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**STATE OF ALASKA
DEPARTMENT OF HEALTH AND SOCIAL SERVICES
OFFICE OF HEARINGS AND APPEALS**

In the Matter of:)
)
 [REDACTED],) OHA Case No. 09-FH-2146
)
 Claimant.) DHCS Case No. [REDACTED]
 _____)

FAIR HEARING DECISION

STATEMENT OF THE CASE

[REDACTED] (Claimant) was a Medicaid recipient (undisputed hearing testimony). On September 15, 2009 the Claimant's eye doctor submitted a request for prior authorization of "transition gray photochromic trifocal [eyeglass] lenses" ¹ to First Health Services Corporation (FHSC) ² (Ex. E1). This request was received by FHSC on October 8, 2009 (Ex. E1). The request (that Medicaid pay for tinted eyeglass lenses) was denied by FHSC on October 15, 2009 (Ex. E1). FHSC mailed a written notice denying the request for prior authorization to the Claimant on October 16, 2009 (Ex. D1 – D2). The Claimant requested a Fair Hearing regarding this issue on November 25, 2009 (Ex. C1).

This Office has jurisdiction to resolve this dispute pursuant to 7 AAC 49.010.

The Claimant's hearing was held as scheduled on December 30, 2009 before Hearing Officer Claire Steffens. ³ The Claimant participated by phone, represented himself, and testified on his own behalf. [REDACTED], Medical Assistance Administrator III for the Division of Health Care Services

¹ For purposes of brevity, in this decision the terms "tinted lenses" or "transition lenses" will be used to refer to these special lenses.

² First Health Services Corporation was, at the time of these events, a private entity under contract with the State of Alaska Division of Health Care Services (DHCS or Division). During the period in which this case was pending, the functions previously performed by First Health Services Corporation were assumed by Affiliated Computer Services (ACS).

³ Following completion of the hearing this case was reassigned to Hearing Officer Jay Durych. Mr. Durych reviewed the entire case file, and listened to the digital recording of the hearing, prior to issuing this decision.

(DHCS or Division), attended the hearing in person, represented DHCS, and testified on its behalf. The parties' testimonies and exhibits were received into evidence. At the end of the hearing the record was closed and the case was submitted for decision.

ISSUE

Was the Division correct when, on October 16, 2009, it denied prior authorization for Medicaid coverage for the Claimant's tinted eyeglass lenses?

FINDINGS OF FACT

The following facts were established by a preponderance of the evidence:

1. The Claimant has "one hell of an astigmatism" (Claimant testimony). Regular (non-tinted) eyeglass lenses are totally useless to him because of light refraction and/or reflection problems. *Id.* The Claimant also sees "halos" around light sources if he uses regular (non-reflective) lenses. *Id.* Accordingly, the Claimant requires tinted lenses for proper vision. *Id.*
2. The Claimant previously received tinted lenses in 2005, 2007, and 2008, although it was not clear from the record whether these tinted lenses were paid for by Medicare, Medicaid, or the Veterans' Administration (Claimant testimony; see also Ex. E1).
3. On September 15, 2009 a Doctor of Optometry (O.D.) completed a Medicaid Prior Authorization Request Form on behalf of the Claimant (Ex. E1). The doctor prescribed and sought authorization for "transition gray photochromic trifocal [eyeglass] lenses" (Ex. E1). The doctor certified that, "to the best of [her] knowledge . . . the [tinted lenses were] medically indicated and necessary to the health of the patient." *Id.*
4. On October 15, 2009 the Claimant's prior authorization request for tinted eyeglass lenses was denied by FHSC (Ex. E1). The basis for this denial was that "Medicaid only covers tint with the diagnosis of Albinism" (Ex. E1; see also Ex. E3).
5. On October 16, 2009 ACS mailed a written notice to the Claimant denying the request for prior authorization for tinted lenses (Exs. D1 – D2). ACS' notice stated in relevant part that "the request to purchase transition gray photochromic lenses has been denied – Medicaid only covers tint with the diagnosis of albinism." *Id.*
6. The Claimant requested a Fair Hearing regarding this issue on November 25, 2009 (Ex. C1).
7. At the hearing of December 30, 2009 [REDACTED], Medical Assistance Administrator III for DHCS, testified that Alaska Medicaid / DHCS relies upon its *Alaska Medicaid Provider Billing Manual* for the interpretation of the relevant regulation (7 AAC 43.645(a)). Whereas the regulation states that "tinted lenses are not a covered benefit unless medically necessary for a recipient," the *Provider Billing Manual* states that "tinted lenses are reimbursable only in the case of albinism" (Johnson testimony; see also Ex. F3).
8. The Claimant did not assert that he is an albino.

PRINCIPLES OF LAW

I. Burden of Proof and Standard of Proof.

The party seeking a change in the status quo or existing state of affairs normally bears the burden of proof.⁴ This case involves the denial of an initial application or claim for Medicaid benefits by the Division. Accordingly, the Claimant has the burden of proof here because he is attempting to change the existing status quo by obtaining Medicaid benefits.

A party in an administrative proceeding can assume that preponderance of the evidence is the standard of proof unless otherwise stated.⁵ The Medicaid regulations applicable to this case do not specify any particular standard of proof. Therefore, the “preponderance of the evidence” standard is the standard of proof applicable to this case. This standard is met when the evidence, taken as a whole, shows that the fact sought to be proved is more probable than not or more likely than not.⁶

II. The Medicaid Program – In General.

Medicaid is an entitlement program created by the federal government. See DPA website at <http://health.hss.state.ak.us/dpa/programs/medicaid/> (date accessed July 31, 2009). It is the primary public program for financing basic health and long-term care services for low-income Alaskans. *Id.* Almost 70,000 Alaskans receive medical benefits through the Medicaid Program. *Id.* The Medicaid program is administered in Alaska by the Division of Health Care Services (DHCS). *Id.*

III. Medicaid Visual Care Services.

The Alaska state Medicaid regulations governing visual care services and dispensing are located at 7 AAC 43.630 - 7 AAC 43.656.

7 AAC 43.630 provides in relevant part as follows:

- (a) The division will . . . cover one vision examination per calendar year [and] . . . one pair of eyeglasses for a recipient age 21 or older in each calendar year . . .

7 AAC 43.645 provides in relevant part that “*tinted lenses are not a covered benefit unless medically necessary for a recipient;*” and “prior authorization by the division is required for tinted lenses” [Emphasis added].

⁴ *State of Alaska Alcoholic Beverage Control Board v. Decker*, 700 P.2d 483, 485 (Alaska 1985).

⁵ *Amerada Hess Pipeline Corp. v. Alaska Public Utilities Commission*, 711 P.2d 1170, 1179 n.14 (Alaska 1986).

⁶ *Black’s Law Dictionary* 1064 (West Publishing, Fifth Edition, 1979); see also *Robinson v. Municipality of Anchorage*, 69 P.3d 489 (Alaska 2003).

IV. Agency Manuals Generally Do Not Have the Force of Law.

In *Shalala v. Guernsey Memorial Hospital*, 514 U.S. 87, 96, 115 S.Ct. 1232, 131 L.Ed.2d 106 (1995), the United States Supreme Court stated that a definition in the United States Department of Health and Human Services' Medicare Provider Reimbursement Manual "is a prototypical example of an interpretive rule" and therefore "do[es] not have the force and effect of law and [is] not accorded that weight in the adjudicatory process."

In *Christensen v. Harris County*, 529 U.S. 576, 587, 120 S.Ct. 1655, 146 L.Ed.2d 621 (2000), the United States Supreme Court stated that "[i]nterpretations such as those in opinion letters - like interpretations contained in policy statements, agency manuals, and enforcement guidelines . . . lack the force of law"

In *Moore v. Apfel*, 216 F.3d 864, 868-69 (9th Cir. 2000) the court stated that an agency policy manual "is strictly an internal guidance tool, providing policy and procedural guidelines" and that, "[a]s such, it does not prescribe substantive rules and therefore does not carry the force and effect of law."

In *U.S. v. Ford Motor Co.*, 516 F.Supp.2d 770 (W.D. Tex. 2007), the court stated that an agency's internal guidelines and manuals do not have the equivalent force of law as do statutes and regulations (citing *Cent. Laborers' Pension Fund v. Heinz*, 541 U.S. 739, 748, 124 S.Ct. 2230, 159 L.Ed.2d 46 (2004)).

If a state agency intends that a manual have the force of law, the manual must be adopted pursuant to the procedures required by the Alaska Administrative Procedures Act (A.S. 44.62.010 - .950). See *Kenai Peninsula Fisherman's Coop. Association, Inc. v. State*, 628 P.2d 897, 905 (Alaska 1981); *Reichmann v. State of Alaska Department of Natural Resources*, 917 P.2d 1197 (Alaska 1996). Chief among the requirements of that Act are that the regulation must be adopted in conformity with procedures for public notice and comment (see A.S.44.62.190 - .215; see also *Gilbert v. State Dept. of Fish and Game, Board of Fisheries*, 803 P.2d 391 (Alaska 1990)).

V. Standards Applicable to an Agency's Interpretation of Its Own Regulations.

An agency's interpretation of its own regulations is reviewed under the "reasonable basis" standard. *Lauth v. State*, 12 P.3d 181, 184 (Alaska 2000). Pursuant to this standard, the agency's interpretation of its regulations is deferred to unless the interpretation is "plainly erroneous and inconsistent with the regulation." *Id.*

VI. Standards For Determining Medical Necessity.

In *Thie v. Davis*, 688 N.E.2d 182 (Ind.App.1997), a Medicaid case, the court noted that "neither the federal Medicaid Act nor the accompanying regulations define medical necessity." Accordingly, in the absence of a federal definition of medical necessity, the responsibility for defining medical necessity is left to the states. *Id.*; see also *Pharmcare Oklahoma, Inc. v. State Health Care Authority*, 152 P.3d 267 (Okla. Civ. App., Div. 2, 2006).

The United States Supreme Court appears to define “medically necessary,” for purposes of the Medicaid program, as a professional judgment made by a physician considering the physical, emotional, psychological, and familial factors relevant to the well-being of the patient. See *Doe v. Bolton*, 410 U.S. 179, 93 S.Ct. 739, 35 L.Ed.2d 201 (1973); *Beal v. Doe*, 432 U.S. 438, 444, 97 S.Ct. 2366, 2371, 53 L.Ed.2d 464 (1977).

7 AAC 43.860(p), a definitional provision within the Medicaid regulations pertaining to Rural Health Clinic Services, provides in relevant part as follows:

(p) In this section . . . (2) “medically necessary and appropriate” means

(A) reasonably calculated to diagnose, correct, cure, alleviate, or prevent the worsening of medical conditions that endanger life, cause suffering or pain, result in illness or infirmity, threaten to cause or aggravate a disability, or cause physical deformity or malfunction . . .

ANALYSIS

Introduction.

The relevant facts in this case are undisputed. The Division denied the Claimant’s prior authorization request for tinted lenses because the Division’s *Alaska Medicaid Provider Billing Manual (Manual)* only authorizes tinted lenses when the applicant is an albino (Ex. F p. 3). The Claimant is not an albino. Accordingly, the precise issue raised by this case is whether or not the provision in the Division’s *Alaska Medicaid Provider Billing Manual*, which only authorizes tinted lenses when an applicant is an albino, is controlling. This is a purely legal issue.

I. The Alaska Medicaid Provider Billing Manual Conflicts With The Relevant Regulation.

As noted above, the Division’s *Alaska Medicaid Provider Billing Manual* only authorizes tinted lenses when the applicant is an albino (Ex. F p. 3). However, the relevant state Medicaid regulation, 7 AAC 43.645(a), authorizes the Medicaid program to pay for tinted lenses as long as such lenses are “medically necessary for a recipient.” See Principles of Law, above. Thus, the coverage standard stated in the *Alaska Medicaid Provider Billing Manual* conflicts with the coverage standard stated in 7 AAC 43.645(a). Which standard must be applied in this case?

II. The Regulation Trumps the Alaska Medicaid Provider Billing Manual.

It is well established that a validly adopted regulation has greater force of law than does an agency manual. See Principles of Law at page 4, above. Accordingly, the standard stated in regulation 7 AAC 43.645(a), authorizing the Medicaid program to pay for tinted lenses as long as such lenses are “medically necessary for a recipient,” takes precedence over, or has more authority than, the *Manual’s* requirement. The *Manual* requires that the applicant be an albino before coverage may be authorized. Stated more simply, the standard stated in the regulation (7 AAC 43.645(a)) takes precedence over, or has more authority than, the standard stated in the *Manual*.

The Division has the authority to give all or part of a manual the same force of law as a regulation by explicitly adopting the manual (or a part thereof) by reference in the text of a regulation. However, if a state agency intends that a manual have the force of law, the manual must be adopted pursuant to the procedures required by the Alaska Administrative Procedures Act (A.S. 44.62.010 - .950). See *Kenai Peninsula Fisherman's Cooperative Association, Inc. v. State*, 628 P.2d 897, 905 (Alaska 1981); *Reichmann v. State of Alaska Department of Natural Resources*, 917 P.2d 1197 (Alaska 1996). Chief among the requirements of that Act are that the regulation must be adopted in conformity with procedures for public notice and comment (see A.S.44.62.190 - .215; see also *Gilbert v. State Department of Fish and Game, Board of Fisheries*, 803 P.2d 391 (Alaska 1990).

In this case the Division did not assert that the vision services section of the *Alaska Medicaid Provider Billing Manual* was adopted in conformity with the procedures required by the Alaska Administrative Procedures Act (AAPA). In addition, there is no evidence in the record indicating that the vision services section of the *Manual* has been adopted pursuant to the AAPA. The *Alaska Medicaid Provider Billing Manual* is referenced in 16 regulations in the Alaska Administrative Code. However, only eight (8) of these regulations adopt portions of the *Manual* by reference.⁷ The other eight (8) regulations refer to portions of the *Manual* but *do not* adopt these portions of the *Manual* into law by reference.⁸ Notably, the *Editor's Notes* to 7 AAC 43.642 reference only Table I-4 of the vision services section of the *Manual*, but *do not adopt the vision services section of the Manual by reference*. Accordingly, the portion of the *Alaska Medicaid Provider Billing Manual* relied upon here by the Division is not itself a regulation, but rather is the Division's *interpretation* of its regulations.

The Division's interpretation of its own regulation is reviewed under the "reasonable basis" standard. *Lauth v. State*, 12 P.3d 181, 184 (Alaska 2000). Pursuant to this standard (set forth by the Alaska Supreme Court), the Division's interpretation is deferred to *unless* the interpretation is "plainly erroneous and inconsistent with the regulation." Here, the Division's interpretation of regulation 7 AAC 43.645(a)'s "medically necessary" requirement limits the availability of tinted lenses to cases of albinism based on a provision in the Division's *Manual*. However, this interpretation is "plainly erroneous and inconsistent with the regulation" based on the plain text of the regulation. Accordingly, the Division's interpretation of 7 AAC 43.645(a)'s "medically necessary" requirement, as limiting the availability of tinted lenses to cases of albinism based on the Division's *Manual*, fails the "reasonable basis" test and therefore does not require deference.

In summary, regulation 7 AAC 43.645(a) is controlling, and the applicable test is thus not whether the Claimant is an albino, but whether the tinted lenses at issue are "medically necessary" for the Claimant. This issue is discussed in the next section.

⁷ The regulations adopting specific portions of the *Alaska Medicaid Provider Billing Manual* by reference are 7 AAC 43.106, 7 AAC 43.109, 7 AAC 43.115, 7 AAC 43.385, 7 AAC 43.517, 7 AAC 43.921, 7 AAC 43.923, and 7 AAC 43.926.

⁸ 7 AAC 43.030, 7 AAC 43.065, 7 AAC 43.453, 7 AAC 43.642, 7 AAC 43.830, 7 AAC 43.910, 7 AAC 43.922, and 7 AAC 43.942 all reference portions of the *Alaska Medicaid Provider Billing Manual* but *do not* adopt any portion of the *Manual* by reference.

III. Are Tinted Lenses “Medically Necessary” For the Claimant?

Initially, before it can be determined whether tinted lenses are medically necessary for the Claimant based on the facts of this case, the term “medically necessary” must be defined.

A. Definition of “Medically Necessary.”

This case involves Medicaid benefits. In *Thie v. Davis*, 688 N.E.2d 182 (Ind.App.1997), a Medicaid case, the court noted that “neither the federal Medicaid Act nor the accompanying regulations define medical necessity.” Accordingly, in the absence of a federal statute or regulation defining medical necessity for purposes of the Medicaid program, the responsibility for defining medical necessity is left to the states. *Id.*; see also *Pharmcare Oklahoma, Inc. v. State Health Care Authority*, 152 P.3d 267 (Okla. Civ. App., Div. 2, 2006).

The term “medically necessary” is not defined by the State of Alaska’s Medicaid regulations governing visual care services. See 7 AAC 43.630 - 7 AAC 43.656. Likewise, the state Medicaid regulations do not provide a generally applicable definition of “medically necessary.” See 7 AAC 43.1990 and 7 AAC 100.990. Further, research indicates that although the term “medically necessary” is used in 42 different regulations within the Alaska Administrative Code, the term is not defined except in a few limited contexts not directly applicable here. Similarly, the Alaska Statutes do not provide an applicable definition of when a treatment is “medically necessary.” Finally, although the term “medically necessary” has to date been used in 12 Alaska Supreme Court opinions, none of those decisions provide any definition of the term.

State of Alaska Medicaid regulation 7 AAC 43.860(p), a definitional provision within the Medicaid regulations pertaining to Rural Health Clinic Services, provides the most closely applicable definition of “medically necessary.” That regulation states in relevant part as follows:

(p) In this section . . . (2) “medically necessary and appropriate” means

(A) reasonably calculated to diagnose, correct, cure, alleviate, or prevent the worsening of medical conditions that endanger life, cause suffering or pain, result in illness or infirmity, threaten to cause or aggravate a disability, or cause physical deformity or malfunction . . .

The United States Supreme Court has, in Medicaid abortion cases, defined “medically necessary” more broadly as constituting a professional judgment made by a physician considering the physical, emotional, psychological, and familial factors relevant to the well-being of the patient. See *Doe v. Bolton*, 410 U.S. 179, 93 S.Ct. 739, 35 L.Ed.2d 201 (1973); *Beal v. Doe*, 432 U.S. 438, 444, 97 S.Ct. 2366, 2371, 53 L.Ed.2d 464 (1977).

In the absence of a directly applicable regulation defining “medically necessary,” it is appropriate to apply the definitions stated by the United States Supreme Court and in State of Alaska Medicaid regulation 7 AAC 43.860(p), both discussed above. All that remains is to apply these definitions to the facts of this case.

B. The Record Shows Tinted Lenses Are Medically Necessary.

As discussed above, the Division's position in this case was based on the language of the *Alaska Medicaid Provider Billing Manual*. That provision bases the availability of tinted lenses on whether a person is an albino rather than whether the tinted lenses are medically necessary. Accordingly, the Division did not take a position on whether tinted lenses are medically necessary for the Claimant.

The Claimant clearly asserted that tinted lenses are a medical necessity for him. See Findings of Fact at Paragraph 1. However, the most persuasive evidence of medical necessity in the record is found in the physician's certification in the Division's *Prior Authorization Request Form* (Ex. E1). That certification states in relevant part that, "to the best of my knowledge . . . the requested services [i.e. tinted lenses] *are medically indicated and necessary for the health of the patient.*" [emphasis added].

The doctor's certification in Exhibit E1, although brief, clearly shows that tinted lenses are medically necessary for the Claimant's health and well-being based on the definitions of medical necessity found in the applicable case law and in State of Alaska Medicaid regulation 7 AAC 43.860(p) (both discussed in subsection A, above). Accordingly, the Claimant satisfied his burden and proved, by a preponderance of the evidence, that tinted lenses are "medically necessary" for him pursuant to State of Alaska Medicaid regulation 7 AAC 43.645(a). The Division was therefore not correct when it denied the Claimant's request that Medicaid provide him with tinted eyeglass lenses.

CONCLUSIONS OF LAW

1. The Division's *Alaska Medicaid Provider Billing Manual*, which authorizes tinted eyeglass lenses only for persons who are albinos, is not a regulation but rather is the Division's interpretation of its regulations.
2. The pertinent vision care regulation, State of Alaska Medicaid regulation 7 AAC 43.645(a), authorizes tinted eyeglass lenses as long as they are found to be "medically necessary." Therefore, the regulation does not limit the availability of tinted lenses to albinos.
3. That portion of the Division's *Alaska Medicaid Provider Billing Manual* concerning vision services was not promulgated pursuant to the standards required by the Alaska Administrative Procedures Act (AAPA). Accordingly, the *Manual* does not have the same legal force or authority as does State of Alaska Medicaid regulation 7 AAC 43.645(a).
4. The Division's interpretation of its regulation, as limiting tinted lenses to albinos, is plainly erroneous and inconsistent with the plain text of State of Alaska Medicaid regulation 7 AAC 43.645(a). Accordingly, the Division's interpretation of this regulation, as limiting the availability of tinted lenses to cases of albinism, fails the "reasonable basis" test as set forth in the Alaska Supreme Court decision *Lauth v. State*, 12 P.3d 181, 184 (Alaska 2000), and does not require deference.
5. The Claimant satisfied his burden and proved, by a preponderance of the evidence, that tinted lenses are "medically necessary" for him pursuant to State of Alaska Medicaid regulation 7

AAC 43.645(a). The Division was therefore not correct when, on October 16, 2009, it denied the Claimant's request that Medicaid pay for tinted eyeglass lenses.

DECISION

The Division erred when, on October 16, 2009, it denied the Claimant's September 15, 2009 request for prior authorization of Medicaid coverage for tinted eyeglass lenses.

APPEAL RIGHTS

If for any reason the Claimant is not satisfied with this decision, the Claimant has the right to appeal by requesting a review by the Director. To do this, send a written request directly to:

Director, Division of Health Care Services
Department of Health and Social Services
4501 Business Park Boulevard, Suite 24
Anchorage, Alaska 99503-7167

If the Claimant appeals, the request must be sent within 15 days from the date of receipt of this Decision. Filing an appeal with the Director could result in the reversal of this Decision.

DATED this 10th day of February, 2010.

Jay Durych
Hearing Authority

CERTIFICATE OF SERVICE

I certify that on this 10th day of February 2010 true and correct copies of the foregoing document were sent to the Claimant via USPS certified mail, and to the remainder of the service list by e-mail, as follows:

Claimant - via USPS Certified Mail, Return Receipt Requested
[REDACTED], Fair Hearing Representative

[REDACTED], Deputy Commissioner, DHSS
[REDACTED], Director, DHCS
[REDACTED], Policy & Program Development
[REDACTED], Policy & Program Development
[REDACTED], Staff Development & Training

J. Albert Levitre, Jr.
Law Office Assistant I