AHCCCS

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ARIZONA HEALTH CARE COST CONTAINMENT SYSTEM

Janet Napolitano, Governor

Anthony D. Rodgers, Director

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BEFORE THE DIRECTOR OF
THE ARIZONA HEALTH CARE COST CONTAINMENT SYSTEM

v. Mercy Care Plan	**DIRECTOR'S DECISION**
In Re:	

PURSUANT TO the authority granted to me by A.R.S. §§ 41-1092.08(B) and 36-2903.01(B)(4), and in consideration of the record in the above matter, I hereby make the following Decision and Order:

IT IS ORDERED that the attached Administrative Law Judge Decision dated October 13, 2005, by the Office of Administrative Hearings Administrative Law Judge in this matter is modified as follows: Enumerated paragraph two (2) of the conclusions of law is hereby stricken in its entirety and not adopted as part of this Decision to the extent it concludes that AHCCCS Policy 310 is invalid or in conflict with statute and/or rule, and the last four (4) sentences of paragraph three (3) of the conclusions of law are hereby stricken in their entirety and are not adopted as part of this Decision.[1] The Administrative Law Judge Decision is otherwise accepted.[2]

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[1] Again, these portions of paragraph 3 are stricken to the extent they conclude that AHCCCS Policy 310 is invalid or in conflict with statute and/or rule. In addition, the mere fact that Complainant is in the last stage of liver disease and there is no other treatment which will prolong her life does not establish the medical necessity of the requested liver transplant, as concluded by the Administrative Law Judge. Furthermore, it is incorrect to state that there is no evidence supporting the truth of the evidentiary justification behind AHCCCS Policy 310, or that such

IT IS FURTHER ORDERED that this appeal is sustained.

1. This appeal by Complainant challenges the determination by Respondent Mercy Care Plan ("MCP") to deny Complainant's request for authorization for the provision of a liver transplant.

2. Complainant is a forty nine (49) year old female who has been diagnosed with hepatitis C and cirrhosis of the liver, which has been described as "end stage liver disease.". Complainant is also HIV positive.

3. At all times relevant, Complainant has been Arizona Health Care Cost Containment System ("AHCCCS") eligible and enrolled with Respondent MCP. Accordingly, a request was submitted to MCP seeking authorization for the provision of a liver transplant for Complainant due to Complainant's hepatitis C and cirrhosis of the liver. However, MCP denied the requested authorization on the basis that Complainant is HIV positive and pursuant to the AHCCCS Medical Policy Manual ("AMPM"), being HIV positive is a contraindication to a liver transplant. This appeal by Complainant challenges that denial of authorization by MCP.

4. Policy 310 of the AMPM sets forth a general heading as follows: "General overall contraindications to solid organ and tissue transplantation include, but are not limited to:". Listed thereunder are several contraindications; one such contraindication states simply "HIV positive." "Contraindication" is defined as a "symptom, indication, or condition in which a remedy or a method of treatment is inadvisable or

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justification applies to HIV conditions today; liver transplants for individuals who are HIV positive are successful only to the extent the HIV is controlled, as stated by Dr. Martin, and there are numerous reasons and conditions under which an individual's HIV status may not be controlled.

[2] However, although the Administrative Law Judge Decision may correctly set forth what is identified as the testimony of a witness, this Director's Decision does not necessarily adopt the substance of that testimony as a correct recitation of the facts or law.

improper." Blakiston's Gould Medical Dictionary, Fourth Edition. See also Dorland's Illustrated Medical Dictionary, 29th Edition (wherein "contraindication" is defined as "any condition, especially any condition of disease, which renders some particular line of treatment improper or undesirable.")

5. At hearing, Complainant presented testimony from four (4) medical experts. Dr. Dean Martin, a family physician specializing in HIV medicine, testified that HIV treatment and drugs have become more effective since 1996, and that transplant surgery has become more efficacious in light of improved HIV treatment. Dr. Martin testified that based on recent tests and Complainant's condition, Complainant meets transplant criteria in the context of being HIV positive. Dr. Janet Reiser, gastroenterologist and hepatologist, and Dr. Peter Stock, a transplant surgeon and professor of surgery at the University of California-San Francisco, as well as Dr. Martin, testified that current results show that the outcomes of liver transplants for HIV and non-HIV patients are essentially the same, provided the patient's HIV is controlled. Dr. Reiser further testified that a liver transplant will not aggravate Complainant's HIV condition.

6. In order to be a covered service, the service must be medically necessary and cost effective. A.A.C. R9-22-201. "Medically necessary" is defined at A.A.C. R9-22-101 as a covered service provided by a physician or other licensed practitioner of the healing arts and within the scope of practice under state law to prevent disease, disability, and other adverse health conditions or their progression, or to prolong life.

7. The medical information that Complainant had admitted into evidence at the hearing as well as the testimony Complainant presented from medical experts outweighs the limited evidence presented by MCP at hearing. Pursuant to A.R.S. §41-1092.07(F)(6), "[f]indings of fact shall be based exclusively on the evidence and on matters officially noticed." A review of

the record in this matter shows that MCP based its denial of authorization solely on the basis of AHCCCS Policy 310. However, MCP presented no specific evidence to explain the rationale or basis for AHCCCS Policy 310. Although MCP's Medical Director testified that he believed AHCCCS Policy 310 was based on the advice of Cyrca, an AHCCCS consultant, MCP presented no evidence as to the basis for Cyrca's advice. Similarly, although MCP's Medical Director testified that the AHCCCS Policy 310 was based in part on liver transplants for HIV positive individuals being considered experimental, MCP did not present any evidence to support a finding that such transplants are experimental; MCP's Medical Director simply testified that the number of liver transplants in HIV positive individuals in the studies referenced and/or presented into evidence by Complainant was too small to conclude that liver transplants in HIV positive individuals had the same success and survival rate as liver transplants in non HIV positive individuals. However, MCP's Medical Director could not state what number would be sufficient. The testimony of MCP'S Medical Director was conclusory and often mere conjecture, and was insufficient to rebut the testimony and evidence presented by Complainant. Based on the evidence submitted at hearing, Complainant has established that the requested transplant is medically necessary and is not experimental[3]; however, this conclusion is limited solely to the facts of this case and the evidence presented by the parties in this case.

8. Complainant has therefore met her burden of proof of showing, by a preponderance of the evidence, that the requested liver transplant is medically necessary, and that MCP violated statute, regulation

[3] Mercy Care Plan did not rely on the argument that a liver transplant for HIV-positive individuals is experimental in either its original denial of Complainant's request for authorization or in its July 8, 2005, letter denying Complainant's appeal. Furthermore, the Notice of Hearing for AHCCCS-Related Matters identifies the issues to be resolved at hearing as whether the liver transplant is medically necessary. It is therefore improper for Mercy Care Plan to raise this as an issue at hearing, in any event.

and/or general legal principle by denying Complainant's request for authorization for the provision of a liver transplant.

9. This appeal by Complainant is therefore sustained, and MCP is ordered to authorize the provision of an evaluation at an appropriate transplant center to determine whether Complainant is a viable candidate for a liver transplant and, if Complainant is determined to be a viable candidate for such a transplant, to authorize the provision of the requested liver transplant for Complainant.

10. It should be noted, parenthetically, that AHCCCS Policy 310 is not improper or in conflict with applicable statute and/or regulation. The mere fact the HIV positive status is identified as a contraindication to a transplant does not equate to HIV positive status as being a complete bar to a transplant. A contraindication simply requires further analysis to determine whether a transplant is advisable under the circumstances, such as whether the HIV infection is controlled and the individual has no complications from the infection.

If you disagree with this decision, you may ask the Administration to reconsider its decision or you can appeal to the Superior Court. If you choose to file a Motion for Rehearing or Review, it must be in writing and must describe one of the causes for rehearing or review mentioned in the attachment. See Arizona Administrative Code R9-34-223. Pursuant to A.R.S. § 41-1092.09, a Motion for Rehearing or Review may be filed with the AHCCCS Administration no later than thirty (30) days after service of this Director's Decision. A Motion for Rehearing or Review is not required in order to exhaust administrative remedies; you may choose to appeal directly to court. If you choose to appeal directly to court, you must commence a legal action in Superior court in accordance with the provisions of A.R.S. §§ 12-901 through 12-914, and you must do so within

thirty-five (35) days after the personal delivery or mailing of this decision.

Todd J. Jensen

Administrative Hearing
Decision Administrator

Director's Designee

Original sent by certified mail
this 25 day of October, 2005, to:

Srinivasan Varadarajan
Community Legal Services
305 South 2nd Avenue
Phoenix, Arizona 85036-1538

Copy mailed this 25 day of October 2005, to:

Michelle Alcoba
Appeals Specialist
Mercy Care Plan
2800 North Central Avenue, Suite 400
Phoenix, Arizona 85004-1036

By Gloria Hamilton

Copy hand delivered this 25 day of October, 2005, to:

Cliff J. Vanell, Director
Office of Administrative Hearings
1400 West Washington, Suite 101
Phoenix, Arizona 85007

PB/TJJ/tjj
GRIV-DEC.DOC

ATTACHMENT TO DIRECTOR'S DECISION

A rehearing or review may be granted only if you can establish one of the following causes:

1. Irregularity in the proceedings of the hearing that deprived you of a fair hearing;

2. Misconduct of a party or an agency;

3. Newly discovered material evidence, that could not, with reasonable diligence, have been discovered and produced at the hearing;

4. That the Director's Decision is the result of passion or prejudice;

5. That the Director's Decision is not justified by the evidence or is contrary to law; or,

6. Good cause is established for the nonappearance of a party at the hearing.

Please note: If you choose to file a Motion for Rehearing or Review you have thirty (30) days to do so. The thirty (30) days start five (5) days after the postmark date of the Director's Decision if the Decision is mailed to you. Also, the Motion for Rehearing or Review must be received by the AHCCCS Administration by the thirtieth (30th) day; if your Motion for Rehearing or Review is mailed or postmarked on or before the thirtieth (30th) day, but not received by AHCCCS until after the thirtieth (30th) day, it will be considered untimely and will be denied. If you do file a Motion for Rehearing or Review, you should mail a copy of your Motion to all other parties.

IN THE OFFICE OF ADMINISTRATIVE HEARINGS

IN RE: Complainant, vs. MERCY CARE PLAN, Respondent.	**ADMINISTRATIVE LAW JUDGE DECISION**

HEARING: September 30, 2005

APPEARANCES: Srinivasan Varadarajan, Esq. appeared for the Complainant Molly Greenwade, Representative, appeared for the Respondent.

ADMINISTRATIVE LAW JUDGE: Allen Reed

The hearing of this matter concluded on September 30, 2005. The Complainant submitted extensive documentation supporting its position shortly prior to hearing.[1] Although the hearing record closed on September 30, 2005, the Respondent was given a week to review said documentation and submit a response by October 7, 2005. Absent such a response, the record would remain closed.

The Respondent did not submit a response to the Complainant's pre-hearing documentation.

Findings of Fact

1. The Complainant is a 49 year old female. She is Arizona Health Care Cost Containment System (AHCCCS) eligible.
2. The Respondent is the Complainant's AHCCCS assigned insurer.

[1] This evidence has been reviewed and is a part of this record. It is not specifically relied upon in light of the testimony which was presented at the hearing. The review of the documentary evidence submitted prior to hearing, showed that it supports the Complainant's case and adds greater weight to the final recommended decision.

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3. The Complainant is infected with the human immunodeficiency virus (HIV), has hepatitis C and cirrhosis of the liver.
4. The Complainant has "end stage liver disease"[2].
5. The Complainant requested a liver transplant.
6. The Respondent denied the request under AHCCCS Policy 310[3] which provides that "General contraindications ((inadvisability) to solid organ and tissue transplantation include...4. HIV positive".
7. Liver transplants can be done using living donors who provide a lobe for the recipient. Both the donor's liver and the recipient's liver will regenerate and provide full functionality.
8. Janet Reiser M.D., gastroenterologist and hepatologist, testified that current results of liver transplants for HIV and non HIV patients are essentially the same. According to Dr. Reiser, the Policy 310 contraindication is 15 years out of date and a liver transplant will not aggravate the HIV condition. Dr. Reiser has seen the Complainant several times, reviewed her records and evaluated her condition.
9. Dean Martin M.D., a family physician specializing in HIV medicine, testified that HIV treatment and drugs have become more effective since 1996, and that transplant surgery has become more efficacious in light of improved HIV treatment. According to Dr. Martin, liver transplants for HIV patients have been done since 1999 and early survival appears the same for non HIV patients and HIV patients with hepatitis C, as long as the HIV is controlled. Dr. Martin has had the Complainant as a patient since June of 2002. He testified that based on recent tests and the Complainant's condition, the Complainant meets transplant criteria in the context of being HIV positive.
10. Peter Stock M.D. is a transplant surgeon and a professor of surgery at the University of California-San Francisco. Dr. Stock testified that he has performed 400 to 500 liver transplants, 20 HIV liver transplants and eight HIV and hepatitis C liver transplant cases[4]. Of the eight, one death, a child was caused by hepatitis

[2] A possible life expectancy of 1 to 5 years with a potential for abrupt deterioration.
[3] Rev. June 1, 2005
[4] This includes 20 to 30 living donor transplants per year.

C. The hepatitis C virus returns in all transplant patients.[5] Dr. Stock testified HIV should no longer be considered as contraindicating a transplant. He has reviewed the Complainant's history and she appears to be good candidate for a liver transplant. Dr. Stock's 11 page Declaration reinforces his testimony.

11. Michelle Roland M.D. is an Associate Professor of Medicine and HIV/AIDS specialist. She testified that the liver transplant for an HIV patient is no longer an experimental procedure. Transplants for HIV patients were excluded in the early 1990's because there was a limited benefit[6]. This has changed with time and Dr. Roland cited a Spanish study for HIV/hepatitis C liver transplants which showed similar outcomes with non HIV transplants over the first three years.

12. The Respondent's medical director, Angelo Demis, M.D. and the Respondent's medical director[7], testified he believed AHCCCS Policy 310 was based on the advice of an AHCCCS consultant, Cyrca. Dr. Demis testified AHCCCS was not contemplating changing the policy. According to Dr. Demis the policy was in part based on the idea that the proposed liver transplant procedure for HIV patients, is experimental. Dr. Demis also testified that the number of HIV liver transplants referenced by the Complainant's witnesses (whether 8, 20 or 40) was too small to establish a valid conclusion that an HIV liver transplant has approximately the same success and survival rate as a non HIV liver transplant.

Conclusions of Law

The issue for hearing is "the requested liver transplant medically necessary".

A.R.S. §36-2909 (F) provides that the Director of AHCCCS or a contractor may deny payment for medical care which is not authorized or deemed medically necessary in accordance with rules adopted by the Director.

A.A.C. R22-9-101 defines "medically necessary" in pertinent part as a covered service provided by a physician or other licensed practitioner of the healing arts within the scope of practice under state law to prevent disease, disability, other adverse health conditions or their progression, or to prolong life.

[5] Hepatitis C is not one of the conditions cited as contraindicating transplants under policy 310.
[6] Based on the evidence, HIV treatment is significantly more effective today.
[7] Dr. Demis is an internist specializing in hematology and oncology.

A.A.C. R 9-28-201 provides in relevant part that covered services must be "medically necessary, cost effective and federally reimbursable".

A.A.C. R2-19-119 places the burden of proof on the party asserting the right, claim, or entitlement.

1. The evidence in this case is one sided. Four doctor-medical experts[8] testified that although the Complainant is HIV positive, this does not make a liver transplant less likely to be successful than if she did not have the condition[9].
2. In *Cochise County v. Arizona Health Care*, 170 Ariz. 443 (App. 1991) the Court stated:

> "The scope of an agency's power is measured by statute and may not be expanded by agency fiat."

Agency policy 310 advises against the transplant procedure for an HIV patient. Policy is not law, is not binding, and does not establish a mandatory requirement under the law. At best, it is directive. It is to be given consideration and deference but it cannot be contrary to the law as set forth by statute, or a rule which has the force and effect of law. Simply stated, if there is a conflict between a statute and rule on one hand and policy on the other, the statute and rule prevail[10].

3. The cited rule regarding the burden of proof and weight of the evidence is also controlling. It governs hearings before the Office of Administrative Hearings (OAH) as well as legal proceedings generally. It is clear that the evidence overwhelmingly favors the Complainant. The transplant procedure meets the definition of what is medically necessary because the Complainant is in the last stage of liver disease and there is no other treatment which will prolong her life. The only argument against the Complainant's evidence is a policy which provides the procedure is contraindicated for HIV positive patients. Although the policy may have had an

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[8] The Complainant's witnesses were not technically established as experts. However, A.R.S. §42-1092.07 (D) and (F)(1) do not require adherence to and application of the technical rules of evidence. The record establishes the expertise of the witnesses. Dr. Roland's Curriculum Vitae is over 17 pages and speaks for itself

[9] This presupposes the Complainant will continue to follow her HIV treatment regimen. The numerical data which is a matter of record, does not show a significant difference for HIV and non HIV transplants

[10] This is true even if the conflict is only between a rule and policy.

evidentiary justification in the 1990's[11], there is no evidence of record that such evidence is true or applies to HIV conditions today. An Administrative Law Judge is obligated to decide a case based on the most competent evidence.

4. The following recommendation is based on the facts as established by the most competent evidence, and the clear application of the law to those facts.

Recommended Order

It is recommended the decision denying the requested liver transplant be reversed.

Done this day, October 13, 2005.

Allen Reed
Administrative Law Judge

Original transmitted by mail this
14 day of October, 2005, to:

Anthony D. Rodgers, Director
Arizona Health Care Cost Containment System -19
Attn: Gloria Hamilton
701 East Jefferson
Phoenix, AZ 85034

By

[11] Aside from the evidence regarding the improved efficacy of HIV treatment, there was no specific evidence presented by the Respondent of the reasons for the origin of the policy. The Complainant's "Exhibits to Appellant's Position Statement –(A) " concludes cases should be individually evaluated presents a more detailed picture of the issue in the late 1990's. It may well be that when AHCCCS policies are at issue, obtaining an AHCCCS witness or joining AHCCCS as a party might be advisable in order to present evidence which explains the policy.