a typographical error; Mr. J undoubtedly intended the reference to be to "Covered Services provided in 7 AAC 105.100."

Mr. J submitted a letter from his wife's physician stating "[t]his is to confirm that the use of ferrous sulfate is important due to the history of iron deficiency anemia and the Restless leg syndrome, and should be continued and covered by insurance." Claimant's Supplement to Record, letter from Dr. U to the claimant, August 11, 2014.

(2) not properly prescribed or medically necessary in accordance with criteria established under 7 AAC 105 - 7 AAC 160 or by standards of practice applicable to the prescribing provider;

. . . .

These regulations do reference "medical necessity" as part of the analysis of whether a drug or service will be paid for under Medicaid. But a drug must be <u>both</u> medically necessary <u>and</u> "identified as a covered service in accordance with" other Division regulations. No authority has been cited that indicates that ferrous sulfate is "identified as a covered service" as required by 7 AAC 105.100. Furthermore, these regulations contain no language specifically referencing either ferrous sulfate or non-prescription medications as a category.

In addition, the Division points out that federal law authorizes it to determine what drugs will be paid for under Medicaid, under 42 U.S.C. § 1396r–8 (entitled "Payment for Covered Outpatient Drugs"). Subsection (d)(1)(B) of that federal statute provides that "[a] State may exclude or otherwise restrict coverage of a covered outpatient drug if ... (ii) the drug is contained in the list referred to in paragraph (2)." The referenced paragraph (2), entitled "list of drugs subject to restriction," then states that "[t]he following drugs or classes of drugs ... may be excluded from coverage or otherwise restricted: ... (F) Prescription vitamins and mineral products ...; (G) Nonprescription drugs... ."<sup>13</sup>

As discussed above, effective May 18, 2014, 7 AAC 120.110(a)(4) no longer identifies ferrous sulfate as a drug that will be paid for when it "has been prescribed even if that drug may be sold without a prescription." In addition, 7 AAC 120.112 explicitly states that "the department will not pay for ... a non-prescription drug, <sup>14</sup> vitamin, or dietary or herbal supplement, except as listed in 7 AAC 120.110(a)(4)." These two regulations, when read

, 11110 120:112(0)

<sup>&</sup>lt;sup>13</sup> 42 U.S.C. § 1396r–8(d)(2).

Although a definition of the term "non-prescription drug" does not appear in the Division's regulations, Alaska regulation 7 AAC 160.990 defines "prescription drug" as having "the meaning given in AS 08.80.480." AS 08.80.480 gives the following definitions:

<sup>(16) &</sup>quot;nonprescription drug" means a nonnarcotic medicine or drug that may be sold without a prescription and that is prepackaged for use by the consumer and labeled in accordance with the requirements of the statutes and regulations of the state and the federal government;

<sup>(30) &</sup>quot;prescription drug" means a drug that, under federal law, before being dispensed or delivered, is required to be labeled with either of the following statements: (A) "Caution: Federal law prohibits dispensing without prescription"; (B) "Caution: Federal law restricts this drug to use by, or on the order of, a licensed veterinarian"; or a drug that is required by an applicable federal or state law or regulation to be dispensed only under a prescription drug order or is restricted to use by practitioners only....

7 AAC 120.112(6).

together, appear to fully answer the contention that the Division is obliged to pay for ferrous sulfate. The regulations, adopted pursuant to the federal law cited above, explicitly exclude prescribed ferrous sulfate from the category of drugs for which the Division will pay, even if one were to assume that it is medically necessary.

The Division's determination on the issue of whether ferrous sulfate is a covered drug for which payment will be made under Medicaid is affirmed.

## B. Ms. H's Notice Argument

Mr. J argued at the hearing that the Division was required to give advance written notice to Ms. H of its determination that it would no longer pay for ferrous sulfate.

The Alaska regulation governing this question is 7 AAC 49.060, which provides, with certain exceptions not relevant here, that "[t]he department will give written notice to the recipient not later than 10 days before the date the department intends to take action denying, reducing, suspending, or terminating assistance...."

As described above, Ms. H did not learn that the Division would not pay for ferrous sulfate until Mr. J was informed of that fact by the claimant's pharmacist. Notwithstanding Division Director Brodie's advice to Mr. J, he was unable to obtain a written notice of the change from the pharmacy or the Division. Ms. H was not given written confirmation of the Division's determination that it would not pay for her prescription until the Division submitted its position statement for this proceeding. Thus it was

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The full regulation reads as follows:

<sup>7</sup> AAC 49.060. Notice of proposed agency action

The department will give written notice to the recipient not later than 10 days before the date the department intends to take action denying, reducing, suspending, or terminating assistance, unless

<sup>(1)</sup> factual evidence exists of the death of the recipient;

<sup>(2)</sup> a recipient indicates in writing that the recipient no longer desires assistance, or gives information that requests termination or reduction of assistance and also indicates in writing that the recipient understands the consequences of reporting this information;

<sup>(3)</sup> a recipient has been admitted or committed to an institution in which residents are not eligible for assistance of the type the recipient has been receiving;

<sup>(4)</sup> the recipient's whereabouts are unknown and department mail directed to the recipient's last known address has been returned by the post office indicating no known forwarding address;

<sup>(5)</sup> factual evidence exists that a recipient has been accepted for assistance in another jurisdiction;

<sup>(6)</sup> a change in the level of medical care is prescribed by the recipient's physician;

<sup>(7)</sup> the notice involves an adverse determination made with regard to the preadmission screening requirements of 42 U.S.C.  $\underline{1396r(e)}$  (7) (sec.  $\underline{1919(e)}$ (7) of the Social Security Act); or

<sup>(8)</sup> federal regulations governing the Medicaid or food stamp programs specify shorter notice time limits or allow advance notice to be waived for certain groups of recipients.

Ironically, Mr. J's attempt to orally request this hearing was rejected by the Division on the basis that hearing requests must be made <u>in writing</u>. *See* 7 AAC 49.030.

The position statement included the following language: "The medication Ferrous Sulfate 325 mg denied as it is an over the counter drug and is no longer covered by Alaska Medicaid." Division Position Statement, p. 2. The

not until the hearing of this matter that she was formally informed of the specific basis for the Division's denial of payment for her ferrous sulfate prescription.

The Division argued at the hearing that general public notice regarding the change to the Division's regulations was sufficient to put the claimant on notice of the proposed reduction in her prescription drug benefit. As noted above, the Division opted to not provide a supplemental response on this issue after the hearing.

After the proposed decision was issued, the Division submitted a proposal for action and argued for the first time that the determination to not pay for Ms. H's prescription did not constitute an "action denying, reducing, suspending, or terminating assistance." In support of this argument the Division cited NB v. District of Columbia, a recent federal district court case that addresses Medicaid advance notice requirements.<sup>20</sup> In that case the court examined the plaintiffs' claims that the District of Columbia failed to provide them the procedural protections required by law when it denied Medicaid coverage of their prescription drugs. After reviewing the relevant federal Medicaid regulations, <sup>21</sup> the court held that the plaintiffs failed to state a claim because, in pertinent part, "if a prescription does not meet certain threshold criteria established by state law, it is not a 'covered' drug, and therefore a pharmacy's refusal to fill it is not a legal 'denial' of a covered benefit."<sup>22</sup> The court concluded that "defendants' obligation to comply with the notice requirements of Medicaid law only arises where there has been a 'termination, suspension, or reduction' of a benefit created by the Medicaid program, i.e. a covered drug."<sup>23</sup> Therefore, if a claimant's prescription was denied because the drug was not a "covered drug" under state (or District of Columbia) law, then notice was not required, because there was no "termination, suspension, or reduction" of a Medicaid benefit. 24

Division, however, included with the position statement the <u>old version</u> of the regulations, which identified ferrous sulfate as a covered drug. At the beginning of the hearing the Division's representative acknowledged that the wrong version of the regulations had been provided, and at that time she provided Mr. J with a copy of the new regulations. Thus the Division did not fully explain, in writing, the basis for the denial of payment to Ms. H until during the actual hearing.

<sup>&</sup>lt;sup>19</sup> 7 AAC 49.060; *see* Division's Proposal for Action, 10/21/14. The proposal for action process does not contemplate a party raising new arguments after the hearing record is closed; otherwise the opposing party would not have an opportunity to respond. *See* AS 44.64.060(e).

<sup>34</sup> F.Supp.3d 146, 2014 WL 1385132 (D.D.C. March 31, 2014).

<sup>42</sup> C.F.R. §431.206(b) and (c)(2) together provide that a Medicaid recipient is entitled to written notice of his right to a hearing "at the time" the state takes "any action affecting his ... claim." 42 C.F.R. § 431.201, in turn, defines "action" as "a termination, suspension, or reduction of Medicaid eligibility or covered services."

NB v. Dist. of Columbia, 34 F.Supp.3d at 153.

<sup>23</sup> *Id.* at 154.

<sup>24</sup> *Id*.

The *NB* decision, although not binding in this proceeding, is highly persuasive and directly addresses Ms. H's arguments regarding notice in this case. Ms. H's post-remand brief argues that the relevant May 2014 change in Alaska regulations (resulting in ferrous sulfate no longer being covered) constituted a "reduction in coverage" that would necessitate notice. This argument, however, fails to recognize that it is a "termination, suspension or reduction of ... *covered services*" that triggers the notice requirement under Medicaid law, not a "reduction in *coverage*." In addition, as discussed in section A above, federal law authorizes the state to determine what drugs will be paid for under Medicaid, i.e., to determine the breadth of "covered services" in the context of prescribed medications. In other words, the state via statute and regulation defines "covered services," and if a medication no longer falls within that category, then notice is not required when payment is denied for that prescription. This result is fully in accord with the analysis set forth in *NB*.

The holding in *NB* is also buttressed by another federal Medicaid regulation cited by the Division in its post-remand brief, 42 C.F.R. §431.220, which defines the circumstances in which the state must grant an opportunity for a hearing.<sup>25</sup> 42 C.F.R. §431.220(b) explicitly provides that the state "need not grant a hearing if the sole issue is a Federal or State law requiring an automatic change adversely affecting some or all beneficiaries." This is precisely the situation presented in this case. In response, Ms. H's post-remand brief argues that the change in Alaska regulation that removed ferrous sulfate was not a change in the law, but was really "agency action." The Alaska Supreme Court has explicitly confirmed, however, that "regulations are laws in every meaningful sense." Therefore, the removal of ferrous sulfate from the Alaska regulation defining Medicaid-covered non-prescription drugs was a change in "State law requiring an automatic change adversely affecting some … beneficiaries." Consequently, the Division was not required to provide advance notice to Ms. H regarding the denial of payment for her ferrous sulfate prescription.

The Commissioner's order remanding this case directed the undersigned to "take additional evidence about the need for and efficacy of advance notification" and "make

It is unfortunate that the Division did not cite the *NB* case and the related federal regulations until <u>after</u> the issuance of the proposed decision in this case; had they done so, the remand and associated expenditure of resources may have been avoided.

State v. A.L.I.V.E. Voluntary, 606 P.2d 769, 777 (Alaska 1980).

<sup>42</sup> C.F.R. §431.220(b)

additional findings about the length of time [Ms. H's] prescription will be covered."<sup>28</sup> This Decision, however, finds that advance notification was not required regarding the denial of payment for Ms. H's prescription. Given that finding, there is no basis for continued coverage of the prescription, and therefore, there is no need to make additional findings regarding the duration of coverage.

## V. Conclusion

The Division's determination that ferrous sulfate is not a covered drug for which payment will be made under Medicaid, and the denial of payment for Ms. H's May 2014 prescription, are affirmed.

Dated this 24<sup>th</sup> day of February, 2015.

Signed
Andrew M. Lebo
Administrative Law Judge

# Adoption

The undersigned, by delegation from the Commissioner of Health and Social Services, adopts this Decision 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 3<sup>rd</sup> day of March, 2015.

By: Signed

Name: Jared C. Kosin, J.D., M.B.A.

Title: Executive Director

Agency: Office of Rate Review, DHSS

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

See Scheduling Order, November 6, 2014.