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

In the Matter of:	)	
	)	
F F	)	OAH No. 12-0556-MDS
	)	HCS Case No.
	)	Medicaid ID No.

DECISION

I. Introduction

There were originally two issues in this case. The first issue involved the proper interpretation of Alaska's Medicaid regulations governing prescription drugs. The second issue involved the interplay between the Medicaid prescription drug program and the Medicaid Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) program.

During the post-hearing briefing in this case, however, the parties informed the administrative law judge that a third-party insurer had paid for the prescription drug for which the Division of Health Care Services (DHCS or Division) had declined preauthorization. Accordingly, there is now a threshold issue as to whether the third-party insurer's payment for the prescription medication at issue has rendered this case moot.

This decision concludes that the third-party insurer's payment renders this case moot. Accordingly, the legal issues originally raised by the parties, concerning Alaska's prescription drug regulations and the Medicaid EPSDT program, should await a future case in which a live controversy exists presenting an occasion for meaningful relief.

II. Facts

A. Mr. F' Medical Condition and use of Botox Injections

F F ("F") is a five year old boy who suffers from spastic quadriplegic cerebral palsy.[1] This condition causes F to have dystonia (muscle tightness and spasticity).[2] This dystonia has made perineal hygiene difficult and uncomfortable for both F and his caregivers.[3] This in turn puts F at risk for skin breakdown and infection.[4]

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1 Letter from Mary M. Netlow, M.D. dated April 17, 2012 (Ex. 1 p.1). F also has a neurodevelopmental disorder and static encephalopathy, among other medical problems (Ex. 3 p.1).

2 K F hearing testimony.

3 Letter from Mary M. Netlow, M.D. dated April 17, 2012 (Ex. 1 p.1); see also Ex. E2.

4 *Id*.

F has received regularly scheduled injections of Botulinum neurotoxin or "Botox" since he was three years old.[5] The injections are usually given every three to six months.[6] The initial medical goal of the Botox injections was to increase F's hip abduction to facilitate toileting and hygiene and to help stabilize the subluxation of his right hip.[7] According to F's mother, Botox has been very helpful to him.[8] Since receiving Botox injections F has less adductor tone, which has made his perineal care easier.[9] He is now also able to sit comfortably in a variety of chairs, benches, and swings, and to ride a modified bicycle.[10] Since receiving Botox injections in March 2012 F has been able to stand with both feet on the ground, supporting his own body weight, for the first time.[11]

Roderic Smith, M.D. has reported that "Botox has clearly been helpful" to F's dystonia and that "his lower extremities have shown a great deal of benefit."[12] F's physical therapist has stated that "the Botox injections have demonstrated their effectiveness in ameliorating the effects of spasticity and dystonia in F's lower extremities."[13] This in turn has improved his ability to sit, stand, and participate in activities of daily living.[14] F's treating physician has flatly stated that, in her medical opinion, there is "no other option available to adequately treat F's spasticity."[15]

Linda Knott is a registered nurse who has worked with F since he was about two years old.[16] She testified at hearing that several articles published in respected medical periodicals endorse the "off-label" use of Botox for conditions like F's dystonia.[17]

Medicaid has not previously covered Botox injections for F.[18] Until recently F received his Botox injections at the Shriners Hospital; the Shriners originally covered the cost of the injections in-house, but in the last two years the hospital has begun billing its patients' insurance in an effort to

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5 Letter from Naomi Gravdal, P.T. dated April 6, 2012 (Ex. 4 p.1); Ex. 5, p.2.
6 K F hearing testimony at 24:10 - 24:15.
7 Letter from Naomi Gravdal, P.T. dated April 6, 2012 (Ex. 4 p.1).
8 K F hearing testimony.
9 Letter from Mary M. Netlow, M.D. dated April 17, 2012 (Ex. 1 p.1); see also Ex. E2.
10 Letter from Naomi Gravdal, P.T. dated April 6, 2012 (Ex. 4 p.1).
11 *Id.*
12 Ex. 2 p.1.
13 Letter from Naomi Gravdal, P.T. dated April 6, 2012 (Ex. 4 p.1).
14 Letter from Naomi Gravdal, P.T. dated April 6, 2012 (Ex. 4 p.1).
15 Letter from Mary M. Netlow, M.D. dated April 17, 2012 (Ex. 1 p.1).
16 Linda Knott hearing testimony.
17 *Id.*
18 K F hearing testimony at 31:50 - 32:30.

defray the expense.[19] As of the date of hearing, F's mother did not know of any health insurance carrier covering Botox injections.[20]

B. The FDA's and the Division's Position on Botox Injections

Since 1962, the U.S. Food and Drug Administration (FDA) has required that all new drugs have an approved use or application as a prerequisite to their continued marketing in the United States.[21] The FDA itself acknowledges, however, that "[g]ood medical practice and the best interests of the patient require that physicians use legally available drugs, biologics and devices according to their best knowledge and judgment," and that this duty may require that "physicians use a product for an indication not in the [FDA's] approved labeling . . . ."[22] When a physician prescribes medication to treat a condition before that use has been approved by the FDA, that use is called "off-label" use.[23] Off-label drug use is common, and the off-label use of a drug sometimes becomes the predominant treatment for a condition.[24]

The FDA has approved Botox injections for a number of indications or uses.[25] However, the uses for Botox thus far approved by the FDA do not include the use of Botox to treat lower limb spasticity in children,[26] which is the use for which F requires Botox injections.

The Division's Drug Utilization Review Committee (DURC) authorizes Alaska Medicaid to pay for Botox injections for certain specific uses which the DURC considers to be "safe and effective" uses.[27] DURC generally considers a medication to be "safe and effective" in a particular use only when the medication has first been approved by the FDA for that particular use.[28] It thus follows that DURC generally considers the "off-label" use of any medication *not to be* "safe and effective."

As discussed above, the uses for which FDA has authorized Botox injections do not include the use of Botox to treat lower limb spasticity in children. Accordingly, DURC (and thus the

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19 *Id.*

20 K F hearing testimony at 41:40 - 42:05.

21 *See* FDA website at http://www.fda.gov/AboutFDA/Transparency/Basics/ucm213030.htm (date accessed November 14, 2012).

22 *See* FDA website at http://www.fda.gov/RegulatoryInformation/Guidances/ucm126486.htm (date accessed November 14, 2012).

23 *E.g.,* Chad Hope hearing testimony (a medication is used "off-label" when the medication is prescribed by a physician for a use for which the FDA has not approved the medication).

24 *Id.*

25 Ex. F.

26 Ex. F.

27 Exs. E4, E5, Chad Hope hearing testimony. Prior authorization is required even for approved uses (Ex. E8).

28 Chad Hope hearing testimony.

Division) does not consider the use of Botox to treat lower limb spasticity in children to be a "safe and effective" use of that medication.[29]

C. Relevant Procedural History

On February 3, 2012 F received a Botox injection at Providence Alaska Medical Center.[30] On February 13, 2012 F's treating physician, Mary M. Netlow, M.D., submitted a prior authorization request[31] for this Botox injection to Alaska Medicaid.[32] Alaska Medicaid responded to Dr. Netlow that her request was denied because "request is for diagnosis of lower limb spasticity which is not covered by Medicaid and note that [F] is less than 12 years old," and because "Botox is not covered for ages less than 12 years old."[33] On February 21, 2012 Alaska Medicaid notified F's parents that the Botox prior authorization request had been denied, stating:[34]

> Botox injections require a prior authorization. The information submitted [by] your provider was insufficient to establish medical necessity for prior authorization as established under 7 AAC 120.130.

Although Alaska Medicaid denied prior authorization, F's parents proceeded to obtain Botox injections for F later in February 2012,[35] but payment for these later injections is not at issue in this case. On March 23, 2012 K F requested a hearing on behalf of her son with respect to the February 21 denial.[36] On June 22, 2012 the Division, in response to a letter from F's attorney, issued a supplemental denial letter. That letter stated in relevant part as follows:[37]

> [Alaska Medicaid] denies Botox injections for [F] under the Early and Periodic Screening, Diagnosis and Treatment (EPSDT) program as the service has not been found to be medically necessary - 7 AAC 105.100(5), 7 AAC 110.200(2); the FDA has not found the service to be safe and effective, and Botox injections for the treatment of lower limb spasticity in pediatric patients is not generally employed by the medical profession - 7 AAC 120.130(a)(f).

F's hearing was held on June 28, 2012. F did not attend but was represented by Leslie Jaehning of the Disability Law Center of Alaska. K F, N N, and Linda Knott participated in the hearing by telephone and testified on F's behalf. Kimberly Allen of the Attorney General's Office

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29 Exs. E4, E5, Chad Hope hearing testimony.

30 *See* Tricare Claim Summary dated June 23, 2012, submitted as an attachment to the parties' Request for Leave to File Additional Information and Extension of Time to File Responsive Briefs dated August 15, 2012.

31 Because the "prior authorization request" was actually submitted ten days *after* the Botox injections were provided, this case appears to involve questions of retroactive Medicaid eligibility under 7 AAC 100.072. However, the parties have not raised this as an issue.

32 Exs. E1, E3. As used in this decision, "Alaska Medicaid" includes the Division and its private contractors.

33 Ex. E14.

34 Ex. D1.

35 K F hearing testimony at 25:35 - 25:45.

36 Ex. C1.

37 Ex. 6-1.

attended the hearing and represented the Division. Chad Hope and Jeri Powers of DHCS attended the hearing and testified on behalf of the Division. Post-hearing briefing was completed on August 20, 2012, at which time the record closed.

On August 15, 2012 the parties informed this Office that, just the day before, F's counsel had received a claim summary from F's father's health insurance company (Tricare). The claim summary showed that Tricare had allowed coverage for the Botox injections which F received at Providence Alaska Medical Center (PAMC) on February 3, 2012.[38] Strangely, the claim summary indicates that PAMC did not actually *charge* for the February 2012 Botox injections.[39] However, the claim summary shows that Tricare paid PAMC $968.40 towards the "claim".[40] The claim summary states that Tricare had "mandated payment level reduction because required preauthorization was not obtained."[41] However, the claim summary clearly shows the F' portion of the charges as being zero.[42]

III. Discussion

The merits of this case, if reached, involve legal issues concerning the interaction between the Medicaid prescription drug program and the Medicaid Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) program. These are clearly significant legal issues.

However, it is a fundamental legal principle that adjudicative bodies should ordinarily refrain from deciding a question where the facts have rendered the legal issues moot.[43] A prime concern in determining questions of mootness is whether the relief requested is still effectively available.[44] Stated another way, the central question of all mootness problems is whether changes in the circumstances that prevailed at the beginning of the case "have forestalled any occasion for meaningful relief."[45] The Alaska Supreme Court has stated that an issue is moot if it has lost its character as a present, live controversy,[46] or if the claimants would not be entitled to relief even were they to prevail.[47] Mootness is a question of law.[48]

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38 *See* Tricare Claim Summary dated June 23, 2012, submitted as an attachment to the parties' Request for Leave to File Additional Information and Extension of Time to File Responsive Briefs dated August 15, 2012.

39 *Id.*

40 *Id.*

41 *Id.*

42 *Id.*

43 *Akpik v. State, Office of Management & Budget*, 115 P.3d 532, 535 (Alaska 2005); *see also Vanek v. State, Bd. of Fisheries*, 193 P.3d 283, 287 (Alaska 2008).

44 *FireFighters Local 1590 v. City of Wilmington*, 824 F.2d 262, 265 (3d Cir.1987).

45 *Jersey Central Power & Light Co. v. New Jersey*, 772 F.2d 35, 39 (3d Cir.1985).

46 *Id.*

47 *O'Callaghan v. State*, 920 P.2d 1387, 1388 (Alaska 1996).

In this case it is apparent that, at a minimum, Tricare has paid the vast majority of the charges for the February 2012 Botox injections at issue. The statement provided indicates that the amount of Tricare's payment was reduced (by an unknown amount) because the F family did not obtain prior authorization for the injections from Tricare.[49] However, the bill also states that no further monies are owed by the F family for the treatment.[50]

In summary, the evidence in the record indicates that there is a *small* chance that some small portion of the original charges for the Botox injections *could* still be owed. However, the preponderance of the evidence[51] indicates that the F family has no further liability for the charges at issue.[52]

In resisting the claim of mootness, F's counsel has relied on 42 U.S.C. § 1396a(25)(E), which provides that, with respect to certain "preventive pediatric care (including early and periodic screening and diagnosis services under section 1396d(a)(4)(B) of this title," Medicaid is to make payment without regard to third-party liability and then seek reimbursement from the third party. This argument fails for two reasons. First, the Botox injections are not "screening and diagnosis services under section 1396d(a)(4)(B)," but rather "treatment" services under that provision. Second, § 1396a(25)(E) does not mandate that Medicaid pay claims that have *already been paid* by a third party; the provision addresses only the situation where there is an outstanding, unpaid claim, requiring Medicaid to pay it rather than insist that the third party be approached first.

There *is* a "public interest" exception to the mootness doctrine. In *In re Tracy C.*, 249 P.3d 1085, 1090 (Alaska 2011), the Alaska Supreme Court stated that it would "consider the merits of a claim that would otherwise be moot if the claim falls within the public interest exception to the mootness doctrine." *Id.* "Whether the public interest exception applies depends on three factors: (1) whether the disputed issues are capable of repetition, (2) whether the mootness doctrine, if applied, may cause review of the issues to be repeatedly circumvented, and (3) whether the issues presented are so important to the public interest as to justify overriding the mootness doctrine." [Internal

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48 *Akpik*, 115 P.3d at 534.

49 *See* Tricare Claim Summary dated June 23, 2012, submitted as an attachment to the parties' Request for Leave to File Additional Information and Extension of Time to File Responsive Briefs dated August 15, 2012.

50 *Id.*

51 Preponderance of the evidence is the normal standard of proof in an administrative proceeding. *Amerada Hess Pipeline Corp. v. Alaska Pub. Util. Comm'n*, 711 P.2d 1170, 1179 n.14 (Alaska 1986). A preponderance of the evidence is "[e]vidence which is of greater weight or more convincing than the evidence which is offered in opposition to it; that is, evidence which as a whole shows that the fact sought to be proved is more probable than not." Black's Law Dictionary 1064 (5th Ed. 1979).

52 "[M]ootness is fundamentally a matter of degree; there is no precise test for ascertaining with precision whether a particular claim has become moot." *International Brotherhood of Boilermakers v. Kelly*, 815 F.2d 912, 915 (3d Cir.1987).

quotation marks and footnotes omitted]. In this case, the first and third factors are arguably met. However, the second factor is not satisfied here because the substantive issues raised in this case will necessarily be decided in any future Botox injection case in which the claimant has no health insurance (other than Medicaid). That is the situation which exists in the vast majority of Medicaid cases. Accordingly, the public interest exception to the mootness doctrine does not apply in this case.

IV. Conclusion

Tricare's recent payment of the charges for the Botox injections at issue, for which F originally sought coverage from Medicaid, has rendered this case moot. The Division's denial of prior authorization for the Botox injections at issue is neither affirmed nor reversed. The case is dismissed as moot.

Dated this 19th day of November, 2012.

Signed
Jay Durych
Administrative Law Judge

Adoption

The undersigned, by delegation from of the Commissioner of Health and Social Services, 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 28th day of November, 2012.

By: *Signed*
Name: Jay D. Durych
Title: Administrative Law Judge

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