# APPENDIX B

Subject to the Nondisclosure Provisions of H. Res. 895 of the 110<sup>th</sup> Congress as Amended

## OFFICE OF CONGRESSIONAL ETHICS UNITED STATES HOUSE OF REPRESENTATIVES

### **REPORT**

Review No. 11-0243

The Board of the Office of Congressional Ethics (hereafter "the Board"), by a vote of no less than four members, on January 27, 2012, adopted the following report and ordered it to be transmitted to the Committee on Ethics of the United States House of Representatives.

SUBJECT: Representative Shelley Berkley

NATURE OF THE ALLEGED VIOLATION: Representative Shelley Berkley may have violated House rules and precedent regarding conflicts of interest by advocating for the University Medical Center of Southern Nevada ("UMC") kidney transplant program, in an effort to prevent the Centers for Medicare and Medicaid Services ("CMS") from terminating Medicare approval of that program for failing to meet CMS standards regarding patient survival. At the time Representative Berkley advocated for the UMC program, she had a financial interest in that program through her husband, a partner in Kidney Specialists of Southern Nevada, which held the contract to provide nephrology services to UMC.

If Representative Berkley advocated to CMS in order to keep the UMC kidney transplant program open while she had a financial interest in that program through her husband, she may have violated House Rule 23 and House precedent regarding conflicts of interest.

RECOMMENDATION: The Board recommends that the Committee further review the above allegation, as there is substantial reason to believe that Representative Berkley advocated to CMS in order to keep the UMC kidney transplant program open while she had a financial interest in that program through her husband, in violation of House Rule 23 and House precedent regarding conflicts of interest.

VOTES IN THE AFFIRMATIVE: 6

VOTES IN THE NEGATIVE: 0

ABSTENTIONS: 0

MEMBER OF THE BOARD OR STAFF DESIGNATED TO PRESENT THIS REPORT TO THE COMMITTEE ON ETHICS: Omar S. Ashmawy, Staff Director & Chief Counsel.

## FINDINGS OF FACT AND CITATIONS TO LAW

Review No. 11-0243

## **TABLE OF CONTENTS**

I.	INT	RODUCTION3
	A.	Summary of Allegations
	В.	Jurisdictional Statement
	C.	Procedural History
	D.	Summary of Investigative Activity
II.	TRA	PRESENTATIVE BERKLEY ADVOCATED FOR THE UMC KIDNEY ANSPLANT PROGRAM AT A TIME WHEN SHE HAD A FINANCIAL EREST IN THAT PROGRAM THROUGH HER HUSBAND6
	A.	Applicable Law, Rules, and Standards of Conduct
	В.	Representative Berkley Had a Financial Interest in the UMC Kidney Transplant Program Through Her Husband's Nephrology Practice
	C.	The Centers for Medicare and Medicaid Services Determined to Terminate Medicare Approval of the UMC Kidney Transplant Program
	D.	Representative Berkley Advocated for Continued Medicare Approval of the UMC Kidney Transplant Program
	E.	CMS Reached an Agreement with UMC to Withdraw Termination of the UMC Kidney Transplant Program
	F.	The Medical Practice of Representative Berkley's Husband Secured a New Contract to Provide Nephrology Services, including Transplant Nephrology, to UMC
	G.	Representative Berkley Recognized the Potential Conflict of Interest at the Time of Her Advocacy for the UMC Kidney Transplant Program
III.	CO	NCLUSION 18
IV.		ORMATION THE OCE WAS UNABLE TO OBTAIN AND COMMENDATIONS FOR THE ISSUANCE OF SUBPOENAS18

Subject to the Nondisclosure Provisions of H. Res. 895 of the 110<sup>th</sup> Congress as Amended

### OFFICE OF CONGRESSIONAL ETHICS UNITED STATES HOUSE OF REPRESENTATIVES

### **FINDINGS OF FACT AND CITATIONS TO LAW**

Review No. 11-0243

On January 27, 2012, the Board of the Office of Congressional Ethics (hereafter "the Board") adopted the following findings of fact and accompanying citations to law, regulations, rules and standards of conduct (in italics).

The Board notes that these findings do not constitute a determination of whether or not a violation actually occurred.

### I. INTRODUCTION

### A. Summary of Allegations

- Representative Shelley Berkley may have violated House rules and precedent regarding conflicts of interest by advocating for the University Medical Center of Southern Nevada ("UMC") kidney transplant program, in an effort to prevent the Centers for Medicare and Medicaid Services from terminating Medicare approval of that program. At the time Representative Berkley advocated for the UMC transplant program, she had a financial interest in that program through her husband, a partner in Kidney Specialists of Southern Nevada, which held the contract to provide nephrology services to UMC, including transplant nephrology services.
- 2. The OCE Board finds there is substantial reason to believe that Representative Berkley violated House Rule 23 and House precedent regarding conflicts of interest when advocating on behalf of the UMC transplant program while she had a financial interest in that program through her husband.

### **B.** Jurisdictional Statement

3. The allegations that were the subject of this review concern Representative Shelley Berkley, a Member of the United States House of Representatives from the 1st District of Nevada. The Resolution the United States House of Representatives adopted creating the Office of Congressional Ethics (hereafter "OCE") directs that, "[n]o review shall be undertaken ... by the board of any alleged violation that occurred before the date of adoption of this resolution." The House adopted this Resolution on March 11, 2008. Because the conduct under review occurred after March 11, 2008, review by the Board is in accordance with the Resolution.

<sup>&</sup>lt;sup>1</sup> H. Res 895, 110th Cong. §1(e) (2008) (as amended).

### C. Procedural History

- 4. The OCE received a written request for preliminary review in this matter signed by at least two members of the Board on September 28, 2011. The preliminary review commenced on September 29, 2011. The preliminary review was scheduled to end on October 28, 2011.
- 5. At least three members of the Board voted to initiate a second-phase review in this matter on October 28, 2011. The second-phase review commenced on October 29, 2011. The second-phase review was scheduled to end on December 12, 2011.
- 6. The Board voted to extend second-phase review for an additional period of fourteen days on December 2, 2011. The additional period ended on December 26, 2011.
- 7. Pursuant to Rule 9(B) of the OCE Rules for the Conduct of Investigations, Representative Berkley submitted a written statement to the Board on January 25, 2012.
- 8. The Board voted to refer the matter to the Committee on Ethics for further review and adopted these findings on January 27, 2012.
- 9. The report and its findings in this matter were transmitted to the Committee on Ethics on February 9, 2012.

## D. Summary of Investigative Activity

- 10. The OCE requested documentary and, in some cases, testimonial information from the following sources:
  - (1) Representative Shelley Berkley;
  - (2) Matthew Coffron, former Legislative Assistant for Representative Berkley;
  - (3) David Cherry, Communications Director for Representative Berkley;
  - (4) Kidney Specialists of Southern Nevada ("KSSN");
  - (5) Dr. Larry Lehrner, KSSN;
  - (6) Physician #1, KSSN;
  - (7) University Medical Center of Southern Nevada ("UMC");
  - (8) Former Chief Executive Officer, UMC;
  - (9) Current Chief Executive Officer and former Chief Operating Officer, UMC;

<sup>&</sup>lt;sup>2</sup> A preliminary review is "requested" in writing by members of the Board of the OCE. The request for a preliminary review is "received" by the OCE on a date certain. According to the Resolution, the timeframe for conducting a preliminary review is thirty days from the date of receipt of the Board's request.

<sup>&</sup>lt;sup>3</sup> According to the Resolution, the Board must vote on whether to conduct a second-phase review in a matter before the expiration of the thirty-day preliminary review. If the Board votes for a second-phase, the second-phase begins when the preliminary review ends. The second-phase review does not begin on the date of the Board vote.

Subject to the Nondisclosure Provisions of H. Res. 895 of the 110<sup>th</sup> Congress as Amended

- (10) Former Transplant Administrator, UMC;
- (11) Attorney #1, outside counsel to UMC;
- (12) Attorney #2, outside counsel to UMC;
- (13) Centers for Medicare and Medicaid Services ("CMS");
- (14) Former Acting Administrator, CMS;
- (15) Former Acting Director, Office of Legislation, CMS;
- (16) Health Insurance Specialist, Office of Legislation, CMS; and
- (17) Director, Survey and Certification Group, CMS.
- 11. While Representative Berkley and KSSN provided documents in response to Requests for Information, the following individuals declined to be interviewed by the OCE and were determined to be non-cooperating witnesses:
  - (1) Representative Shelley Berkley;<sup>4</sup>
  - (2) Matthew Coffron, former Legislative Assistant for Representative Berkley;
  - (3) David Cherry, Communications Director for Representative Berkley; and
  - (4) Dr. Larry Lehrner, KSSN.

<sup>&</sup>lt;sup>4</sup> In response to the OCE's interview requests, counsel for Representative Berkley, Mr. Coffron, and Mr. Cherry informed the OCE on December 9, 2011 that their clients required certain assurances before they would agree to be interviewed. First, counsel stated that the clients "would like to know the matters they will be asked to discuss, so that they can be confident that the questions will be limited to the allegation disclosed by OCE at the commencement of its review." Second, counsel stated that the clients "would like to understand precisely how OCE intends to memorialize and present their comments in any findings that are prepared for public release."

On December 12, 2011, the OCE responded to the concerns, first informing counsel that the interviews would relate to matters raised in the statement of the nature of the review and the request for information previously provided to Representative Berkley, but that the OCE reserves the authority to address additional, potential violations discovered during the review. Second, the OCE informed counsel that, as in all investigations, an OCE staff member prepares a Memorandum of Interview based on notes taken during an interview, in which all pertinent matters discussed with the witness are memorialized. These memoranda may be cited in findings of fact prepared by the OCE or transmitted to the Committee on Ethics with any written report in a matter under review.

In a December 15, 2011 letter to the OCE, counsel restated the concerns previously expressed, again objecting to the scope of the requested interviews as "beyond the sole allegation contained in the statement of the nature of the review provided to Representative Berkley," and again asking for assurance that their clients' statements would be "neither inaccurately nor sensationally described in any findings drafted for eventual public release."

On December 20, 2011, the OCE informed counsel that the scope of the requested interviews had not changed and reiterated its commitment to confidentiality and accuracy.

On December 23, 2011, three days before the end of the second-phase review period, after the OCE had twice addressed counsel's concerns, the OCE was informed that Representative Berkley, Mr. Coffron, and Mr. Cherry would continue to decline the OCE's requests for interviews.

Subject to the Nondisclosure Provisions of H. Res. 895 of the 110<sup>th</sup> Congress as Amended

## II. REPRESENTATIVE BERKLEY ADVOCATED FOR THE UMC KIDNEY TRANSPLANT PROGRAM AT A TIME WHEN SHE HAD A FINANCIAL INTEREST IN THAT PROGRAM THROUGH HER HUSBAND

### A. Applicable Law, Rules, and Standards of Conduct

### 12. House Rule 23 (Code of Conduct)

Under House Rule 23 clause 1, Members "shall behave at all times in a manner that shall reflect creditably on the House."

*Under House Rule 23 clause 2, Members "shall adhere to the spirit and the letter of the Rules of the House...."* 

Under House Rule 23 clause 3, Members "may not permit compensation to accrue to the beneficial interest of such individual from any source, the receipt of which would occur by virtue of influence improperly exerted from the position of such individual in Congress."

The House Ethics Manual advises that "[t]he rules and standards that prohibit the use of one's official position for personal gain . . . are fully applicable to Members and staff persons with regard to their spouse's employment. Specifically, a provision of the House Code of Official Conduct, prohibits a Member from receiving any compensation, or allowing any compensation to accrue to the Member's beneficial interest, from any source as a result of an improper exercise of official influence (House Rule 23, cl. 3)."

### 13. Conflict of Interest

The House Ethics Manual discusses at length the precedents guiding Members' actions on matters of personal interest. Quoting 673 of the Jefferson's Manual and Rules of the House of Representatives, the manual states, "It is a principle of 'immemorial observance' that a Member should withdraw when a question concerning himself arises; but it has been held that the disqualifying interest must be such as affects the Member directly, and not as one of a class."

Although the manual states that Rule III only applies to a Member voting on the House floor, it makes clear that contacting an executive branch agency entails "a degree of advocacy above and beyond that involved in voting." As such, the manual cautions that a "Member's decision on whether to take any such action on a matter that may affect his or her personal financial interest requires added circumspection." A Member who considerers advocating on a matter that may affect her "personal financial interests...should first contact the Standards Committee for guidance." \*\*

<sup>&</sup>lt;sup>5</sup> House Ethics Manual (2008) at 245 (emphasis in original).

<sup>6</sup> Id.at 234.

<sup>&</sup>lt;sup>7</sup> *Id.* at 237

<sup>&</sup>lt;sup>8</sup> *Id*.

## B. Representative Berkley Had a Financial Interest in the UMC Kidney Transplant Program Through Her Husband's Nephrology Practice

- 14. Dr. Lawrence Lehrner is a board certified nephrologist and the President of Bernstein, Pokroy and Lehrner, Ltd., a domestic professional corporation in Nevada, doing business as Kidney Specialists of Southern Nevada.<sup>9</sup>
- 15. KSSN is a nephrology practice established in Las Vegas in 1976, which now employs approximately nineteen physicians and thirty support staff in six offices across greater Las Vegas and Pahrump, Nevada. <sup>10</sup>
- 16. Dr. Lehrner and Representative Shelley Berkley married in March 1999. 11
- 17. Following a Request for Proposals ("RFP") process, on August 21, 2007, KSSN entered into a contract to provide nephrology services to UMC, a public hospital located in Las Vegas, Nevada. <sup>12</sup> The contract provided that KSSN would provide, among other things, transplant nephrology services for the UMC kidney transplant program. <sup>13</sup>
- 18. Under the contract with UMC, KSSN was paid \$50,000 per year to provide medical directorship services for the nephrology department, and \$538,200 per year to provide professional medical services to the hospital.<sup>14</sup>
- 19. The term of the contract ran from August 1, 2007 to July 31, 2010. 15

## C. <u>The Centers for Medicare and Medicaid Services Determined to Terminate Medicare Approval of the UMC Kidney Transplant Program</u>

20. On May 28, 2008, CMS informed UMC that its kidney transplant program was out of compliance with certain conditions of participation in the Medicare program, including failure to meet certain patient outcome requirements. <sup>16</sup> Specifically, CMS found that the rate of survival for patients receiving kidney transplants through the UMC program was lower than the expected rate of survival. <sup>17</sup> CMS informed UMC that it would terminate the program's Medicare approval if it did not correct the outcome-related deficiencies by

<sup>&</sup>lt;sup>9</sup> Biography of Dr. Lehrner, available at http://www.ksosn.com/ksosn-care-team/physicians/lawrence-lehrner-md (Exhibit 1 at 11-0243\_0002); Nevada Secretary of State Records (Exhibit 2 at 11-0243\_0004).

<sup>&</sup>lt;sup>10</sup> See http://www.ksosn.com/about-ksosn (Exhibit 3 at 11-0243 0009).

<sup>&</sup>lt;sup>11</sup> Biography of Rep. Shelley Berkley, available at http://berkley house.gov/about/biography.shtml (Exhibit 4 at 11-0243\_0011).

<sup>&</sup>lt;sup>12</sup> Agreement for Physician Medical Directorship of the Nephrology Department and Related Professional Services, August 12, 2007 (Exhibit 5 at 11-0243 0014-0030).

<sup>&</sup>lt;sup>13</sup> *Id.* at § 2.4(j).

<sup>&</sup>lt;sup>14</sup> *Id.* at §§ 5.2 & 5.3.

<sup>15</sup> *Id.* at § 6.1.

<sup>&</sup>lt;sup>16</sup> Letter from Operations Manager, CMS Western Consortium, to UMC Transplant Administrator, May 28, 2008 (Exhibit 6 at 11-0243\_0032). CMS identified both program deficiencies and outcome deficiencies in its notification letter to UMC. UMC had sufficiently addressed the program deficiencies by August 2008, but the outcome deficiencies persisted. *See* Memorandum of Interview of CMS Survey & Certification Group ("SCG") Director, November 15, 2011 (Exhibit 7 at 11-0243\_0037) (hereafter "CMS SCG Director MOI").

<sup>&</sup>lt;sup>17</sup> Letter from Operations Manager, CMS Western Consortium, to UMC Transplant Administrator, May 28, 2008 (Exhibit 6 at 11-0243\_0032); CMS SCG Director MOI (Exhibit 7 at 11-0243\_0037).

- October 13, 2008. According to public reporting, termination of the UMC program's Medicare approval would have led to the program's closure. 19
- 21. On August 6, 2008, CMS informed UMC that the kidney transplant program continued to be out of compliance with Medicare outcome requirements and outlined three options for the program: (1) voluntarily withdraw from Medicare participation; (2) request approval based on mitigating factors; or (3) take no action, which would result in involuntary termination from Medicare.<sup>20</sup>
- 22. On September 11, 2008, UMC submitted to CMS a request for approval based on mitigating factors. On September 29, 2008, CMS informed UMC via conference call that the request for approval based on mitigating factors had been denied, and that termination of Medicare approval of the kidney transplant program would proceed. UMC, through its attorneys, continued to negotiate with CMS in an attempt to avoid termination of the transplant program. <sup>23</sup>
- 23. To accommodate patient notification obligations, CMS extended the termination date to November 20, 2008.<sup>24</sup> At the request of UMC, the termination date was further extended to December 3, 2008, to allow UMC additional time to consider its options and to notify Medicare beneficiaries on the transplant waiting list.<sup>25</sup>

## D. Representative Berkley Advocated for Continued Medicare Approval of the UMC Kidney Transplant Program

24. At some point in October 2008, after CMS had denied UMC's request for approval based on mitigating factors, the hospital and its attorneys concluded that they could expect "no further movement" by CMS with regard to the termination decision. <sup>26</sup> UMC then

<sup>&</sup>lt;sup>18</sup> Letter from Operations Manager, CMS Western Consortium, to UMC Transplant Administrator, May 28, 2008 (Exhibit 6 at 11-0243\_0034).

<sup>&</sup>lt;sup>19</sup> Annette Wells, *UMC loses kidney program*, LAS VEGAS REVIEW-JOURNAL, October 25, 2008 (Exhibit 8 at 11-0243 0041).

<sup>&</sup>lt;sup>20</sup> Letter from Director, CMS Survey and Certification Group, to UMC Transplant Administrator, August 6, 2008 (Exhibit 9 at 11-2043\_0045-0046).

<sup>&</sup>lt;sup>21</sup> Letter from UMC Chief Executive Officer to CMS Survey and Certification Group, September 11, 2008 (Exhibit 10 at 11-0243 0048).

<sup>&</sup>lt;sup>22</sup> CMS SCG Director MOI (Exhibit 7 at 11-0243\_0037); CMS Timeline: University Medical Center of Southern Nevada; Kidney Transplant Program; Survey, Correspondence and Enforcement Action (undated) (Exhibit 11 at 11-0243\_0058).

<sup>&</sup>lt;sup>23</sup> Memorandum of Interview of UMC Attorney #1, December 7, 2011 (Exhibit 12 at 11-0243\_0060) (hereafter "UMC Attorney #1 MOI").

<sup>&</sup>lt;sup>24</sup> Letter from Operations Manager, CMS Western Consortium, to the UMC Transplant Administrator, October 16, 2008 (Exhibit 13 at 11-0243 0064).

<sup>&</sup>lt;sup>25</sup> Email from UMC Attorney #1 to Operations Manager, CMS Western Consortium, October 21, 2008 (Exhibit 14 at 11-0243\_0068-0069); letter from Operations Manager, CMS Western Consortium, to UMC Transplant Administrator, October 23, 2008 (Exhibit 15 at 11-0243\_0071).

<sup>&</sup>lt;sup>26</sup> Memorandum of Interview of former UMC Chief Executive Officer, December 8, 2011 (Exhibit 16 at 11-0243 0076) (hereafter "UMC CEO MOI").

Subject to the Nondisclosure Provisions of H. Res. 895 of the 110<sup>th</sup> Congress as Amended decided to contact Nevada's elected officials to seek assistance in persuading CMS to reconsider the termination decision.<sup>27</sup>

- 25. On or about October 22, 2008, the then-serving UMC Chief Executive Officer called Dr. Larry Lehrner, whom she knew from his ongoing relationship with the hospital, and explained that UMC had reached an impasse with CMS regarding its termination decision.<sup>28</sup> The CEO asked Dr. Lehrner if his wife, Representative Shelley Berkley, would be willing to speak with her about this issue.<sup>29</sup> Dr. Lehrner gave Representative Berkley's cell phone number to the CEO and told her that he would let his wife know that she would be calling.<sup>30</sup>
- 26. UMC's CEO spoke with Representative Berkley on or about October 22, 2008. 31 According to the CEO, Representative Berkley told her that she did not know what she could do about the CMS decision, but that she would make some inquiries.<sup>32</sup>
- 27. On October 22, 2008, attorneys representing UMC made initial contact with staff members of the Nevada congressional delegation to ask for assistance with CMS.<sup>33</sup> This included outreach to the staffs of Representatives Shelley Berkley, Jon Porter, and Dean Heller, as well as Senators Harry Reid and John Ensign.<sup>3</sup>
- 28. As part of this outreach to staff, one of the attorneys representing UMC sent an email to Matthew Coffron, then serving as a legislative assistant to Representative Berkley, with copies to Representative Berkley's legislative director and a law firm colleague. 35 In the email, the attorney provided background information about the CMS termination decision and asked for Representative Berkley's assistance in preventing the termination, <sup>36</sup>
- 29. A second UMC attorney sent Mr. Coffron an email later in the evening of October 22, 2008, apparently following up on a telephone call he had with Mr. Coffron earlier that day, in which he expressed appreciation for Representative Berkley's assistance.<sup>37</sup>

<sup>&</sup>lt;sup>27</sup> Id.

<sup>&</sup>lt;sup>28</sup> *Id*.

<sup>31</sup> Id.; see also email from UMC Chief Executive Officer to Rory J. Reid, October 22, 2008 ("I heard from Shelley Berkeley [sic] this morning and we have a call with her staff this afternoon...") (Exhibit 17 at 11-0243 0079). <sup>32</sup> UMC CEO MOI (Exhibit 16 at 11-0243\_0076).

<sup>33</sup> See. e.g., email from UMC Attorney #2 to Legislative Director for Rep. Jon Porter, October 22, 2008 (Exhibit 18 at 11-0243 0081-0082).

<sup>&</sup>lt;sup>34</sup> Memorandum of Interview of UMC Attorney #2, December 16, 2011 (Exhibit 19 at 11-0243 0085) (hereafter "UMC Attorney #2 MOI").

<sup>35</sup> Email from UMC Attorney #3 to Matthew Coffron, October 22, 2008 (Exhibit 20 at 11-0243 0089). The attorney who initially contacted Rep. Berkley's office was also the spouse of Representative Berkley's legislative director. See UMC Attorney #2 MOI (Exhibit 19 at 11-0243 0084-0085).

<sup>&</sup>lt;sup>36</sup> Email from UMC Attorney #3 to Matthew Coffron, October 22, 2008 (Exhibit 20 at 11-0243\_0089).

<sup>&</sup>lt;sup>37</sup> Email from UMC Attorney #2 to Matthew Coffron, October 22, 2008 (Exhibit 21 at 11-0243 0094).

30. On October 23, 2008, at 1:29 PM, Mr. Coffron emailed the UMC attorney an update regarding the actions Representative Berkley and her staff had already taken, and the actions that they intended to take, with respect to the CMS decision.<sup>38</sup>

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From: Coffron, Natthew [mailto: mail.house.gov]
Sent: Thursday, October 23, 2008 1:29 PM
To: Luband, Charles A.
Subject: RE: UMC Conference Call

Wello Charlie,

I spoke with the Congressweman this morning. She confirmed that she is happy to send a letter (which I am currently drafting) and would be open to doing something as a delegation in the future. She also mentioned having spoken with Senator Reid on this issue.

I also tried to call Ed Japitana at CMS to get some clarification on their position, but learned that he is cut this week.
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Flease keep me posted on the response you get from other offices if you can.

Thanks,

-Matt.

Matthew Coffron
Legislative Assistant
Office of Congresswoman Shelley Berkley
405 Cannon House Office Building
202-225-
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- 31. In addition to calling the CMS official identified in the email, Mr. Coffron may have made additional calls to other CMS officials.<sup>39</sup>
- 32. Shortly after Mr. Coffron sent the above email, Representative Porter's legislative director emailed Mr. Coffron and a legislative assistant for Representative Heller asking, "Hey you guys want to do a joint letter?"

<sup>39</sup> Email from UMC Attorney #2 to Matthew Coffron, October 23, 2008 (Exhibit 21 at 11-0243\_0093); UMC Attorney #2 MOI (Exhibit 19 at 11-0243\_0086-0087).

<sup>&</sup>lt;sup>38</sup> Email from Matthew Coffron to UMC Attorney #2, October 23, 2008 (Exhibit 21 at 11-0243\_0093-0094).

Heller, October 23, 2008 (Exhibit 22 at 11-0243\_0097). Representative Berkley's responses to media inquiries regarding her efforts on behalf of the UMC kidney transplant program seem to suggest that she had little role in preparing and sending the delegation letter. For example, Representative Berkley's Senate campaign manager provided a written response to the media in which she stated that "it was at the request of UMC and her Republican colleague that Congresswoman Berkley signed onto a letter with the Nevada delegation...." See Statement from Jessica Mackler, Campaign Manager at Berkley for Senate (undated) (Exhibit 23 at 11-0243\_0099). In addition, a document apparently prepared by Representative Berkley's congressional office states: "Rep. Porter's Office Initiated the Letter. Staff from Rep. Porter e-mailed the offices of Reps. Berkley and Heller to suggest a joint letter after urging from UMC." See "Facts on Berkley Record on Kidney Care" (undated) (citing an October 23, 2008 email from Rep. Porter's office to Rep. Berkley's office) (Exhibit 24 at 11-0243\_0102). However, information obtained by the OCE indicates that Representative Berkley and her congressional staff took the lead in drafting, circulating, and sending the delegation letter. See, e.g., UMC Attorney #2 MOI (noting that Representative Berkley "spearhead[ed]" the delegation letter effort) (Exhibit 19 at 11-0243\_0087).

- 33. Mr. Coffron prepared a draft delegation letter to the CMS Acting Administrator. Mr. Coffron also coordinated revision of the delegation letter among the three House offices and UMC attorneys, and he circulated the final draft to the three offices for signature. The letter was faxed and mailed to the CMS Acting Administrator by Representative Berkley's office on October 24, 2008.
- 34. The delegation letter expressed the Members' "strong disagreement with the apparent CMS decision to revoke Medicare approval of Nevada's only kidney transplant program" and asked that CMS "reconsider this decision."

#### Congress of the United States Washington, DC 20515

October 24, 2008

Kerry Weems
Acting Administrator
Centers for Medicare & Medicaid Services
7500 Senarity Blvd
Baltimore, Maryland 21244-1849

Dear Acting Administrator Weens.

We are writing to express our strong disagreement with the apparent CMS decision to revoke Medicare sporved of Nevada's only kidney transplant-program at the University Medical Center (UMC) in Las Vegas. We are concerned that this decision does not protect Medicare beneficiaries, and could have strong negative consequences for our constituents.

If has been brought to our attention that the kidney transplant program at UMC will have its Medicare approval revoked effective December 3, 2008. We are troubled that this revocation is proceeding despite the fact that UMC bestuplemented measures to improve quality and taken substantial steps to address the shorteomings cited. This decision also ignores significant mitigating factors and circumstances out of the center's control.

Since originally norified of the deficiencies in the transplant program, UMC has submitted a Corrective Action Plan to CMS and taken significant steps to improve quality of care and improve both management procedures and patient outcomes.

The one remaining unresolved deficiency arted in the August 4, 2008 letter sent to UMC by CMS is the one-year patient survived condition of participation. For two separate but overlapping Scientific Registry of Transplant Recipient (SRTR) colors reporting periods, UMC did not used the compliance standard because of the inclusion of a death that resulted from a patient's suicide in May, 2005. This death from over three and a half years ago still falls in the overlapping segment of the two reporting periods (July 1, 2004 to December 31, 2005 and Jamary 1, 2005 to June 30, 2007).

This suivide of an otherwise successful iranspiral patient is lamentable, but beyond the control of UMC. Additionally, data for the latest cohort reporting period from July 1, 2005 to December 31, 2007 set to be released in January will show that UMC has come back into compliance with this final requirement.

Revoking Medicare approval for the UMC kidney transplant program is uncalled for and will joundize the health of hundreds of our constituents while placing a sewere burden on transplant centers in aurounding states. We selt that you reconsider this decision, and would be happy to discuss this situation with you further if pecessary. Thank you for your consideration and look-forward to your response.

Sincerely,

SHELLEY GREEKLINY
Member of Concress

her of Concress Member of

DBANH

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<sup>&</sup>lt;sup>41</sup> Email from Legislative Director for Rep. Jon Porter to Matthew Coffron, October 28, 2008 ("Thanks for drafting matt.") (Exhibit 25 at 11-0243\_0112).

<sup>&</sup>lt;sup>42</sup> Email from Matthew Coffron to Legislative Assistant to Rep. Dean Heller, and Legislative Director for Rep. Jon Porter, October 23, 2008 ("I made a couple very small changes to the letter. Please let me know if everything is o k. If so I will send somebody around for signatures.") (Exhibit 26 at 11-0243 0114).

<sup>&</sup>lt;sup>43</sup> Email from Matthew Coffron to UMC Attorney #2, October 24, 2008 ("This has been faxed over and is in the mail.") (Exhibit 27 at 11-0243 0117).

<sup>&</sup>lt;sup>44</sup> Letter from the Nevada House Delegation to CMS Acting Administrator, October 24, 2008 (Exhibit 28 at 11-0243 0119);

Subject to the Nondisclosure Provisions of H. Res. 895 of the 110th Congress as Amended

- 35. Representative Berkley appears to have discussed her advocacy on behalf of the UMC kidney transplant program with her husband, Dr. Lehrner. On October 23, 2008, Dr. Lehrner emailed the UMC CEO: "Shelley tells me that she and Porter (? Heller) sent a letter to CMS today . . . ."<sup>45</sup>
- 36. In addition to coordinating the delegation letter effort, according to public reporting, Representative Berkley contacted Senate Majority Leader Harry Reid and Clark County commissioners to ask them to join her in advocating for continued Medicare approval of the UMC transplant program. 46
- 37. According to comments made by Representative Berkley to the *Las Vegas Review Journal*, she urged constituents who contacted her congressional office about the CMS termination decision to forward their concerns directly to CMS.<sup>47</sup>
- 38. Although neither Mr. Coffron nor Mr. Cherry would agree to interview with the OCE, evidence before the OCE indicates that Representative Berkley's congressional staff worked closely with UMC in coordinating advocacy efforts.
  - a. On October 23, 2008, a UMC attorney provided Mr. Coffron with a "quick status report" regarding the hospital's contacts with other congressional offices.<sup>48</sup>
  - b. An October 23, 2008 email from another UMC attorney to his law firm colleagues references a conversation with Representative Berkley's staff, in which they discussed the possibility of Representative Berkley reaching out to the House Ways & Means Committee leadership on this issue.<sup>49</sup>
  - c. Mr. Coffron spoke to the UMC CEO on October 27, 2008, asking if anyone at UMC "had heard from the Senate side" and updating the CEO on Representative Berkley's intention to call the CMS Acting Administrator. <sup>50</sup>

<sup>&</sup>lt;sup>45</sup> Email from Dr. Larry Lehrner to UMC CEO, October 23, 2008 (Exhibit 29 at 11-0243\_0121). Dr. Lehrner was himself involved in efforts to reverse the CMS decision, noting in the same email to the UMC CEO that he had spoken with Senator Harry Reid's staff that day "and urged them to support UMC transplant program to the fullest extent possible." *Id.*; *see also* email from Rory J. Reid, son of Senator Harry Reid and member of the Clark County Board of Commissioners, to UMC CEO, October 23, 2008 ("i talked to my father.. he was aware of the [CMS] problem...had heard about it from dr. lerner [*sic*]....") (Exhibit 17 at 11-0243\_0079). Dr. Lehrner had earlier expressed concern regarding the future of the UMC kidney transplant program and how that would affect KSSN's ongoing recruitment of a transplant nephrologist. He left a telephone message for the UMC CEO on September 30, 2008, asking to hear directly from the CEO "about UMC's commitment to the Transplant Program, so he can reassure transplant nephrologist candidates. *See* email from Assistant to the UMC CEO to UMC CEO, September 30, 2008 (Exhibit 30 at 11-0243\_0123).

<sup>&</sup>lt;sup>46</sup> Associated Press, Lawmakers call for keeping University Medical Center kidney transplant program certified, October 28, 2008 (Exhibit 31 at 11-0243\_0125).

<sup>&</sup>lt;sup>47</sup> Annette Wells, *Kidney patients may face hardship*, LAS VEGAS REVIEW-JOURNAL, October 28, 2008 (Exhibit 32 at 11-0243\_0129).

<sup>&</sup>lt;sup>48</sup> Email from UMC Attorney #2 to Matthew Coffron, October 23, 2008 (Exhibit 21 at 11-0243 0093).

<sup>&</sup>lt;sup>49</sup> Email from UMC Attorney #4 to UMC Attorney #2, et al., October 24, 2008 (Exhibit 33 at 11-0243\_0133).

<sup>&</sup>lt;sup>50</sup> Email from UMC CEO to UMC Attorney #2, October 27, 2008 (Exhibit 34 at 11-0243\_0136).

Subject to the Nondisclosure Provisions of H. Res. 895 of the 110<sup>th</sup> Congress as Amended

- d. On or about October 29, 2008, a UMC attorney attempted to reach Mr. Coffron to discuss a telephone conversation that Representative Jon Porter had had with the CMS Acting Administrator.<sup>51</sup> That same day, Mr. Coffron appears to have discussed Representative Berkley's attempts to reach the Acting Administrator with UMC attorneys.<sup>52</sup>
- e. On October 30, 2008, the UMC CEO and/or UMC attorneys appear to have spoken with Mr. Coffron by telephone regarding the termination decision.<sup>53</sup>
- 39. Representative Berkley's congressional staff evidently communicated with CMS Office of Legislation ("OL") staff about the termination decision. During the week of October 27, 2008, Mr. Coffron may have had one or more conversations with OL officials seeking information about the termination decision and requesting assistance in arranging a call between Representative Berkley and the CMS Acting Administrator. 54
- 40. On October 30, 2008, Representative Berkley contacted the CMS Acting Administrator directly regarding the decision to terminate Medicare approval of the UMC transplant program. While Representative Berkley declined to interview with the OCE, at the time of the call she told the *Las Vegas Review-Journal*: "No decision has been made, but I hung up the phone feeling very encouraged." She told local television reporters: "I spoke with the head of CMS yesterday . . . . When I got off the phone, I had a good-faith belief that we were going to come up with a compromise that works for everybody." She told local television reporters: "I spoke with the head of CMS yesterday . . . . When I got off the phone, I had a good-faith belief that we were going to come up with a compromise that works for everybody."
- 41. According to the CMS Acting Administrator, Representative Berkley asked him to consider looking for a pathway forward that would allow the kidney transplant center to retain Medicare approval and thereby remain open. In his interview with the OCE, he stated that Representative Berkley may have told him about her husband's connection to the UMC transplant program during the call, but he could not be sure. The Acting Administrator had previously told the *New York Times* that he could not recall whether Representative Berkley mentioned her husband's relationship with the program.

<sup>&</sup>lt;sup>51</sup> Email from UMC Attorney #2 to Matthew Coffron, October 29, 2008 (Exhibit 35 at 11-0243 0140).

<sup>&</sup>lt;sup>52</sup> Email from UMC Attorney #2 to Matthew Coffron, October 29, 2008 (Exhibit 36 11-0243\_0143); UMC Attorney #2 MOI (Exhibit 19 11-0243\_0087).

<sup>&</sup>lt;sup>53</sup> Email from UMC CEO to UMC Attorney #1, October 30, 2008 (Exhibit 37 at 11-0243\_0146).

<sup>&</sup>lt;sup>54</sup> Memorandum of Interview of former Acting Director, CMS Office of Legislation (Exhibit 38 at 11-0243\_0149) (hereafter "Acting Director, CMS OL MOI"); Memorandum of Interview of CMS Office of Legislation Health Insurance Specialist (Exhibit 39 at 11-0243\_0153); email from Matthew Coffron to CMS Official, November 5, 2008 (in which Mr. Coffron expresses "thanks for your help last week") (Exhibit 40 at 11-0243\_0156).

<sup>55</sup> Email from David Cherry to Matthew Coffron, October 30, 2008 (Exhibit 41 at 11-0243 0158).

<sup>&</sup>lt;sup>56</sup> Annette Wells, Officials: Transplant center talks go well, suggest hope, LAS VEGAS REVIEW-JOURNAL, October 31, 2008 (Exhibit 42 at 11-0243 0160).

<sup>&</sup>lt;sup>57</sup> Eric Lipton, A Congresswoman's Cause is Often Her Husband's Gain, THE NEW YORK TIMES, September 5, 2011 (Exhibit 43 at 11-0243 0166).

<sup>&</sup>lt;sup>58</sup> Memorandum of Interview of former CMS Acting Administrator, December 1, 2011 (Exhibit 44 at 11-0243\_0171) (hereafter "CMS Acting Administrator MOI").
<sup>59</sup> Id.

<sup>&</sup>lt;sup>60</sup> Eric Lipton, A Congresswoman's Cause is Often her Husband's Gain, THE NEW YORK TIMES, September 5, 2011 (Exhibit 43 at 11-0243\_0166).

Subject to the Nondisclosure Provisions of H. Res. 895 of the 110<sup>th</sup> Congress as Amended

- 42. Representative Jon Porter also took several actions with regard to the CMS termination decision. According to information received by the OCE, Representative Porter spoke with the CMS Acting Administrator on October 28, 2008. The Acting Administrator, however, found Representative Porter to be "actually sympathetic (privately)" with the CMS position on the UMC kidney transplant program. Representative Porter also may have met with the Acting Administrator at some point.
- 43. According to the UMC CEO, of the members of the Nevada congressional delegation, Representative Berkley and her congressional office were the most involved in the CMS termination issue. One of the UMC attorneys agreed, telling the OCE that Representative Berkley's office was particularly engaged in this matter. Establishment of the UMC attorneys agreed, telling the OCE that Representative Berkley's office was particularly engaged in this matter.

## E. CMS Reached an Agreement with UMC to Withdraw Termination of the UMC Kidney Transplant Program

- 44. On October 30, 2008, UMC and CMS reached a tentative resolution to avoid imminent termination of the UMC kidney transplant program. CMS agreed to postpone the termination date to January 8, 2009, providing time for UMC and CMS to negotiate a Systems Improvement Agreement ("SIA"), to include specific benchmarks that UMC would be required to meet to improve the transplant program. Once the SIA was executed, CMS would further postpone the termination date to give UMC time to meet the obligations included in the SIA. If UMC met those obligations, CMS would withdraw its intention to terminate approval of the program.
- 45. The CMS Acting Administrator told the OCE that the congressional intervention in this matter "impelled" the agency and him to take the "next step" toward finding a compromise that would allow the UMC kidney transplant program to retain Medicare approval. According to the Acting Administrator, without the congressional intervention, it is unlikely that the pathway to termination would have been altered. Other CMS officials told the OCE that they believed the congressional advocacy had no effect on the decision to enter into the SIA with UMC.

<sup>&</sup>lt;sup>61</sup> Email from Legislative Director for Rep. Porter to UMC Attorneys #1 and #2, UMC CEO, October 28, 2008 (Exhibit 45 at 11-0243 0174).

<sup>62</sup> Email from CMS Acting Administrator to Barry Straube, et al., October 28, 2008 (Exhibit 46 at 11-0243\_0177).
63 CMS Acting Administrator MOI (Exhibit 44 at 11-0243\_0170); Annette Wells, Lawmakers intervene in bid to retain transplant services, LAS VEGAS REVIEW-JOURNAL, October 30, 2008 (Exhibit 47 at 11-0243\_0184).
64 UMC CEO MOI (Exhibit 16 at 11-0243\_0076).

<sup>&</sup>lt;sup>65</sup> UMC Attorney #2 MOI (Exhibit 19 at 11-0243\_0087). Another UMC attorney told the OCE that he believed Representative Porter was "in front" on this issue. *See* UMC Attorney #1 MOI (Exhibit 12 at 11-0243\_0061).

<sup>&</sup>lt;sup>66</sup> Email from UMC Attorney #2 to Matthew Coffron, et al., October 30, 2008 (Exhibit 48 at 11-0243\_0188).

<sup>67</sup> Letter from Operations Manager, CMS Western Consortium, to UMC Chief Executive Officer, October 31, 2008 (Exhibit 49 at 11-0243\_00190).

<sup>&</sup>lt;sup>68</sup> CMS SCG Director MOI (Exhibit 7 at 11-0243 0038).

<sup>&</sup>lt;sup>69</sup> CMS Acting Administrator MOI (Exhibit 44 at 11-0243 0171).

<sup>&</sup>lt;sup>70</sup> Id.

<sup>&</sup>lt;sup>71</sup> CMS SCG Director MOI (Exhibit 7 at 11-0243\_0039); Acting Director, CMS OL MOI (Exhibit 38 at 11-0243\_0149). The Director of the CMS Survey and Certification Group told the OCE that four considerations, taken together, convinced the agency to propose and enter into the SIA: (1) a legal argument involving language in the

- 46. UMC officials believed the congressional intervention to have been a key factor in reaching the resolution. The UMC CEO noted that public statements by the hospital should not "dismiss the importance of our political intervention but also respect the willingness of cms [sic] to negotiate an alternative with us." A UMC attorney suggested a similar message from the hospital: "We are grateful to our Congressional members, who were instrumental in facilitating a constructive and collaborate dialogue with CMS that allowed both sides to achieve a result that puts the best interests of patients first."
- 47. In reaching this tentative resolution, CMS expressed concern to UMC attorneys that it not appear that the agency was "browbeaten" into the agreement with UMC.<sup>74</sup>
- 48. An SIA was executed in December 2008.<sup>75</sup> CMS extended the termination date from January 8, 2009 to June 8, 2009, providing UMC with the opportunity to meet the obligations of the SIA.<sup>76</sup> On April 1, 2009, CMS conducted an unannounced revisit survey of the kidney transplant program, and on May 27, 2009, CMS informed UMC that the transplant program had satisfied the criteria established by the SIA and the program was therefore approved for continued Medicare participation.<sup>77</sup>

## F. The Medical Practice of Representative Berkley's Husband Secured a New Contract to Provide Nephrology Services, including Transplant Nephrology, to UMC

- 49. The contract between UMC and KSSN for nephrology services was set to expire on July 31, 2010.<sup>78</sup> In May 2010, UMC issued an RFP for a new contract to provide nephrology services to the hospital.<sup>79</sup>
- 50. On June 15, 2010, the contract between UMC and KSSN was extended through December 31, 2010, to permit the hospital to complete the RFP process.<sup>80</sup>

transplant program regulations that UMC argued would prevent CMS from terminating the program while an appeal of the termination decision was pending; (2) concerns over patient access to care; (3) UMC had developed good institutional support by this time; and (4) UMC had developed a specific plan to improve the transplant program. See CMS SCG Director MOI (Exhibit 7 at 11-0243 0038).

<sup>&</sup>lt;sup>72</sup> Email from UMC CEO to UMC Attorney #1, October 30, 2008 (Exhibit 50 at 11-0243 0197).

<sup>&</sup>lt;sup>73</sup> Email from UMC Attorney #1 to UMC CEO, October 30, 2008 (Exhibit 50 at 11-0243\_0197).

<sup>&</sup>lt;sup>74</sup> Email from UMC Attorney #1 to Legislative Director for Rep. Porter, October 30, 2008 ("CMS let UMC know that it is of the utmost importance that public statements not suggest that CMS was 'browbeaten' into this agreement.") (Exhibit 50 at 11-0243\_0199); email from UMC Attorney #4 to UMC Attorney #1,, et al., October 30, 2008 ("Let's make sure we coordinate with the delegation in any formal announcement (and also let them know we have agreed not to beat up on CMS).") (Exhibit 51 at 11-0243\_0201).

<sup>&</sup>lt;sup>75</sup> Systems Improvement Agreement for Improving Patient Safety and Health Care Outcomes, between University Medical Center of Southern Nevada Transplant Program and Centers for Medicare & Medicaid Services (Exhibit 52 at 11-0243\_0205-0211).

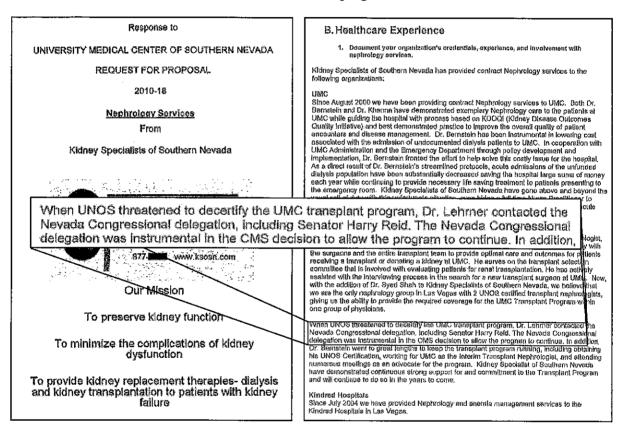
<sup>&</sup>lt;sup>76</sup> Id. (Exhibit 52 at 11-0243 00207).

<sup>&</sup>lt;sup>77</sup> Letter from Operations Manager, CMS Western Consortium, to UMC Transplant Administrator, May 27, 2009 (Exhibit 53 at 11-0243, 0213).

<sup>&</sup>lt;sup>78</sup> See ¶ 19, supra.

<sup>&</sup>lt;sup>79</sup> Notice of UMC Request for Proposals No. 2010-18 for Nephrology Services, May 18, 2010 (Exhibit 54 at 11-0243\_0216).

- 51. KSSN submitted a proposal in response to the UMC RFP on June 18, 2010. While one other provider requested information about the RFP, KSSN was the only provider to submit a proposal in response to the RFP. 82
- 52. In its proposal to UMC, KSSN cited Dr. Lehrner's involvement with the CMS termination decision: "When [the United Network for Organ Sharing] threatened to decertify the UMC transplant program, Dr. Lehrner contacted the Nevada Congressional delegation, including Senator Harry Reid. The Nevada Congressional delegation was instrumental in the CMS decision to allow the program to continue." 83



53. UMC and KSSN entered into negotiations over the terms of the new contract, including the annual compensation to be provided KSSN. The UMC CEO told the OCE that Dr.

83 KSSN RFP Response at ¶ B.1 (Exhibit 56 at 11-0243\_0226).

<sup>&</sup>lt;sup>80</sup> Amendment One to Agreement for Physician Medical Directorship of the Nephrology Department and Related Professional Services, June 15, 2010 (Exhibit 55 at 11-0243 0222-0223).

Response to University Medical Center of Southern Nevada Request for Proposal 2010-18, Nephrology Services, from Kidney Specialists of Southern Nevada (Exhibit 56 at 11-0243\_0225) (hereafter "KSSN RFP Response").
 UMC Confirmation Forms for Receipt of RFP No. 2010-18, Nephrology Services (Exhibit 57 at 11-0243\_0228-0229); UMC Report of RFP Receipt, June 22, 2010 (Exhibit 58 at 11-0243\_0231-0233).

- Lehrner raised the near-termination of the kidney transplant program during the negotiations, and that he felt he deserved credit for the program's continued existence.<sup>84</sup>
- 54. On December 8, 2010, UMC and KSSN entered into a new five-year contract, under which KSSN would continue to provide nephrology services, including transplant nephrology, to the hospital. Under the new contract, KSSN was to be paid \$25,000 per year for medical directorship services and \$713,720 per year for professional medical services, an increase of approximately 25 percent over the compensation provided under the previous contract. 86
- 55. Counsel for KSSN represented to the OCE that the current income from the transplant nephrology portion of the KSSN agreement with UMC is a small fraction of KSSN's annual revenue and Dr. Lehrner's annual income. However, because Dr. Lehrner declined to be interviewed, the OCE was unable to confirm this information.
- 56. KSSN Physician #1 told the OCE that although he was unfamiliar with the financial aspects of the UMC contract, noting that Dr. Lehrner handles the financial affairs of the practice, he believes the UMC contract is marginally profitable. He added that there were other reasons for pursuing the agreement, including intellectual benefits, good will, and the ability to form a complete medical practice.<sup>87</sup>

## G. Representative Berkley Recognized the Potential Conflict of Interest at the Time of Her Advocacy for the UMC Kidney Transplant Program

57. Questions about a potential conflict of interest, given Representative Berkley's interest in the UMC transplant program through her husband, arose at the time the resolution with CMS was reached at the end of October 2008. On October 30, 2008, the communications director for Representative Berkley received an inquiry from a reporter for the *Las Vegas Sun*: "Did [Representative Berkley] disclose to the CMS director that her husband is partners with the director of nephrology at UMC, who is over the transplant program? Does she consider it to be a conflict of interest for her to advocate for a program where she has a personal interest through her husband?" A November 4, 2008 article in the *Sun* noted that Representative Berkley's husband was a partner in KSSN, the nephrology practice holding the contract to provide nephrology services to UMC.

<sup>84</sup> UMC CEO MOI (Exhibit 16 at 11-0243 0077).

<sup>&</sup>lt;sup>85</sup> Agreement for Physician Medical Directorship and Physician Professional Services, December 8, 2010 (Exhibit 59 at 11-0243 0237-0262).

<sup>&</sup>lt;sup>86</sup> Id. at Section V (Exhibit 59 at 11-0243 0246).

Memorandum of Interview of KSSN Physician #1, December 9, 2011 (Exhibit 60 at 11-0243\_0266).

<sup>88</sup> Email from Marshall Allen to David Cherry, October 30, 2008 (Exhibit 61 at 11-2043 0268).

<sup>&</sup>lt;sup>89</sup> Marshall Allen, Focus shifts to fixing kidney program's faults, LAS VEGAS SUN, November 4, 2008 (Exhibit 62 at 11-0243 0272).

Subject to the Nondisclosure Provisions of H. Res. 895 of the 110<sup>th</sup> Congress as Amended

58. Also on October 30, 2008, the Director of the CMS Survey and Certification Group expressed concern to his colleagues when he learned of Representatives Berkley's ties to the UMC transplant program through her husband. 90

Fronts Hamilton, Thomas E. (CMS/CMSO)

Johnson, Donald N. (CMS/OK): Bansom, Robert S. (CMS/OA)

Čæ Store, Daudas (CMS/OA): Chadwick, Alphays K. (CMS/OA): Smith, Amelia I. (CMS/OL) RE: transplant center

Subjects

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Note that I learned from a reporter today that Congresswoman Berkley is married to a physician (nephrologist) that has a personal financial interest in the success of UMC - so I was gled to be able to say that I'd had no conversation with her. So - perhaps you might want to suggest to one of the other congressional contacts that we want to inform, that they could let Rep Berkley know, so there is no contact and no appearance of any pressure or reacting to pressure.

59. As noted above, Representative Berkley declined to be interviewed by the OCE. In September 2011, however, she told the Las Vegas Review-Journal that "she thought it was well-known that Dr. Larry Lehrner was involved with [UMC], but she now would take further actions to publicize the connection. . . . [S]he saw at the time that there could be a perceived conflict of interest but decided to act anyway."91

#### III. CONCLUSION

To

- 60. Although permitted by House Resolution 895 and OCE rules to draw a negative inference from Representative Berkley's lack of cooperation, the Board judged the evidence adduced to be more than sufficient to support its determination that there is substantial reason to believe that Representative Berkley violated House Rule 23 and House precedent regarding conflicts of interest.
- 61. For the foregoing reasons, the Board recommends that the Committee on Ethics further review the above-described allegations concerning whether Representative Berkley advocated for the UMC kidney transplant program at a time when she had a financial interest in that program through her husband.

#### IV. INFORMATION THE OCE WAS UNABLE TO OBTAIN AND RECOMMENDATIONS FOR THE ISSUANCE OF SUBPOENAS

- 62. The following individuals, by declining to be interviewed by the OCE, did not cooperate with the OCE's review:
  - a. Representative Shelley Berkley;

<sup>90</sup> Email from CMS SCG Director to Donald Johnson, et al., October 30, 2008 (Exhibit 63 at 11-0243\_0274).

<sup>91</sup> Steve Tetreault, In hindsight, Berkley says she should have disclosed, LAS VEGAS REVIEW-JOURNAL, September 12, 2011 (Exhibit 64 at 11-0243 0276).

Subject to the Nondisclosure Provisions of H. Res. 895 of the 110<sup>th</sup> Congress as Amended

- b. Matthew Coffron, former Legislative Assistant for Representative Berkley;
- c. David Cherry, Communications Director for Representative Berkley; and
- d. Dr. Larry Lehrner, KSSN.
- 63. As a result, the OCE was unable to obtain certain information regarding Representative Berkley's advocacy on behalf of the UMC kidney transplant program.
- 64. The Board recommends the issuance of subpoenas to Representative Berkley, Mr. Coffron, Mr. Cherry, and Dr. Lehrner.

## **EXHIBIT 1**

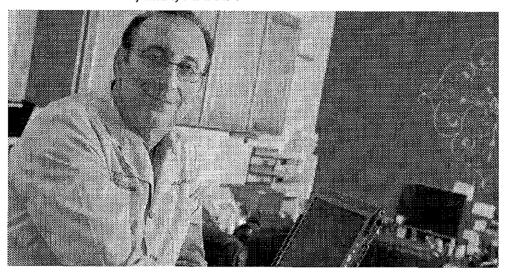
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#### Physicians

Ayoola Adekile, M.D. Marvin Bernstein, M.D. Adin Boldur, M.D. Venu Bolia, M.D. Jay K. Chu, M.D. Bindu Khanna, M.D. Lawrence Lehrner, M.D. Marc Leisenwitz M.D. Thomas Lim, Jr., M.D. Robert Merrell, M.D. Seyedqumars Mirfendereski, M.D. Chidi Okafor, M.D. Neville Pokrov, M.D. Rizwan Qazi, M.D Ramchand Ranai, M.D. Cristy Robertson, M.D. Zvi Sela, M.D. Syed iflikhar Shah, M.D. Raj Prabhjot Singh, M.D. Kurt Sowers, M.D. Vincent Yang, M.D. Mid-Level Providers

### Lawrence Lehrner, M.D., F.A.C.P.



Primary office location: Central-Rancho

The army brought Dr. Lawrence Lehrner to nephrology and the sunshine brought him to Vegas.

After earning his medical degree at Indiana University School of Medicine, Dr. Lehrner Joined the United States Army and was stationed at William Beaumont Army Medical Center. On track to a career in the gastrointestinal field, a twist of fate led him to nephrology where he was instantly fascinated.

Dr. Lehrner takes an integrative approach to the treatment of CKD. That approach includes working closely with the patient and their primary care physician. He believes in being honest and forthright, empowering patients with the knowledge they need to make important decisions about their health.

Dr. Lehrner is Board Certified in both Internal Medicine and Nephrology. He is actively involved with local and national medical organizations that work to improve the quality of care for the population at large. Dr. Lehrner serves on the Board of Directors of the Renal Physician Association that is active in many areas of kidney care including patient safety, defining clinical practice guidelines and measuring quality of patient care.

Originally from Cincinnati, Ohio, Dr. Lehmer made his way to the warmer, sunnier climate of Las Vegas in 1985. He joined KSOSN in 1987 when there were just four physicians. The practice now has 14 nephrologists. Dr. Lehmer's current faculty appointments include the University of Nevada Las Vegas School of Medicine and Touro University in Henderson, Nevada.

#### Education

Nephrology Fellowship, University of Texas, Dallas, Texas Nephrology Mini-Fellowship, Brooke Army Medical Center San Antonio, Texas Residency, Internal Medicine, William Beaumont Army Medical Center, El Paso, Texas Medical Degree, Indiana University, Bloomington, Indiana

#### Professional Associations

Board of Directors, Renal Physicians Association American Board of Internal Medicine American Board of Internal Medicine, Nephrology American Medical Association Fellow, American College of Physicians American Society of Nephrology

## **EXHIBIT 2**

## BERNSTEIN, POKROY & LEHRNER, LTD.

Business Entity Information					
Status: Active File Date: 4/28/1976					
Туре:	Domestic Professional Corporation	Entity Number:	C1579-1976		
Qualifying State:	NV	List of Officers Due:	4/30/2012		
Managed By:		Expiration Date:			
NV Business ID:	NV19761002452	Business License Exp:	4/30/2012		

Additional Information	
Central Index Key:	

Registered Agent Information						
Name:	HUTCHISON & STEFFEN, LLC	Address 1:	10080 W ALTA DRIVE STE 200			
Address 2:		City:	LAS VEGAS			
State:	NV	Zip Code:	89145			
Phone:		Fax:				
Mailing Address 1:		Mailing Address 2:				
Mailing City:		Mailing State:	NV			
Mailing Zip Code:						
Agent Type:	e: Commercial Registered Agent - Corporation					
Jurisdiction:	NEVADA	Status:	Active			

Financial Information					
No Par Share Count: 2,500.00	Capital Amount:   \$ 0				
No stock records found for this company					

Officers			Include Inactive Officers
Secretary - MARV	/IN J BERNSTEIN M.D.	***************************************	***************************************
Address 1:	500 SOUTH RANCHO DRIVE	Address 2:	SUITE #12
City:	LAS VEGAS	State:	NV
Zip Code:	89106	Country:	
Status:	Active	Email:	
President - LAWF	RENCE LEHRNER M.D.		
Address 1:	500 SOUTH RANCHO DRIVE	Address 2:	SUITE #12
City:	LAS VEGAS	State:	NV
Zip Code:	89106	Country:	
Status:	Active	Email:	
	NCE LEHRNER, M.D.		
Address 1:	500 SOUTH RANCHO DRIVE, STE. #12	Address 2:	
City:	LAS VEGAS	State:	NV
Zip Code:	89106	Country:	
Status:	Active	Email:	
Treasurer - NEVIL	LE POKROY, M.D.		
Address 1:	500 SOUTH RANCHO DRIVE	Address 2:	SUITE #12

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## **EXHIBIT 3**



KIDNEY SPECIALISTS



Home About KSOSN KSOSN Care Team Referring Physicians Patients Contact Us

Job Posting
Our Services
KSOSN Services
Vascular Access Center
Hospital Affiliations
News Archive

## The Kidney Specialists of Southern Nevada story

Kidney Specialists of Southern Nevada (KSOSN) was established in Las Vegas by Allen Busby, MD in 1976. Over the past 30 years, the practice has grown to meet the needs of the community we serve and now includes nineteen physicians, nearly thirty support staff in six offices across greater Las Vegas and Pahrump, a chronic kidney disease support program and a vascular access center.

KSOSN offers the region's most comprehensive kidney care services. We have assembled an entire team of caregivers—physicians, nurse practitioner, physician assistant, nurses, dietician, medical assistants and patient care coordinators—to both treat and educate patients on how best to manage their kidney disease. Our approach provides our patients with the best resources for slowing the progression of kidney disease and helping improve their quality of life.

Our integrated approach incorporates every aspect of nephrology with intensive patient education and support, close collaboration with dialysis centers offering a range of in-center and at-home services, a state-of-the-art vascular access center, and transplant nephrologists who are part of the region's transplant team.

We are a practice that stays on the leading edge of medical care. We have memberships in both national and international nephrology and medical associations. All KSOSN offices are equipped with a state of the art charting system and paperless medical records to provide more efficient patient care and more accurate record keeping.

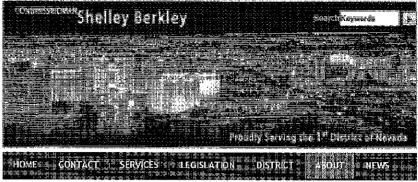
Our nephrologists mentor medical students and resident physicians at area medical schools. Kidney Specialists of Southern Nevada is on academic faculty for nephrology at University Medical Center of Southern Nevada, University of Nevada School of Medicine, Las Vegas, Valley Hospital Medical Center, Las Vegas and Touro University School of Osteopathic Medicine, Las Vegas.

Click here for our hospital affiliations.

 $\underline{\text{Click here}}$  to watch a video about some of KSOSN's recent advances in CKD patient care.

## **EXHIBIT 4**





#### Berkley Biography

Congresswoman Berkley Biography
A Lifetime of Commitment to Nevada

As dynamic as the community she serves, Congresswoman Shelley Berkley has represented the families of Nevada's First Congressional District since 1999 and is currently in her seventh term as a Member of the U.S. House of Representatives.

A Las Vegas resident for more than four decades, Shelley has a deep sense of commitment to her community and has never forgotten that when her family headed West in search of a better life, they found it in southern Nevada. After completing junior high and high school in Las Vegas, Shelley became the first member of her family to attend college when she enrolled as an undergraduate at the University of Nevada – Las Vegas (UNLV). Elected student body president her senior year, Shelley graduated with honors in 1972, earning a B.A. in Political Science. After obtaining her law degree in 1976 from the University of San Diego School of Law, Shelley returned to Las Vegas and began her professional career. Working to meet the needs of the rapidly growing Las Vegas Valley is a key focus of Shelley's work in Congress. Her priorities include jump-starting the economy; creating jobs; helping families stay in their homes; securing more resources for education and transportation in southern Nevada; increasing access to affordable, high-quality health care for America's families; developing clean, alternative energy sources; fighting the proposed Yucca Mountain nuclear waste dump; protecting Social Security; and strengthening American alliances abroad to work toward international stability and peace.

#### House Committee Assignments for the 111th Congress

- Committee on Ways and Means
  - · Subcommittee on Social Security
- Subcommittee on Select Revenue Measures

#### Caucus and Task Force Membership

- Congressional Gaming Caucus (co-chair) Congressional Osteoporosis Caucus (co-chair)
   Congressional Stop DUI Caucus (co-chair) Congressional Taiwan Caucus (co-chair)Friends of Kazakhstan Caucus (co-chair)
- For a complete list click here

International Organization Membership

• Transatlantic Legislators' Dialogue (chair of the U.S. delegation)

#### Previous Public Offices

Shelley is a former Vice Chair of the Nevada University and Community College System Board of Regents. Appointed in 1990 by the Governor of Nevada, she subsequently served two terms and completed her work on the Board in 1998. Throughout her tenure, Shelley worked to keep higher education in Nevada affordable and accessible to all qualified students.

Serving in the Nevada State Assembly from 1982 through 1984, Shelley championed consumer protection for car buyers and mobile home owners, fought for tougher drunk driving laws, and founded the Senior Law Project.

#### Accomplishment in Industry

Shelley Berkley has held key positions in the private sector during a career that spans nearly a quarter of a century: Former Vice President of Government and Legal Affairs, Sands Hotel. Former Chair, Board of the Nevada Hotel and Motel Association.

Past member, Board of Trustees of Sunrise-Columbia Hospital (an unpaid position).

Former In-House counsel for Southwest Gas Corp.

Former Deputy Director, Nevada State Commerce Department.

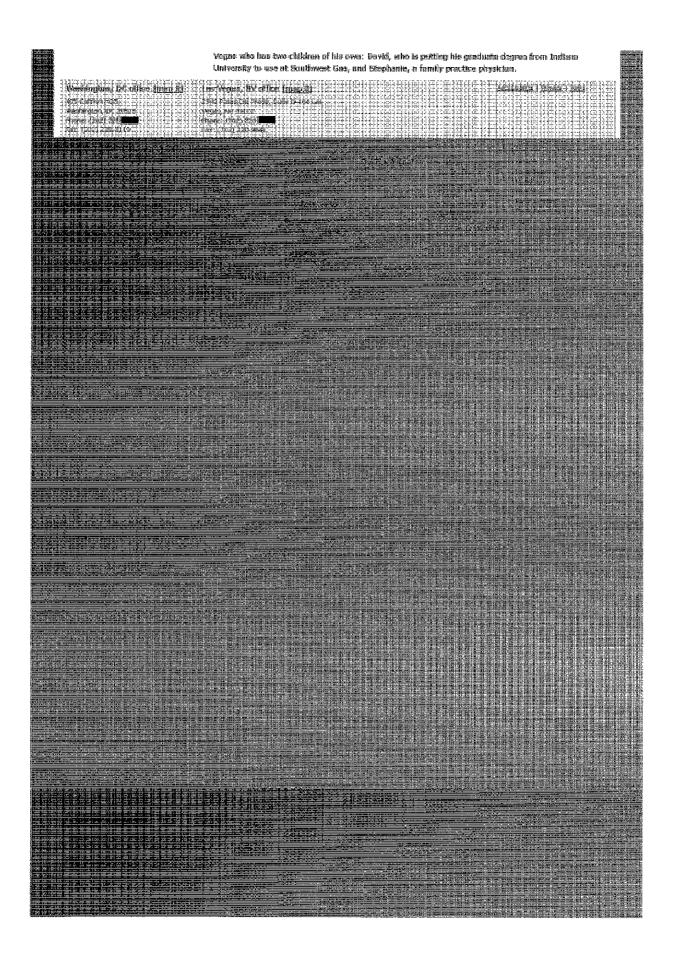
Member, County, State and National Bar Association.

Former National Director of the American Hotel-Motel Association.

Served as a Delegate to the White House Conference on Tourism,

#### Persona

Congresswoman Berkley is the proud mother of two sons: Sam, who is studying for an undergraduate degree at UNLV, and Max, who graduated from the UNLV Boyd School of Law In 2009. In March of 1999, Shelley married Dr. Lawrence Lehrner, a practicing Nephrologist in Las



## **EXHIBIT 5**

## UNIVERSITY MEDICAL CENTER OF SOUTHERN NEVADA BOARD OF HOSPITAL TRUSTEES AGENDA ITEM

Issue:	Award of Contract	Васк-ир:
Petitioner:	Kathleen Silver, Interim Chief Executive Officer, University Medical Center	Clerk Ref. #

#### Recommendation:

That the Board of Hospital Trustees approve and authorize the Agreement for Physician Medical Directorship of the Nephrology Department and Related Professional Services (RFP No. 2007-18) between University Medical Center of Southern Nevada (UMC) and Kidney Specialists of Southern Nevada for supervision and direction of qualified Nephrology Physicians for the period August 1, 2007, through July 31, 2010; and authorize the Interim Chief Executive Officer to sign the agreement.

#### FISCAL IMPACT:

Directorship Services

\$50,000 annually

Professional Medical Services

\$538,200 annually subject to a 3 percent annual increase

## BACKGROUND:

On May 1, 2007, Request for Proposal No. 2007-18 requesting nephrology services was advertised in the Las Vegas Review-Journal and mailed to 6 physicians. Proposals were received from:

Kidney Specialists of Southern Nevada

R.D Prahbu-Lata K Shete, MD's LTD (received late and not accepted)

An ad hoc committee reviewed the proposals submitted, and recommends the selection of, and contract approval with Kidney Specialists of Southern Nevada.

This contract is for the medical directorship of the nephrology department including 24-hour-aday, 7-day-a-week coverage to the hospital as well as providing necessary follow-up services.

The term of the contract is for the period from August 1, 2007 through July 31, 2010.

The Interim Chief Executive Officer and staff have reviewed the proposed contract and costs and found them to be equitable for the work to be performed.

Respectfully submitted

VIRGINIA VALENTINE

County Manager

Cleared for Agenda

Agenda OT

Agenda Item# 85

UMC\_01754 **11-0243 0014** 

## AGREEMENT FOR PHYSICIAN MEDICAL DIRECTORSHIP OF THE NEPHROLOGY DEPARTMENT AND RELATED PROFESSIONAL SERVICES

This Agreement, made and entered into this 21st day of August, 2007, by and between University Medical Center of Southern Nevada (hereinafter referred to as "Hospital"), a publicly owned and operated hospital created by virtue of Chapter 450 of the Nevada Revised Statutes with its principal place of business at 1800 West Charleston Boulevard, Las Vegas, Nevada, 89102, and Kidney Specialists of Southern Nevada (hereinafter referred to as "Provider"), a Nevada professional corporation, duly organized and existing under and by virtue of the laws of the State of Nevada, engaged in the practice of medicine specializing in nephrology with its principal place of business at 500 South Rancho, Suite 12, Las Vegas, Nevada, 89106.

#### WITNESSETH:

WHEREAS, Hospital provides nephrology services which requires a Medical Directorship and professional medical services; and

WHEREAS, Hospital recognizes that the proper functioning of the same requires supervision and direction by a physician who has been properly trained and is fully qualified and competent to practice medicine as an nephrologist; and

WHEREAS, Provider is associated with a group of physicians specializing in nephrology services who are duly licensed to practice medicine in the State of Nevada and who have met the requirements for membership on the Medical Staff of Hospital; and

WHEREAS, Provider desires to contract for and provide said Medical Directorship and professional medical services; and

WHEREAS, the parties desire to provide a full statement of their agreement in connection with the operation of nephrology services in Hospital during the term of this Agreement;

NOW, THEREFORE, in consideration of the covenants and mutual promises made herein, the parties agree as follows:

### I. DEFINITIONS

For the purposes of this Agreement, the following definitions apply:

- 1.1 <u>Provider</u>: Kidney Specialists of Southern Nevada and all physicians specializing in nephrology providing services pursuant to this Agreement who are members, associates, partners and/or employees of Kidney Specialists of Southern Nevada.
- 1.2 <u>Principal Physician</u>: One of Provider's members, partners or associates designated by Provider and approved by Hospital to serve as the Medical Director of Hospital's Nephrology Department.
- 1.3 <u>Member Physicians</u>: Physicians associated with Provider providing services pursuant to this Agreement. Unless the context requires otherwise, the term "Member Physicians" shall include the Principal Physician.

- 1.4 Allied Health Providers: Individuals other than a licensed physician, dentist, or D.O. who exercise independent or dependent judgment within the areas of their scope of practice and who are qualified to render patient care services under the supervision of a qualified physician who has been accorded privileges to provide such care in Hospital.
- 1.5 <u>Clinical Services</u>: Services performed for the diagnosis, prevention or treatment of disease or for assessment of a medical condition.
- 1.6 <u>Department</u>: Unless the context requires otherwise, Department refers to Hospital's Nephrology Department.
- 1.7 <u>Services to Patients</u>: Those services personally rendered by Provider's Member Physicians to the patient.
  - a. To qualify as "services to patients" services must, in general: (i) be personally furnished by Provider's Member Physicians; (ii) contribute directly to the diagnosis or treatment of the patient; and (iii) ordinarily require performance by a physician.
  - b. Services to patients include: (i) consultative services; and (ii) services personally performed by Provider's Member Physicians in the administration of procedures to an individual patient.
- 1.8 <u>Services to Hospital</u>: Those services which do not qualify as "services to patients" as herein defined, but which are services provided by Provider to Hospital and are related to the provision of patient care in Hospital; including, but not limited to, administrative and supervisory services. Clinical services which do not meet the requirements of "services to patients" shall be considered "services to Hospital."

### II. PROVIDER'S OBLIGATIONS

- 2.1 <u>Coverage</u>: Provider, through its Member Physicians hereby agrees to perform the following services as requested by Hospital and in a manner reasonably satisfactory to Hospital:
  - a. Provider shall provide professional services in the best interests of Hospital's patients with all due diligence.
  - b. Provider shall conduct and professionally staff nephrology services in such a manner that Hospital, its Medical Staff, and patients shall at all times have immediately available adequate nephrology coverage. Provider shall render and supervise nephrology services and consult with the Medical Staff of Hospital when requested.
  - c. Provider shall provide Hospital with on-site consultative coverage on a twenty-four (24) hour-a-day, seven (7) day-a-week basis. For this purpose consultive coverage consists of patient examination/assessment, diagnosis, medical intervention and follow-up care. This coverage includes all Hospital inpatients, Hospital outpatients, Emergency Department patients and Trauma Department patients who are not designated patients of other physicians.
  - d. Provider shall provide consultative, diagnostic or medical service coverage to Hospital's outpatient nephrology clinic patients during the term of this Agreement.

- e. Provider shall provide service on an emergency and on-call basis to meet the needs of Hospital's inpatients and outpatients.
- f. Provider shall coordinate the schedules and assignments of the physicians performing nephrology services.
- g. Provider shall encourage the participation of other physicians in the community to assist Provider in the provision of the services outlined in this Agreement.

#### 2.2 Medical Staff Appointment:

- a. Physicians employed or contracted by Provider shall at all times hereunder, be members in good standing of Hospital's medical staff with appropriate clinical privileges and appropriate Hospital credentialing. Any of Provider's Member Physicians who fail to maintain staff appointment of clinical privileges in good standing will not be permitted to render services to Hospital's patients and will be replaced promptly by Provider. Provider shall replace a Member Physician who is suspended, terminated or expelled from Hospital's Medical Staff, loses his license to practice medicine, tenders his resignation, or violates the terms of this Agreement. In the event Provider replaces or adds a Member Physician, such new physician shall meet all of the conditions set forth herein, and shall agree in writing to be bound by the terms of this Agreement. In the event an appointment to the Medical Staff is granted solely for purposes of this Agreement, such appointment shall automatically terminate upon termination of this Agreement.
- b. It is expressly agreed that continuation of this Agreement is dependent upon the continued appointment of one of Provider's Member Physicians as Director of Hospital's Nephrology Department. For the purposes of this Agreement, Marvin Bernstein, M.D., shall be designated as Provider's Principal Physician.
- Provider shall be fully responsible for the performance and supervision of any of its
   Member Physicians, including its Principal Physician, or others
   under its direction and control, in the performance of services under this Agreement.
- d. Allied Health Providers employed or utilized by Provider, if any, must apply for privileges and remain in good standing in accordance with the University Medical Center of Southern Nevada Allied Health Providers Manual.
- 2.3 <u>Medical Director</u>: Provider's Principal Physician shall assume medical responsibility for nephrology services during the term of this Agreement. The Principal Physician shall at all times during the term of this Agreement hold a current license to practice medicine from the State of Nevada and be Board Certified.

# 2.4 <u>Clinical Responsibilities of Principal Physician</u>:

- a. Provide nephrology services:
- b. Provide clinical direction of Hospital's Nephrology Department;

- c. Ensure clinical effectiveness by providing direction and supervision in accordance with recognized professional medical specialty standards and the requirements of local, State and national regulatory agencies and accrediting bodies;
- d. Provide consultive interpretations and documentation in accordance with the standards and recommendations of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and the Bylaws, Rules and Regulations of the Medical and Dental Staff, as may then be in effect;
- e. Provide ongoing patient contact as medically necessary and appropriate; this would include daily rounding on patients assigned to Nephrology Service, and Consultative availability seven (7) days per week, fifty-two (52) weeks per year.
- f. Coordinate and integrate clinically related nephrology services activities both inter and intra departmentally within Hospital;
- g. Participate in scheduled clinical staff meetings and conferences;
- h. Provide training in nephrology to resident physicians at Hospital; and
- i. Perform such other clinical duties as necessary to operate nephrology services.
- j. Provide Tranplant Nephrologist to offer training and support of Hospital's Kidney
  Transplant Program. Support of the Transplant Program requires the provision of two
  four (4) hour clinics per week within the Transplant Center. The Transplant Nephrologist
  will provide medical examination and clearance for all prospective transplant patients.
- k. Provide a minimum of three (3) outpatient nephrology clinics per month at four (4) hours each in the Lied Outpatient Center. If appointment waiting times exceed four (4) weeks, Provider will staff such additional clinics as required to reduce waiting time to less than four (4) weeks.

## 2.5 Administrative Responsibilities of Principal Physician:

- a. Contribute to a positive relationship among Hospital's Administration, Hospital's Medical Staff and the community;
- b. Promote the growth and development of nephrology services in conjunction with Hospital with special emphasis on expanding diagnostic and therapeutic services;
- c. Inform the Medical Staff of new equipment and applications;
- d. Recommend innovative changes directed toward improved patient services;
- e. Develop and implement guidelines, policies and procedures in accordance with recognized professional medical specialty standards and the requirements of local, state and national regulatory agencies and accrediting bodies;
- f. Recommend the selection and development of appropriate methods, instrumentation and supplies to assure proper utilization of staff and efficient reporting of results;

- g. Represent nephrology services on Hospital's medical staff committees and at Hospital department meetings as the need arises;
- h. Participate in Quality Assurance and Performance Improvement activities by monitoring and evaluating care; communicating findings, conclusions, recommendations and actions taken; and using established Hospital mechanisms for appropriate follow-up;
- Assess and recommend to Hospital's Administration and the Administrative Director of nephrology services a sufficient number of qualified and competent staff members to provide nephrology care;
- j. Assess and recommend to Hospital's Administration and the Administrative Director of nephrology services the need for capital expenditure for equipment, supplies and space required to maintain and expand nephrology services;
- k. Provide for the education of Medical Staff and Hospital personnel, residents and medical students in a defined organized structure and as the need presents itself;
- 1. Monitor the use of equipment and report any malfunction to Hospital Administration and the Administrative Director of nephrology services;
- m. Assist Hospital in the selection of outside sources for needed services;
- n. Assist Hospital in the appeal of any denial of payment of Hospital charges; and
- o. Assist Hospital's Administrative Director of nephrology services with the performance of such other administrative duties as necessary to operate nephrology services.
- 2.6 <u>Time Studies</u>: Provider shall record in fifteen minute increments time spent in teaching, administration and supervision and submit this information for one week each month. Provider shall submit such time studies to Hospital's Fiscal Services Department by the 12<sup>th</sup> of each month. Failure to submit the required time study by the 12<sup>th</sup> of the month will delay that month's payment until the time study is received. A copy of the Physician's Weekly Time Study is incorporated herein as Attachment "A".

## 2.7 Standards of Performance:

- a. Provider promises to adhere to Hospital's established standards and policies for providing good patient care. In addition, Provider shall ensure that its Member Physicians shall also operate and conduct themselves in accordance with the standards and recommendations of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and the Bylaws, Rules and Regulations of the Medical and Dental Staff, as may then be in effect. It is agreed that services provided under this Agreement will not be bound under the timelines established for On-Call Physician coverage as noted in the Rules and Regulations.
- b. Hospital expressly agrees that the professional services of Provider may be performed by such physicians as Provider may associate with, so long as Provider has obtained the prior written approval of Hospital. So long as Provider is performing the services required

hereby, its employed or contracted physicians shall be free to perform private practice at other offices and hospitals.

2.8 <u>Independent Contractor</u>: In the performance of the work duties and obligations performed by Provider under this Agreement, it is mutually understood and agreed that Provider is at all times acting and performing as an independent contractor practicing the profession of medicine. Hospital shall neither have, nor exercise any, control or direction over the methods by which Provider shall perform its work and functions.

# 2.9 <u>Industrial Insurance</u>:

- a. As an independent contractor, Provider shall be fully responsible for premiums related to accident and compensation benefits for its shareholders and/or direct employees as required by the industrial insurance laws of the State of Nevada.
- b. Provider agrees, as a condition precedent to the performance of any work under this Agreement and as a precondition to any obligation of Hospital to make any payment under this Agreement, to provide Hospital with a certificate issued by the appropriate entity in accordance with the industrial insurance laws of the State of Nevada. Provider agrees to maintain coverage for industrial insurance pursuant to the terms of this Agreement. If Provider does not maintain such coverage, Provider agrees that Hospital may withhold payment, order Provider to stop work, suspend the Agreement or terminate the Agreement.

# 2.10 Professional Liability Insurance:

- a. Provider shall carry professional liability insurance on its Member Physicians and employees at its own expense in accordance with the minimums established by the Bylaws, Rules and Regulations of the Medical and Dental Staff. Said insurance shall annually be certified to Hospital's Administrator and Medical Staff, as necessary.
- b. As Medical Director of nephrology services, Provider is covered for the performance of administrative duties under Hospital's current Directors and Officers Liability policy.
- 2.11 <u>Provider Personal Expenses</u>: Provider shall be responsible for all its personal expenses, including, but not limited to, membership fees, dues and expenses of attending conventions and meetings, except those specifically requested and designated by Hospital.

#### 2.12 Maintenance of Records:

- a. All medical records, histories, charts and other information regarding patients treated or matters handled by Provider hereunder, or any data or data bases derived therefrom, shall be the property of Hospital regardless of the manner, media or system in which such information is retained. Provider shall have access to and may copy relevant records upon reasonable notice to Hospital.
- b. Provider shall complete all patient charts in a timely manner in accordance with the standards and recommendations of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and Regulations of the Medical and Dental Staff, as may then be in effect.

# 2.13 Health Insurance Portability and Accountability Act of 1996:

- a. For purposes of this Agreement, "Protected Health Information" shall mean any information, whether oral or recorded in any form or medium, that: (i) was created or received by either party; (ii) relates to the past, present, or future physical condition of an individual, the provision of health care to an individual, or the past, present or future payment for the provision of health care to an individual; and (iii) identifies such individual.
- b. Provider shall use its reasonable efforts to preserve the confidentiality of Protected Health Information it receives from Hospital, and shall be permitted only to use and disclose such information to the extent that Hospital is permitted to use and disclose such information pursuant to the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d-1329d-8; 42 U.S.C. 1320d-2) ("HIPAA"), regulations promulgated there under ("HIPAA Regulations") and applicable state law. Hospital and Provider shall be an Organized Health Care Arrangement ("OCHA"), as such term is defined in the HIPAA Regulations.
- c. Hospital shall, from time to time, obtain applicable privacy notice acknowledgments and/or authorizations from patients and other applicable persons, to the extent required by law, to permit the Hospital, Provider and their respective employees and other representatives, to have access to and use of Protected Health Information for purposes of the OHCA. Hospital and Provider shall share a common patient's Protected Health Information to enable the other party to provide treatment, seek payment, and engage in quality assessment and improvement activities, population-based activities relating to improving health or reducing health care costs, case management, conducting training programs, and accreditation, certification, licensing or credentialing activities, to the extent permitted by law or by the HIPAA Regulations.
- 2.14 <u>Voluntary Absence</u>: Provider's Principal Physician may require personal time away from Hospital for vacation, seminars and so forth. In such event, Principal Physician shall advise Hospital's Administrator in a reasonable time prior to such absence, however, such absence shall not diminish the requirements for administration and supervision of nephrology services and Principal Physician shall arrange for administrative and supervisory coverage during his absence.
- 2.15 <u>UMC Policy #I-66</u>: Provider shall ensure that its staff and equipment utilized at Hospital, if any, are at all times in compliance with University Medical Center Policy #I-66, set forth in Attachment "B," incorporated and made a part hereof by this reference.
- 2.16 <u>Special Personnel</u>: Provider shall maintain, at its own expense, any personnel used in connection with its private practice. Such personnel will not have any administrative duties or responsibilities in Hospital at any time.

# III. HOSPITAL'S OBLIGATIONS

- 3.1 Space, Equipment and Supplies:
  - a. Hospital shall provide space within Hospital for nephrology services (excluding Provider's private office space); however, Provider shall not have exclusivity over any space or equipment provided therein and shall not use the space or equipment for any purpose not related to the proper functioning of nephrology services.

- b. Hospital shall make available during the term of the Agreement such equipment as is determined by Hospital to be required for the proper operation and conduct of nephrology services. Hospital shall also keep and maintain said equipment in good order and repair.
- c. Hospital shall purchase all necessary supplies for the proper operation of nephrology services and shall keep accurate records of the cost thereof.
- 3.2 <u>Hospital Services</u>: Hospital shall, at its expense, furnish the Principal Physician with ordinary janitorial service, in-house messenger service and telephone service as may be required by the administrative duties of Principal Physician. Hospital shall also provide the services of other hospital departments including, but not limited to, Accounting, Administration, Engineering, Human Resources, Material Management, Medical Records and Nursing.
- 3.3 Personnel: Other than Member Physicians and Allied Health Providers, all personnel required for the proper operation of nephrology services shall be employed by Hospital. The selection and retention of such personnel shall be in cooperation with Principal Physician, but Hospital shall have final authority with respect to such selection and retention. Salaries and personnel policies for persons within personnel classifications used in nephrology services shall be uniform with other Hospital personnel in the same classification insofar as may be consistent with the recognized skills and/or hazards associated with that position, providing that recognition and compensation be provided for personnel with special qualifications in accordance with the personnel policies of Hospital.
- 3.4 <u>Exclusivity of Services</u>: This Agreement does not preclude an attending physician on Hospital's Staff from requesting a specific physician, not a party to this Agreement, to provide a specific procedure or consultation for a patient, provided that such independent physician is a member of Hospital's Medical Staff.

#### IV. BILLING

#### 4.1 Direct Billing:

- a. Provider shall directly bill patients and/or third party payors for all professional components. Hospital shall provide, at Hospital's expense, usual social security and insurance information to facilitate direct billing. Unless specifically agreed to in writing or elsewhere in this Agreement, Hospital is not otherwise responsible for the billing or collection of professional components.
- b. Provider agrees to maintain a mandatory assignment contract with Medicare and Medicaid.
- c. Fees will not exceed that which is usual, reasonable and customary for the community. Provider shall furnish a list of these fees upon request of Hospital.
- d. Provider shall not bill patients or Hospital in violation of NRS 450.440 for Provider services rendered to patients deemed to be indigents by Clark County Social Services, or applicable law.
- e. If Hospital desires to enter into preferred provider, capitated or other managed care contracts, to the extent permitted by law, Provider agrees to cooperate with Hospital and to attempt to negotiate reasonable rates with such managed care payors.

# 4.2 Physician Billing/Compliance:

- a. Provider agrees to comply with all applicable federal and state statutes and regulations (as well as applicable standards and requirements of non-governmental third-party payors) in connection with Provider's submission of claims and retention of funds for Provider's services provided to patients at Hospital's facilities (collectively "Billing Requirements").
- b. In furtherance of the foregoing and without limiting in any way the generality thereof, Provider agrees:
  - 1. To ensure that all claims by Provider for Provider's services provided to patients at Hospital's facilities are complete and accurate:
  - 2. To cooperate and communicate with Hospital in the claim preparation and submission process to avoid inadvertent duplication by ensuring that Provider does not bill for any item or service that has been or will be appropriately billed by Hospital as an item or service provided by Hospital at Hospital's facilities:
  - 3. To keep current on applicable Billing Requirements as the same may change from time to time; and
  - 4. In addition to any other indemnification provision contained herein, to indemnify, defend, and hold harmless Hospital, its governing board members, officers, employees, agents, successors and assigns from and against any and all claims, injuries, lawsuits, investigations, losses, damages, demands, expenses and liabilities, including, but not limited to, legal expenses and cost of settlements, of whatever nature, arising out of Provider's breach of the foregoing covenants.

## V. COMPENSATION

- 5.1 <u>Direct Billing</u>: Except as provided in Paragraphs 5.2 and 5.3, hereinbelow, each of Hospital's patients receiving services from Provider shall be directly billed by Provider for such services.
- 5.2 <u>Directorship Services</u>: During the term of this Agreement and subject to paragraphs 7.5 and 7.14, hereinbelow, Hospital will compensate Provider Fifty Thousand Dollars (\$50,000.00) per year at the rate of Four Thousand One Hundred Sixty-Six Dollars and Sixty-Seven Cents (\$4,166.67) per month for the previous month's directorship duties provided to the Nephrology Department.
- 5.3 <u>Professional Medical Services</u>: During the term of this Agreement and subject to paragraphs 7.5 and 7.14, hereinbelow, Hospital will compensate Provider Five Hundred Thirty-Eight Thousand Two Hundred dollars (\$538,200.00) per year at the rate of Forty-Four Thousand Eight Hundred Fifty Dollars (\$44,850.00) per month for the previous month's professional medical services rendered to Hospital's Nephrology Department:
- 5.4 Payment Date: Hospital will compensate Provider on the third (3rd) Friday of each month, or if the third (3rd) Friday falls on a holiday, the following Monday, for the previous month's services.

5.5 <u>Annual Increases:</u> Professional Medical Services as listed in section 5.3 will be subject to an increase of three (3%) per cent per year on the anniversary date of the effective date of this contract.

#### VI. TERM/MODIFICATIONS/TERMINATION

- 6.1 Term of Agreement: This Agreement shall become effective on the 1<sup>st</sup> day of August, 2007, and, subject to paragraphs 7.5 and 7.14, hereinbelow, shall remain in effect for a period of three (3) years through July 31, 2010.
- 6.2. <u>Modifications</u>: Provider shall notify Hospital in writing of:
  - a. Any change of address of Provider:
  - b. Any change in membership or ownership of Provider's group or professional corporation.
  - c. Any action against the license of any of Provider's Member Physicians;
  - d. Any action commenced against Provider which could materially affect this Agreement;
  - e. Any exclusionary action initiated or taken by a federal health care program against Provider or any of Provider's Member Physicians; or
  - f. Any other occurrence known to Provider that could materially impair the ability of Provider to carry out its duties and obligations under this Agreement.

# 6.3 <u>Termination For Cause:</u>

- a. This Agreement shall immediately and automatically terminate, without notice by Hospital, upon the occurrence of any one of the following events:
  - 1. The exclusion of Provider from participation in a federal health care program:
  - 2. The expulsion, termination or suspension of Provider's Principal Physician by Hospital's Medical Staff or loss of Provider's Principal Physician's license to practice medicine, subject to the right of Provider to nominate another member Physician to Hospital for consideration and approval as Principal Physician. (Hospital maintains the sole and unilateral right to accept or reject such nominee Medical Director, but will not unreasonably withhold such acceptance/approval.); or
  - 3. The conviction of Provider's Principal Physician of any crime punishable as a felony involving moral turpitude or immoral conduct, subject to the right of Provider to nominate a replacement Principal Physician as outlined in 6.3(a)(2), above.
- b. This Agreement may be terminated by Hospital at any time with thirty (30) days written notice, upon the occurrence of any one of the following events which has not been remedied within thirty (30) days after written notice of said breach:

- 1. Professional misconduct by any of Provider's Member Physicians as determined by the Bylaws, Rules and Regulations of the Medical and Dental Staff and the appeal processes thereunder;
- 2. Conduct by any of Provider's Member Physicians which demonstrates an inability to work with others in the institution and such behavior presents a real and substantial danger to the quality of patient care provided at the facility as determined by Hospital;
- 3. Disputes among the Member Physicians, partners, owners, or principals of Provider's group or professional corporation that, in the reasonable discretion of Hospital, are determined to disrupt the provision of good patient care:
- 4. Absence of Provider's Principal Physician, by reason of illness or other cause, for a period of ninety (90) days, unless adequate coverage is furnished by Provider. Such adequacy will be determined by Hospital's Administrator; or
- 5. Breach of any performance standard or any other material term or condition of this Agreement.
- 6.4 <u>Termination Without Cause</u>: After the first anniversary date of this Agreement, either party may terminate this Agreement, without cause, upon one hundred (180) days written notice to the other party.
- Renegotiation of terms: After the first anniversary date of this Agreement in any successive six (6) month period, if the patient volume changes by more than 25%, either negatively or positively, either party may ask for reconsideration of the compensation set forth above. Patient volume will be understood to mean the number of hospital inpatient, emergency room and outpatient clinic patients seen by Provider having no identifiable insurance coverage. The base line for this calculation will be the total number of billable Evaluation and Management (E&M) services from January 1, 2007 through June 30, 2007 divided by six (6) to obtain a monthly average. If the average patient volume has changed from the base line by 25% or more, either up or down, renegotiation of the contract may be requested by either party. Provider shall provide Hospital with monthly volume information for inpatient and emergency room billable Evaluation and Management (E&M) services within fifteen days after the end of each month for purposes of tracking this information. Hospital will provide outpatient clinic and transplant clinic volume to Provider upon request in a reporting format currently in use and available at Hospital.

#### VII. MISCELLANEOUS

Access to Records. Upon written request of the Secretary of Health and Human Services or the Comptroller General or any of their duly authorized representatives, Provider shall, for a period of four (4) years after the furnishing of any service pursuant to this Agreement, make available to them those contracts, books, documents, and records necessary to verify the nature and extent of the costs of providing its services. If Provider carries out any of the duties of this Agreement through a subcontract with a value or cost equal to or greater than \$10,000 or for a period equal to or greater than twelve (12) months, such subcontract shall include this same requirement. This section is included pursuant to and is governed by the requirements of the Social Security Act, 42 U.S.C. § 1395x (v) (1) (1), and the regulations promulgated thereunder.

- 7.2 <u>Amendments.</u> No modifications or amendments to this Agreement shall be valid or enforceable unless mutually agreed to in writing by the parties.
- Assignment/Binding on Successors. No assignment of rights, duties or obligations of this Agreement shall be made by either party without the express written approval of a duly authorized representative of the other party. Subject to the restrictions against transfer or assignment as herein contained, the provisions of this Agreement shall inure to the benefit of and shall be binding upon the assigns or successors-in-interest of each of the parties hereto and all persons claiming by, through or under them.
- 7.4 <u>Authority to Execute</u>. The individuals signing this Agreement on behalf of the parties have been duly authorized and empowered to execute this Agreement and by their signatures shall bind the parties to perform all the obligations set forth in this Agreement.
- 7.5 <u>Budget Act</u>. In accordance with NRS 354.626, the financial obligations under this Agreement between the parties shall not exceed those monies appropriated and approved by Hospital for the then current fiscal year under the Local Government Budget Act. Hospital agrees that this section shall not be utilized as a subterfuge or in a discriminatory fashion as it relates to this Agreement.
- 7.6 <u>Captions/Gender/Number/Tense</u>. The articles, captions, and headings herein are for convenience and reference only and should not be used in interpreting any provision of this Agreement. Whenever the context herein requires, the gender of all words shall include the masculine, feminine and neuter and the number of all words shall include the singular and plural. All verbs should be construed in the appropriate tense required by the context of the Agreement.
- 7.7 <u>Confidential Records.</u> All Hospital statistical, financial, confidential, and/or personnel records and any data or data bases derived therefrom shall be the property of Hospital regardless of the manner, media or system in which such information is retained. All such information received, stored or viewed by Provider shall be kept in the strictest confidence by Provider and its employees and contractors.
- Corporate Compliance. Provider recognizes that it is essential to the core values of Hospital that its contractors conduct themselves in compliance with all ethical and legal requirements. Therefore, in performing its services under this contract, Provider agrees at all times to comply with all applicable federal and state laws and regulations in effect during the term hereof and further agrees to comply with the relevant compliance policies of Hospital, including its corporate compliance program and Code of Ethics, the relevant portions of which are available to Provider upon request, set forth in Attachment "C", incorporated and made a part hereof by this reference.

## 7.9 Disagreements/Arbitration,

All matters involving the performance of Provider's duties, as set forth in this Agreement, shall be determined jointly by Provider and Hospital's Administrator. Any disagreement between Provider and Hospital's Administrator shall be resolved according to the following procedures:

a. In all matters concerning the <u>adequacy of coverage and the performance of Provider's duties set forth in the Agreement</u>, the decision of Hospital's Administrator shall be binding upon both parties unless the same is appealed to the Board of Hospital Trustees within ten (10) days after the decision of Hospital's Administrator is announced. The determination of the Board of Trustees shall be final with respect to such matters.

- b. All disputed matters pertaining to the Medical and Dental Staff Bylaws, Rules and Regulations shall be addressed through the mechanisms and procedures adopted and established by the Bylaws, Rules and Regulations of the Medical and Dental Staff.
- c. All other matters concerning the application, interpretation or construction of the provisions of this Agreement shall be submitted to binding arbitration. Arbitration shall be initiated by either party making a written demand for arbitration on the other party. Each party, within fifteen (15) days of said notice, shall choose an arbitrator, and the two selected arbitrators shall then chose a third arbitrator. The panel of three (3) arbitrators shall then proceed in accordance with the applicable provisions of the Nevada Revised Statutes, with the third arbitrator ultimately responsible for arbitrating the matter. Either party to the arbitration may seek judicial review by way of petition to the Eighth Judicial District Court of the State of Nevada to confirm, correct or vacate an arbitration award in accordance with the requirements of the Nevada Revised Statutes and the Nevada Rules of Civil Procedure.
- 7.10 Entire Agreement. This document constitutes the entire agreement between the parties, whether written or oral, and as of the effective date hereof, supersedes all other agreements between the parties which provide for the same services as contained in this Agreement. Excepting modifications or amendments as allowed by the terms of this Agreement, no other agreement, statement, or promise not contained in this Agreement shall be valid or binding.

#### 7.11 False Claims Act.

- The state and federal False Claims Act statutes prohibit knowingly or recklessly a. submitting false claims to the Government, or causing others to submit false claims. Under the False Claims Act, a provider may face civil prosecution for knowingly presenting reimbursement claims: (1) for services or items that the provider knows were not actually provided as claimed; (2) that are based on the use of an improper billing code which the provider knows will result in greater reimbursement than the proper code; (3) that the provider knows are false; (4) for services represented as being performed by a licensed professional when the services were actually performed by a nonlicensed person; (5) for items or services furnished by individuals who have been excluded from participation in federally-funded programs; or (6) for procedures which the provider knows were not medically necessary. Violation of the civil False Claims Act may result in fines of up to \$10,000 for each false claim, treble damages, and possible suspension from federally-funded health programs. Accordingly, all employees, volunteers, medical staff members, vendors, and agency personnel are prohibited from knowingly submitting to any federally or state funded program a claim for payment or approval that includes fraudulent information or is based on fraudulent documentation.
- b. Hospital is committed to complying with all applicable laws, including but not limited to Federal and State False Claims statutes. As part of this commitment, Hospital has established and will maintain a Corporate Compliance Program, has a Corporate Compliance Officer, and operates an anonymous 24-hour, seven-day-a-week compliance Hotline. A copy of Hospital's Compliance Manual and Code of Ethics is attached to this Agreement as Attachment "C". Provider is expected to immediately report to Hospital's Corporate Compliance Officer directly at 702-383-11.

  Corporate Compliance Officer directly at 702-383-11.

  Or in writing, any actions by a medical staff member, Hospital vendor, or Hospital

employee which Provider believes, in good faith, violates an ethical, professional or legal standard. Hospital is prohibited by law from retaliating in any way against any individual who, in good faith, reports a perceived problem.

- 7.12 <u>Federal, State, Local Laws.</u> Provider will comply with all federal, state and local laws and/or regulations relative to its activities in Clark County, Nevada.
- 7.13 <u>Financial Obligation</u>. Provider shall incur no financial obligation on behalf of Hospital without prior written approval of Hospital or the Board of Hospital Trustees.
- 7.14 Fiscal Fund Out Clause. This Agreement shall terminate and Hospital's obligations under it shall be extinguished at the end of any of Hospital's fiscal years in which Hospital's governing body fails to appropriate monies for the ensuing fiscal year sufficient for the payment of all amounts which could then become due under this Agreement. Hospital agrees that this section shall not be utilized as a subterfuge or in a discriminatory fashion as it relates to this Agreement. In the event this section is invoked, this Agreement will expire on the 30<sup>th</sup> day of June of the current fiscal year. Termination under this section shall not relieve Hospital of its obligations incurred through the 30<sup>th</sup> day of June of the fiscal year for which monies were appropriated.
- 7.15 Force Majeure. Neither party shall be liable for any delays or failures in performance due to circumstances beyond their control.
- 7.16 Governing Law. This Agreement shall be construed and enforced in accordance with the laws of the State of Nevada without regard to its choice of law provisions.

## 7.17 Indemnification.

- a. To the extent provided in Chapter 41 of Nevada Revised Statutes, Hospital shall indemnify and hold harmless, Provider, its officers and employees from any and all claims, demands, actions or causes of action, of any kind or nature, arising out of the negligent or intentional acts or omissions of Hospital, its employees, representatives, successors or assigns. Hospital shall resist and defend at its own expense any actions or proceedings brought by reason of such claim, action or cause of action. Provider acknowledges Hospital is self-insured.
- b. Provider shall indemnify and hold harmless, Hospital, its officers and employees from any and all claims, demands, actions or causes of action, of any kind or nature, arising out of the negligent or intentional acts or omissions of Provider, its employees, representatives, successors or assigns. Provider shall resist and defend at its own expense any actions or proceedings brought by reason of such claim, action or cause of action.
- c. Each of the Party's obligation to indemnify and/or defend the other shall survive the termination of this Agreement if the incident requiring such indemnification or defense occurred during the Agreement term, or any extension thereof, and directly or indirectly relates to the Party's obligations or performance under the terms of this Agreement.
- 7.18 Interpretation. Each party hereto acknowledges that there was ample opportunity to review and comment on this Agreement. This Agreement shall be read and interpreted according to its plain meaning and any ambiguity shall not be construed against either party. It is expressly agreed by

- the parties that the judicial rule of construction that a document should be more strictly construed against the draftsperson thereof shall <u>not</u> apply to any provision of this Agreement.
- 7.19 Non-Discrimination. Neither party shall discriminate against any person on the basis of age, color, disability, gender, handicapping condition (including AIDS or AIDS related conditions), national origin, race, religion, sexual orientation or any other class protected by law or regulation.
- 7.20 <u>Notices</u>. All notices required under this Agreement shall be in writing and shall either be served personally or sent by certified mail, return receipt requested. All mailed notices shall be deemed received three (3) days after mailing. Notices shall be mailed to the following addresses or such other address as either party may specify in writing to the other party:

To Hospital:

Chief Executive Officer

University Medical Center of Southern Nevada

1800 West Charleston Boulevard

Las Vegas, Nevada 89102

To Provider:

Kidney Specialists of Southern Nevada

500 South Rancho, Suite 12 Las Vegas, Nevada 89106

- 7.21 <u>Publicity</u>. Neither Hospital nor Provider shall cause to be published or disseminated any advertising materials, either printed or electronically transmitted which identify the other party or their facilities with respect to this Agreement without the prior written consent of the other party.
- 7.22 <u>Performance</u>. Time is of the essence in this Agreement.
- 7.23 Severability. In the event any provision of this Agreement is rendered invalid or unenforceable, said provision(s) hereof will be immediately void and may be renegotiated for the sole purpose of rectifying the error. The remainder of the provisions of this Agreement not in question shall remain in full force and effect.
- 7.24 Third Party Interest/Liability. This Agreement is entered into for the exclusive benefit of the undersigned parties and is not intended to create any rights, powers or interests in any third party. Hospital and/or Provider, including any of their respective officers, directors, employees or agents, shall not be liable to third parties by any act or omission of the other party.
- 7.25 <u>Waiver</u>. A party's failure to insist upon strict performance of any covenant or condition of this Agreement, or to exercise any option or right herein contained, shall not act as a waiver or relinquishment of said covenant, condition or right nor as a waiver or relinquishment of any future right to enforce such covenant, condition or right.
- 7.26 <u>Warranties</u>. Each party represents and warrants that it is not an Excluded Provider. For purposes of this Section, the term "Excluded Provider" means a person or entity that either (1) has been convicted of a crime related to health care, or (ii) is currently listed by a federal agency as debarred, excluded or otherwise ineligible for participation in federally funded programs (including without limitation federally-funded health care programs such as Medicare and Medicaid). Further, each party agrees to immediately disclose to the other party any debarment, exclusion or other event that makes the party or any individual employed by the party an Ineligible Person with respect to participation in any federal health care program, upon which

disclosure the other party may, without penalty, immediately terminate this Agreement.

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed on the day and year first above written,

Provider:

Hospital:

**Kidney Specialists of Southern** Nevada

University Medical Center of Southern Nevada

President

Interim Chief Executive Officer

## APPROVED AS TO FORM:

David Roger District Attorney

# **EXHIBIT 6**

# DEPARTMENT OF HEALTH & HUMAN SERVICES



die

CENTERS FOR MEDICARE & MEDICAID SERVICES
WESTERN CONSORTIUM
DIVISION OF SURVEY AND CERTIFICATION

May 28, 2008

Hospital Certification Number: Pending
Transplant Center Identification Number: Pending

Ms. Karen Watnem University Medical Center of Southern Nevada Transplantation Services 1800 W. Charleston Boulevard Las Vegas, NV 89102

Dear Ms. Watnem:

On March 12, 2008, Healthcare Management Solutions (HMS) conducted an initial Medicare approval survey of the organ transplant program at the University Medical Center of Southern Nevada (UMC-Southern Nevada). The initial survey involved the Adult Kidney Transplant Program.

Based on the survey results, the Centers for Medicare and Medicaid Services (CMS) has determined that UMC-Southern Nevada does not meet the requirements for participation in the Medicare Organ Transplant Program for the Adult Kidney Transplant Program and is out of compliance with the Conditions of Participation listed below. Regulations at 42 CFR § 488.3 require that a provider must be in compliance with the applicable Conditions of Participation.

42 CFR § 482.80 Data Submission, Clinical Experience, and Outcome Requirement

42 CFR § 482.90 Patient and Living Donor Selection

42 CFR § 482.92 Organ Recovery and Receipt

42 CFR § 482.96 Quality Assessment and Performance Improvement

Enclosed is form CMS-2567, Statement of Deficiencies documenting both the Condition-level and Standard-level deficiencies found during the survey. All deficiencies cited on the CMS-2567 require a Plan of Correction (PoC). You are required to respond within 10 days of receipt of this notice. Please indicate your corrective actions on the right side of the form CMS-2567 in the column labeled "Provider Plan of Correction" corresponding to the deficiencies on the left. Additionally, indicate your anticipated completion dates in the column labeled "Completion Date."

Denver Regional Office 1600 Broadway, Suite 700 Denver, CO 80202 San Francisco Regional Office 90 7<sup>th</sup> Street, Suite 5-300 (5W) San Francisco, CA 94103-6707 Seattle Regional Office 2201 Sixth Avenue, RX-48 Seattle, WA 98121

# Karen Watnem Page 2

An acceptable plan of correction must contain the following elements:

- The plan for correcting each specific deficiency cited;
- Efforts to address improving the processes that led to the deficiency cited;
- The procedure(s) for implementing the acceptable plan of correction for each deficiency cited;
- The completion date for correction of each deficiency cited;
- A description demonstrating how the hospital has incorporated systemic improvement actions into its Quality Assessment and Performance Improvement (QAPI) program in order to prevent the likelihood of the deficient practice from reoccurring;
- The procedures for monitoring and tracking to ensure that the plan of correction is effective and that specific deficiencies cited remain corrected and/or in compliance with the regulatory requirements; and
- The title of the person responsible for implementing the acceptable plan of correction.

Please submit your Plan of Correction by June 11, 2008 to:

Ed Q Japitana
Nurse Consultant
Division of Survey and Certification
Centers for Medicare and Medicaid Services
San Francisco Regional Office
90 7th Street, Suite 5-300 (5W)
San Francisco, CA 94103-6707

You (or an authorized program representative) must also sign and date the bottom of the first page of the CMS-2567.

The correction dates on the Plan of Correction must be no later than 45 days for Standard-level deficiencies and for the Condition-level deficiencies cited under 42 CFR § 482.90 Patient and Living Donor Selection; 42 CFR § 482.92 Organ Recovery and Receipt; and 42 CFR § 482.96 Quality Assessment and Performance Improvement.

For the Condition-level deficiency cited under 42 CFR § 482.80 Data Submission, Clinical Experience, and Outcome Requirements, the correction date on the Plan of Correction must be no later than 180 days. Although the latest correction date may be 180 days, a plan of correction will not be considered acceptable unless it outlines the steps that the transplant program will take <u>immediately</u> to develop and implement a comprehensive plan of correction.

You should also be aware that copies of the Form CMS-2567 and subsequent plans of correction are releasable to the public upon request in accordance with the provisions at 42 CFR § 401.133.

Karen Watnem Page 3

Deficiencies which resulted in non-compliance with the Conditions of Participation must be corrected in order for payment for covered transplant services to continue. CMS will terminate your participation in Medicare as an approved transplant program for the Adult Kidney Transplant Program if you do not achieve compliance with the Conditions of Participation by July 14, 2008 for Condition-level deficiencies cited under 42 CFR § 482.90; 42 CFR § 482.92; and 42 CFR § 482.96; or by October 13, 2008 for Condition-level deficiencies cited under 42 CFR § 482.80. You will receive a notice from CMS advising you of the termination process and your appeal rights. CMS will review the next Scientific Registry of Transplant Recipients (SRTR) Center-Specific Report that will be released in July 2008 to assess whether or not compliance with the Medicare Condition of Participation at 42 CFR § 482.80 has been achieved.

The requirement that UMC-Southern Nevada Adult Kidney Transplant Program must submit a plan to correct its Medicare deficiencies before it is granted approval of the above listed transplant programs does not affect the current status of UMC-Southern Nevada as a participating provider of hospital services in the Medicare Program.

If you have any questions regarding the content of this letter, please contact Ed Q. Japitana at 415-744-11., or by email at the content of this letter, please contact Ed Q.

Sincerely,

Deborah Romero Operations Manager

CMS Western Consortium

# **EXHIBIT 7**

Subject to the Nondisclosure Provisions of H. Res. 895 of the 110th Congress as Amended

# OFFICE OF CONGRESSIONAL ETHICS UNITED STATES HOUSE OF REPRESENTATIVES

#### MEMORANDUM OF INTERVIEW

IN RE:

Director of the Survey and Certification Group, Centers for Medicare and

Medicate Services

REVIEW No.:

11-0243

DATE:

November 15, 2011

LOCATION:

Centers for Medicare and Medicaid Services

7500 Security Blvd, Baltimore, MD 21244

TIME:

4:57 p.m. to 6:15 p.m. (approximately)

PARTICIPANTS:

Scott Gast

Kedric L. Payne

Gemma Flamberg, Senior Advisor to the General Counsel, HHS

Kristine Blackwood, Deputy Director, Oversight and Investigations, HHS

<u>SUMMARY</u>: The witness is the Director of the Survey and Certification Group at the Centers for Medicare and Medicaid Services ("CMS"). The OCE requested an interview with the witness on November 15, 2011, and he consented to an interview. The witness made the following statements in response to our questioning:

- 1. The witness was given an 18 U.S.C. § 1001 warning and consented to an interview. He signed a written acknowledgement of the warning, which will be placed in the case file in this review.
- 2. The witness is the director of the Survey and Certification Group at CMS. The Group sets policy and enforces conditions of participation for Medicare providers. The witness has been in this position since August 2003. Previously, he was the director of the Disabled and Elderly Programs Group.
- 3. The witness briefly outlined the requirements that transplant programs must satisfy to participate in Medicare. A transplant program must satisfy two separate categories of requirements: program requirements and outcome requirements.
- 4. To satisfy the program requirements, a transplant program must have certain policies and procedures in place (i.e., to ensure informed consent, or to ensure proper matching of organ donors and recipients). CMS determines whether a program is meeting the program requirements through on-site surveys.
- 5. If a deficiency is identified through the on-site survey, CMS issues a deficiency notice. A deficiency may fall within one of three categories: (1) immediate jeopardy

MOI - Page 1 of 4

OFFICE OF CONGRESSIONAL ETHICS

- Subject to the Nondisclosure Provisions of H. Res. 895 of the 110th Congress as Amended deficiencies, which must be addressed within 23 days; (2) condition-level deficiencies, which must be addressed within 90 days; and (3) standard-level deficiencies.
- 6. In addition to satisfying program requirements, a transplant program must satisfy patient and graph survival outcome requirements. Data from the Scientific Registry of Transplant Recipients ("SRTR") is used to determine whether patient and graph survival outcome requirements are being met.
- 7. According to the witness, an on-site survey of the University Medical Center of Southern Nevada ("UMC") kidney transplant program conducted in March 2008 identified several conditional-level program deficiencies. Further, SRTR data indicated that the UMC program failed to meet minimum outcome requirements.
- 8. UMC was notified of these deficiencies by letter and given dates on which Medicare participation would terminate unless the deficiencies were adequately addressed. For the program deficiencies, UMC was given a termination date of July 14, 2008 (later extended to August 29, 2008). UMC was given 210 days to improve the outcome deficiencies; if they were not corrected, Medicare participation would terminate on October 13, 2008.
- 9. An on-site re-survey conducted in August 2008 determined that UMC had satisfactorily addressed the program deficiencies, but SRTR data released in July 2008 indicated that UMC had not yet corrected the outcome deficiencies.
- 10. In early August, the witness had a conference call with UMC to discuss its options, given the failure to correct the outcomes deficiencies: (1) the program could voluntarily withdraw from Medicare participation; (2) the program could be involuntarily terminated by CMS; or (3) the program could seek approval based on mitigating factors.
- 11. The witness stated that the UMC program submitted an application for approval based on mitigating factors, but that the application was denied by CMS. As a result of the denial, the October 13, 2008 termination date remained in effect.
- 12. The witness did not recall any intervention from Congress prior to the denial of the application for approval based on mitigating factors.
- 13. The witness indicated that UMC continued to argue against termination after the denial of its application for approval based on mitigating factors. Attorney Glenn Krinsky, UMC Chief Executive Officer Kathy Silver, and Transplant Administrator Karen Watnem were involved in the negotiations on behalf of UMC. The witness, Karen Tritz, and Sherry Clark of the Survey and Certification Group; the acting CMS deputy administrator; and legal counsel were involved in the negotiations on behalf of CMS.

Subject to the Nondisclosure Provisions of H. Res. 895 of the 110th Congress as Amended

- 14. According to the witness, UMC gave CMS a number of reasons why its Medicare participation should not be terminated. Four considerations, taken together, convinced CMS to propose and ultimately enter into a Systems Improvement Agreement with UMC, to provide the hospital with additional time to make improvements in the transplant program, thereby avoiding termination.
- 15. According to the witness, the most significant consideration was a legal argument made by UMC, based upon language erroneously included in the preamble to the transplant program regulations, that UMC argued precluded termination while an appeal was pending. CMS had historically stopped Medicare payments to providers during the appeals process and did not wish to set a new precedent that would allow providers to continue Medicare participation while appealing a termination decision.
- 16. The witness stated that CMS also considered patient access to care should the transplant program be shut down, and the facts that, by this time, the hospital appeared to have good institutional support and a specific plan for improving the kidney transplant program.
- 17. Because of these factors, CMS agreed to delay termination for a period of approximately one month, to allow CMS and UMC to negotiate a Systems Improvement Agreement. Under this Agreement, CMS would further postpone termination for a period of approximately six months, during which time UMC would be required to make specific changes to its transplant program. If the hospital made substantial progress, termination would be avoided
- 18. The witness noted that this was the first time CMS had entered into a Systems Improvement Agreement with a transplant program, but that CMS had used such an approach in the past with other types of providers, including nursing homes.
- 19. The witness stated that the Systems Improvement Agreement for UMC's kidney transplant program included detailed milestones that the hospital was required to meet, together with extensive follow-up with CMS.
- 20. According to the witness, there were several contacts between CMS and Members of Congress or congressional staff during the negotiations with UMC that led to the Systems Improvement Agreement approach.
- 21. The witness participated in at least one conference call set up by the CMS Office of Legislation, during which he explained the CMS survey and certification process as well as the relevant facts considered by CMS in deciding to terminate the UMC program's Medicare participation. The witness was not sure who participated in the conference call, but he believes the audience was congressional staff members.

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- 22. The witness was aware that the CMS acting administrator had received a letter from the Nevada congressional delegation expressing disagreement with the termination decision. The witness could not recall whether the letter was sent to CMS before or after his telephone briefing. The witness assisted in preparing a response to the delegation letter.
- 23. The witness stated that he was aware of telephone calls made to CMS by parties from Congress, but he was not aware of who made the calls, who at CMS received the calls, or when the calls were made.
- 24. The witness could not recall any other contacts with Members of Congress or congressional staff.
- 25. According to the witness, the level of congressional interest and involvement in the UMC matter was "somewhere in the middle" when compared to similar situations.
- 26. OCE asked the witness about references in emails that CMS not appear "browbeaten" into the agreement with UMC. The witness stated that CMS was not browbeaten into the agreement, but wanted to discourage such an impression for future matters.
- 27. The witness stated that the congressional involvement in the UMC kidney transplant program matter had no effect on the decisions to terminate participation or to enter into the Systems Improvement Agreement.
- 28. The witness was shown an email he wrote on October 30, 2008, in which he stated that he had learned from a reporter "that Congresswoman Berkley is married to a physician (nephrologist) that has a personal financial interest in the success of UMC...." According to the witness, the contact with the reporter was the first time he had learned of Representative Berkley's connection to the UMC program.
- 29. Given that Representative Berkley's efforts on behalf of the UMC program had no effect on the termination decision, the witness declined to say that her advocacy efforts on behalf of the program were inappropriate.

This memorandum was prepared on November 16, 2011, based on the notes that the OCE staff prepared during the interview with the witness on November 15, 2011. I certify that this memorandum contains all pertinent matter discussed with the witness on November 16, 2011.

Kedric L. Payne Deputy Chief Counsel

MOI - Page 4 of 4

OFFICE OF CONGRESSIONAL ETHICS

# **EXHIBIT 8**

# reviewjournal.com



# UMC loses kidney program

BY ANNETTE WELLS ©2008 REVIEW-JOURNAL

Posted: Oct. 25, 2008 | 10:00 p.m.

Four months after becoming the state's only kidney transplant program, University Medical Center has been stripped of that privilege, leaving in doubt where more than 200 Nevadans awaiting kidney transplants might go for their procedures.

UMC was notified in a Thursday letter by Centers for Medicare and Medicaid Services, or CMS, that its certification for the transplant center will be revoked effective Dec. 3.

That means the hospital will not receive any payments for transplant services on or after that date, effectively closing the program.

The letter goes on to say the program was revoked because it did not meet required patient survival outcomes based on surveys CMS conducted in March and August.

"More people are dying than necessary at UMC," Jack Cheevers, a spokesman for CMS' Region IX, said about the federal health agency's decision. "The hospital's actual death rate for kidney transplant recipients is more than 50 percent higher than its expected death rate. And, the hospital hasn't done what it needs to do to address its quality of care problems."

However, hospital officials and others say the program is being unfairly penalized. One of the deaths used to justify the CMS findings was a suicide, they said. Were it not for that death, UMC Chief Executive Officer Kathy Silver said, the program would be in compliance.

But according to a 52-page report summarizing the March 12 survey at UMC, roughly 45 deficiencies in the hospital's transplant program were documented.

# Among the findings:

- The program failed to document that donor blood type and other vital data were compatible with the intended recipient prior to transplantation.
- The program "failed to keep their waiting lists up to date on an ongoing basis."
- The program failed to timely notify the Organ Procurement and Transplantation

Network that patients had a successful transplant and should be taken off the network's list.

UMC was asked to provide a plan of correction for those deficiencies, which it did. During a follow-up Aug. 7 survey, UMC was found to still be not in compliance for three deficiencies.

As in the March survey, one of those deficiencies was inadequate patient survival outcomes.

The hospital now has two options: allow CMS to decertify the program on Dec. 3, or voluntarily withdraw its certification. Silver said the latter course will be taken, but UMC still plans to challenge the decision.

Silver said Friday she was disappointed in CMS' action.

"We're trying to point out to them that the implications of closing this program would mean people having to travel several hours or more to get a kidney transplant. Some people can't afford that," Silver said. "This affects the whole region. These people will now be on the waiting lists of other transplant centers. This will impact those other facilities, even though the patients retain their status on the waiting lists."

Patients in need of kidney transplants may now have to travel to out-of-state facilities such as the Mayo Clinic in Scottsdale, Ariz., or UCLA, officials say.

The CMS letter to the hospital says UMC must assist waiting list patients transferring to another transplant facility "without loss of time accrued on the waiting list."

Silver said the hospital has already sought help from the state's congressional delegation, which is now pleading with CMS to reconsider.

"We have reached out to both the House and the Senate side of this delegation," Silver said. "We feel very frustrated by this whole process and we are hopeful that between some of the administration remedies, and pressure applied through our congressional leaders, we can get CMS to reconsider."

On Friday, Reps. Shelley Berkley, Jon Porter and Dean Heller sent a letter to CMS' acting administrator, Kerry Weems, expressing their "strong disagreement" with the agency's decision.

In their letter, they reference what they believe is the remaining unresolved deficiency -- the patient survival outcomes. The May 2005 suicide caused UMC to not meet compliance standards for two overlapping reporting periods -- July 1, 2004 to Dec. 31, 2007 and Jan. 1 2005 to June 30, 2007.

"This suicide of an otherwise successful transplant patient is lamentable, but beyond the control of UMC," the letter states.

"Our argument to CMS is that death should not be counted for purposes of a statistical calculation," Silver said.

Berkley spokeswoman David Cherry said the congresswoman felt she needed to act considering the importance of a kidney transplant program in Nevada.

As of Friday, according to the United Network for Organ Sharing, 208 people were awaiting kidney transplants in Nevada. Ken Richardson, executive director of the Nevada Donor Network, said about 200 other patients are awaiting heart, liver and other transplants.

Richardson said he was shocked at CMS' decision.

"This is important to our community," he said. "This puts our community at a disadvantage. It is not a very good situation when a government agency recklessly disregards the needs of the people."

In July, Sunrise Hospital and Medical Center's kidney transplant program was folded into UMC's to improve the county hospital's performance. The goal was to turn UMC's kidney transplant program into a "center of excellence" so it could eventually offer heart and liver transplants.

Richardson said UMC has been aggressively recruiting for surgeons and nephrologists to staff the kidney transplant program.

Sunrise had offered kidney transplants for nearly two decades before merging its program with UMC.

Because of the small number of kidney transplants performed in Southern Nevada -- 26 at Sunrise last year and 40 at UMC -- Sunrise officials said it made sense to consolidate the programs.

Contact reporter Annette Wells at @reviewjournal.com or 702-383-

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# **EXHIBIT 9**

DEPARTMENT OF HEALTH & HUMAN SERVICES Centers for Medicare & Medicaid Services 7500 Security Boulevard, Mail Stop 52-12-25 Baltimore, Maryland 21244-1850



# Center for Medicaid and State Operations/Survey and Certification Group

August 6, 2008

Ms. Karen Watnem University Medical Center Transplantation 1800 W. Charleston Boulevard Las Vegas, NV 89102

Dear Ms. Watnern:

This letter outlines the options we discussed during our conference call on August 5, 2008, regarding Medicare participation for the adult kidney transplant program at University Medical Center. As we discussed, based on the survey findings from March 2008, the adult kidney transplant program did not meet Medicare's outcome requirements based on the January 2008 report from the Scientific Registry of Transplant Recipients (SRTR). As a result, the program was given a prospective termination date of **October 13, 2008**, if the July 2008 SRTR report did not show that the program's outcomes were back in compliance. Based on the July 2008 SRTR report, the adult kidney transplant program continues to be out of compliance with the Medicare Conditions of Participation for patient survival, 1-year post-transplant.

As outlined in the conference call, University Medical Center has three options:

- 1) Voluntary Withdrawal Within 7 calendar days of the conference call (August 12, 2008) the transplant program has the option of contacting the Centers for Medicare & Medicaid Services (CMS) and voluntarily withdrawing from the Medicare program. The transplant program may reapply for Medicare at any later time period.
- 2) Request Approval Based on Mitigating Factors —Within 10 calendar days of the conference call (August 15, 2008) the transplant program may notify CMS that it intends to apply for approval based on mitigating factors. Within 30 calendar days (September 4, 2008), the program should submit any additional information that it would like CMS to consider. You should have received a document outlining the items you must include in your application for CMS consideration of mitigating factors and clearly detail the specific factors which you feel represent mitigating factors.
- 3) Involuntary Termination The transplant program also has the option of not taking any action which would allow the termination from Medicare to proceed as planned. If termination were to occur, the transplant program would still have appeal rights under 42 CFR §498.

# Page 2 - Ms. Karen Watnern

For your reference, we have also attached a table of the program's recent 1-year patient and graft survival rates. If you have any questions about any of the information contained in this letter, please feel free to contact Sherry Clark (2008).

Sincerely,

Thomas E. Hamilton

Director

cc: CMS Regional Office

# **EXHIBIT 10**

Sherry Clark
Survey and Certification Group, CMSO
Centers for Medicare and Medicaid Services
7500 Security Blvd, Mailstop S2-12-25
Baltimore, MD 21244

Dear Ms. Clark:

This letter supplements our Request for Approval Based on Mitigating Factors dated August 11, 2008. To reiterate, our request is for the following:

#### Name:

University Medical Center of Southern Nevada ("UMC")

#### Program:

Kidney Transplant Service

#### Contact:

Karen Watnem, RN
Transplant Administrator
702-671- office
cell
@umcsn.com

Conditions of Participation for which UMC is requesting CMS review for mitigating factors are:

42 CFR 482.80 – Data submission, clinical experience and outcome requirements for initial approval of transplant centers.

42 CFR 482.82 – Data submission, clinical experience and outcome requirements for re-approval of transplant centers.

-1-

#### INTRODUCTION

UMC is requesting approval based on mitigating factors for all of the reasons set forth in Appendix One of the Process for Requesting Consideration of Mitigating Factors in CMS' Determination of Medicare Approval of Organ Transplant Centers ("Process for Requesting Consideration").

<u>First</u>, UMC is barely out of compliance with the Final Rule's standard for one-year patient survival, and would actually be in compliance with the applicable standard but for the suicide death of one patient for reasons wholly unrelated to the patient's (successful) kidney transplant.

Second, decertification of UMC would cause a catastrophic loss of access to care for the patients on UMC's wait list and for the large and growing population of Southern Nevada. Indeed, Nevada's only other kidney transplant program closed just two months ago on July 1, 2008, and that program's wait-listed patients are still in the process of being merged into UMC's wait list. The closest existing kidney transplant centers (in Phoenix, Arizona, Salt Lake City, Utah; Southern California; and Northern California) are all at least four to six hours' drive from UMC.

Third, factors beyond the control of UMC have had a negative effect on the program's outcomes, including the untimely illness and death of Dr. Joseph Snyder, the program's primary nephrologist, and the current serious illness of the program's primary surgeon.

Fourth, UMC's kidney transplant program has successfully implemented major quality assessment and performance improvement measures in the past six months and additionally enjoys unprecedented support—both financial and otherwise—from UMC's new executive leadership team.

# \*\*\*IMPORTANT NOTE\*\*\*

In addition to the factors summarized above, please note that on September 9, 2008, UMC informed the OPTN of its decision to initiate immediately a period of "functional inactivation" as described in the OPTN Bylaws, Appendix B, Section II, Part C, and as further described in the Final Rule at 42 CFR 488.61(e). UMC took this step, out of an abundance of caution, after learning on September 8, 2008, of a serious illness requiring the hospitalization (in an intensive care unit) of the kidney program's primary (and sole fulltime) surgeon. As previously described in UMC's corrective action plan submitted to the OPTN (see Exhibit A-5) and described during CMS' validation survey on August 5, 2008, UMC has been actively recruiting additional surgical staff to the program. At this time, UMC is finalizing a contract pursuant to which the University of Utah will supply four experienced surgeons from its highly successful kidney transplant program to UMC's program on a rotating, fulltime basis until such time as UMC successfully recruits permanent additional surgical staff. In light of the current serious illness of UMC's primary surgeon, UMC decided to initiate its period of functional inactivation until such time as the contract with the University of Utah is executed and the Utah physicians are licensed to practice in Nevada by the appropriate Nevada authorities. UMC will not reactivate its program

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-2-

<sup>&</sup>lt;sup>1</sup> The UNOS peer review survey team noted in February 2008 that the primary surgeon is "well trained, skilled, and dedicated to the kidney transplant program" (see Exhibit A-4).

with the OPTN until the Utah team is in place and ready to perform transplants or until UMC has successfully recruited additional fulltime, experienced kidney transplant surgical staff.

#### A. PATIENT SURVIVAL OUTCOMES

CMS' letter to UMC dated August 6, 2008, correctly notes that UMC's program does not satisfy the Final Rule's one-year patient survival condition of participation. For the SRTR cohort of July 1, 2004 – December 31, 2006, the "expected" number of deaths was 1.81. For the SRTR cohort of January 1, 2005 – June 30, 2007, the "expected" number of deaths was 1.75. Thus, for each of those SRTR reporting periods, UMC would be in compliance with the outcomes requirement if the actual number of deaths had been four (i.e., 4.00 < 1.81 + 3.00; and 4.00 < 1.75 + 3.00). In each reporting period, a fifth death would place UMC just outside of the compliance standard (by .19 for the first SRTR cohort and by .25 for the second SRTR cohort).

In each reporting period, UMC's program had five actual deaths, thus barely missing the compliance standard. However, in each of the SRTR cohorts, one of the five deaths resulted from a patient's suicide for reasons wholly unrelated to the success of the patient's transplant. This patient was transplanted on March 25, 2005. The transplant was successful and on May 6, 2005, the patient's creatinine was 1.1 and her BUN was 12. The patient committed suicide on May 8, 2005. At the time of listing, the patient had a history of mental illness. She was deemed to satisfy selection criteria based upon regular psychiatric care, a successful compliance history, high cognitive functioning and a supportive husband of 14 years. In the program's judgment, this patient's death was not due to inadequate transplant care. But for this patient's continued inclusion in the SRTR cohorts, UMC would be in compliance with the Final Rule's outcomes standard. Ironically, this patient will "drop off" the next SRTR reporting cohort for the period July 1, 2005 through December 31, 2007. As can be seen in the three-year table below (requested by CMS to be set forth in this submission), UMC will report a total of four deaths in the next SRTR reporting period; consequently, UMC's program will be in compliance with the Final Rule's outcomes standard when the SRTR issues its next report in January, 2009.

As can also be seen in the table below, UMC's trendline has been improving, particularly in the final year of the three-year table (i.e., calendar year 2007). In that year, with 39 total transplants, this were no one-month deaths, one one-month graft failure, one one-year death and one one-year graft failure.

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- 3 -

Two of the other four deaths that occurred during the SRTR's two most recent reporting periods were patients who were listed pursuant to looser selection criteria than now exists at the program. One patient, age 74, with hypertension and diabetes (but with no cardiac symptoms and a satisfactory pre-transplant cardiac evaluation) died of myocardial infarction shortly after transplant in Pebruary 2006. Another patient, age 62, with hypertension, diabetes and a history of coronary artery disease, died of cardiac arrest shortly after transplant in March 2006. Neither of these patients would have satisfied the program's revised selection criteria that was published in March 2008 (see the program's OPTN corrective action plan, Exhibit A-5). Of the remaining two deaths in the reported SRTR cohorts, one patient's death was reported by the coroner as caused by chronic renal failure even though the patient's last creatinine result (three weeks prior to death) was 0.9. This patient was repeatedly non-compliant post-operatively and self-reported post-operative drug abuse (pre-transplant evaluation revealed no psychiatric concerns and no evidence of substance abuse). The patient refused advice to report to the ER and was found dead at home. The program suspects that drug abuse was likely the proximate cause of death.

TABLE: UMC'S THREE-YEAR OUTCOMES AT SIX-MONTH INTERVALS

	Kidney Transplants	1 Month Deaths	1 Year Deaths	Total Grafts	1 Month Graft Failures	l Year Graft Failures
1/1/05- 6/30/05	22	0	2	22	1	0 -
7/1/05- 12/31/05	13	0	0	13	0	1
1/1/06- 6/30/06	20	2	0	20	2	1
7/1/06- 12/31/06	19	0	1	19	0	2
1/1/07- 6/30/07	13	0	0	13	0	Ó
7/1/07- 12/31/07	26	0	1	26	1	1

#### B. ACCESS-TO-CARE ISSUES

# 1) Evidence of Access:

Closure of UMC's kidney transplant program would have a devastating effect on the patient population in the State of Nevada, southwest Utah, and northern Arizona. The July 1, 2008 closure of the kidney transplant program at Sunrise Hospital and Medical Center ("Sunrise")—the only other transplant hospital in the area—means that the UMC wait list, already large, is growing rapidly as former Sunrise patients are merged onto UMC's list. Prior to the closure of Sunrise, UMC had 137 total patients on its wait list, 73 of whom were status 1. Currently, UMC lists 159 total patients, 85 of whom are status 1. Of a total 162 patients who were referred to UMC from Sunrise, 20 have been listed so far, and 139 patients are still being evaluated. In other words, UMC's wait list could shortly more than double as a result of Sunrise's closure.

In addition to the rapidly growing wait list at UMC, closure of UMC's transplant program would severely impact the patient population because the nearest transplant hospitals are several hundred miles from Las Vegas. Patients would have a much more difficult time accessing transplants with that kind of distance barrier and almost surely many patients would de-list.

#### 2) Population Considerations:

The patient population served by UMC includes a large transient contingent attracted by cultural and other factors unique to Las Vegas. This population has a demonstrably high incidence of diabetes, drug and alcohol abuse, and prostitution, all of which make the wait list population high risk compared with other wait list populations.

### 3) Organ-Type Considerations:

Las Vegas is a large city with a rapidly growing population, and as such is necessarily the source of a large number of cadaveric organs. If UMC closes, many of those organs will be lost because of the great distances to the nearest transplant centers.

# C. FACTORS BEYOND THE CONTROL OF THE HOSPITAL

The UMC program nephrologist, Dr. Joseph Snyder, who at the time was being shared with the then-existing transplant center at Sunrise, was diagnosed with a life-threatening disease in 2006 and became increasingly unavailable to the program until his untimely death on December 17, 2007. Dr. Snyder's illness and subsequent unavailability caused strains on the program that might well have indirectly affected UMC's outcomes for parts of 2006 and 2007. Furthermore, while not related to the cohort period of 1/1/2005-6/30/2007, UMC's primary transplant surgeon is also now ill with a serious illness which prompted the program to inactivate as of September 9, 2008. The program will not be reactivated until new surgical personnel have been hired.

# D. QUALITY IMPROVEMENT AND MANAGEMENT INTERVENTIONS

# 1) Analysis:

UMC has engaged in a comprehensive, thorough, and far-reaching root cause analysis, leading to the extensive Corrective Action Plan submitted to CMS (see Exhibit B). Furthermore, UMC submitted a final Corrective Action Plan to the OPTN within the last two weeks, and in a September 5, 2008 telephone call, OPTN staff confirmed that the plan is satisfactory (see Exhibit A-5).

## 2) QAPI:

UMC meets all three of the QAPI criteria set forth in the Process for Requesting Consideration: significant improvements in its QAPI Program, implementation of improvements, and insufficient time for improvements to manifest in SRTR data. UMC has instituted a major revision of its policies and procedures to conform to OPTN and CMS guidelines (see Exhibits A-5 and B). In March 2008, UMC established a Transplant QAPI Committee, which has been meeting monthly for the purpose of developing transplant-specific policies. Specific policy changes include the following: On March 19, 2008, UMC revised its policies in the management of recipient and living donors to encompass all of the program's multidisciplinary team. Multidisciplinary rounds were re-instituted on March 19, 2008, and a multidisciplinary documentation tool was adopted and is completed on every inpatient affiliated with the transplant program. The transplant social worker was dedicated to the transplant department on a fulltime basis on May 27, 2008. On March 19, 2008, UMC also implemented revised

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procedures for consent for the potential recipient and living donor. All potential recipients and donors are required to sign informed consents for evaluation and surgery prior to proceeding with work-up. Consent forms have been revised to incorporate components that must be contained in the consent process as required by the Final Rule and the OPTN, and the forms are given to each patient in the initial patient packet.

In March 2008, a revision of clinic charts was begun to provide a more structured and streamlined process for correlating patient medical records. The new charting process is now complete. On March 19, 2008, UMC implemented revised procedures for ABO verification, and the new process was approved by the Medical Executive Committee on March 25, 2008. An inservice training was provided to all operating room nurses on utilization of the revised ABO forms on June 5, 2008. On March 31, 2008, a new clinic process was implemented, including a new evaluation process for living donors. At that time a living donor coordinator was also established.

In April 2008, several transplant policies were revised in collaboration with the transplant surgeon, nephrologists, transplant administrator, and coordinators, including the pre-transplant process, post-transplant process, and the living donor process from entrance into the program through post-donation. In April a policy was also implemented to ensure collaboration and communication between the transplant center and dialysis centers. With all of these policy changes, UMC has moved from a "surgeon-driven" program (as characterized by the UNOS peer review survey team in February 2008) to a comprehensive multidisciplinary approach.

A sufficient amount of time has not yet passed to allow for these improvements to be reflected in the SRTR data, but as stated in response to Patient Outcomes, section A above, when the next SRTR report is published for the period 7/1/2005-12/31/2007, two deaths will fall out of the cohort, and UMC will be in compliance with the Final Rule's outcomes standard. Further improvement is expected as the QAPI takes deeper root within the program.

### 3) Governing Body and Management:

UMC's new executive leadership team has demonstrated an unprecedented financial and philosophical commitment to supporting UMC's kidney transplant program. The three criteria of improvements in management, implementation of those improvements, and insufficient time for the improvements to manifest in the SRTR data, as set forth in the Process for Requesting Consideration, have all been met. UMC has achieved impressive changes in executive leadership and administration according to the corrective action plan recently submitted to the OPTN (see Exhibit A-5), including the following:

- 1) Appointment of Kathy Silver as the permanent Chief Executive Officer as of April 15, 2008.
- 2) Appointment of Karen Watnem as a fulltime, dedicated Transplant Administrator on March 14, 2008.
- 3) Appointment of Mario Paquette, LPN, as Data Coordinator for Transplant Service on May 27, 2008.

- 6 -

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4) Appointment of two additional Clinical Transplant Coordinators; one of whom began work on July 14, 2008, the other of whom began work on August 4, 2008. One of these new coordinators is dedicated to the crucial task of wait list management.

A critical management change that UMC has instituted, as noted in the OPTN Corrective Action Plan, is that for the first time the dedicated Transplant Administrator, Karen Watnem, reports directly to the Chief Executive Officer, so the fragmented reporting noted by the UNOS peer review survey team in February 2008 is no longer in existence.

### **CONCLUSION**

As acknowledged in its Corrective Action Plans to both CMS and the OPTN, UMC has previously suffered from systemic deficiencies that may have adversely affected its patient outcomes. Over the past six months, a concerted effort has been put forth to analyze and correct these deficiencies. A comprehensive corrective action plan has been successfully implemented. New executive leadership has demonstrated unprecedented support for the program. Critical policies, including patient selection criteria, have been revamped, updated and improved. A model QAPI program is in place. Lines of communication are clear and, for the first time, a fulltime, dedicated transplant administrator reports directly to the CEO.

The program has for some time been aggressively recruiting for additional permanent surgical staff. Out of an abundance of caution, when the program's sole fulltime surgeon fell seriously ill last week, the program decided that it was in the best interests of its patients to initiate a period of functional inactivation to ensure that all of the systemic improvements that have been implemented are matched by a first-class surgical team with appropriate levels of breadth and depth. As noted above, UMC will not re-activate its program until such a surgical staff is fully in place. The program knows of no better way of demonstrating its commitment to outstanding patient outcomes than by calling this "timeout" to allow for the retention of a robust surgical team.

We request that CMS seriously consider these mitigating factors when making its certification decision. We believe that UMC has already satisfied the Final Rule's outcomes standard once the non-transplant-related patient death is taken into account. Even so, UMC has already demonstrated its commitment to improve its outcomes by implementing the measures noted above. Finally, closing the program would mean great hardship for the patients on its wait list, given the recent closure of the program at Sunrise and the migration of Sunrise's patients to UMC's wait list, and the fact that UMC is the only kidney transplant program within several hundred miles of Las Vegas. We ask that CMS grant approval to UMC based on these mitigating circumstances.

If there are any questions concerning this request please feel free to contact Karen Watnern or me.

Sincerely,

Kathleen Silver Chief Executive Officer University Medical Center of Southern Nevada

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## Timeline: University Medical Center of Southern Nevada Kidney Transplant Program Survey, Correspondence and Enforcement Action

March 2008 10-12	Initial Onsite Survey
<u>May 2008</u> 28	CMS Regional Office sent letter to UMC with survey findings. Condition-level findings for: Outcomes, Patient and Living Donor Selection, ABO Verification, and Quality Assessment and Performance Improvement (Original termination dates July 14, 2008, and October 13, 2008-both later extended)
June 2008 11	Plan of Correction for 2567 due from UMC
<u>July 2008</u> 14	Original termination date for Condition-level deficiencies other than outcomes.
August 2008 4	CMS RO sent letter to UMC extending termination date for deficiencies not related to patient survival outcomes
5	Conference call with UMC to outline that the program did not meet the July 2008 SRTR outcomes and describe program's options 1) voluntary withdrawal; 2) request approval based on mitigating factors; 3) allow termination to proceed.
5-7	Surveyors conduct onsite revisit at UMC to review correction of earlier cited deficiencies. Three deficiencies still outstanding including: 1) patient survival outcomes; and 2) ABO verification during organ recovery
6	Send follow-up letter to UMC confirming August 5, 2008 conference call findings.
11	UMC submits letter to CMS outlining intent to apply for approval based on mitigating factors

September 2008

5	CMS RO sent letter to UMC with findings from re-visit and requesting plan of correction
11	UMC submits full request for approval based on mitigating factors
15	Discussion by CMS Mitigating Factors Panel
23	Discussion by CMS management and decision to deny approval based on mitigating factors, de-certification timetable proceeds.
29	Conference call with UMC to relay that the termination will continue (i.e. the request for approval based on mitigating factors was not successful)
October 2008	
13	Original termination date for Condition-level deficiencies related to outcomes
16	Letter to UMC from CMS Regional Office, Medicare decertification set at November 20, 2008 unless the program chooses to withdraw by October 24, 2008
21	Received call from attorney representing UMC. The facility does not have sufficient time to provide beneficiaries with 30 day notice and there was an error in the type of outcomes not met. CMS agreed to re-send the letter with later termination date to allow sufficient time for beneficiary notice and to correct the notice.
23	Re-send Letter to UMC from CMS Regional Office, extension of Medicare-de-certification date to December 3, 2008, unless the program chooses to voluntarily withdraw by November 6, 2008

Subject to the Nondisclosure Provisions of H. Res. 895 as Amended

## OFFICE OF CONGRESSIONAL ETHICS UNITED STATES HOUSE OF REPRESENTATIVES

### MEMORANDUM OF INTERVIEW

IN RE:

Attorney #1, outside counsel to the University Medical Center of Southern

Nevada

REVIEW #(s):

11-0243

DATE:

December 7, 2011

LOCATION:

Jones Day

555 South Flower Street, Los Angeles, CA

TIME:

1:02 PM to 2:05 PM (approximate)

PARTICIPANTS:

Paul Solis Scott Gast

Brian Hershman (counsel)

<u>SUMMARY</u>: The witness is Of Counsel at the law firm of Jones Day. The OCE requested an interview with the witness and he consented to an interview. The witness made the following statements in response to our questioning:

- 1. The witness was given an 18 U.S.C. § 1001 warning and consented to an interview. The witness signed a written acknowledgement of the warning, which will be placed in the case file in this review.
- 2. The witness is an attorney in the healthcare law group at Jones Day. He has been at Jones Day for two and a half years. Prior to joining Jones Day, he was an attorney at the law firm Ropes and Gray for approximately five years, also in healthcare law. Before that, the witness served as general counsel at City of Hope medical center.
- 3. The witness stated that he was the "head coach" in representing the University Medical Center of Southern Nevada ("UMC") in negotiations with the Centers for Medicare and Medicaid Services ("CMS") regarding potential decertification of the UMC kidney transplant program. He began working on this matter during the summer of 2008. Other attorneys involved in the representation were Larry Gage, who had an existing relationship with UMC; Charles Luband, who had experience in dealing with Capitol Hill; and Peter Brody, an administrative litigation attorney.
- 4. The witness stated that he was involved in preparing UMC's request for Medicare approval of its kidney transplant program based on mitigating factors, which was denied by CMS in September 2008. After that request was denied, the witness continued to advocate for approval of the transplant program, focusing on three prongs: (1) improving the program's clinical situation; (2) initiating litigation, if necessary, with regard to a dispute over regulatory language that UMC argued would preclude CMS from decertifying the UMC program while an appeal of that decision was pending; and (3) seeking help from UMC's legislative representatives.

MOI - Page 1 of 3

OFFICE OF CONGRESSIONAL ETHICS

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- 5. The witness recalled that it had been his idea to reach out to elected representatives sometime after CMS decided to go forward with decertification. According to the witness, the idea gained traction when CMS continued to refuse to abide by their own regulations. The witness stated that it is never far from a lawyer's mind, when representing clients that deal with CMS, to reach out to elected representatives in Washington, DC.
- 6. The witness stated that the initial outreach to congressional officials may have been made by his colleagues Mr. Gage and Mr. Luband, and that Mr. Luband became the point person for these outreach efforts.
- 7. The witness was shown an October 23 email from Mr. Luband to him and the UMC CEO at the time, in which Mr. Luband references a conference call with a member of Representative Jon Porter's congressional staff. The witness stated that he does not believe that he spoke to Representative Porter, but that he had spoken with his staff. The witness stated that it was clear that Representative Porter was going to reach out to CMS and/or the Health and Human Services Secretary's office.
- 8. When asked if other members of the Nevada congressional delegation were involved, the witness stated that he believed a decision had been made not to reach out to Senator Harry Reid, and he did not recall Senator John Ensign being very involved. When asked if Representative Dean Heller was involved in this issue, the witness said he did not even recognize that name. The witness said he had no recollection of having had contact with anyone on Representative Shelley Berkley's staff. The witness stated that he believed that Representative Porter and his staff were the ones "in front" on the issue.
- 9. The witness could not recall what type of contact the congressional delegation had with CMS, whether it was a call or a letter, but he said he felt that this prong (reaching out to elected officials for assistance), had borne fruit.
- 10. When the witness was asked about references in emails that CMS expressed concern about not appearing to have been "browbeaten" into an agreement with UMC, the witness stated that this came out of a call he received from the Director of the CMS Survey and Certification Group. According to the witness, the contacts made by elected officials to the Director's superiors at CMS had "raised his hackles." The witness said that the Director told him that he did not appreciate someone looking over his shoulder. The witness stated that the Director did not want it to appear that CMS was coming to a decision regarding the UMC program based on anything other than reason and logic.
- 11. The witness stated that he believed that the congressional involvement on behalf of the UMC program had an impact, but that there was no way to know if it was dispositive. He noted that it was only after the congressional intervention that CMS took action and had to "get creative" in searching for a way to be responsive.

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- 12. The witness stated that had CMS not acted after the congressional intervention, UMC would have likely gone to court to seek an injunction against CMS. He was confident that UMC would have won that injunctive relief had they filed in court.
- 13. When asked about his knowledge of a potential conflict concerning Representative Berkley and her husband's work with UMC, the witness stated that he had learned of it through a *New York Times* article. He described the article as "misleading and inaccurate." He added that Representative Berkley's named did not even register when he read the article because her role had been peripheral.
- 14. The witness stated that he remembered the UMC CEO telling him that one member of the congressional delegation had a spouse who was on staff at UMC, but he did not recall being told that the spouse was a nephrologist. The witness stated that he was sure that the UMC CEO told him at the time that it was Representative Berkley.
- 15. When asked if he had any discussions with UMC officials about whether it was appropriate to enlist the help of Representative Berkley when her husband had a connection to the UMC transplant program, the witness stated that the only discussions about appropriateness concerned Senator Reid and his son, who was a member of the Country Board of Commissioners at the time. The witness added that he found the leadership at UMC to be solid, serious, ethical, and professional and would never have done anything unethical.
- 16. The witness stated that he was "quite sure" he had not spoken to Representative Berkley's husband, but added that did speak with other physicians about the UMC transplant program and decertification.

This memorandum was prepared on January 4, 2012 after the interview was conducted on December 7, 2011. I certify that this memorandum contains all pertinent matter discussed with the witness on December 7, 2011.

Paul Solis Investigative Counsel



## DEPARTMENT OF HEALTH & HUMAN SERVICES

CENTERS FOR MEDICARE & MEDICAID SERVICES WESTERN CONSORTIUM

DIVISION OF SURVEY AND CERTIFICATION



October 16, 2008

Ms. Karen Watnem University Medical Center—Southern Nevada Transplant Program 1800 W. Charleston Boulevard Las Vegas, NV 89102

Re: Adult Kidney Transplant program

Dear Ms. Watnem:

As we informed you in August 2008, the Centers for Medicare and Medicaid Services (CMS) has determined that the Adult Kidney-Only transplant center at the University Medical Center does not satisfy Federal requirements for participation as a Medicare-approved transplant program. Specifically, we found that the transplant center does not meet the graft survival outcome requirements contained in 42 C.F.R. §482.80. As you also are aware, CMS subsequently denied your request for approval based on mitigating factors under 42 C.F.R. § 488.61(a)(4). Accordingly, Medicare approval for the transplant center will be revoked effective November 20, 2008. No Medicare payment will be made for transplant services furnished by the center on or after that date. This action does not affect the Medicare hospital provider agreement for University Medical Center.

We will publish a public notice of the revocation in the Las Vegas Sun, You will be advised of the actual publication date for the notice, which will be no later than November 5, 2008.

In lieu of CMS revocation of your certification, the program may voluntarily withdraw from Medicare. If the program elects this option, you must notify Ed Q Japitana at 415-744electronic mail at constant at the second of the second of

No later than October 21, 2008 you must inform Medicare beneficiaries on the waiting list that Medicare will not pay for transplants performed by the transplant center after November 19, 2008. 42 C.F.R. § 482.102(2)(ii). You must also assist waiting list patients who choose to transfer to another Medicare-approved transplantation center without loss of time accrued on the waiting list. 42 C.F.R. § 482.102(2)(ii).

The transplant center may seek re-entry into the Medicare program at any time by following the initial approval procedures described in 42 C.F.R. § 488.61(a)(4) More specific information on the application and approval process may be found at: http://www.cms.hhs.gov/CertificationandComplianc/20 Transplant.asp.

If you disagree with this determination, you or your legal representative may request a hearing before an administrative law judge with the Civil Remedies Division of the Departmental Appeals Board for the Department of Health and Human Services, in accordance with

Denver Regional Office 1600 Broadway, Suite 700 Denver, GO 80202

San Francisco Regional Office 75 Hawthorne Street, 4th Floor San Francisco, CA 94105

Seattle Regional Office 2201 Sixth Avenue, RX-48 Seattle, WA 98121

Kareñ Watnem Page 2

regulations contained in 42 C.F.R. Part 498. A written request for a hearing must be filed no later than 60 days from the date you receive this notice. Such a request (accompanied by a copy of this notice) should be directed to:

Departmental Appeals Board Civil Remedies Division Attention: Oliver Potts, Chief Cohen Building, Room G-644 330 Independence Avenue, SW Washington DC 20201

Please send a copy of the request to my attention at the following address:

Centers for Medicare & Medicaid Services (CMS)
Division of Survey and Certification, Non-LTC Branch
90 7<sup>th</sup> Street, Suite 5-300 (5W)
San Francisco, CA 94103-6707

A request for hearing must contain the information specified in 42 CFR 498,40(b) and must identify the specific issues and the findings of fact and conclusions of law with which you disagree. It should also specify the basis for contending that the findings and conclusions are incorrect. Completion of the administrative review process is a prerequisite to obtaining judicial review.

Please be advised that pursuing the administrative review process will neither delay the effective date of the revocation nor extend the date of eligibility for Medicare payment for services furnished by the transplant center. Revocation and cessation of payment will still take effect on November 20, 2008.

If the program elects to voluntarily withdraw from Medicare, such withdrawal waives your right to appeal CMS' decision to terminate the provider agreement.

If you have any questions concerning this letter, please contact Ed Q Japitana at 415-744 or by email at a second concerning this letter, please contact Ed Q Japitana at 415-744 or by email at a second concerning this letter, please contact Ed Q Japitana at 415-744.

Sincerely.

Deborah Romero Operations Manager

CMS Western Consortium

<sup>&</sup>lt;sup>1</sup> We emphasize this point in view of language in the preamble to the publication of the final rules for approval and re-approval of organ transplant centers which indicates erroneously -- and contrary to regulation and long-standing CMS policy -- that Medicare payment may continue pending the exhaustion of appeals under 42 C.F.R. Part 498, 72 Fed. Reg. 15198, 15247-15248 (March 30, 2007).

Karen Watnem Page 3

Cc: Fiscal Intermediary/Medicare Administrative Contractor State Of Nevada Bureau of Licensure and Certification CMS Central Office – Karen Tritz

From: Krinsky, Glenn < @ropesgray.com>

Sent: Tuesday, October 21, 2008 4:23 PM

To: Kathy Silver < @umcsn.com>; Karen Watnem < @umcsn.com>

Cc: Gage, Larry S. < @ropesgray.com>; Luband, Charles A.

@ropesgray.com>; Brody, Peter M. < @ropesgray.com>

Subject: FW: University Medical Center of Southern Nevada ("UMC")

It's official. See below.

Glenn L. Krinsky ROPES & GRAY LLP

T 415-315-4818

One Embarcadero Center, Suite 2200

San Francisco, CA 94111-3711 @ropesgrav.com

www.ropesgray.com

From: Romero, Deborah C. (CMS/WC) [mailto: @cms.hhs.gov]

Sent: Tuesday, October 21, 2008 1:22 PM

To: Krinsky, Glenn

Subject: RE: University Medical Center of Southern Nevada ("UMC")

Mr. Kinsky, This is correct.

Thank you Deb Romero

From: Krinsky, Glenn [ @ropesgray.com]

Sent: Tuesday, October 21, 2008 11:58 AM

To: Romero, Deborah C. (CMS/WC)

Subject: University Medical Center of Southern Nevada ("UMC")

Dear Ms. Romero:

This e-mail serves to memorialize the telephone conversation that you and I had in the last few minutes. We have agreed as follows:

- 1) CMS will withdraw its letter to UMC dated October 16, 2008, in which CMS (i) specified a decertification date of November 20, 2008, (ii) stated that it would publish a notice of revocation in the <u>Las Vegas Sun</u> no later than November 5, 2008; (iii) requested that UMC notify CMS of a decision to voluntarily withdraw from Medicare by October 24, 2008, and (iv) mandated that UMC notify Medicare beneficiaries on its waiting list by October 21, 2008 that CMS will not pay for transplants performed at UMC after November 19, 2008.
- 2) CMS reserves the right and intends to issue a new letter to UMC specifying a new proposed decertification date, a new date by which CMS requests that UMC notify CMS of a decision to voluntarily withdraw from Medicare, a new date by which UMC is obligated to send notice of the revocation to the Medicare beneficiaries on its waiting list, and a new date by which UMC may file a notice of appeal pursuant to 42 CFR Part 498. You have agreed that such new letter will allow UMC adequate time (which we request consist of at least five business days from receipt of the letter) to consider its

options and, if necessary, prepare a notice letter to Medicare beneficiaries on its waiting list.

Please contact me by reply e-mail to confirm that this e-mail accurately memorializes our agreement.

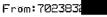
Thank you and best regards, Glenn Krinsky

Glenn L. Krinsky
ROPES & GRAY LLP
T 415-315- Market Proposed | F 415-315- Market Proposed Pro

Circular 230 Disclosure (R&G): To ensure compliance with Treasury Department regulations, we inform you that any U.S. tax advice contained in this communication (including any attachments) was not intended or written to be used, and cannot be used, for the purpose of avoiding U.S. tax-related penalties or promoting, marketing or recommending to another party any tax-related matters addressed herein.

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2008



CMS, DSC

415 744

P. 02

### DEPARTMENT OF HEALTH & HUMAN SERVICES

CENTERS FOR MEDICARE & MEDICAID SERVICES WESTERN CONSORTIUM DIVISION OF SURVEY AND CERTIFICATION

October 23, 2008

14:44

Ms. Karen Watnem University Medical Center—Southern Nevada Transplant Program 1800 W. Charleston Boulevard Las Vegas, NV 89102

Re: Adult Kidney Transplant program

Dear Ms. Wathem.

As we informed you in August 2008, the Centers for Medicare and Medicaid Services (CMS) has determined that the Adult Kidney-Only transplant center at the University Medical Center does not satisfy federal requirements for participation as a Medicare-approved transplant program. Specifically, we found that the transplant center does not meet the patient survival outcome requirements contained in 42 C.F.R. §482.80. As you also aware, CMS subsequently denied your request for approval based on mitigating factors under 42 C.F.R. § 488.61(a)(4). Accordingly, Medicare approval for the transplant center will be revoked effective December 3, 2008. No Medicare payment will be made for transplant services furnished by the center on or after that date. This action does not affect the Medicare hospital provider agreement for University Medical Center.

We will publish a public notice of the revocation in the Las Vegas Sun. You will be advised of the actual publication date for the notice, which will be no later than November 20, 2008.

In lieu of CMS revocation of your certification, the program may voluntarily withdraw from Medicare. If the program elects this option, you must notify Ed Q Japitana at 415-744- or via mems has soy no later than November 6, 2008. electronic mail at

No later than November 3, 2008 you must inform Medicare beneficiaries on the waiting list that Medicare will not pay for transplants performed by the transplant center after December 2, 2008. 42 CF,R. § 482,102(2)(ii). You must also assist waiting list patients who choose to transfer to another Medicare-approved transplantation center without loss of time accrued on the waiting list. 42 C.F.R. § 482.102(2)(ii),

The transplant center may seek re-entry into the Medicare program at any time by following the initial approval procedures described in 42 C.F.R. § 488.61(a)(4) More specific information on the application and approval process may be found at: Into: Noww.cms.hhs.gov/CertificationandComplianc/20 Transplant.asp.

If you disagree with this determination, you or your legal representative may request a hearing before an administrative law judge with the Civil Remedies Division of the Departmental Appeals Board for the Department of Health and Human Services, in accordance with

Denver Regional Office 1600 Bjoadway, Suite 700 Denver, CO 80202

San Francisco Regional Office 75 Hawthorne Street, 4th Floor San Francisco, CA 94105

Seattle Regional Office 2201 Sixth Avenue, RX-48 Seattle, WA 98121

CMS, DSC

415 744

Karen Watnem Page 2

regulations contained in 42 C.F.R. Part 498. A written request for a hearing must be filed no later than 60 days from the date you receive this notice. Such a request (accompanied by a copy of this notice) should be directed to:

Departmental Appeals Board Civil Remedies Division Attention: Oliver Potts, Chief Cohen Building, Room G-644 330 Independence Avenue, SW Washington DC 20201

Please send a copy of the request to my attention at the following address:

Centers for Medicare & Medicaid Services (CMS)
Division of Survey and Certification, Non-LTC Branch
90 7th Street, Suite 5-300 (5W)
San Francisco, CA 94103-6707

A request for hearing must contain the information specified in 42 CFR 498,40(b) and must identify the specific issues and the findings of fact and conclusions of law with which you disagree. It should also specify the basis for contending that the findings and conclusions are incorrect.

Completion of the administrative review process is a prerequisite to obtaining judicial review.

Please be advised that pursuing the administrative review process will neither delay the effective date of the revocation nor extend the date of eligibility for Medicare payment for services furnished by the transplant center. Revocation and cessation of payment will still take effect on December 3, 2008.

If the program elects to voluntarily withdraw from Medicare, such withdrawal waives your right to appeal CMS' decision to terminate the provider agreement.

If you have any questions concerning this letter, please contact Ed Q Japitana at 415-744- or by email at

Sincerely,

Deberali Romero
Operations Manager

CMS Western Consortium

Deborah Romano

We emphasize this point in view of language in the preamble to the publication of the final rules for approval and re-approval of organ transplant centers which indicates erroneously -- and contrary to regulation and long-standing CMS policy -- that Medicare payment may continue pending the exhaustion of appeals under 42 C.F.R. Part 498. 72 Feb. Reg. 15198, 15247-15248 (March 30, 2007).

OCT-23-2008 15:04

From: 7023832742

OCT-23-2008 14:44.

CM5+ DSC

415 744 2692 P.04

Cc: Fiseal Intermediary/Medicare Administrative Contractor
State Department of Health
CMS Central Office - Karen Tritz

Subject to the Nondisclosure Provisions of H. Res. 895 as Amended

## OFFICE OF CONGRESSIONAL ETHICS UNITED STATES HOUSE OF REPRESENTATIVES

## **MEMORANDUM OF INTERVIEW**

IN RE:

Former Chief Executive Officer of the University Medical Center of

Southern Nevada

REVIEW #(s):

11-0243

DATE:

December 8, 2011

LOCATION:

University Medical Center of Southern Nevada

1800 West Charleston Blvd., Las Vegas, NV

TIME:

9:39 AM to 10:40 AM (approximate)

PARTICIPANTS:

Paul Solis

Scott Gast

<u>SUMMARY</u>: The witness is the former Chief Executive Officer of the University Medical Center of Southern Nevada ("UMC"). The OCE requested an interview with the witness and she consented to an interview. The witness made the following statements in response to our questioning:

- 1. The witness was given an 18 U.S.C. § 1001 warning and consented to an interview. The witness signed a written acknowledgement of the warning, which will be placed in the case file in this review.
- 2. The witness is currently the President of the Culinary Health Fund, a health insurance plan for culinary workers. She began serving in this position in September 2011. Prior to this, she served as the CEO of UMC from January 2007 to July 2011. She had been employed at UMC since 1999.
- 3. The witness said that she knows Representative Shelley Berkley casually, meeting her once every couple years. As CEO of UMC, she saw Representative Berkley's husband, Dr. Larry Lehrner, once or twice a year. She saw Dr. Lehrner's colleagues, Dr. Bernstein and Dr. Shah, more often. While CEO, she was aware of the fact that Representative Berkley and Dr. Lehrner were married.
- 4. The witness learned of the decision by the Centers for Medicare and Medicaid Services ("CMS") to terminate Medicare approval of the UMC kidney transplant program in approximately May 2008. Before receiving notice of the termination decision, she thought that UMC was making progress with the program.
- 5. After receiving notification of the termination decision, UMC retained the law firm Ropes & Gray, and specifically attorney Glenn Krinsky, to represent the hospital in discussions with CMS. UMC, with the help of its outside counsel, prepared and submitted to CMS a request for approval based on mitigating circumstances. This request was ultimately denied.

MOI - Page 1 of 3

OFFICE OF CONGRESSIONAL ETHICS

## Subject to the Nondisclosure Provisions of H. Res. 895 as Amended

- 6. When asked how the idea to reach out to UMC's elected officials for assistance with CMS first arose, the witness stated that this likely came up while brainstorming with Mr. Krinsky and members of the UMC team about how to respond to the CMS decision. The witness thought she suggested reaching out using UMC's connections to elected officials. She recalled Mr. Krinsky saying that he was not sure that such an approach would work, because CMS did not like political intervention in its decisions. The goal in involving the congressional delegation was to ask them to make UMC's case to CMS.
- 7. At some point, when Mr. Krinksy got the sense that UMC was getting "no further movement" from CMS on the termination decision, despite the arguments made by UMC, they decided to move forward with contacting elected officials. The witness said she believes that many of the contacts may have been made through a government relations official at UMC. She was also aware that Ropes & Gray attorneys were reaching out to members of the Nevada congressional delegation.
- 8. The witness recalled calling Dr. Lehrner on or about October 22, 2008, and explaining the CMS issue to him. The witness then asked Dr. Lehrner if his spouse, Representative Berkley, would be willing to talk with her about it. Dr. Lehrner gave the witness Representative Berkley's cell phone number, and said he would let his wife know that the witness would be calling.
- 9. The witness believes she called and a left a message for Representative Berkley, who later called the witness back. The witness gave her background information about the transplant program and the CMS termination decision. The witness explained that termination of the transplant program would be a "tragic thing for the state" and asked Representative Berkley for help. The witness stated that Representative Berkley told her that she did not know what she could do, but that she would make some inquiries. When asked if Representative Berkley said anything about what Dr. Lehrner had told her, the witness stated "not really." The witness stated that Representative Berkley agreed that the program was good for Nevada and was sympathetic.
- 10. The witness does not believe she personally spoke with any other delegation members. She had no face-to-face meetings with delegation members on this issue.
- 11. The witness stated that Representative Berkley is more communicative on many issues, including healthcare, and that she had a sense that Representative Berkley understood the CMS issue better than anyone. The witness did not know how engaged Representative Heller was, but would say that Representative Berkley, then Representative Porter, were the more involved, supportive, and understanding about the issue.
- 12. The witness was asked about other contacts she had with Representative Berkley's congressional office. She stated that she thought she knew that Representative Berkley was getting others to sign on to the delegation letter, perhaps through contacts the Ropes & Gray attorneys had with Representative Berkley's staff. She could not recall specific

Subject to the Nondisclosure Provisions of H. Res. 895 as Amended

conversations she may have had with staff members. She said she relied on Mr. Krinsky and other Ropes & Gray to work with the congressional contacts.

- 13. The witness stated that the congressional involvement "obviously" had an impact and that it "changed the course of events." The witness stated that she was very grateful to the congressional delegation for the assistance they provided.
- 14. When asked about references to concerns expressed by CMS staff that the agency not appear to have been "browbeaten" into an agreement, the witness stated that Mr. Krinsky told her that CMS staff did not like to be tapped on their shoulders with intervention, and that they like independence from political influence.
- 15. The witness believes that Dr. Lerner had no role in the interactions with CMS other than giving her Representative Berkley's cell phone number.
- 16. The witness was asked about the renewal of the contract between UMC and Dr. Lerner's medical group, Kidney Specialists of Southern Nevada ("KSSN") in 2010. The witness stated that UMC had made it part of the initial KSSN contract to provide transplant nephrology services. The witness said that she had been upset with Dr. Lehrner because it had taken his medical practice group so long some two years to identify a transplant nephrologist to work at the UMC program.
- 17. The witness said that Dr. Lehrner was responsible for negotiating the terms of the new contract with UMC, calling him a "shrewd businessman." The witness was shown a copy of the KSSN proposal submitted to UMC, in which Dr. Lehrner cites his involvement in getting CMS to reverse its decision to decertify the UMC kidney transplant program. The witness stated that during contract negotiations, she was sure that Dr. Lehrner raised the issue of preventing decertification of the transplant program. She thought that Dr. Lehrner felt he deserved more credit and thanks for the program's continuation.
- 18. When asked if Dr. Lehrner's connection to Representative Berkley was discussed during the contract negotiations, the witness stated that if you're in health care in Nevada, you know that Dr. Lerner is married to Representative Berkley. She added that he has never used this relationship as leverage. The decision to renew the contract with his medical practice had nothing to do with Representative Berkley. Rather, UMC had an existing relationship with the practice.
- 19. The witness stated that a potential conflict of interest issue concerning Representative Berkley and her husband never came up in her mind.

This memorandum was prepared on January 9, 2012 after the interview was conducted on December 8, 2011. I certify that this memorandum contains all pertinent matter discussed with the witness on December 8, 2011.

Paul Solis Investigative Counsel

MOI - Page 3 of 3

OFFICE OF CONGRESSIONAL ETHICS

From:

Kathy Silver </O=UMCSN/OU=FIRST ADMINISTRATIVE

GROUP/CN=RECIPIENTS/CN=KSILVER>

Sent:

Thursday, October 23, 2008 8;24 PM

To:

'Rory J. Reid' < allianelsawyer.com>

Subject:

RE: Kidney Transplant program

We did speak with her this morning, as well as Janice Miller from the office here in LV. Both were very helpful and were going to circle back with the Senator to see how he would like them to proceed. Thank you for all your help and we certainly appreciate the help coming from your father. We will see where it takes us, but it looks as though the entire Nevada delegation is on board.

From: Rory J. Reid [ @lionelsawyer.com]

Sent: Thursday, October 23, 2008 4:03 PM

To: Kathy Silver

Subject: RE: Kidney Transplant program

i talked to my father . . .he was aware of the problem. . .had heard about it from dr. lerner. . .he said cms is after people all over the country . . .he asked that you talk to kate leone in his office. . .feel free to drop both my name and my father's . . kate's numbers are

Work: (202) 224-

Cell: |

From: @umcsn.com [

@umcsn.com]

Sent: Wed 10/22/2008 10:20 AM

To: Rory J. Reid

Subject: Kidney Transplant program

Sorry to bother you about this, but did you have a chance to mention to Senator Reid about our needing his help regarding the problems we are having with CMS and the Transplant program? I heard from Shelley Berkeley this morning and we have a call with her staff this afternoon. I have also asked a close friend, who is related by marriage to John Ensign to try to get some assist from him as well. At this point I feel that we must reach out to our Federal folks if we are to stay an action by CMS. Thanks for your help.

Kathleen Silver Chief Executive Officer University Medical Center of Southern Neveda (702) 383

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From:

Kathy Silver </O=UMCSN/OU=FIRST ADMINISTRATIVE

GROUP/CN=RECIPIENTS/CN=KSILVER>

Sent:

Wednesday, October 22, 2008 11:57 PM

To:

@ropesgray.com'

Subject:

Re: UMC Kidney Transplant Program

I can make 1 And 3 work

Kathy Silver

CEO

**UMC** Administration

From: Luband, Charles A.
To: Kathy Silver; Krinsky, Glenn
Sent: Wed Oct 22 20:12:00 2008

Subject: FW: UMC Kidney Transplant Program

Alanna Porter from Congressman Porter's office is available tomorrow afternoon. Do you folks have a good time?

Charles A. Luband ROPES & GRAY LLP

Washington, DC 20005-3948
@ropesgray.com

www.ropesgray.com

From: Porter, Alanna [ @mail.house.gov]

Sent: Wednesday, October 22, 2008 11:01 PM

To: Luband, Charles A.

Subject: Re: UMC Kidney Transplant Program

Yes. Call my cell tomorrow. I'm in nevada.

---- Original Message -----

From: Luband, Charles A. < @ropesgrav.com>

To: Porter, Alanna

Cc: Luband, Charles A. < @ropesgray.com>

Sent: Wed Oct 22 22:28:26 2008

Subject: UMC Kidney Transplant Program

Alanna ---

I am an attorney in Washington with Ropes & Gray. We represent UMC of Southern Nevada, which has a rather desperate issue regarding the Medicare status of UMC's kidney transplant program. This is a very urgent matter - CMS has indicated that it plans to take steps as soon as November to terminate the program's Medicare eligibility status, which would result in closure of the program and the loss of a transplant

center that currently has over 250 people on its waitlist.

I have attached a background paper that explains the issue and sets forth UMC's request for Congressman Porter's and your assistance. Relevant correspondence between UMC and CMS is also attached.

I understand from the folks at UMC that the Congressman will be at UMC on Friday. They may want to speak with him about this issue when he is on site. However, we would be pleased to speak with you about the issue tomorrow if you would like. We have already spoken with staff from Sen. Ensign's and Rep. Berkley's offices. Please let me know if you have some time tomorrow (preferably early afternoon) to discuss these issues and help prevent the elimination of Nevada's only kidney transplant center.

Charles A. Luband
ROPES & GRAY LLP
T 202-508- Market Marke

Circular 230 Disclosure (R&G): To ensure compliance with Treasury Department regulations, we inform you that any U.S. tax advice contained in this communication (including any attachments) was not intended or written to be used, and cannot be used, for the purpose of avoiding U.S. tax-related penalties or promoting, marketing or recommending to another party any tax-related matters addressed herein.

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Subject to the Nondisclosure Provisions of H. Res. 895 as Amended

## OFFICE OF CONGRESSIONAL ETHICS UNITED STATES HOUSE OF REPRESENTATIVES

### MEMORANDUM OF INTERVIEW

IN RE: Attorney #2, outside counsel to the University Medical Center of Southern

Nevada

REVIEW #(s): 11-0243

DATE: December 16, 2011 LOCATION: New York City, NY

TIME: 1:15 p.m. to 2:00 p.m. (approximate)

PARTICIPANTS: Omar S. Ashmawy

Scott Gast

<u>SUMMARY</u>: The witness is Of Counsel at the law firm Ropes & Gray. The OCE requested an interview with the witness and he consented to an interview. The witness made the following statements in response to our questioning:

- 1. The witness was given an 18 U.S.C. § 1001 warning and consented to an interview. The witness signed a written acknowledgement of the warning, which will be placed in the case file in this review.
- 2. The witness is currently Of Counsel at the law firm Ropes & Gray in New York City, NY. Previous to joining Ropes & Gray, the witness was a partner at Powell Goldstein in Washington, DC. While a partner at Powell Goldstein, the witness practiced health care law and represented the University Medical Center of Southern Nevada ("UMC"). The witness's specialty is the law related to Medicare reimbursements.
- 3. In August 2008, the witness' usual contact at UMC asked if the witness had any experience with challenges to Medicare certification of health care providers specifically transplant program certification. The witness was not familiar with that area of the law, but found another individual at the firm who was Glenn Krinsky. The firm represented UMC in discussions with the Centers for Medicare and Medicaid Services ("CMS") regarding Medicare certification of the UMC kidney transplant program.
- 4. The witness identified other Ropes & Gray attorneys involved in the representation of UMC regarding the Medicare certification issue. Larry Gage, who had served as President of the National Association of Public Hospitals, was involved in the representation of UMC, but not deeply. Peter Brody was a litigator with the firm; he was involved because litigation was one strategy the firm was considering.
- 5. Sandra Caron George was a junior associate with the firm. She was assisting on the matter because she had Capitol Hill experience as a legislative assistant for Representative Bernie Sanders and as a senior legislative assistant for Senator Jon

Subject to the Nondisclosure Provisions of H. Res. 895 as Amended

Corzine. Ms. George's husband was serving as Representative Shelley Berkley's legislative director at the time.

- 6. There may have been other litigation associates involved in the representation, but no other senior attorneys were involved.
- 7. The witness explained that the CMS decision to decertify UMC's kidney transplant program was based on CMS' observation of certain deficiencies. These included both program deficiencies and outcome deficiencies.
- 8. The witness recalled that UMC made a submission to CMS requesting that CMS not decertify the program because of mitigating circumstances. The legal team at Ropes & Gray was involved in preparing this submission. CMS ultimately denied the request.
- 9. Until UMC's request to CMS was denied, the witness did not think there was any outreach to Capitol Hill. The first outreach the witness was aware of was on October 22, 2008 including an email from Sandra Caron George to Representative Shelley Berkley's health legislative assistant.
- 10. The witness was then shown a September 11, 2008 email, in which his colleague Mr. Krinsky mentioned to the UMC chief executive officer the possibility of briefing the Nevada delegation in Washington, DC about the CMS decertification issue. The witness did not remember the email. He did not remember if the briefing referred to in the email actually happened, though he had no reason to think it did not. If it did, the goal in September would have been to inform the Members of Congress. They would not have asked for help from the Members yet, but instead prepared them to get involved to intervene on behalf of UMC if CMS denied UMC's request for approval based on mitigating circumstances.
- 11. The witness did not remember where the suggestion to seek Capitol Hill support came from. It may have come from the witness and the other Ropes & Gray attorneys, but he added that UMC is not a politically naïve institution. They may have come up with the idea on their own. The first direct outreach that Ropes & Gray made that the witness could recall was on October 22, 2008, when he and Ms. George emailed various staff members of the Nevada congressional delegation members. The witness and Ms. George drafted a two page background information attachment to include with the emails.
- 12. There was some discussion among the attorneys and UMC about which Members of Congress in the Nevada delegation might be better champions for UMC. Two Members, Rep. Berkley and Rep. Jon Porter, had districts that comprised parts of Las Vegas. Rep. Dean Heller was more to the north and therefore they were not initially sure if he would be supportive of UMC's effort. It turned out he was. In the end, they decided that the issue was a "Nevada issue" and approached the entire delegation.
- 13. The witness did not remember if there was discussion about Rep. Berkley's husband and his role in the nephrology department of UMC. However, the witness and the other attorneys knew about the relationship Rep. Berkley's husband had with UMC. In an email to Glenn Krinsky that the witness found while responding to the OCE Request for

Subject to the Nondisclosure Provisions of H. Res. 895 as Amended

Information in the matter, the witness told Mr. Krinsky that Rep. Berkley's husband worked for UMC and that an internet search showed that he was in nephrology. He also recalled saying that the delegation was "well placed" to help on this issue.

- 14. The witness did not remember ever speaking directly with Rep. Berkley. The witness did not remember discussing the subject of the relationship between Rep. Berkley's husband and UMC with either Matt Coffron, Rep. Berkley's health legislative assistant, or with Rep. Berkley's legislative director.
- 15. The witness did not know whether the UMC CEO, Kathy Silver, had a telephone call with Rep. Berkley regarding this issue, but it would not have been inconsistent with briefing members of the Nevada delegation.
- 16. The witness was shown an October 24, 2008 email from Larry Gage to the witness, his law firm colleagues, and the UMC CEO, in which he states that, "[p]er our discussion with her staff, Rep. Berkley should also take this to Ways and Means Committee leadership (Pete Stark and/or Charlie Rangel)." The witness did not believe any outreach was made by Ropes & Gray attorneys to any committees or committee staff members. He did not recall whether UMC officials made any outreach to any House committees or committee staff. The witness did not remember what the words "[p]er our discussion" in the email related to. He thought what happened was that after the initial emails were sent to the various staff members, he then had one-on-one conversations with staff members in each of the delegation offices.
- 17. According to the witness, all five offices of the Nevada congressional delegation were interested in supporting UMC. Rep. Berkley's office, along with Rep. Porter's office, was particularly "hot to trot" on the issue.
- 18. The witness spoke to Matt Coffron in Rep. Berkley's office on October 22, 2008, after Ms. George sent the initial email to him. The witness asked the office to call CMS and urge them to rescind the termination.
- 19. The witness was shown an October 23, 2008 email from Mr. Coffron to the witness, in which Mr. Coffron discusses a conversation he had with Representative Berkley and steps that had taken with respect to the UMC transplant program. The witness thought they asked Rep. Berkley to call Tom Hamilton, the Director of the CMS Survey and Certification Group.
- 20. The witness did not recall who came up with the idea of a delegation letter. He thought that Mr. Coffron may have come up with the idea.
- 21. The witness also recalled that Rep. Berkley was happy to send her own letter and also do something with the delegation to support UMC. Rep. Berkley was going to do a letter on her own at first, because the plan was to get a letter out quickly. However, what ended up happening was that Rep. Berkley's letter got "rolled up" into the letter from the Nevada delegation.

## Subject to the Nondisclosure Provisions of H. Res. 895 as Amended

- 22. The witness was shown an October 23, 2008 email, in which Mr. Coffron forwards a draft of the delegation letter language to the witness. Referencing this email, the witness stated that Rep. Berkley's office was coordinating the delegation letter. He recalled that it was the suggestion of Rep. Berkley's office to write the letter. The witness was very pleased with Rep. Berkley's "spearheading" the letter.
- 23. The witness was shown an October 27, 2008 email, in which the UMC CEO told the witness that she had spoken with Mr. Coffron that morning about the CMS decertification issue. The witness did not know how much direct contact, similar to this email, Rep. Berkley's office had with UMC officials.
- 24. The witness was shown an October 29, 2008 email from the witness to Mr. Coffron, in which the witness notes that Don Johnson is the Acting Director of the CMS Office of Legislation. The witness did not remember what the reference in the email was to. He guessed that he probably had a phone conversation with Mr. Coffron, probably urging them to call someone substantive at CMS, such as Mr. Hamilton, the Director of the Survey and Certification Group, or Kerry Weems, the Acting Administrator, but that they had been referred to Mr. Johnson.
- 25. The witness' colleague Glenn Krinsky recalled Rep. Porter's office being more involved, but the witness recalls Rep. Porter's office just following up more often. The witness recalled having more contact with Rep. Berkley's office than his colleague.
- 26. There was "lesser" involvement from Rep. Heller's office and the offices of the Nevada Senators. The witness stated that he always thought Senator Reid should have been more interested in the issue, but perhaps he felt there was some sort of conflict because his son was on the County Board of Supervisors.
- 27. The witness stated that Rep. Berkley may have reached out to the Chairman of the Way and Means Committee on this issue, but he was not certain.
- 28. The witness did not know how much the congressional involvement affected CMS' decision to rescind the termination.
- 29. The witness recalled conversations about CMS not wanting to appear "browbeaten," but did not know if CMS felt that it had been browbeaten into the result.

This memorandum was prepared on December 22, 2011 after the interview was conducted on December 16, 2011. I certify that this memorandum contains all pertinent matter discussed with the witness on December 16, 2011.

Scott Gast Investigative Counsel

## Elhawary, Katherine M. (Perkins Cole)

From:

George; Sandra Caron [ @ropesgray.com]

Sent:

Wednesday, October 22, 2008 3:46 PM

To:

Coffron, Matthew

Cc:

George, Bryan; Luband, Charles A.

Subject:

UMC Conference Call

Attachments:

CMS-UMC Correspondence.pdf; Wash 7337137 3 UMC TPs for Hill.DOC

Hi Matt,

I understand that you will be speaking with University Medical Center and several of my colleagues at Ropes & Gray (including Charlie Luband, who I have copied above) regarding UMC's kidney transplant program. As you know, this is a very urgent matter - CMS has indicated that it plans to take steps as soon as November to terminate the program's Medicare eligibility status, which would result in closure of the program.

I have attached a background paper that explains the issue and sets forth UMC's request for the Congresswoman's and your assistance. Relevant correspondence between UMC and CMS is also attached.

We very much appreciate your taking the time to discuss the issue (particularly on a sunny recess day) and hope that we can count on the Congresswoman's assistance to prevent the elimination of Nevada's only kidney transplant center.

Thanks, again.

Best regards, Sandra

> Sandra Caron George ROPES & GRAY LLP

T 202-508- F 202-383-

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Washington, DC 20005-3948

@ropesgray.com

www.ropesgray.com

Not admitted in the District of Columbia. Supervised by Ropes & Gray LLP Partners who are members of the District of Columbia Bar.

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### Assistance Needed to Preserve Nevada's Kidney Transplant Center

Earlier this year, University Medical Center of Southern Nevada (UMC) merged its kidney transplant program with a program previously operated by Sunrise Hospital & Medical Center. UMC absorbed both patients and physicians associated with the Sunrise program. Today, UMC's kidney transplant program is the only Medicare approved program in Nevada. Over 250 patients, mostly Nevadans, are on UMC's waitlist and in desperate need of a new kidney. CMS has threatened to terminate UMC's transplant program.

We request your immediate assistance in urging CMS not to take this unnecessary action, which will result in Nevada's loss of its only kidney transplant program.

### Background

In August 2008, the Centers for Medicare and Medicaid Services (CMS) informed UMC that, based on CMS' review of Scientific Registry of Transplant Recipients (SRTR) reports issued in January and July 2008, UMC's kidney transplant program did not meet Medicare's outcome requirements. In particular, UMC failed to meet the one-year patient survival criterion. However, UMC would have met this criterion but for the unfortunate suicide of one of its successful kidney transplant patients within a year after the transplant.

CMS stated that if no action were taken by UMC, CMS would terminate the program's Medicare approval, a step that would result in closure of UMC's program. CMS further indicated that UMC could request "approval based on mitigating factors," pursuant to which CMS would reconsider its termination decision. On August 11, 2008, UMC submitted a request for approval based on mitigating factors, which was supplemented on September 11, 2008. (Some of the correspondence between CMS and UMC is attached.)

In addition, due to the hospitalization of the program's primary surgeon and in light of CMS' letter, on September 9, 2008, UMC voluntarily initiated a period of "functional inactivation" for its kidney transplant program. As a result, UMC, temporarily, is not providing kidney transplant services. Instead, UMC has been pursuing substantial program improvements, including a contract with experienced kidney transplant surgeons from the University of Utah.

UMC believed that its request for approval based on mitigating factors combined with its voluntary functional inactivation and its efforts to improve its kidney transplant outcomes would preserve Nevada's only remaining kidney transplant center. However, despite UMC's good faith actions to improve its program and to address CMS' concerns, CMS informed UMC by letter dated October 16, 2008, that it would revoke the program's Medicare approval. Although CMS has agreed, temporarily, to withdraw that letter, CMS intends to reissue a letter revoking UMC's approval. Consequently, Nevada is at risk of losing its only kidney transplant center.

<sup>&</sup>lt;sup>1</sup> Medicare regulations allow a transplant center to "remain inactive and retain its Medicare approval for a period not to exceed 12 months during the 3-year approval cycle." 42 CFR § 488.61(e).

### Request

UMC requests your assistance in urging CMS to reconsider its decision to terminate Medicare approval of UMC's kidney transplant program for the following reasons:

- \* Terminating UMC's program will not protect patient safety. Since UMC's program is currently functionally inactive, no transplants are currently being provided. Terminating UMC's program will place the lives of Nevadans in need of kidney transplant services in the future in jeopardy. Additionally, permanent closure of UMC's program will result in greater demands on a small number of transplant centers in surrounding states and will force needy Nevadans to travel further to receive kidney transplant services. The next closest kidney transplant centers are at least four to six hours from UMC (Phoenix, Arizona; Salt Lake City, Utah; Southern California; and Northern California).
- <u>UMC should not be terminated based on factors outside its control.</u> UMC's program should not be terminated based on one patient's unfortunate suicide, which was unrelated to the success of the patient's kidney transplant.
- The next report will show that UMC is in compliance with the patient survival standard. The data period for the next SRTR report has already closed, and UMC has received its draft report. The SRTR report, to be finalized in January 2009, will show that UMC is now in compliance with the patient survival requirement. The Medicare program, and the State of Nevada, should not lose a transplant center, causing significant harm to Medicare beneficiaries, because of anomalous past negative results.
- CMS's threatened termination does not comply with its own regulations. According to CMS' regulations, a transplant center may "remain inactive and retain its Medicare approval for a period not to exceed 12 months during the 3-year approval cycle." 42 CFR § 488.61(e). As a matter of federal law, CMS may not terminate UMC's Medicare approval while UMC is inactive. Further, CMS has informed UMC that it intends to require termination of UMC's program approval during UMC's appeal of the termination decision, in contravention of CMS guidance issued just last year. 72 Fed. Reg. 15198, 15242 (Mar. 30, 2007) ("Thus, if a transplant center appeals a termination of Medicare approval under 42 CFR, part 498, the termination will not occur until the appeals process, if any, is completed.).
- If terminated, it is unlikely that UMC will be able to be approved again. Because of the strict Medicare approval requirements, it is extremely difficult for a new kidney transplant program to receive Medicare approval. Because so many kidney transplants are covered by Medicare, a kidney transplant program cannot survive without Medicare approval. Thus, CMS' actions in terminating UMC's program would result in a substantial and possibly permanent loss of medical capabilities for Nevadans.

UMC has agreed not to reactivate its program until CMS resurveys UMC's program. Termination would be an unnecessary fatal blow.

In order to preserve UMC's ability to serve Medicare beneficiaries and other Nevadans in need of kidney transplant services, we ask that you call CMS and request that the agency reconsider its decision to terminate Medicare's approval for UMC's kidney transplant center.

# Elhawary, Katherine M. (Perkins Cole)

From:

Luband, Charles A. [ @ropesgray.com]

Sent:

Thursday, October 23, 2008 2:05 PM

To: Cc: Coffron, Matthew Luband, Charles A.

Subject:

RE: UMC Conference Call

Thank you so much.

We're still working through the offices, but here's a quick status report:

I think Sen. Ensign's office is also inclined to help, but Michelle wanted to look through the materials and discuss with the Senator.

We spoke this morning with Sen. Reid's office (Kate Leone and Janice Miller in Las Vegas) and they very much want to help, although the staff needs to reach the Senator to coordinate.

I just spoke with Alanna Porter in Rep. Porter's office. They would very much like to do a delegation letter. I also encouraged her to call the two numbers I'm providing you below and she also offered to have the Congressman call Kerry Weems and Herb Kuhn.

I will reach out shortly to Leanne Walker in Dean Heller's office.

If you want to call someone at CMS the person to call at the Regional Office is Deborah Romero at 415-744- or Karen Tritz at 410-786- The message at this point is to not issue a new letter terminating UMC's approval. You should know that yesterday we received an email fourth hand where Ms. Romero indicated that they intend to resend the letter very shortly.

Charles A. Luband
ROPES & GRAY LLP
T 202-508- | M | F 202-383One Metro Center, 700 12th Street, NW, Suite 900
Washington, DE 20005-3948

@ropesgray.com
www.ropesgray.com

----Original Message

From: Coffron, Matthew [mailto: @mail.house.gov]

Sent: Thursday, October 23, 2008 1:29 PM

To: Luband, Charles A.

Subject: RE: UMC Conference Call

Hello Charlie,

I spoke with the Congresswoman this morning. She confirmed that she is happy to send a letter (which I am currently drafting) and would be open to doing something as a delegation in the future. She also mentioned having spoken with Senator Reid on this issue.

I also tried to call Ed Japitana at CMS to get some clarafication on their position, but learned that he is out this week.

36

Please keep me posted on the response you get from other offices if you can.

Thanks,

-Matt

Matthew Coffron
Legislative Assistant
Office of Congresswoman Shelley Berkley
405 Cánnon House Office Building
202-225-

----Original Message----

From: Luband, Charles A. [ Propesgray.com]

Sent: Wednesday, October 22, 2008 10:07 PM

To: Coffren, Matthew Co: Luband, Charles A.

Subject: RE: UMC Conference Call

Matt --

I just wanted to send an email following on our call this afternoon. We very much appreciate the Congresswoman's help in this matter. Please feel free to contact me if you have any questions or need anything.

We spoke with Michelle Spence in Ensign's office after we spoke with  $you_T$  and are hoping to speak with Kate Leone tomorrow.

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From: George, Sandra Caron

Sent: Wednesday, October 22, 2008 3:46 PM

To: @mail.house.gov Cc: George, Bryan; Luband, Charles A.

Subject: UMC Conference Call

Hi Matt,

I understand that you will be speaking with University Medical Center and several of my colleagues at Ropes & Gray (including Charlie Luband, who I have copied above) regarding UMC's kidney transplant program. As you know, this is a very urgent matter - CMS has indicated that it plans to take steps as soon as November to terminate the program's Medicare eligibility status, which would result in closure of the program.

I have attached a background paper that explains the issue and sets forth UMC's request for the Congresswoman's and your assistance. Relevant correspondence between UMC and CMS is also attached.

We very much appreciate your taking the time to discuss the issue (particularly on a sunny recess day) and hope that we can count on the Congresswoman's assistance to prevent the elimination of Nevada's only kidney transplant center.

Thanks, again.

Best regards, Sandra

Sandra Caron George
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Not admitted in the District of Columbia. Supervised by Ropes & Gray LLP Partners who are members of the District of Columbia Bar.

## Elhawary, Katherine M. (Perkins Cole)

From: Sent:

Porter, Alanna

To:

Thursday, October 23, 2008 1:54 PM Coffron, Matthew, Walker, Legann

Subject:

FW: UMC Kidney Transplant Program

Attachments:

CMS-UMC Correspondence.pdf; Wash\_7337137\_3\_UMC TPs for Hill.DOC

Hey - you guys want to do a joint letter?

----Original Message----

From: Luband, Charles A. [ Propesgray.com]

Sent: Wednesday, October 22, 2008 10:28 PM

To: Porter, Alanna Cc: Luband, Charles A.

Subjects UMC Kidney Transplant Program

Alanna --

I am an attorney in Washington with Ropes & Gray. We represent UMC of Southern Nevada, which has a rather desperate issue regarding the Medicare status of UMC's kidney transplant program. This is a very urgent matter - CMS has indicated that it plans to take steps as soon as November to terminate the program's Medicare eligibility status, which would result in closure of the program and the loss of a transplant center that currently has over 250 people on its waitlist.

I have attached a background paper that explains the issue and sets forth UMC's request for Congressman Porter's and your assistance. Relevant correspondence between UMC and CMS is also attached.

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#### **RESPONSE:**

### Statement from Congresswoman Shelley Berkley:

I won't stop fighting to give Nevadans access to affordable healthcare just because my husband is a doctor, just as I won't stop standing up for veterans because my father served in World War II. I've worked closely with other members of our delegation over many years to make care available to veterans and to patients suffering from cancer, diabetes, autism, heart disease, kidney disease, and other illnesses, while trying to prevent bureaucrats in health insurance companies and in government from adding to the heavy burdens patients are already bearing.

Statements from Jessica Mackler, Campaign Manager at Berkley for Senate as they relate to the topics you have brought up:

#### **UMC Kidney Transplant Center Intervention**

As Brian Brannman, CEO of UMC, told *The New York Times*, it was at the request of UMC and her Republican colleague that Congresswoman Berkley signed onto a letter with the Nevada delegation to save the state's only kidney transplant program. If the program had been revoked, sick patients would have had to travel to Arizona or California for care. Reps. Porter, Heller and Berkley worked with the Medicare program and UMC to make sure that Nevada patients had the access to care they deserve. At the time, the consumer watchdog group Citizens for Responsibility and Ethics in Washington (CREW), stated that Congresswoman Berkley's work to ensure her constituents had access to kidney care was not a conflict of interest.

#### Kidney Specialists of Southern Nevada (KSOSN) Contract with UMC

After the previous transplant nephrologist passed away, Dr. Marvin Bernstein agreed to temporarily lead the program, and work with the United Network for Organ Sharing (UNOS) and UMC to ensure quality care. During the time period that Dr. Bernstein led the program, the Kidney Specialists of Southern Nevada and UMC worked aggressively to recruit another transplant nephrologist to take over the program. As Brian Brannman, CEO of UMC, has noted, the problems associated with the program at UMC were due to a lack of resources provided by the hospital for the kidney treatment program and not the untimely death of Dr. Snyder.

#### Lobbying/Ethics Rule

Dr. Lehmer is a doctor, not a lobbyist. Congresswoman Berkley has honored both the spirit and the letter of the ethics law, which was never intended to suggest that spouses could not talk with each other about their opinions on issues. Congresswoman Berkley's sole motivation has been to make sure that Nevadans have access to quality care. She strongly opposed moving to a bundled payment system that includes oral-only drugs because affordable access to care is her top priority and the bundle system will require a 20 percent Medicare copayment for many Nevadans and could close small dialysis centers in the state by imposing overwhelming new regulations.

#### DaVita/Kidney Care Partners

This implication is ridiculous and has no basis in fact or evidence. Congresswoman Berkley has been a champion for the more than 4,000 Nevadans diagnosed with renal disease each year. Congresswoman Berkley believes that sick patients in Nevada, where the doctor to patient ratio is ranked near last in the country, deserve the best care possible and that is why she has fought to provide access to the highest quality care for kidney patients, as well as patients with diabetes, osteoporosis and cancer. She strongly opposed moving to a bundled payment system that includes oral-only drugs because affordable access to

care is her top priority and the bundle system will require a 20 percent Medicare copayment for many Nevadans and could close small dialysis centers in the state by imposing overwhelming new regulations. BACKGROUND: Of the 39 dialysis centers in Nevada, less than half are operated by DaVita. DaVita is just one of 13 entities that make up the Kidney Care Partners organization. Berkley work on kidney care issues is motivated by her desire to improve care for sick patients across Nevada and the country.

### **Congressional Certificate**

Congresswoman Berkley gives out more than 1,000 certificates like this one each year on a wide range of issues from birthdays to honoring school groups. There are many people doing work in Pahrump at the treatment center and they deserve recognition. The expanded dialysis center means that the patients who get care at the Pahrump center no longer have to travel nearly 120 miles round-trip to get care. That's a great service to the community. This is just one part of Berkley's long record of championing access to care for under-served populations.

#### **Campaign Contributions**

These events have nothing to do with one another. Congresswoman Berkley does not apologize for being a champion for the health of Nevada residents, including the more than 4,000 Nevadans diagnosed with renal failure in 2008 alone. Congresswoman Berkley is proud to be a champion for sick patients who deserve leaders in Congress that stand up for them and fight for them to have the best care possible. That is what she has done both for kidney patients those with diabetes, osteoporosis and cancer.

### **AN ADDITIONAL STATEMENT:**

In addition to responding to certain written questions, Ms. Berkley's office prepared its own statement detailing her record on kidney care.

# Facts on Berkley Record on Kidney Care

# UMC Kidney Transplant Center Intervention

As Brian Brannman, CEO of UMC, told *The New York Times*, it was at the request of UMC and her Republican colleague that Congresswoman Berkley joined with the rest of the Nevada delegation to save the state's only kidney transplant program. If the program had been revoked, sick patients would have had to travel to Arizona or California for care. Reps. Porter, Heller and Berkley worked with the Medicare program and UMC to make sure that Nevada patients had the access to care they deserve. At the time, the consumer watchdog group Citizens for Responsibility and Ethics in Washington (CREW), stated that Congresswoman Berkley's work to ensure her constituents had access to kidney care was not a conflict of interest.

# The Facts

# PORTER AND HELLER SIGNED LETTER TO CMS OFFICIALS ABOUT UMC'S KIDNEY TRANSPLANT PROGRAM

Rep. Jon Porter Was The First Member Of The Nevada Delegation To Meet With CMS Officials About UMC's Kidney Transplant Program. According to the Review-Journal, "Nevada's only kidney transplant program might have a lifeline. Rep. Jon Porter R-Nev...said Wednesday he has had productive conversations twice in two days with Centers for Medicare and Medicaid Services, the agency that informed University Medical Center that certification for its transplant center is being revoked effective Dec. 3. Porter said in one of his conversations with CMS, he received assurance that the investigation of UMC's transplant program would be re-examined. 'The acting director has committed to me that CMS will review the whole investigation to ensure it was handled appropriately,' Porter said. 'I have made it clear to CMS that this is a critical program for Nevadans' ... Porter met with Kerry Weems, CMS' acting administrator, on Tuesday in Las Vegas. He spoke with CMS officials again Wednesday while back in Washington. David Cherry, a spokesman for Berkley, said the congresswoman is scheduled to meet with CMS officials sometime today. It was unclear whether Heller would be speaking with CMS." [Review-Journal, 10/30/08]

**Rep. Porter's Office Initiated the Letter.** Staff from Rep. Porter e-mailed the offices of Reps. Berkley and Heller to suggest a joint letter after urging from UMC. [E-Mail from Rep. Porter's office to Rep. Berkley's office, 10/23/08]

Rep. Dean Heller Signed Onto Letter With Rep. Jon Porter And Rep. Shelley Berkley "Expressing Their 'Strong Disagreement' With The Agency's Decision." In October 2008, the Las Vegas Review-Journal wrote, "On Friday, Reps. Shelley Berkley, Jon Porter and Dean Heller sent a letter to CMS' acting administrator, Kerry Weems, expressing their 'strong disagreement' with the agency's decision. In their letter, they reference what they believe is the remaining unresolved deficiency -- the patient survival outcomes. The May 2005 suicide caused UMC to not meet compliance standards for two overlapping reporting periods -- July 1, 2004 to Dec. 31, 2007 and Jan. 1 2005 to June 30, 2007. 'This suicide of an otherwise successful transplant patient is lamentable, but beyond the control of UMC,' the letter states." [Las Vegas Review-Journal, 10/25/08]

# CREW: NO CONFLICT OF INTEREST FOR BERKLEY BECAUSE DR. LARRY LEHRNER "DOES NOT HAVE A DIRECT FINANCIAL TIE TO MEDICARE."

CREW: No Conflict Of Interest For Berkley Because Dr. Larry Lehrner "Does Not Have A Direct Financial Tie To Medicare." In November 2008, the Las Vegas Sun wrote, "The political appeals for leniency included a letter and personal conversations with the head of Medicare by Rep. Shelly Berkley, D-Las Vegas, and Republican Reps. Jon Porter and Dean Heller. Berkley's husband, Dr. Larry Lehrner, is a partner at Kidney Specialists of

Southern Nevada, which has a \$588,200 annual contract to provide nephrology services at UMC, which includes the kidney transplant program. UMC officials said Lehrner handles the business aspects of the contract, not the medical services. Officials from Citizens for Responsibility and Ethics in Washington said they do not consider Berkley's advocacy for UMC a conflict of interest because Lehrner does not have a direct financial tie to Medicare." [Las Vegas Sun, 11/4/08] (Emphasis added)

# <u>PATIENTS WOULD HAVE HAD TO GO TO SCOTTSDALE OR LOS ANGELES FOR TREATMENT IF</u> UMC HAD LOST THE KIDNEY TRANSPLANT PROGRAM

Clark County Patients Would Have Had To Go To Scottsdale Or Los Angeles For Treatment If UMC Had Lost The Kidney Transplant Program. According to the Review-Journal, "Four months after becoming the state's only kidney transplant program, University Medical Center has been stripped of that privilege, leaving in doubt where more than 200 Nevadans awaiting kidney transplants might go for their procedures. UMC was notified in a Thursday letter by Centers for Medicare and Medicaid Services, or CMS, that its certification for the transplant center will be revoked effective Dec. 3. That means the hospital will not receive any payments for transplant services on or after that date, effectively closing the program ... Patients in need of kidney transplants may now have to travel to out-of-state facilities such as the Mayo Clinic in Scottsdale, Ariz., or UCLA, officials say. "
[Review-Journal, 10/25/08]

- Review-Journal: "Additionally, since the center is the only one of its kind in Nevada, some 200 people awaiting kidneys in Nevada would have to travel at least 300 miles out of the state for the procedure." [Review-Journal, 10/31/08]
- Cancer Institute Co-Founder: "It's Just Not Right For People To Have To Get On A Plane Or Drive To California Or Arizona ... When They Get Sick." In March 2002, Nevada Cancer Institute Co-Founder Jim Murren told the Sun, "There's universal agreement that it's just not right for people to have to get on a plane or drive to California or Arizona (for treatment) when they get sick ... There's certainly a big need for this here, because of our demographics." [Las Vegas Sun, 3/18/02]

## 2008: 4,800 PATIENTS DIED WHILE WAITING FOR KIDNEY TRANSPLANT

2008: 4,800 Patients Died While Waiting For Kidney Transplant. According to CBS, "In 2008, of the 82,000 patients on the waiting list in the United States, 16,520 received kidney transplants whereas 4,800 died waiting for one." [CBS42.com, 7/28/11]

# Kidney Specialists of Southern Nevada (KSOSN) Contract with UMC

After the previous transplant nephrologist passed away, Dr. Marvin Bernstein agreed to temporarily lead the program, and work with the United Network for Organ Sharing (UNOS) and UMC to ensure quality care. During the time period that Dr. Bernstein led the program, the Kidney Specialists of Southern Nevada and UMC worked aggressively to recruit another transplant nephrologist to take over the program. As Brian Brannman, CEO of UMC, has noted, the problems associated with the program at UMC were due to a lack of resources provided by the hospital for the kidney treatment program and not the untimely death of Dr. Snyder.

# Lobbying/Ethics

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percent Medicare copayment for many Nevadans and could close small dialysis centers in the state by imposing overwhelming new regulations.

# The Facts

"The New ESRD Payment Structure Will Require Patients To Pay A 20 Percent Co-Payment On The Entire Bundled ESRD Payment." According to the American Kidney Fund, "The new ESRD payment structure will require patients to pay a 20 percent co-payment on the entire bundled ESRD payment. The new bundled payment system will include services such as your dialysis treatments, dialysis labs and injectable medications received during treatment, like Epogen, iron, and vitamin D. Also included will be the oral form of iron and vitamin D, particularly for patients using home dialysis. Even if you do not use all of these services, you will still be responsible for sharing the costs." [American Kidney Fund, February 2011]

# DaVita/Kidney Care Partners

This implication is ridiculous and has no basis in fact or evidence. Congresswoman Berkley has been a champion for the more than 4,000 Nevadans diagnosed with renal disease each year. Congresswoman Berkley believes that sick patients in Nevada, where the doctor to patient ratio is ranked near last in the country, deserve the best care possible and that is why she has fought to provide for kidney patients, as well as patients with diabetes, osteoporosis and cancer. She strongly opposed moving to a bundled payment system that includes oral-only drugs because affordable access to care is her top priority and the bundle system will require a 20 percent Medicare copayment for many Nevadans and could close small dialysis centers in the state by imposing overwhelming new regulations.

BACKGROUND: Of the 39 dialysis centers in Nevada, less than half are operated by DaVita. DaVita is just one of 13 entities that make up the Kidney Care Partners organization. Berkley has worked on kidney care issues to improve care for sick patients across Nevada and the country.

### The Facts

# <u>DAVITA OPERATES LESS THAN HALF OF THE 39 DIALYSIS CLINICS IN NEVADA AND IS ONE</u> OF 32 MEMBERS OF KIDNEY CARE PARTNERS

**DaVita Operated 18 Of The 39 Dialysis Clinics In Nevada.** According to Data.gov, DaVita operates 18 of the 39 dialysis clinics in the state of Nevada. [Data.gov, Dialysis Facility Compare, accessed 8/31/11]

**DaVita One Of 32 Members Of Kidney Care Partners.** According to their web site, DaVita is one of 32 partners of Kidney Care Partners. [Kidney Care Partners web site, accessed 9/01/11]

# BERKLEY CO-SPONSORED AT LEAST 95 BILLS RELATED TO VARIOUS MEDICAL ISSUES AND DISEASES...

Berkley Co-Sponsored At Least 95 Bills Related To Various Medical Issues And Diseases. Berkley sponsored or co-sponsored at least 95 bills related to a number of medical issues and diseases –from breast cancer to heart disease to kidney disease to inflammatory bowel disease. [Thomas.gov, accessed 8/19/11]

#### ...SUCH AS DIABETES

Berkley Co-Sponsored Diabetes Prevention Access and Care Act. In 2003, Berkley co-sponsored H.R.1916, Diabetes Prevention Access and Care Act. The bill was referred to the Subcommittee on Health. [HR 1916, Introduced 5/01/03]

Berkley Co-Sponsored Preventing Diabetes in Medicare Act of 2007. In 2007, Berkley co-sponsored H.R.2922, Preventing Diabetes in Medicare Act of 2007. The bill was referred to the Subcommittee on Health. [HR 2922, Introduced 6/28/07]

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Berkley Was Lead Sponsor Of Medicare Fracture Prevention and Osteoporosis Testing Act. In 2007, Berkley was lead sponsor of H.R.4206: Medicare Fracture Prevention and Osteoporosis Testing Act of 2007. The bill was referred to House subcommittee. Status: Referred to the Subcommittee on Health. In 2009, Berkley was lead sponsor of H.R.1894: Medicare Fracture Prevention and Osteoporosis Testing Act of 2009. The bill was referred to the Subcommittee on Health. [Thomas.gov, accessed 8/19/11]

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# ESRD PAYMENT STRUCTURE REQUIRES PATIENTS TO PAY 20 PERCENT CO-PAYMENT ON THE ENTIRE BUNDLED ESRD PAYMENT

"The New ESRD Payment Structure Will Require Patients To Pay A 20 Percent Co-Payment On The Entire Bundled ESRD Payment." According to the American Kidney Fund, "The new ESRD payment structure will require patients to pay a 20 percent co-payment on the entire bundled ESRD payment. The new bundled payment system will include services such as your dialysis treatments, dialysis labs and injectable medications received during treatment, like Epogen, iron, and vitamin D. Also included will be the oral form of iron and vitamin D, particularly for patients using home dialysis. Even if you do not use all of these services, you will still be responsible for sharing the costs. However, not every patient will have the same costs. Factors such as age, body size, and whether a patient has other illnesses are variables which can change your payment. Depending on the patients' individual health condition, co-pay amounts may increase, decrease or stay the same." [American Kidney Fund, February 2011]

# SMALL DIALYSIS COMPANIES STRUGGLE TO MAINTAIN NECESSARY FINANCIAL VIABILITY TO CONTINUE TO SERVE PATIENTS

NRAA: "As A (Small Or Medium Sized) Dialysis Facility We Are Struggling To Maintain The Necessary Financial Viability To Continue To Serve Our Patients..." According to a letter to Congress from the National Renal Administrators Association, "While a much smaller reduction in the per treatment reimbursement would be

necessary in order to maintain budget neutrality, it would be significantly less than \$6.75. As a (small or medium sized) dialysis facility we are struggling to maintain the necessary financial viability to continue to serve our patients, which is now being made even more difficult by CMS' reluctance to provide us with the reimbursement we deserve. Our Medicare margins are small or non-existent and (percent of overall revenue) is derived from serving Medicare beneficiaries. In a December 2010 analysis, the Medicare Payment Advisory Committee (MedPAC) found that the Medicare margin for dialysis facilities other than the two largest chains was 0.3 percent and that the margin for rural facilities was minus 1.4 percent. These numbers speak for themselves. We urge you to take whatever legislative action may be necessary to provide us with a fair reimbursement." [National Renal Administrators Association, accessed 8/31/11]

• "The National Renal Administrators Association (NRAA), A Nonprofit Organization That Represents Small Dialysis Organizations Throughout The United States..." "The National Renal Administrators Association (NRAA), a nonprofit organization that represents small dialysis organizations throughout the United States, also told us that small dialysis organizations generally did not provide oralonly ESRD drugs or any other oral drugs in 2010." [United States Government Accountability Office, Report to Congressional Committees, "End-Stage Renal Disease: CMS Should Assess Adequacy of Payment When Certain Oral Drugs Are Included And Ensure Availability of Quality Monitoring Data, March 2011]

### NEVADA RANKED 48TH IN DOCTORS PER PATIENT AND "DEAD LAST" IN SPECIALTIES

- Silver State Ranked No. 48 In Doctors Per Patient And "Dead Last" In Specialties. According to the Las Vegas Review Journal, "A 2009 study from the University of Nevada School of Medicine found that the Silver State ranked No. 48 in doctors per patient... In specialties such as pediatric heart surgery, orthopedic surgery and spine surgery, the Silver State places 'dead last,' said Larry Matheis, executive director of the Nevada State Medical Association. So acute are the shortages that Nevada could double its number of pediatric-surgery specialists and still be last in the country for its share of doctors specializing in kids' care." [Las Vegas Review-Journal, 4/11/10]
- Nevada Has 190 Practicing Doctors Per 100,000 People. According to the Las Vegas Review Journal, "To understand how bad the state's shortages already are, consider that Nevada has 190 practicing doctors per 100,000 people. As of 2007, Nevada would have needed 262 practicing docs per 100,000 residents to post an average doctor-patient ratio, noted Dr. Annette Teijeiro, president of the Clark County Medical Society... The scarcity of physicians already means big wait times for nonemergency specialist care...It's gotten so bad that doctors and insurers increasingly send Nevadans out of state for specialty care because there aren't enough doctors here to handle the referrals." [Las Vegas Review-Journal, 4/11/10]

#### **DOCTORS NO LONGER ACCEPTING MEDICARE BECAUSE OF LOW PAYMENT RATES**

Number Of Doctors Refusing New Medicare Patients Because Of Low Government Payment Rates Setting A New High. According to USA Today, "The number of doctors refusing new Medicare patients because of low government payment rates is setting a new high, just six months before millions of Baby Boomers begin enrolling in the government health care program. Recent surveys by national and state medical societies have found more doctors limiting Medicare patients, partly because Congress has failed to stop an automatic 21% cut in payments that doctors already regard as too low. The cut went into effect Friday, even as the Senate approved a six-month reprieve. The House has approved a different bill.

- The American Academy of Family Physicians says 13% of respondents didn't participate in Medicare last year, up from 8% in 2008 and 6% in 2004.
- The American Osteopathic Association says 15% of its members don't participate in Medicare and 19% don't accept new Medicare patients. If the cut is not reversed, it says, the numbers will double.

• The American Medical Association says 17% of more than 9,000 doctors surveyed restrict the number of Medicare patients in their practice. Among primary care physicians, the rate is 31%.

The federal health insurance program for seniors paid doctors on average 78% of what private insurers paid in 2008." [USA Today, 6/21/10]

Doctors No Longer Accepting Medicare, Either Because They Have Opted Out Of The Insurance System Or They Are Not Accepting New Patients With Medicare Coverage. According to the New York Times, "Some doctors — often internists but also gastroenterologists, gynecologists, psychiatrists and other specialists — are no longer accepting Medicare, either because they have opted out of the insurance system or they are not accepting new patients with Medicare coverage. The doctors' reasons: reimbursement rates are too low and paperwork too much of a hassle." [New York Times, 4/01/09]

Medicare Payment Advisory Commission: 29 Percent Of The Medicare Beneficiaries It Surveyed Who Were Looking For A Primary Care Doctor Had A Problem Finding One To Treat Them. According to the New York Times, "In a June 2008 report, the Medicare Payment Advisory Commission, an independent federal panel that advises Congress on Medicare, said that 29 percent of the Medicare beneficiaries it surveyed who were looking for a primary care doctor had a problem finding one to treat them, up from 24 percent the year before. And a 2008 survey by the Texas Medical Association found that while 58 percent of the state's doctors took new Medicare patients, only 38 percent of primary care doctors did." [New York Times, 4/01/09]

# **Congressional Certificate**

Congresswoman Berkley gives out more than 1,000 certificates like this one each year on a wide range of issues from birthdays to honoring school groups. There are many people doing work in Pahrump at the treatment center and they deserve recognition. The expanded dialysis center means that the patients who get care at the Pahrump center no longer have to travel nearly 120 miles round-trip to get care. That's a great service to the community. This is just one part of Berkley's long record of championing access to care for underserved populations.

# The Facts

Pahrump Dialysis Facility Was "The Beginning Of Attempting To Keep Treatment Local" And To "Prevent A Need For Patients To Travel 60 Miles Or So To Las Vegas To Get Their Care." In October 2001, when dedicating his new kidney dialysis center, Dr. Neville Pokroy was quoted by the Pahrump Valley Times as stating, "I tried to help establish a centralized medical campus for this community. So we tried to enhance the quality of patient care and hopefully this will continue to expand and prevent a need for patients to travel 60 miles or so to the city of Las Vegas to get their care. Obviously, we'll not be able to cover all the needs, but hopefully this is the beginning of attempting to keep treatment local. [Pahrump Valley Times, 10/13/10]

**Dr. Larry Lehrner Doesn't Even Practice At The Facility.** According to Kidney Specialists of Southern Nevada's website, Dr. Larry Lehrner isn't listed as one of the three primary doctors that service the Pahrump location. [Kidney Specialists of Southern Nevada website, accessed <u>8/31/11</u>]

# Campaign Contributions

These events have nothing to do with one another. Congresswoman Berkley does not apologize for being a champion for the health of Nevada residents, including the more than 4,000 Nevadans diagnosed with renal failure in 2008 alone. Congresswoman Berkley is proud to be a champion for sick patients who deserve leaders in Congress that stand up for them and fight for them to have the best care possible. That is what she has done both for kidney patients those with diabetes, osteoporosis and cancer.

# The Facts

### THERE WERE 4,134 DIAGNOSES OF RENAL FAILURE IN NEVADA IN 2008 ALONE

2008: There Were 4,134 Diagnoses Of Renal Failure In Nevada. "In 2008 there were 4,134 diagnoses of renal failure in Nevada. The average length of stay was 5.19 days for both sexes. The average charge was \$38,785." [Norah Langendorf, M.Ed, Nevada Compare Care, "Renal Failure & Kidney Transplants, A Comparison of Hospitals and Trends in Nevada," 2008]

368,544 U.S. Residents With ESRD Received Dialysis. In 2007, 368,544 U.S. residents with ESRD received dialysis. [National Kidney & Urologic Diseases Information Clearinghouse, accessed 8/21/11]

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Berkley Diagnosed With Osteoporosis And Said Her Experience Highlighted The Need For Serious Reforms To The Nation's Health Care System, Specifically The Services Provided By Group Medical Plans Or Health Maintenance Organizations. According to the Las Vegas Review-Journal, Democratic congressional hopeful Shelley Berkley "thought she had bad posture and nothing more last year when she reluctantly agreed to be tested for osteoporosis," but "the results of the bone scan were immediately obvious to her physician: Berkley was diagnosed with osteoporosis." Berkley has "responded well to 10 months of treatment, but one of the things she said she learned about the condition is how few women know they have it until it's too late and they break a bone. Worse, she said, few health insurance plans cover the cost of the simple bone scan that could detect osteoporosis in its earliest stages, when treatment can make a difference. Berkley said her experience highlights the need for serious reforms to the nation's health care system, specifically the services provided by group medical plans or health maintenance organizations." Berkley: "I believe it is time for Congress to guarantee that medical decisions will be made only by doctors and patients. We must ensure that our doctors' offices and clinics do not become assembly lines, as they have already in some cases." The Journal added, "The centerpiece of the legislation Berkley supports is the Democrats' Patient Bill of Rights, which would broaden coverage options for people covered by

HMOs and managed care groups and guarantee treatment of conditions that require a specialist. Berkley focuses on HMO reform in a new television spot that will debut this week. The advertisement pokes fun at HMO accountants and urges support for a system that gives doctors more control." [Las Vegas Review-Journal, 9/30/98]

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# Elhawary, Katherine M. (Perkins Cole)

From:

Porter, Alanna

Sent:

Thursday, October 23, 2008 4:33 PM Walker, Leeann; Coffron, Matthew

To: Subject:

Re: UMC Letter

Woohool We rock. Thanks for drafting matt.

From: Walker, Leeann

**To:** Coffron, Matthew; Porter, Alanna **Sent:** Thu Oct 23 16:31:58 2008

**Subject:** UMC Letter Hi Matt and Alanna,

My boss is happy to sign on. Thanks to you both for your work on this and let me know if there's anything else we can do!

1w

Leeann Walker Legislative Assistant Congressman Dean Heller (NV-2).

1023 Longworth Building: Washington, D.C. 20515 Phone (202) 225-Fax (202) 225-5679

## Elhawary, Katherine M. (Perkins Cole)

From:

Walker, Leeann

Sent:

Thursday, October 23, 2008 5:39 PM

To: Subject: Coffron, Matthew RE: UMC letter

Looks good!

From: Coffron, Matthew

Sent: Thursday, October 23, 2008 5:25 PM

To: Walker, Leeann; Porter, Alanna

Subject: UMC letter

I made a couple very small changes to the letter. Please let me know if everything is o.k. If so I will send somebody around tomorrow for signatures.

Thanks:

-Matt

Matthew Coffron
Legislative Assistant
Office of Congresswoman Shelley Berkley
405 Cannon House Office Building
202-225-

October 24, 2008

Kerry Weems
Acting Administrator
Centers for Medicare & Medicaid Services
7500 Security Blvd
Baltimore, Maryland 21244-1849

Dear Acting Administrator Weems,

We are writing to express our strong disagreement with the apparent CMS decision to revoke Medicare approval of Nevada's only kidney transplant program at the University Medical Center (UMC) in Las Vegas. We are concerned that this decision does not protect Medicare beneficiaries, and could have strong negative consequences for our constituents.

It has been brought to our attention that the kidney transplant program at UMC will soon have its Medicare approval revoked. We are troubled that this revocation is proceeding despite the fact that UMC has implemented measures to improve quality and taken substantial steps to address the shortcomings cited. This decision also ignores significant mitigating factors and circumstances out of the center's control.

Since originally notified of the deficiencies in the transplant program, UMC has submitted a Corrective Action Plan to CMS and taken significant steps to improve quality of care and improve both management procedures and patient outcomes.

The one remaining unresolved deficiency cited in the August 4, 2008 letter sent to UMC by CMS is the one-year patient survival condition of participation. For two separate but overlapping Scientific Registry of Transplant Recipient (SRTR) cohort reporting periods, UMC did not meet the compliance standard because of the inclusion of a death that resulted from a patient's suicide in May, 2005. This death from over three and a half years ago still falls in the overlapping segment of the two reporting periods (July 1, 2004 to December 31, 2006 and January 1, 2005 to June 30, 2007).

This suicide of an otherwise successful transplant patient is lamentable, but beyond the control of UMC. Additionally, data for the latest cohort reporting period from July 1, 2005 to December 31, 2007 set to be released in January will show that UMC has come back into compliance with this final requirement.

Revoking Medicare approval for the UMC kidney transplant program is uncalled for and will jeopardize the health of hundreds of our constituents while placing a severe burden on transplant centers in surrounding states. We ask that you reconsider this decision, and would be happy to discuss this situation with you further if necessary. Thank you for your consideration and look forward to your response.

Sincerely,

SHELLEY BERKLEY
Member of Congress

JON PORTER
Member of Congress

DEAN HELLER Member of Congress

From:

Luband, Charles A. < @ropesgray.com>

Sent:

Friday, October 24, 2008 12:31 PM

To:

Kathy Silver < @umcsn.com>; Krinsky, Glenn

@ropesgray.com>; Brody, Peter M. <

Cc:

Gage, Larry S. < @ropesgray.com>

Subject:

FW: Final letter

Attach:

UMC transplant center 10-24-08.pdf

FYI. The Nevada House members sent the attached delegation letter this morning. I will also forward to the Senate-side staffers.

@ropesgray.com>

#### Charles A. Luband ROPES & GRAY LLP

@ropesgray.com www.ropesgray.com

Circular 230 Disclosure (R&G): To ensure compliance with Treasury Department regulations, we inform you that any U.S. tax advice contained in this communication (including any attachments) was not intended or written to be used, and cannot be used, for the purpose of avoiding U.S. tax-related penalties or promoting, marketing or recommending to another party any tax-related matters addressed herein.

This message (including attachments) is privileged and confidential. If you are not the intended recipient, please delete it without further distribution and reply to the sender that you have received the message in error.

From: Coffron, Matthew [ mail.house.gov]

**Sent:** Friday, October 24, 2008 12:20 PM

To: Luband, Charles A. Subject: Final letter

This has been faxed over and is in the mail.

Matthew Coffron Legislative Assistant Office of Congresswoman Shelley Berkley 405 Cannon House Office Building 202-225-

# Congress of the United States Washington, DC 20515

October 24, 2008

Kerry Weems
Acting Administrator
Centers for Medicare & Medicaid Services
7500 Security Blvd
Baltimore, Maryland 21244-1849

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Revoking Medicare approval for the UMC kidney transplant program is uncalled for and will jeopardize the health of hundreds of our constituents while placing a severe burden on transplant centers in surrounding states. We ask that you reconsider this decision, and would be happy to discuss this situation with you further if necessary. Thank you for your consideration and look forward to your response.

Sincerely.

HELLEY () WKIRY

Member of Congress

ION LD CD TEED

Member of Congress

DEAN HELLER

Member of Congress

PRINTED ON: RECYCLED PAPER

Confidential under OCE Code of Conduct Rule 8

OCE Review No. 11-0243 Berkley-000074

From:

Sent:

Thursday, October 23, 2008 11:07 PM

To:

Kathy Silver < @umcsn.com>

Subject:

FW: Dr. Shah

#### Kathy-

Shelley tells me that she and Porter (? Heller) sent a letter to CMS today. I spoke with Sen. Reid's staff today and urged them to support UMC transplant program to the fullest extent possible.

Below is the e-mail I sent you early in Oct with Dr. Shah's phone numbers.

Larry

----Original Message-----From: Lawrence Lehrner

Sent: Thursday, October 09, 2008 11:35 AM

To: @umcsn.com' Subject: RE: Dr. Shah

Thanks. I will keep you informed of our negotiations with him.

Larry

----Original Message-----

From: @umcsn.com

@umcsn.com1

Sent: Thursday, October 09, 2008 11:26 AM

**To:** Lawrence Lehrner **Subject:** RE: Dr. Shah

I spoke w/him this morning. I think the conversation went well. I have a few questions regarding pathology that he asked that I need to get answers for him, but all in all I think I was able to reassure him that we support the program and that I have a very positive vision of the future of the program.

Sent: Thursday, October 09, 2008 12:20 PM

To: Kathy Silver Subject: Dr. Shah

Kathy-

I spoke with Dr. Shah for about 30 minutes yesterday. I really think he is interested in joining us. He does want to talk to you to understand your vision for the transplant program.

Thanks

Larry

Vipul A. Shah, M.D.

TEL: office

804-828-

Home

This message is for the sole use of the intended recipient(s) and may contain confidential and/or privileged information. Any unauthorized review, use, disclosure or distribution is prohibited. If you are not the intended recipient, please contact the sender by reply email and destroy all copies of the original. -University Medical Center of Southern Nevada

From:

Cindy Dwyer </O=UMCSN/OU=FIRST ADMINISTRATIVE

GROUP/CN=RECIPIENTS/CN=CDWYER>

Sent:

Tuesday, September 30, 2008 6:17 PM

To:

Kathy Silver < @umcsn.com>

Subject:

Dr. Lehrner

cell - office - 877-

Needs to hear direct from you about UMC's commitment to the Transplant Program, so he can reassure transplant nephrologist candidates.

#### Elhawary, Katherine M. (Perkins Cole)

From:

George, Bryan

Sent:

Tuesday, October 28, 2008 2:42 PM

To:

Coffron, Matthew

Subject:

FW: Lawmakers call for keeping University Medical Center kidney transplant program certified

#### Lawmakers call for keeping University Medical Center kidney transplant program certified

APRS000020081028e4as006wk

408 Words

28 October 2008

18:35 GMT

Associated Press Newswires

English

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LAS VEGAS (AP) - Nevada's three congressional representatives are calling for a federal agency to let University Medical Center continue to operate Nevada's only kidney transplant program, despite a report that found high death rates for transplant recipients.

Democratic Rep. Shelley Berkley, and Republicans Jon Porter and Dean Heller sent a letter to Centers for Medicare and Medicaid Services acting administrator Kerry Weems, expressing "strong disagreement" with the pending certification revocation.

The lawmakers cited the program's importance to the region, where the United Network for Organ Sharing said 208 people were awaiting kidney transplants on Monday.

Agency officials said Monday they received the letter, but were not ready to respond. Medicare pays for nearly 100 percent of the costs of transplants at UMC.

Officials said decertification, effective Dec. 3, resulted from a finding during surveys in March and August that the death rate for kidney transplant recipients was more than 50 percent higher than the federal standard.

The agency also expressed concern about timely submittal of patient and living donor information, and verification of proper blood type and donor identification.

Hospital officials say the CMS survey, which came just after Sunrise Hospital and Medical Center consolidated its transplant program with UMC, improperly counted a suicide.

Berkley said her office has received dozens of calls and e-mails from current and former UMC transplant program patients, and said she asked Democratic Senate Majority Leader Harry Reid and Clark County commissioners to join the effort to keep certification.

Officials said UMC can voluntarily withdraw from the transplant program by Nov. 3 to avoid revocation Dec. 3.

UMC chief executive Kathy Silver said the county-run hospital plans to challenge the CMS decision, But officials said the program would have to close during the appeal.

If UMC loses the appeal, it would have to reapply for certification, which could take a year or more.

Brian Brannman, hospital chief operating officer, said UMC recently contracted with three University of

Utah surgeons to perform kidney transplants at the Las Vegas hospital on a rotating basis.
The additional surgeons fill a need posed by the illness of UMC's only other transplant surgeon, which prompted officials on Sept. 10 to declare the program inactive for 90 days.
No and No. 20.
On the Net:
University Medical Center of Southern Nevada: http://www.umcsn.com/
M G and to 20
Information from: Las Vegas Review-Journal, http://www.lvrj.com
7
Your complete results are available online at <a href="http://global.factiva.com/redir/default.aspx?p=vf&amp;view=a&amp;fid=10927387&amp;aid=9USH000200&amp;ns=99&amp;ft=g&amp;ep=AE&amp;OD=V2AUbiNaqd6b5CPhXw4B66W55PvjiLmG1NRDI5sdoWITm0L%2f9s%2bA8BJ0%3d%3d%7c2">http://global.factiva.com/redir/default.aspx?p=vf&amp;view=a&amp;fid=10927387&amp;aid=9USH000200&amp;ns=99&amp;ft=g&amp;ep=AE&amp;OD=V2AUbiNaqd6b5CPhXw4B66W55PvjiLmG1NRDI5sdoWITm0L%2f9s%2bA8BJ0%3d%3d%7c2</a>
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### reviewjournal.com



### Kidney patients may face hardship

BY ANNETTE WELLS REVIEW-JOURNAL

Posted: Oct. 28, 2008 | 10:00 p.m.

Alexa Blair's hospital bag was packed.

Her parents were set to care for her 6-year-old daughter. Blair's employer understood the 33-year-old might be away from the office for up to six months after her operation.

All Blair needed was a phone call from her transplant coordinator confirming a matching kidney and she was out the door.

Those were last week's plans.

Today, Blair's plans are in disarray, as are those of the 200 Nevadans awaiting kidney transplants through the University Medical Center's kidney transplant program.

The Centers for Medicare and Medicaid Services has told UMC that certification for the state's only kidney transplant center is being revoked, effective Dec. 3. Medicare pays for nearly 100 percent of the costs of transplants at UMC.

The move is leaving patients such as Blair, who are fighting end-stage renal disease with dialysis several times a week, with one option: travel at least 300 miles to an out-of-state facility. It's a challenge Blair is uncomfortable with because she needs to be at the transplant center within three hours of getting the notification call.

Blair also was told by her transplant coordinator that if she has the procedure outside of Nevada, she should plan to stay near that facility up to 12 weeks.

"That means my care provider would have to go with me. My mother is my care provider who also watches my daughter," said Blair, sitting in a recliner at Fresenius Medical Care South Pecos Dialysis.

Blair undergoes dialysis at the facility three times a week, from 6 p.m. to 10 p.m.

"I can't imagine being away from home because I am sick," she said.

Because of the transplant center's importance to the region, Reps. Shelley Berkley, Jon Porter and Dean Heller sent a letter to CMS acting administrator Kerry Weems

expressing their "strong disagreement" with the agency's decision.

The letter, sent Friday, urges CMS to reconsider the decision.

Berkley said Monday that she had yet to hear from the federal agency.

"I asked them to please contact me immediately," Berkley said. "I am hopeful that the new administrator would re-examine this decision and prevent this travesty from occurring."

In addition to the letter, Berkley said she has called Senate Majority Leader Harry Reid, as well as Clark County commissioners, about the revocation. She said her office has received dozens of calls and e-mails from current and former patients of UMC's transplant program.

Berkley has asked callers and writers to send letters to CMS.

CMS officials said Monday that they had received the letter from Nevada's congressional leaders but were not ready to respond. CMS did reiterate that the transplant center's revocation was the result of it not meeting minimum required patient survival outcomes based on surveys conducted in March and August.

The two other areas of concern include timely submission of key information about patients and living donors, and proper verification of blood type and donor identification.

According to the March and August survey reports, the hospital's actual death rate for kidney transplant recipients was more than 50 percent higher than the federal standard allows.

However, hospital officials and others say the program is unfairly penalized because one of the deaths used was a suicide in 2005. They say the suicide overlapped two reporting periods -- July 1, 2004 to Dec. 31, 2007 and Jan. 1 2005 to June 30, 2007.

Berkley said UMC's kidney transplant program has rectified the problems and its status should be reinstated.

CMS officials say arguments presented by UMC still indicate that its administration has not done a comprehensive review of other factors that caused the outcomes to be lower than expected since January 2007. Also, CMS says that UMC has not taken steps to correct issues so that deaths do not occur in the future.

Unless UMC and lawmakers can persuade the federal agency to change course, the state's only kidney transplant program is left with just two options: involuntary decertification on Dec. 3, or voluntarily withdrawing its certification by Nov. 3.

UMC Chief Executive Officer Kathy Silver said the latter course will be taken, but

that UMC still plans to challenge the decision.

The problem with challenging the CMS decision is that the program will still have to close during the appeal. It can't be operational during the appeals process, said Brian Brannman, the hospital's chief operating officer. If UMC loses the appeal, then it would have to re-apply for certification, which could take a year or more.

"We're trying to get a hearing now," he said. "This is a very complex process with a lot of nuances. ... The situation is, these cases took place between 2005 and 2007, before Kathy and I got here."

Ironically, Brannman said, UMC's kidney transplant team received an award this weekend for decreasing the time transplant patients are on the waiting list. UMC also just negotiated contracts with three University of Utah surgeons to perform kidney transplants at the hospital on a rotating basis.

One of the surgeons recently got his Nevada medical license.

The two other surgeons are set to get their licenses "any minute now," Brannman said.

The additional surgeons were needed because UMC's only other transplant surgeon became ill a few months ago. As a result of the surgeon's illness, UMC administrators inactivated the program until a new surgeon was brought on staff.

Patients were sent a letter on Sept. 10 notifying them that the program would be "functionally inactive" for 90 days, meaning it would not be accepting organs from donors or conducting any transplants.

Blair said she became concerned when she received the letter but assumed everything would work itself out. With CMS' move, she's now unsure.

"This is absolutely devastating," said Amy Allen, who underwent a kidney transplant at UMC last November. "I can't say anything negative about UMC and its transplant team. This is just not right."

Allen credits part of her recovery to the fact that her family and friends were close after the surgery. Without them, she said, "I don't know if I would have made it" emotionally.

Allen, 30, said she can't imagine undergoing a transplant in another state, especially with the follow-up care.

"They will have to live in that state for at least three months," she said.

The traveling is a concern to Blair and her family.

Blair said her insurer, Health Plan of Nevada, will pay for the transplant. Under the

plan, she is allowed up to \$10,000 for travel expenses. However, since she and her mother will need an emergency flight, the cost of the flight alone could use up much of that money.

What remains will probably not be enough to support two people during the 12 weeks of follow-up care, she said.

"I don't know how that's going to happen, not to mention me wanting my daughter with me," Blair said.

Blair's mother, Kaylin Somavia, said she would have to take a leave of absence from her job.

"This is an absolute nightmare," Somavia said. "We haven't even begun to figure out where she is going to have this procedure done if our lawmakers can't get CMS to change their minds."

The CMS survey of UMC's kidney transplant programs came just after Sunrise Hospital and Medical Center consolidated its transplant program with UMC.

As of Monday, according to the United Network for Organ Sharing, 208 people were awaiting kidney transplants in Nevada.

Contact reporter Annette vveils at	@reviewjournal.com or 702-383-

#### Find this article at:

http://www.lvrj.com/news/33433099.html

Check the box to include the list of links referenced in the article.

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From:

Gage, Larry S. < @ropesgray.com>

Sent:

Friday, October 24, 2008 12:38 PM

To:

Luband, Charles A. < @ropesgray.com>; Kathy Silver

@umcsn.com>; Krinsky, Glenn <</pre>

@ropesgray.com>; Brody,

Peter M. < @ropesgray.com>

Subject:

RE: Final letter

Very strong letter. Per our discussion with her staff, Rep. Berkley should also take this to Ways and Means Committee leadership (Pete Stark and/or Charlie Rangel). Larry

Larry S. Gage ROPES & GRAY LLP

T 202-508- F 202-383-9366

One Metro Center, 700 12th Street, NW, Suite 900

Washington, DC 20005-3948 @ropesgray.com

www.ropesgray.com

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From: Luband, Charles A.

Sent: Friday, October 24, 2008 12:31 PM

To: @umcsn.com; Krinsky, Glenn; Brody, Peter M.

Cc: Gage, Larry S. Subject: FW: Final letter

FYI. The Nevada House members sent the attached delegation letter this morning. I will also forward to the Senate-side staffers.

Charles A. Luband ROPES & GRAY LLP

T 202-508- M M Francisco | F 202-383-9367 One Metro Center, 700 12th Street, NW, Suite 900

Washington, DC 20005-3948
@ropesgray.com

www.ropesgray.com

From: Coffron, Matthew [mailto:Matthew.Coffron@mail.house.gov]

**Sent:** Friday, October 24, 2008 12:20 PM

**To:** Luband, Charles A. **Subject:** Final letter

This has been faxed over and is in the mail.

Matthew Coffron Legislative Assistant Office of Congresswoman Shelley Berkley 405 Cannon House Office Building 202-225-

From: Luband, Charles A. < @ropesgray.com>Sent: Monday, October 27, 2008 5:11 PM To: Kathy Silver < @umcsn.com> Subject: RE: UMC Kidney Transplant Program I did already send Glen's email to all of the congressional staff, but it can't hurt.... Charles A. Luband **ROPES & GRAY LLP** T 202-508- M F 202-383-9367 One Metro Center, 700 12th Street, NW, Suite 900 Washington, DC 20005-3948 @ropesgray.com www.ropesgray.com From: Kathy.Silver@umcsn.com @umcsn.com] Sent: Monday, October 27, 2008 4:39 PM To: Luband, Charles A. Subject: RE: UMC Kidney Transplant Program I spoke w/him this morning. He was interested in knowing if we had heard from the Senate side. Also, he indicated that it was likely that Congresswoman Berkley was going to call Kerry Weems at CMS. I told him that Porter's office had yet to connect w/CMS but was also calling. The reason for asking for his e-mail was to forward Glen's e-mail to Karen Tritz from last week on the day that we rec'd the letter.

From: Luband, Charles A. @ropesgray.com]

Sent: Monday, October 27, 2008 1:23 PM

To: Kathy Silver

Subject: RE: UMC Kidney Transplant Program

@mail.house.gov. Are you folks planning to contact him on anything in particular? Can you co me?

Charles A. Luband **ROPES & GRAY LLP** 

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@ropesgray.com

www.ropesgray.com

From: @umcsn.com [ @umcsn.com]

Sent: Monday, October 27, 2008 2:38 PM

To: Luband, Charles A.

**Subject:** RE: UMC Kidney Transplant Program

From: Luband, Charles A. @ropesgray.com] Sent: Thursday, October 23, 2008 10:33 AM To: Porter, Alanna; Krinsky, Glenn; Kathy Silver Cc: Luband, Charles A. Subject: RE: UMC Kidney Transplant Program Here is a call in number for the 1:30 PT conference call: (888) 352-Conference Code: (Alanna, let me know if you would prefer that we call you on your cell.) Charles A. Luband **ROPES & GRAY LLP** T 202-508-F 202-383-9367 One Metro Center, 700 12th Street, NW, Suite 900 Washington, DC 20005-3948 @ropesgray.com www.ropesgray.com From: Luband, Charles A. Sent: Thursday, October 23, 2008 9:40 AM To: 'Porter, Alanna' Subject: RE: UMC Kidney Transplant Program Alanna --Can we plan on calling you at 1:30 PT? From: Porter, Alanna @mail.house.gov] Sent: Wednesday, October 22, 2008 11:01 PM To: Luband, Charles A. Subject: Re: UMC Kidney Transplant Program Yes. Call my cell tomorrow. I'm in nevada. ---- Original Message -----From: Luband, Charles A. < @ropesgray.com> To: Porter, Alanna Cc: Luband, Charles A. < @ropesgray.com> Sent: Wed Oct 22 22:28:26 2008 Subject: UMC Kidney Transplant Program Alanna ---I am an attorney in Washington with Ropes & Gray. We represent UMC of

Southern Nevada, which has a rather desperate issue regarding the Medicare status of UMC's kidney transplant program. This is a very

Charlie - do you have an e-mail address for Matt in Congresswoman Berkley's office?

UMC\_59633

urgent matter - CMS has indicated that it plans to take steps as soon as November to terminate the program's Medicare eligibility status, which would result in closure of the program and the loss of a transplant center that currently has over 250 people on its waitlist.

I have attached a background paper that explains the issue and sets forth UMC's request for Congressman Porter's and your assistance. Relevant correspondence between UMC and CMS is also attached.

I understand from the folks at UMC that the Congressman will be at UMC on Friday. They may want to speak with him about this issue when he is on site. However, we would be pleased to speak with you about the issue tomorrow if you would like. We have already spoken with staff from Sen. Ensign's and Rep. Berkley's offices. Please let me know if you have some time tomorrow (preferably early afternoon) to discuss these issues and help prevent the elimination of Nevada's only kidney transplant center.

Charles A. Luband
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#### Elhawary, Katherine M. (Perkins Coie)

From:

Luband, Charles A.

@ropesgray.com]

Sent:

Wednesday, October 29, 2008 1:52 PM

To: Subject: Coffron, Matthew RE: Final letter

Matt --

Can you tell me whether the Congresswoman has heard any response to the letter? We know Congressman Porter had what sounded like a pretty unfruitful conversation with Acting Administrator Weems yesterday. UMC is feeling increasingly desperate. I understand that you are in an all-day meeting, but is there any way you could give me a quick

call on my cell phone:

Charles A. Luband ROPES & GRAY LLP

|| F 202-383-9367

One Metro Center, 700 12th Street, NW, Suite 900

Washington, DC 20005-3948 @ropestray.com

BERNESEER LEVELEE

From: Coffron, Matthew [mailto:Matthew.Coffron@mail.house.gov]

**Sent:** Friday, October 24, 2008 12:32 PM

To: Luband, Charles A. Subject: RE: Final letter

I will. I also was wondering if you would like me to forward it to the regional folks over at CMS. I haven't done

that yet either.

Matthew Coffron
Legislative Assistant
Office of Congresswoman Shelley Berkley
405 Cannon House Office Building
202-225-

From: Luband, Charles A.

@ropesgray.com]

Sent: Friday, October 24, 2008 12:31 PM

To: Coffron, Matthew Subject: RE: Final letter

Matt ---

Thank you so much. Have you forwarded to the Senate-side staff, or should !?

Charles A. Luband ROPES & GRAY LLP

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Confidential under OCE Code of Conduct Rule 8

16

OCE Review No. 11-0243 Berkley-000128



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From: Coffron, Matthew [mailto: @mail.house.gov]

Sent: Friday, October 24, 2008 12:20 PM

To: Luband, Charles A. Subject: Final letter

This has been faxed over and is in the mail.

Matthew Coffron
Legislative Assistant
Office of Congresswoman Shelley Berkley
405 Cannon House Office Building
202-225

#### Elhawary, Katherine M. (Perkins Cole)

From: Luband, Charles A. @ropesgray.com]

Sent: Wednesday, October 29, 2008 2:44 PM

To: Coffron, Matthew

Subject: FW: UMC Kidney Transplant Program

Here is the email I sent Alanna yesterday. BTW, Don Johnson is the Acting Director of the CMS Office of Legislation. I'm not sure why you would be directed to him.

Charles A. Luband ROPES & GRAY LLP

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From: Luband, Charles A.

Sent: Tuesday, October 28, 2008 4:05 PM

To: 'Porter, Alanna'

Cc: Krinsky, Glenn; Luband, Charles A.

Subject: RE: UMC Kidney Transplant Program

#### Alanna --

We thought it might be helpful to set out in writing why what CMS is saying makes no logical sense. Please feel free to pass this along to the Congressman and he can pass along to Weems in whatever form you deem appropriate. Alternatively, the Congressman could send this explanation to Secretary Leavitt or the White House.

From your explanation, it sounds like CMS is stating that (1) there are patient safety reasons that necessitate immediate termination of UMC's kidney transplant center, and (2) termination is appropriate because UMC was given a warning after their patient mortality rate was too high on the January 2008 report and UMC failed to improve on the July 2008 report. Neither explanation makes sense.

In terms of patient safety, there is no immediate risk to any patient, since UMC's program is not currently active. UMC has already offered that it will not reactivate the program until CMS approves the reactivation. Without UMC's program providing any transplants, it is difficult to see how CMS can claim that patient safety necessitates immediate termination. In fact, by closing the only transplant center in Nevada, thus depriving patients desperately needing kidneys of a local transplant center and instead requiring hundreds of miles of travel to get to a transplant center, CMS would be immeasurably increasing risk to Medicare beneficiaries. What is in the best interests of Medicare beneficiaries in Nevada (and elsewhere, since those other transplant centers would need to absorb UMC's waiting list) is to have a safe and active program at UMC. UMC is

working to improve its program and is willing to permit CMS to resurvey its program before reactivating. There is no immediate need for termination.

CMS's claim that UMC received a "warning" regarding its patient survival rate after the January 2008 report and failed to improve on the July 2008 report also makes no sense. The reports each use a 30 month time period. The January 2008 report covered the time period between July 1, 2004 and December 31, 2006. During that time period 5 UMC transplant patients failed to survive one year post-transplant. All of these 5 deaths were in calendar years 2005 and 2006. The July 2008 report covered the time period between January 1, 2005 and June 30, 2007 and UMC still had the same 5 deaths since the report continued to include all of 2005 and 2006. There is nothing that UMC could have done to reduce the number of deaths from 5 in that time period. CMS plans to terminate UMC despite the fact that there is nothing they could have done to improve their status after the "warning". Thus, the "warning" was a completely empty gesture and it makes no sense to terminate UMC for failing to improve in response. In fact, since the next time period report (July 1, 2005 - Dec. 31, 2007) will omit the first six months of 2005, UMC is now IN compliance.

Thanks again for your help. Please let us know if there is anything we can do to help you.

Charles A. Luband ROPES & GRAY LLP

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Washington, DC 20005-3948

www.ropesgray.com

From:

Krinsky, Glenn < @ropesgray.com>

Sent:

Thursday, October 30, 2008 12:37 PM

To:

Kathy Silver @umcsn.com>

Subject:

Re: Matt's phone number

I'll call him right now. All 5 deaths are in both cohorts.

Glenn L. Krinsky ROPES & GRAY LLP

T 415-315-4818

One Embarcadero Center, Suite 2200 San Francisco, CA 94111-3711

@ropesgray.com

www.ropesgray.com

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From: @umcsn.com

To: Krinsky, Glenn

**Sent**: Thu Oct 30 09:36:10 2008 **Subject**: Matt's phone number

Matt's direct line: (202) 226-11. Office (202) 225-11. He said he would be in and out this afternoon.

Kathleen Silver Chief Executive Officer University Medical Center of Southern Nevada (702) 383

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Subject to the Nondisclosure Provisions of H. Res. 895 as Amended

### OFFICE OF CONGRESSIONAL ETHICS UNITED STATES HOUSE OF REPRESENTATIVES

#### MEMORANDUM OF INTERVIEW

IN RE: Former Acting Director, Office of Legislation, Center of Medicare and

Medicaid Services

REVIEW #(s): 11-0243

DATE: December 1, 2011

LOCATION: Department of Health and Human Services Building

Washington, DC

TIME: 11:00 AM to 11:54 AM (approximate)

PARTICIPANTS: Paul Solis

Scott Gast

Gemma Flamberg (counsel)

<u>SUMMARY</u>: The witness is the former Deputy Director of the Center of Medicare and Medicaid Services ("CMS") Office of Legislation. The OCE requested an interview with the witness and he consented to an interview. The witness made the following statements in response to our questioning:

- 1. The witness was given an 18 U.S.C. § 1001 warning and consented to an interview. The witness signed a written acknowledgement of the warning, which will be placed in the case file in this review.
- 2. The witness is currently retired. He had worked in the CMS Office of Legislation since 1983, and spent the last ten years as Deputy Director. He acted as interim Director when the position was open, from approximately April 2008 to January 2009.
- 3. The witness explained that the mission of the Office of Legislation includes helping the administration develop its legislative proposals, respond to congressional committee staff requests, prepare witnesses for congressional hearings, and to serve as a liaison with the personal staffs of Members of Congress.
- 4. The witness told the OCE that he recalled the situation in 2008 involving potential termination of Medicare approval for the kidney transplant program at the University Medical Center of Southern Nevada ("UMC"). He told the OCE that he had looked at emails to refresh his recollection of events surrounding this situation.
- 5. The witness recalled that the termination issue first came to his attention in early fall of 2008, when Nevada Rep. Jon Porter and the House Ways & Means Committee brought the issue to CMS jointly. The witness stated that Rep. Porter asked to speak with the CMS Administrator about the decision to terminate the UMC transplant program. The witness explained that it was not uncommon to hear from Members of Congress who wish to make their case about a termination decision directly to the CMS Administrator.

MOI - Page 1 of 3

OFFICE OF CONGRESSIONAL ETHICS

Subject to the Nondisclosure Provisions of H. Res. 895 as Amended

- 6. Once the issue was brought to the office's attention, it asked Tom Hamilton, the Director of the CMS Survey and Certification Group, for talking points that the Administrator could use when speaking with Rep. Porter. After the call, the office did the usual follow-up with Rep. Porter to ensure that he had received all the information he needed.
- 7. The witness stated that his office does not get involved with the substance of any termination decision; those decisions are made by the CMS Administrator and the Director of the Survey and Certification Group.
- 8. According to the witness, the Office of Legislation heard from the staff of Rep. Berkley and Senator Harry Reid within days of Rep. Porter's call with the Administrator. The witness believes that he only dealt with staff in Senator Reid's office, but that Rep. Berkley requested a call with the Administrator. In the witness' view, Rep. Porter appeared to be the lead on this matter. He stated that the offices of Rep. Dean Heller and Senator John Ensign were not very engaged on this matter.
- 9. The witness was shown an October 30, 2008 email from an employee of the Office of Legislation to the legislative director for Rep. Porter, in which the employee suggests that the witness had met with Representative Porter the day before. The witness did not recall attending such a meeting with Rep. Porter. The witness stated that he did not think he ever personally met with Rep. Berkley or Rep. Porter.
- 10. The witness stated that the UMC termination issue was a routine one for the Office of Legislation to handle. He stated that the level of congressional involvement in this matter was typical and that CMS' response was routine.
- 11. The witness recalled that the UMC transplant program was eventually given additional time by CMS to make improvements to the program, thereby avoiding termination. The witness stated that the congressional interest in this matter did not have an impact on that decision. He believed that the most significant factor leading to this resolution was language in the preamble to certain CMS regulations that UMC argued prevented the termination of the transplant program during its appeal
- 12. The witness did not know who Rep. Berkley's husband was, nor did he recall ever speaking with Rep. Berkley. The witness said he puts "notes of concern" on the talking points he gives to the Administrator, and he did not recall mentioning Rep. Berkley's husband in the talking points. Had he known about her husband, he may have inserted this information into the talking points, but it wouldn't have changed anything else.
- 13. The witness stated that it would not have mattered to him if he had known that Rep. Berkley's husband was connected to the hospital. He said that it is the job of the Office of Legislation to provide Members with the facts surrounding various matters. He could not have simply told Rep. Berkley that he was not going to provide any facts to her because of her husband's relationship to UMC.

Subject to the Nondisclosure Provisions of H. Res. 895 as Amended

This memorandum was prepared on January 4, 2012 after the interview was conducted on December 1, 2011. I certify that this memorandum contains all pertinent matter discussed with the witness on December 1, 2011.

Paul Solis Investigative Counsel

Subject to the Nondisclosure Provisions of H. Res. 895 as Amended

### OFFICE OF CONGRESSIONAL ETHICS UNITED STATES HOUSE OF REPRESENTATIVES

#### MEMORANDUM OF INTERVIEW

IN RE:

Health Insurance Specialist, Office of Legislation, Center of Medicare and

Medicaid Services

REVIEW #(s):

11-0243

DATE:

December 1, 2011

LOCATION:

Department of Health and Human Services Building

Washington, DC

TIME:

10:05 AM to 10:53 AM (approximate)

PARTICIPANTS:

Paul Solis

Scott Gast

Gemma Flamberg (counsel)

<u>SUMMARY</u>: The witness is a Health Insurance Specialist with the Center of Medicare and Medicaid Services ("CMS"), Office of Legislation. The OCE requested an interview with the witness and he consented to an interview. The witness made the following statements in response to our questioning:

- 1. The witness was given an 18 U.S.C. § 1001 warning and consented to an interview. The witness signed a written acknowledgement of the warning, which will be placed in the case file in this review.
- 2. The witness is a health insurance specialist within the CMS Office of Legislation, Congressional Affairs Group. Prior to that, he was employed with the FBI for 11 years performing internal security work in the Administrative Division.
- 3. The witness' duties in the Office of Legislation include working with Members of Congress and congressional staff regarding Medicare, Medicaid, and the Children's Health Insurance Program; scheduling meetings; and speaking to various groups about CMS' work. He interacts daily with Members and congressional staff, primarily responding to constituent concerns relayed through representatives' offices. In 2008, he was responsible for activities within Region 9, the Western region.
- 4. The witness stated that he could "not really" recall the 2008 decision by CMS to decertify the kidney transplant program at the University Medical Center of Southern Nevada ("UMC"). He stated that he had recently refreshed his memory by looking at old emails.
- 5. The witness believes he was first contacted about the UMC transplant program by Nevada Rep. Jon Porter's legislative director. In response to this contact, the witness would have inquired into the issue by calling the CMS Survey and Certification Group, which is responsible for ensuring provider compliance with certain conditions of participation under Medicare.

MOI - Page 1 of 3

OFFICE OF CONGRESSIONAL ETHICS

#### Subject to the Nondisclosure Provisions of H. Res. 895 as Amended

- 6. When he contacted the Survey and Certification Group, the witness learned that the UMC program was deficient in several areas. The witness recalled relaying this information to Rep. Porter's office. At some point in the process, the witness would have sent a notification of the termination decision to the entire Nevada delegation.
- 7. The witness recalled receiving a call from a staffer in Rep. Berkley's office regarding the UMC transplant program after her office had learned that CMS had provided information to Rep. Porter's office. He stated that Rep. Berkley's office asked for a similar update on the UMC transplant center situation.
- 8. The witness was shown the letter sent by the three members of Nevada's congressional delegation to the CMS Acting Administrator. The witness did not recall seeing the letter at the time it was sent, but he has seen it since the OCE began its review in this matter.
- 9. The witness was shown an October 30, 2008 email from the Acting Director of the Office of Legislation, in which the witness was copied, asking about the possibility of the Administrator having a call with Rep. Berkley. The witness stated that he did not remember the email, but his name was on it, so he was sure he got it. The witness stated that he thought the Acting Director contacted the Administrator's office asking if they wanted the Office of Legislation to set up a call or whether they wanted to "take it on."
- 10. The witness was shown an October 30, 2008 email from the witness to Rep. Porter's legislative director, thanking her for the opportunity to meet with Rep. Porter and the legislative director the day before. The witness did not remember attending the meeting discussed in the email; he believes he set up the meeting for Don Johnson, then Acting Director of the Office of Legislation and another Office of Legislation colleague. The witness stated that he did not think he attended any meetings with Members of Congress or congressional staff on the UMC decertification issue.
- 11. The witness may have had a role in setting up a telephone call in which Tom Hamilton, the director of the CMS Survey and Certification Group, briefed the Nevada delegation about the UMC transplant program and the termination decision, but he did not recall participating in the briefing.
- 12. The witness was asked if he was aware of other contacts made by congressional staff to other offices within CMS. He could not recall any such contacts. The witness stated that if Rep. Berkley's or Rep. Porter's staff had called another office at CMS, his group would have been notified.
- 13. When asked if he discussed the congressional interest in the UMC transplant program with the leadership of CMS, he said he had not, but he noted that email traffic he had seen indicated that the leadership was aware of this situation.
- 14. The witness stated that the level of congressional interest in this matter was "about the same" as other issues, but that it was hard to judge. He did not know whether the congressional involvement had an impact on the decision to decertify the UMC program.

Subject to the Nondisclosure Provisions of H. Res. 895 as Amended

- 15. When asked about emails suggesting that CMS was concerned about appearing to have been "browbeaten" into a resolution that allowed the UMC transplant program to remain open, the witness stated that he did not believe that CMS would have made a decision based on congressional "heavy handedness."
- 16. The witness stated that he knew that Rep. Berkley's husband was a health care provider, but did not recall if he knew that fact during interactions with her office about the UMC decertification issue. He stated that he was not aware of her husband's relationship to UMC. He became aware that her husband was a physician because his group needs to know about the Members they service.
- 17. The witness was shown an email in which a legislative staff member from Rep. Berkley's office thanked him for his help. When asked what help he had provided the staff member, the witness stated that he did not recall but believed that it may have related to his helping to arrange the telephone call between Rep. Berkley and the Administrator.

This memorandum was prepared on January 4, 2012 after the interview was conducted on December 1, 2011. I certify that this memorandum contains all pertinent matter discussed with the witness on December 1, 2011.

Paul Solis Investigative Counsel

#### Chadwick, Alpheus K. (CMS/OL)

From:

Coffron, Matthew @mail.house.gov1

Sent:

Wednesday, November 05, 2008 2:41 PM

Chadwick, Alpheus K. (CMS/OL)

To: Subject:

RE: Hill Notification: CMS Grants University Medical Center at Southern Nevada Extension

Thanks Al.

And thanks for your help last week.

-Matt

Matthew Coffron
Legislative Assistant
Office of Congresswoman Shelley Berkley
405 Cannon House Office Building
202-225-

From: Chadwick, Alpheus K. (CMS/OL) [

@cms.hhs.gov]

Sent: Wednesday, November 05, 2008 2:39 PM

To: Coffron, Matthew; Ensign, John; Harry Reid; Walker, Leeann; Porter, Alanna

Cc: Chadwick, Alpheus K. (CMS/OL)

Subject: Hill Notification: CMS Grants University Medical Center at Southern Nevada Extension

U.S. House and Senate Notification Tuesday, November 5, 2008

To: Congressional Health Staff

From: Carleen Talley

Director, Congressional Affairs Group

Office of Legislation

Centers for Medicare & Medicaid Services

Re: CMS Grants University Medical Center at Southern Nevada Extension

CMS has granted a request by the University Medical Center at Southern Nevada to extend the date that Medicare participation would end for the hospital's adult kidney transplant program. CMS extended the termination date from December 3, 2008 to January 8, 2009. The extension will permit CMS additional time to consider recent actions by the hospital to improve quality of care, and to consider additional improvements that the hospital proposed to CMS on October 29, 2008.

During November CMS will review details of the hospital's improvement strategy. If CMS and the hospital agree, CMS may permit a further extension of the prospective termination date and will schedule an onsite survey to verify that the improvements are effective. Should CMS' later survey verify that the transplant program meets all CMS requirements for patient safety and quality of care, CMS may remove the termination.

If you have any questions, please contact Al Chadwick at 202-690- in the CMS Office of Legislation. Thank you.

#### Elhawary, Katherine M. (Perkins Cole)

From:

Cherry, David

Sent:

Thursday, October 30, 2008 7:10 PM

To:

Coffron, Matthew

Subject:

RE: Cell and personal e-mail

She spoke to CMS admin personally. She was OK'd to say they are close to deal.

From: Coffron, Matthew

Sent: Thursday, October 30, 2008 1:03 PM

To: Cherry, David

Subject: Cell and personal e-mail

For while I am out of the office.

Cell:

e-mail I check most often:

@vahoo.com

Matthew Coffron
Legislative Assistant
Office of Congresswoman Shelley Berkley
405 Cannon House Office Building
202-225-

### reviewjournal.com



# Officials: Transplant center talks go well, suggest hope

BY ANNETTE WELLS REVIEW-JOURNAL

Posted: Oct. 31, 2008 | 10:00 p.m.

A telephone conference call Thursday involving parties with a stake in the fate of the state's only kidney transplant program "went as well as could possibly be expected," Congresswoman Shelley Berkley said.

Members of Nevada's congressional delegation, the Centers for Medicare and Medicaid Services and University Medical Center participated in the call, held a week after the federal agency notified UMC the program would lose its certification Dec. 3.

Although Berkley expressed a general optimism, UMC officials went a step further in saying "a joint announcement between CMS and UMC should be imminent."

Berkley, D-Nev., said CMS is currently negotiating with UMC on correcting problems the federal health agency identified during two inspections of the hospital's kidney transplant center earlier this year.

"No decision has been made, but I hung up the phone feeling very encouraged," Berkley said Thursday afternoon.

Neither Berkley nor UMC officials would share many details about the conference call. However, Berkley did say CMS is concerned about the quality of care provided at the state's only transplant center. UMC's focus has to be on proving that it can provide quality of care that is acceptable to CMS, she said.

During inspections in March and August, CMS found that the transplant center's death rate for kidney transplants was significantly higher than its expected death rate, based on federal standards.

CMS identified more than 40 deficiencies in its original March survey, and UMC had corrected all but three of them by August. Because the corrections were not acceptable to CMS, the federal health agency presented two options to UMC: voluntarily withdraw from Medicare's transplant program or allow decertification by CMS.

UMC has until Monday to make a decision. Hospital officials have previously said they would voluntarily withdraw from the program.

In effort to prevent the program's dissolution, Reps. Berkley, Jon Porter, R-Nev., and Dean Heller, R-Nev., sent a letter to CMS urging it to reconsider. The move, they said, would ultimately shut down the program because Medicare pays for nearly 100 percent of all kidney transplants at the center.

Additionally, since the center is the only one of its kind in Nevada, some 200 people awaiting kidneys in Nevada would have to travel at least 300 miles out of the state for the procedure.

Contact reporter Annette Wells at	@reviewjournal.com or 702-383-

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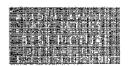
http://www.lvrj.com/news/33628294.html

Check the box to include the list of links referenced in the article.

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September 5, 2011

# A Congresswoman's Cause Is Often Her Husband's Gain

## By ERIC LIPTON

LAS VEGAS — At the University Medical Center here, alarms were set off three years ago — kidney transplants were failing at unusually high rates, and some patients were even dying.

Federal regulators moved to shut down the kidney transplant program, but the proposed penalty brought a rebuke from Representative Shelley Berkley, Democrat of Nevada, who helped lead a successful effort to get the officials from Washington to back down.

In pleading for a reprieve, Ms. Berkley and other members of Nevada's Congressional delegation said they were acting on behalf of the state's families, citing dire health consequences if the program was halted. But the congresswoman's efforts also benefited her husband, a physician whose nephrology practice directs medical services at the hospital's kidney care department — an arrangement that expanded after her intervention and is now reflected in a \$738,000-a-year contract with the hospital.

Ms. Berkley's actions were among a series over the last five years in which she pushed legislation or twisted the arms of federal regulators to pursue an agenda that is aligned with the business interests of her husband, Dr. Larry Lehrner. In addition to the hospital contract, he operates a dozen dialysis centers in Nevada and has played a central role in an industry campaign to lobby members of Congress — including his wife — on behalf of kidney care providers.

Dr. Lehrner helped build a political action committee that has regularly turned to Ms. Berkley to champion its causes. She has co-sponsored at least five House bills that would expand federal reimbursements or other assistance for kidney care, written letters to regulators to block enforcing rules or ease the flow of money to kidney care centers and appeared regularly at fundraising events sponsored by a professional organization her husband has helped run.

"This is a very serious conflict of interest," said James A. Thurber, a former Congressional aide who has helped revise ethics rules and is now director of the Center for Congressional and Presidential Studies at American University. "There is an official use of power here to help him and the family — and I think that is unethical."

Ms. Berkley declined an interview request for this article. But in a statement, she said she was an advocate for a broad range of health care causes and had never acted specifically to help her husband's practice.

"I won't stop fighting to give Nevadans access to affordable health care just because my husband is a doctor, just like I won't stop standing up for veterans because my father served in World War II," she said.

Dr. Lehrner, though, said he was unabashed about pressing his wife on issues that were important to his practice.

"She is definitely aware of my positions, and the R.P.A.'s positions," he said in an interview, referring to the Renal Physicians Association, the trade group he has helped run. "We talk politics all the time. We talk medicine."

Congressional ethics rules are murky — lawmakers can take steps that financially benefit a spouse as long as the benefit is broadly available and there is no "improper exercise of official influence." Lobbying of lawmakers by their spouses is prohibited, but there is no ban on spouses' informally acting as industry advocates, like Dr. Lehrner, who is not a registered lobbyist.

The intermingling of Ms. Berkley's public and private life, though, is striking even among her peers on Capitol Hill, and surfaced in an examination by The New York Times of how lawmakers forge particularly close ties to industries with an agenda in Washington.

As Ms. Berkley has pushed the cause of kidney care in Congress, her husband's practice has boomed, thanks in part to his joint ownership of dialysis centers with DaVita, a giant in the industry and one of Ms. Berkley's biggest campaign contributors. She is one of the richest members of Congress, as she or her husband hold assets valued from \$7 million to \$23 million, according to her most recent financial disclosure forms.

Now running for the Senate seat held by John Ensign until his resignation this spring amid an ethics scandal, Ms. Berkley drives around Nevada in a white Ford Fusion ("United States Congresswoman 1" reads her license plate, referring to her Congressional district).

She often talks about her modest upbringing, in which she ate at Taco Bell while scraping by as a cocktail waitress at a casino resort hotel here. She also frequently mentions her husband's work — she delivered a "certificate of Congressional recognition" at the ribbon cutting of his latest dialysis center last year — and cites his experiences as evidence for why Congress must act to change federal laws or policy.

"I'm sure he didn't think in medical school that in his 60s he still would be taking calls on the weekends, but that's the reality of the situation when you don't have enough nephrologists to

care for the population that you're living in," Ms. Berkley said at a House hearing in 2009, at which she pushed for higher federal reimbursements for medical specialists like her husband.

## **Concerns About Care**

Shawn Rowlett, 40, showed up at the University Medical Center with his wife, pale and weak, four days after he had been discharged from the hospital's transplant center with a new kidney in February 2008. But now he was hemorrhaging, medical records show.

After seeing the hospital's chief transplant surgeon, Mr. Rowlett was left in the emergency room for five hours before being admitted, according to his wife, Dionne Rowlett. He died less than two hours later, court records show.

"The care was just horrible," Ms. Rowlett said in a recent interview, shortly after the hospital settled a malpractice suit for \$77,500 — the maximum amount allowed in Nevada because of a cap on malpractice payments from public hospitals. (Dr. Lehrner and his practice were not named in the lawsuit.)

Mr. Rowlett's death and four recent others in the first year after the surgery, as well as 10 transplant failures, were part of a troubling pattern — the death and failure rates were more than twice the expected level. That led the federal Centers for Medicare and Medicaid Services to issue an order to revoke the certification for the hospital's transplant program — which does about 50 transplants a year — and cut off Medicare financing, effectively shutting the program down.

Brian G. Brannman, the medical center's chief executive, acknowledged that the program was in disarray back then. In a recent interview, he said the hospital was mostly to blame, as its lone transplant surgeon had not been provided with a sufficient support system. Federal regulators also questioned the qualifications of the physician whom Dr. Lehrner and his partners had assigned to help screen transplant patients, leading the hospital to acknowledge in writing that he "was not formally trained in transplantation."

Desperate for a second chance, hospital officials appealed to members of the Nevada Congressional delegation. Ms. Berkley sent a letter, signed by two other lawmakers, warning that cutting off money would "jeopardize the health of hundreds" of constituents. She and the other lawmakers helped set up a series of conference calls between hospital and Medicare officials.

Soon after, the Centers for Medicare and Medicaid Services, for the first time, agreed to override provisions that would have required decertifying the program. In exchange, the hospital promised to remedy the problems.

"I spoke to the head of C.M.S. yesterday," Ms. Berkley told local television reporters in announcing the breakthrough. "When I got off the phone, I had a good-faith belief that we were going to come up with a compromise that works for everybody."

Kerry Weems, then the agency's acting administrator, said he recalled speaking with Ms. Berkley and Jon Porter, then a Republican House member from Nevada, about the program. Mr. Weems could not recall if Ms. Berkley mentioned her husband's ties to the hospital. But he said he would have approved the agreement anyway.

"You want to find a way to 'yes' — not based on any individual stake that a Congress person might have," said Mr. Weems, who recently left the agency. "But this really was the only transplant center in Nevada."

Part of the deal involved significantly expanding the staff of kidney specialists. The hospital turned to Ms. Berkley's husband to recruit two transplant nephrologists, who, Mr. Brannman said, work more directly with the hospital's new transplant surgeon.

Mr. Brannman said the selection of Dr. Lehrner's practice — it was the sole bidder for the contract renewed in December 2010, which increased annual fees by 25 percent — had nothing to do with Ms. Berkley, whom he said he did not know well. The various staffing changes have significantly improved the transplant program's performance in recent years, according to Mr. Brannman and federal officials.

Jessica Mackler, Ms. Berkley's campaign manager, said the congresswoman had no conflict of interest when she intervened, because the money the hospital uses to pay her husband does not directly come from the federal government, and other members of the state's Congressional delegation were involved in the effort to save the transplant program.

"There really is no issue here," Ms. Mackler said.

But Mr. Reems, the former Medicare official, is not so sure, given Ms. Berkley's record of interventions on kidney care issues.

"You never want questions being raised," he said, "and that means you need to try to avoid any move that makes you seem anything less than an impartial public servant."

## **Overlapping Agendas**

At the annual conference of the Renal Physicians Association in Austin, Tex., in 2008, Dr. Lehrner showed a slide of a smiley-faced doctor with a screw being forced into his mouth, and then ticked off a list of steps the group could take to fight cost control efforts in Washington.

"We have been screwed by our policy makers for 20 years," he told the crowd. "Only you can prevent the destruction of our profession."

The doctors, he said, could donate money directly to members of Congress, volunteer on their campaigns, contribute to the political action committee that he had helped build at the Renal Physicians Association and travel to Washington to personally appeal to lawmakers, as he himself does.

Dr. Lehrner added one more option to the list. "Marry an elected official," he said, evoking laughter.

He may have been joking, but Ms. Berkley, 60, who was first elected in 1998 — a year before she and Dr. Lehrner married — has been largely sympathetic to the doctors' cause.

The Medicare system spends an estimated \$27 billion a year, or about 6 percent of overall Medicare spending, to help some of the approximately 550,000 Americans who have so-called end-stage kidney disease. It is the only chronic disease in which the most severely ill patients get nearly free care, regardless of age.

But Congress and federal regulators, alarmed over the surging costs, have sought to control spending in recent years, provoking protests from Dr. Lehrner and the physicians' association, as well as the drug companies and dialysis operators that dominate the industry.

When Dr. Lehrner assumed a series of leadership roles at the renal physicians group, Ms. Berkley's agenda in Washington started to overlap with her husband's. He became the single biggest contributor to the association's political action committee, while also serving as its chairman. And she has received the largest share of its contributions, totaling \$7,000 since 2007. Over all, kidney care doctors, companies and lobbyists have donated at least \$140,000 to Ms. Berkley's Congressional campaigns.

Dr. Lehrner's flourishing practice now includes 21 doctors who work out of seven offices in the Las Vegas area, as well as 11 dialysis centers, 10 of them run in a joint venture, started in 2003, with DaVita. He is a paid national speaker for and has received research grants from Amgen, a major supplier of drugs to dialysis centers.

The activities of these interest groups are closely aligned at times.

In early February 2008, for example, Ms. Berkley received a series of campaign contributions, first \$1,000 from Amgen, then \$2,000 from Kidney Care Partners, a trade group backed by Amgen and DaVita, then \$3,000 from DaVita, and then \$1,000 from Dr. Lehrner's group, the Renal Physicians.

The day that two of those checks were delivered, Ms. Berkley sent a letter to Representative Pete Stark, Democrat of California, then chairman of the House Ways and Means subcommittee with jurisdiction over Medicare, warning him to move carefully in considering changes in compensating doctors who provided dialysis treatments. Echoing concerns raised by the industry, the congresswoman said she worried that patient access to care could be affected.

"While I support initiatives to improve quality and efficiency in Medicare, I do not believe that these efficiencies should come at the cost of patient well being," Ms. Berkley wrote, without mentioning her husband's interest in the matter.

Regulators moved ahead with the new reimbursement system, although it was adjusted in a way that the dialysis and drug companies ultimately embraced. This year, after Medicaid threatened to cut 3.1 percent of the money for dialysis — to save an estimated \$250 million annually — Ms. Berkley led an effort in the House to oppose the cut.

Less than a month later, the agency reversed its position, winning Ms. Berkley a personal thanks from industry leaders in press releases and new campaign donations.

"She is highly knowledgeable about this complicated and critical area of health care that impacts millions of Americans," Skip Thurman, a DaVita spokesman said in a written statement, of the company's donations — which have accelerated as Ms. Berkley runs for the Senate. "The kidney community's support of her is entirely appropriate."

## CONFIDENTIAL

Subject to the Nondisclosure Provisions of H. Res. 895 as Amended

# OFFICE OF CONGRESSIONAL ETHICS UNITED STATES HOUSE OF REPRESENTATIVES

## **MEMORANDUM OF INTERVIEW**

IN RE: Former Acting Administrator, Center for Medicare and Medicaid Services

REVIEW #(s): 11-0243

DATE: December 1, 2011

LOCATION: Department of Health and Human Services Building

Washington, DC

TIME: 2:36 AM to 3:10 AM (approximate)

PARTICIPANTS: Paul Solis

Scott Gast

Mark Davis (counsel)

<u>SUMMARY</u>: The witness is the former Center for Medicare and Medicaid Services ("CMS") Administrator. The OCE requested an interview with the witness and he consented to an interview. The witness made the following statements in response to our questioning:

- 1. The witness was given an 18 U.S.C. § 1001 warning and consented to an interview. The witness signed a written acknowledgement of the warning, which will be placed in the case file in this review.
- 2. The witness is currently the Vice President for Health Solutions at General Dynamics Information Systems. He previously served as the Acting Administrator of CMS from approximately September 2007 through January 2009. Prior to that position, the witness served in a number of positions at the Department of Health and Human Services, including Deputy Chief of Staff, Chief Financial Officer, and Chief Budget Officer.
- 3. The witness learned of the decision to terminate Medicare approval of the kidney transplant program at the University Medical Center of Southern Nevada ("UMC") when the Thomas Hamilton, the director of the CMS Survey and Certification Group, brought the decision to him for ratification. The witness stated that he had final authority for making the decision.
- 4. The CMS decision was also brought to the witness' attention when the three members of the Nevada delegation to the House of Representatives sent a joint letter expressing disagreement with the CMS termination decision.
- 5. In addition to receiving the Nevada delegation letter, the witness met with Nevada Representative Jon Porter. In the witness' view, Representative Porter was leading the congressional effort with respect to the UMC transplant program. Representative Porter was interested in learning the reasons for the CMS decision to de-certify the program. The witness stated that he may also have had a telephone conversation with Representative Porter on this issue.

MOI - Page 1 of 3

OFFICE OF CONGRESSIONAL ETHICS

#### CONFIDENTIAL

## Subject to the Nondisclosure Provisions of H. Res. 895 as Amended

- 6. The witness also had a telephone conversation with Nevada Representative Shelley Berkley, who asked him to consider looking for a pathway forward that would allow the kidney transplant center to retain Medicare approval and remain open. In the witness' view, the telephone conversation with Representative Berkley was less substantive than his conversation with Representative Porter.
- 7. The witness indicated that he was open to finding a pathway forward, noting that such a pathway does not always lead to "yes." The pathway had to fall within the laws and rules applicable to the situation.
- 8. The witness relayed the congressional concerns to Mr. Hamilton, who the witness said agreed that if a way forward that allowed the transplant program to remain open was possible, that way should be taken. The witness believes he also discussed the UMC program with Don Johnson, acting director of the CMS Office of Legislation; Doug Stoss, the witness' chief of staff; and Herb Kuhn, the deputy administrator at the time.
- 9. According to the witness, Mr. Hamilton "cooked up" something somewhat new that allowed the transplant program to remain open while ensuring substantive improvements were made. Under this approach, CMS and UMC would enter into a Systems Improvement Agreement that included real, quantitative steps that the hospital must achieve to continue its Medicare approval.
- 10. According to the witness, the congressional involvement "impelled" he and his agency to take the next step toward finding a way to keep the transplant program open. Without the congressional involvement, the witness believes CMS would have continued with termination of Medicare approval of the UMC program.
- 11. When asked about emails that suggested concern that CMS not appear to have been "browbeaten" into an agreement, the witness stated that CMS had not been "browbeaten." He noted that the UMC program was the only transplant center in Nevada and, given that, it was in everyone's interest to look for a path forward.
- 12. When asked when he became aware of Representative Berkley's relationship to the UMC kidney transplant program through her husband, the witness stated that he learned of the connection prior to the Systems Improvement Agreement being signed. The witness stated that his conversation with Rep. Berkley about the UMC program was so short that it was difficult to remember it well, but that she may have disclosed her husband's relationship with UMC during the call. The witness, however, had no specific memory of such a discussion.
- 13. When asked about his reaction upon learning of the connection between Representative Berkley and the UMC transplant program, the witness stated that he always assumes that Members of Congress were acting for their constituents and not for personal gain.
- 14. The witness had no contact with Rep. Berkley's husband.

## CONFIDENTIAL

Subject to the Nondisclosure Provisions of H. Res. 895 as Amended

This memorandum was prepared on January 4, 2012 after the interview was conducted on December 1, 2011. I certify that this memorandum contains all pertinent matter discussed with the witness on December 1, 2011.

Paul Solis Investigative Counsel

From:

Porter, Alanna < @mail.house.gov>

Sent:

Wednesday, October 29, 2008 2:09 PM

To:

Kathy Silver < @umcsn.com>

Subject:

RE: UMC Kidney Transplant Program

Kathy – what is the best number to reach you? I need to talk to you ASAP. Thanks.

@umcsn.com

@umcsn.com]

**Sent:** Tuesday, October 28, 2008 12:05 PM

To: Porter, Alanna

Subject: RE: UMC Kidney Transplant Program

Alanna - thank you so much. Please let us know how it goes. Good luck.

From: Porter, Alanna

@mail.house.gov]

Sent: Tuesday, October 28, 2008 7:48 AM

To: Luband, Charles A.; Krinsky, Glenn; Kathy Silver Subject: RE: UMC Kidney Transplant Program

I wanted to let you know that Congressman Porter will be speaking with Kerry Weems at noon today in an effort to put the breaks on their recent action. I will let you know how it goes but wanted to let you know we are still working on this.

From: Luband, Charles A.

@ropesgray.com1

Sent: Thursday, October 23, 2008 1:33 PM

To: Porter, Alanna; Krinsky, Glenn; @umcsn.com

Cc: Luband, Charles A.

Subject: RE: UMC Kidney Transplant Program

Here is a call in number for the 1:30 PT conference call:

(888) 352-

Conference Code:

(Alanna, let me know if you would prefer that we call you on your cell.)

Charles A. Luband ROPES & GRAY LLP

| F 202-383-9367 T 202-508-One Metro Center, 700 12th Street, NW, Suite 900

Washington, DC 20005-3948

@ropesgray.com

www.ropesgray.com

From: Luband, Charles A.

Sent: Thursday, October 23, 2008 9:40 AM

To: 'Porter, Alanna'

Subject: RE: UMC Kidney Transplant Program

Alanna --

From: Porter, Alanna [ @mail.house.gov]

Sent: Wednesday, October 22, 2008 11:01 PM

To: Luband, Charles A.

Subject: Re: UMC Kidney Transplant Program

Yes. Call my cell tomorrow. I'm in nevada.

---- Original Message -----

From: Luband, Charles A. < @ropesgray.com>

To: Porter, Alanna

Cc: Luband, Charles A. < @ropesgray.com>

Sent: Wed Oct 22 22:28:26 2008

Subject: UMC Kidney Transplant Program

Alanna --

I am an attorney in Washington with Ropes & Gray. We represent UMC of Southern Nevada, which has a rather desperate issue regarding the Medicare status of UMC's kidney transplant program. This is a very urgent matter - CMS has indicated that it plans to take steps as soon as November to terminate the program's Medicare eligibility status, which would result in closure of the program and the loss of a transplant center that currently has over 250 people on its waitlist.

I have attached a background paper that explains the issue and sets forth UMC's request for Congressman Porter's and your assistance. Relevant correspondence between UMC and CMS is also attached.

I understand from the folks at UMC that the Congressman will be at UMC on Friday. They may want to speak with him about this issue when he is on site. However, we would be pleased to speak with you about the issue tomorrow if you would like. We have already spoken with staff from Sen. Ensign's and Rep. Berkley's offices. Please let me know if you have some time tomorrow (preferably early afternoon) to discuss these issues and help prevent the elimination of Nevada's only kidney transplant center.

Charles A. Luband ROPES & GRAY LLP

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# Chadwick, Alpheus K. (CMS/OL)

From:

Johnson, Donald N. (CMS/OL)

Sent:

Tuesday, October 28, 2008 3:58 PM

To:

Chadwick, Alpheus K. (CMS/OL)

Cc:

Guevara, Natalia T. (CMS/OL); Martino, Maria (CMS/OL) FW: University Medical Center loses kidney program

Subject:

Kerry and Mr. Porter had a discussion.

Al - Pls reach out to Porter's staff if you have not done so before and provide them the timelines and such we have from Thomas Hamilton. I'm not sure I want to get into the details in Barry's note. What do you recommend?

From: Kerry Weems (OA)

Sent: Tuesday, October 28, 2008 1:34 PM

To: Straube, Barry M. (CMS/OCSQ); Johnson, Donald N. (CMS/OL)

Cc: Stoss, Douglas (CMS/OA); Newhart, Diana (CMS/OA); Schild, Molly (CMS/OA); Ransom, Robert S. (CMS/OA)

Subject: Fw: University Medical Center loses kidney program

I had a good conversation w/Cong Porter. He was actually sympathetic (privately). We agreed that he could publicly say that I have agreed to look at and insure all processes were followed.

We need to push to his staff (Don) the timelines and all of the deficiencies found in the intial and follow-up inspections. Also, the press is relying a lot on the suicide being in the mortality counts. Barry's note below is very helpful in that regard.

My sense is that Porter can be supportive, in the end, if we give him the info he needs. He also referenced the ASC problem from earlier in the year.

KW

From: Straube, Barry M. (CMS/OCSO)

To: Kerry Weems (OA) Cc: Stoss, Douglas (CMS/OA) Sent: Tue Oct 28 06:57:42 2008

Subject: Re: University Medical Center loses kidney program

### Kerry

The mortality calculation takes into account all causes of death, since it would be administratively difficult, if not impossible, to know the cause in all cases. Sometimes patients are "lost to follow-up" and their death is surmised, although not cause of death is never known.

You are correct that a suicide of a patient would be considered a preventable death. Indeed, sometimes the steroids (prednisone), other medications being given to the patient, or other factors can lead to depression, anxiety and other behavioral health problems. It is the responsibility of the transplant center to identify and treat such conditions, just as they should treat other medical conditions. Not knowing the details of the suicide case, it is theoretically possible that the suicide was an egregious medical oversight failure, particularly if there were warnings that were not picked up. Indeed, the conditions of participation require a social worker and psychiatric evaluation before, during and after the transplant. We saw a number of patients who we excluded from the transplant list because of the potential risk of their not being adherent to medications, follow-up, or medical regimens. It is possible that their suicide patient should have never been transplanted in the first place.

Although I synpathize with their argument, other centers could argue that a transplant patient who died of a heart attack, but didn't call with symptoms of chest pain for a week was "beyond their control" (and presumably the suiocide was the

patient's responsibility). Others could say that the local referring doctor didn't relay ongoing updates. The list of possible mitigating factors goes on and on such that every death could be explained by something beyond the transplant centers control if we went that route.

I don't know the center's denominator of number of transplants performed. But if this one case made a difference, it sounds like they had 10 or fewer per year, so this puts them in the low volume range. You may remember that in discussions with the Department, we all decided to de-emphasize volume in the Transplant Center Regs and focus first and foremost on outcomes. When centers have less than 10-12 transplants per year, the metrics become not statistically significant, meaning that one case can drastically skew the outcomes, either direction. They may have had some "lucky" cases that tipped them into the "pass" range, any one of which, if the outcome had been different, would have tipped them in the other direction. The point is that the lower the volume of transplants, the more unreliable the center's data becomes and barring lack of other nearby centers, one can question the value added of small programs.

As a final aside, Kerry, I and others were not aware of this action until I read it in the newspaper over the weekend. I did communicate with CMSO that it would be a good idea to give a heads up to other clinical and administrative folks prior to taking action like this and we'll work on that. As a consequence, I don't know all the details of this case, but hopefully the above helps. Thanks.

Barry
Barry M. Straube, M.D.
CMS Chief Medical Officer
Director, Office of Clinical Standards & Quality
Centers for Medicare & Medicaid Services
7500 Security Blvd.
Mailstop: S3-02-01
Baltimore, MD. 21244
Phone: 410-786-

From: Kerry Weems (OA)

To: Straube, Barry M. (CMS/OCSQ)
Cc: Stoss, Douglas (CMS/OA)
Sent: Tue Oct 28 00:07:48 2008

Subject: Fw: University Medical Center loses kidney program

Barry,

Do our CoPs contemplate patient suicide? If so, why? Proper support post-transplant?

From: Ransom, Robert S. (CMS/OA)

To: Kerry Weems (OA)

Sent: Mon Oct 27 17:42:08 2008

**Subject:** RE: University Medical Center loses kidney program Sorry, 9:45am PDT, which is 20 minutes after your speech ends.

Also, the hotel has your updated itinerary.

Robert S. Ransom (202) 690-

@cms.hhs.gov

From: Kerry Weems (OA)

Sent: Monday, October 27, 2008 5:35 PM

To: Ransom, Robert S. (CMS/OA)

Subject: Re: University Medical Center loses kidney program

9:45 EDT?

From: Ransom, Robert S. (CMS/OA)

To: Kerry Weems (OA)

Sent: Mon Oct 27 16:46:28 2008

Subject: RE: University Medical Center loses kidney program

I scheduled the call with Congressman Porter for 9:45am and we will patch the call to you.

Also, there's a mistake on your agenda so I'm faxing a correct one to your hotel, it should be at the front desk when you check in. I mistakenly put down the wrong time zone.

Robert S. Ransom

(202) 690-

@cms.hhs.gov

From: Kerry Weems (OA)

Sent: Monday, October 27, 2008 4:24 PM

To: Ransom, Robert S. (CMS/OA)

Subject: Re: University Medical Center loses kidney program

Tomorrow pls

From: Ransom, Robert S. (CMS/OA)

To: Kerry Weems (OA)

Sent: Mon Oct 27 16:07:46 2008

Subject: FW: University Medical Center loses kidney program

Here are the talking points in word format and also within the body of the email. Also, the National Journal article is

located at the bottom of this email.

Would you like to do this call today or tomorrow?

Thanks

Robert S. Ransom

(202) 690-

@cms.hhs.gov

Subject: RE: From Saturday's Las Vegas Review Journal: University Medical Center loses kidney program

Importance: High

Don and Al:

Our response to the Congressmen/women is on the fast track. UMC-Nevada has submitted documentation—under mitigating factors authority, that CMS has reviewed and considered.

Here are some talking points for reporters et al:

- CMS outlined for the University Medical Center of Southern Nevada (UMC) [kidney] program the minimum quality standards that were not met. The program was required to submit a plan of correction to correct all of the areas identified during the survey. Based on a follow-up visit completed on August 5, 2008, the program still not meet 3 areas of the regulation including outcomes, timely submission of key information about patients and living donors, and proper verification of blood type and donor identification.
- The regulations establishing the Medicare Conditions of Participation for transplant programs were
  promulgated on March 30, 2007. Almost 1-year after the regulations were released, the UMC [kidney]
  program had still not changed its program to meet the minimum standards of care required for Medicareapproved transplant programs.
- The outcomes deficiencies resulted in UMC kidney transplant program being given a prospective termination date of October 13, 2008, unless the July 2008 SRTR [Scientific Registry of Transplant Recipients] report showed that the program's outcomes had improved and were back in compliance with the regulation. Based on the July 2008 SRTR report the program continued to be out of compliance with the patient survival rates, 1-year post transplant.
- CMS had a conference call with UMC on August 5, 2008, to discuss this and outlined the options for UMC going forward. The UMC kidney transplant program could: 1) voluntarily withdraw from Medicare; 2) request approval based on mitigating factors (which is a specific provision in the regulation that allows CMS to consider other factors in determining approval when a Condition-level deficiency is found); or 3) CMS termination.
- UMC chose to request approval based on mitigating factors. The CMS panel reviewing UMC' materials found that the arguments did not make a compelling case.
- None of the arguments made by the program indicate that they have done a comprehensive review of the
  critical factors that have caused the outcomes to be lower than expected since January 2007 and that they
  have taken steps to correct these issues so that they do not occur in the future. CMS' first priority is to
  protect the health and safety of our beneficiaries.
- CMS management subsequently determined that Medicare approval based on the presence of mitigating factors would not be granted. We subsequently had a follow-up call with UMC to share this determination.
- The termination date was ultimately postponed to December 3, 2008, to allow sufficient time for the Medicare beneficiaries to be notified that Medicare-approval was ending. UMC received this final decertification notice on October 23, 2008.

Subject: From Saturday's Las Vegas Review Journal: University Medical Center loses kidney program

# **UMC loses kidney program**

By ANNETTE WELLS

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Four months after becoming the state's only **kidney** transplant program, University Medical Center has been stripped of that privilege, leaving in doubt where more than 200 Nevadans

awaiting kidney transplants might go for their procedures.

**UMC** was notified in a Thursday letter by Centers for Medicare and Medicaid Services, or CMS, that its certification for the transplant center will be revoked effective Dec. 3. That means the hospital will not receive any payments for transplant services on or after that date, effectively closing the program.

The letter goes on to say the program was revoked because it did not meet required patient survival outcomes based on surveys CMS conducted in March and August.

"More people are dying than necessary at **UMC**," Jack Cheevers, a spokesman for CMS' Region IX, sald about the federal health agency's decision. "The hospital's actual death rate for **kidney** transplant recipients is more than 50 percent higher than its expected death rate. And, the hospital hasn't done what it needs to do to address its quality of care problems."

However, hospital officials and others say the program is being unfairly penalized. One of the deaths used to justify the CMS findings was a suicide, they said. Were it not for that death, **UMC** Chief

Executive Officer Kathy Silver said, the program would be in compliance.

But according to a 52-page report summarizing the March 12 survey at **UMC**, roughly 45 deficiencies in the hospital's transplant program were documented. Among the findings:

• The program failed to document that donor blood type and other vital data were compatible with the intended recipient prior to transplantation.

· The program "failed to keep their waiting lists up to date on an ongoing basis."

• The program failed to timely notify the Organ Procurement and Transplantation Network that patients had a successful transplant and should be taken off the network's list.

**UMC** was asked to provide a plan of correction for those deficiencies, which it did. During a follow-up Aug. 7 survey, **UMC** was found to still be not in compliance for three deficiencies. As in the March survey, one of those deficiencies was inadequate patient survival outcomes. The hospital now has two options: allow CMS to decertify the program on Dec. 3, or voluntarily withdraw its certification. Silver said the latter course will be taken, but **UMC** still plans to challenge the decision.

Silver said Friday she was disappointed in CMS' action.

"We're trying to point out to them that the implications of closing this program would mean people having to travel several hours or more to get a **kidney** transplant. Some people can't afford that," Silver said. "This affects the whole region. These people will now be on the waiting lists of other transplant centers. This will impact those other facilities, even though the patients retain their status on the waiting lists."

Patients in need of **kidney** transplants may now have to travel to out-of-state facilities such as the Mayo Clinic in Scottsdale, Ariz., or UCLA, officials say.

The CMS letter to the hospital says **UMC** must assist waiting list patients transferring to another transplant facility "without loss of time accrued on the waiting list."

Silver said the hospital has already sought help from the state's congressional delegation, which is now pleading with CMS to reconsider.

"We have reached out to both the House and the Senate side of this delegation," Silver said. "We feel very frustrated by this whole process and we are hopeful that between some of the administration remedies, and pressure applied through our congressional leaders, we can get CMS to reconsider."

On Friday, Reps. Shelley Berkley, Jon Porter and Dean Heller sent a letter to CMS' acting administrator, Kerry Weems, expressing their "strong disagreement" with the agency's decision.

In their letter, they reference what they believe is the remaining unresolved deficiency — the patient survival outcomes. The May 2005 suicide caused **UMC** to not meet compliance standards for two overlapping reporting periods — July 1, 2004 to Dec. 31, 2007 and Jan. 1 2005 to June 30, 2007.

"This suicide of an otherwise successful transplant patient is lamentable, but beyond the control of **UMC**," the letter states.

"Our argument to CMS is that death should not be counted for purposes of a statistical calculation," Silver said.

Berkley spokeswoman David Cherry said the congresswoman felt she needed to act considering the importance of a **kidney** transplant program in Nevada.

As of Friday, according to the United Network for Organ Sharing, 208 people were awaiting **kidney** transplants in Nevada. Ken Richardson, executive director of the Nevada Donor Network, said about 200 other patients are awaiting heart, liver and other transplants. Richardson said he was shocked at CMS' decision.

"This is important to our community," he said. "This puts our community at a disadvantage. It is not a very good situation when a government agency recklessly disregards the needs of the people."

In July, Sunrise Hospital and Medical Center's **kidney** transplant program was folded into **UMC**'s to improve the county hospital's performance. The goal was to turn **UMC**'s **kidney** transplant program into a "center of excellence" so it could eventually offer heart and liver transplants.

Richardson said **UMC** has been aggressively recruiting for surgeons and nephrologists to staff the **kidney** transplant program.

Sunrise had offered **kidney** transplants for nearly two decades before merging its program with **UMC**.

Because of the small number of **kidney** transplants performed in Southern Nevada - 26 at Sunrise last year and 40 at **UMC** — Sunrise officials said it made sense to consolidate the programs.

Contact reporter Annette Wells at reviewjournal.com or 702-383-

# reviewjournal.com



# Lawmakers intervene in bid to retain transplant services

BY ANNETTE WELLS REVIEW-JOURNAL

Posted: Oct. 30, 2008 | 10:00 p.m.

Nevada's only kidney transplant program might have a lifeline.

Rep. Jon Porter, R-Nev., said Wednesday he has had productive conversations twice in two days with Centers for Medicare and Medicaid Services, the agency that informed University Medical Center that certification for its transplant center is being revoked effective Dec. 3.

Porter said in one of his conversations with CMS, he received assurance that the investigation of UMC's transplant program would be re-examined.

"The acting director has committed to me that CMS will review the whole investigation to ensure it was handled appropriately," Porter said. "I have made it clear to CMS that this is a critical program for Nevadans."

Porter, along with Reps. Shelley Berkley, D-Nev., and Dean Heller, R-Nev., sent a letter to CMS urging the federal health agency to reconsider its decision to decertify the transplant program.

Porter met with Kerry Weems, CMS' acting administrator, on Tuesday in Las Vegas. He spoke with CMS officials again Wednesday while back in Washington.

David Cherry, a spokesman for Berkley, said the congresswoman is scheduled to meet with CMS officials sometime today. It was unclear whether Heller would be speaking with CMS.

Porter said "key areas" that concern CMS about the state's transplant program were discussed. Those concerns center around the federal agency's belief that UMC is not meeting minimum required patient survival outcomes.

According to health surveys in March and August, the transplant center's death rate for kidney transplant recipients was significantly higher than its expected

death rate, based on federal standards.

According to CMS officials, when the March survey was conducted, it was noted that five patients had died within a year of their kidney transplants. The same statistic was noted again in the hospital's August survey.

The expected death rate for that time period, taking a number of factors into account such as the patient volume and age of patients, would be 1.81, according to CMS.

Kathy Silver, the hospital's chief executive officer, says her understanding is that UMC's expected death rate should be 4.8.

Using that calculation, Silver said UMC would be well within the federal guidelines.

"It doesn't work that way," Silver said referring to the calculations CMS used to come up with the expected death rate.

Thomas Hamilton, director of CMS' Survey and Certification Group, says UMC is referring to a calculation method that is used for transplant centers that are new. This higher threshold, he said, helps new programs with a low volume of transplant patients get easier entry into the Medicare transplant program. Nevada's transplant center isn't one of the new programs, he said.

"You can't just pluck a number out of a data set that you don't like. ... That's manipulating the data. The real issue here is whether or not the transplant center has an effectively functional program that provides acceptable levels of quality of care," Hamilton said. "To that end, we've offered them an opportunity to voluntarily withdraw and request reinstatement as soon as they have an effectively functioning program. ... We look forward to that day."

Unless lawmakers can dissuade CMS from decertifying the transplant program, UMC plans to voluntarily withdraw its transplant program out of Medicare. Since Medicare pays for nearly 100 percent of the costs of transplants at the hospital, the program will be lost.

If the hospital chooses to re-open the program, it would have to undergo recertification, which could take years. Either way, the move leaves more than 200 people awaiting kidney transplants in Nevada in limbo. Their option would be to travel at least 300 miles to an out-of-state facility.

Silver, who said there will be a conference call today between UMC and CMS officials, praised the state's congressional delegation for its help.

"We're cautiously optimistic," she said about UMC's transplant program staying operational. "We have at least go them (CMS) to take a step back and take a look at maybe something was overlooked. That's all we're asking for."

Contact reporter Annette Wel	ls at	@reviewjournal.com	or 702-383-

## Find this article at:

http://www.lvrj.com/news/33564414.html

Check the box to include the list of links referenced in the article.

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# Elhawary, Katherine M. (Perkins Coie)

From: Luband, Charles A. gropesgray.com

Sent: Thursday, October 30, 2008 7:27 PM

To: Coffren Matthew; Porter, Alanha; Damail.house.gov;

Cc: Luband, Charles A.

Subject: RE: University Medical Center of Southern Nevada ("UMC")

I wanted all of you to know about the most recent development regarding efforts to allow UMC's kidney transplant program to re-activate and continue its operations for the benefit of Nevada patients.

Today, CMS and UMC reached an agreement that will result in a one month delay of CMS' decertification of UMC's program until January 8, 2009. However, this delay in the decertification is intended as a placeholder, while CMS and UMC negotiate and execute a "System Improvement Agreement" that will incorporate representations from the hospital about its current state of readiness and other elements that demonstrate its ability to operate the program safely. Upon execution of this agreement, CMS will withdraw the January decertification and propose a new decertification date a number of months into the future. This will allow the hospital to re-activate the program and begin to establish a successful track record. Sometime before the future decertification date, CMS will conduct an unannounced survey of the program. If UMC passes that survey, it will obtain new certification.

In sum, the UMC and CMS agreement, pending CMS survey and approval, will allow the continuation of the UMC program.

We greatly appreciate all of the help that your offices have provided in support of UMC and its kidney transplant program. At this point, assisted by your efforts, UMC and CMS are now working together to ensure the best interests of the patients on the wait list and future Nevada patients. CMS is understandably concerned at this point that the public not believe that it was "browbeaten" into this agreement. We do believe, and recommend that any public statements note, that parties are currently working constructively and collaboratively to reach a result that is in the best interests of current and future patients.

Thanks again for all of your help.

## Charles A. Luband ROPES & GRAY LLP

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## DEPARTMENT OF HEALTH & HUMAN SERVICES



CENTERS FOR MEDICARE & MEDICAID SERVICES
Consortium For Quality Improvement and Survey & Certification Operations
Western Consortium – Division of Survey & Certification

Refer to: WCDSC-

October 31, 2008

Ms. Kathy Silver Chief Executive Office University Medical Center – Southern Nevada (UMC) 1800 W. Charleston Boulevard Las Vegas, NV 89102

Re: Adult Kidney Transplant Program

Dear Ms. Silver:

As communicated in the October 23, 2008 letter, the Centers for Medicare & Medicaid Services (CMS) determined that the Adult Kidney-Only transplant center at the University Medical Center does not meet federal requirements for participation as a Medicare-approved transplant program.

After examining the unique circumstances of the UMC, the imminent efforts to effectuate improvements, and most importantly our shared desire to minimize disruption to the health care of potential organ recipients, we will extend the termination date until January 8, 2009. Accordingly, no Medicare payment will be made for transplant services furnished by the center on or after that date. This action does not affect the Medicare hospital provider agreement for UMC itself.

All other due process rights and contact information from the October 23 letter remain unchanged. Furthermore, you continue to have available to you the option to voluntarily withdraw prior to the termination effective date. The associated publication of public notice in the Las Vegas Sun, will therefore occur no later than December 8, 2008, unless a binding, mutual agreement is achieved between the parties (with performance milestones), and the agreement is executed prior to December 8, 2008. We reaffirm the basis for taking the termination action and reserve the right to pursue termination based on those original survey findings previously conveyed to you and the history of unacceptable outcomes (as indicated in the July 2008 risk-adjusted outcomes report from the Scientific Registry of Transplant Recipients Report).

Further, we are extending the scheduled termination date to January 8, 2009 based on the understanding that the interim milestones in the Attachment to this letter (enclosed) are met. This extension will permit the hospital additional time to explain recent actions taken by hospital to come into compliance with federal requirements for patient safety and quality of care, reduce mortality rates, and implement additional improvements that the hospital proposed to CMS on October 29, 2008.

In November 2008 CMS will review details of the hospital's improvement strategy. Should CMS determine that the improvement actions are not likely to enable fulfillment of the Medicare

Denver Regional Office 1600 Broadway, Suite 700 Denver, CO 80202 San Francisco Regional Office 90 7<sup>th</sup> Street, Suite 5-300 (5W) San Francisco, CA 94103-6707 Seattle Regional Office 2201 Sixth Avenue, RX-48 Seattle, WA 98121 Conditions of Participation, CMS will provide a written explanation of the determination prior to December 8, 2008 and the scheduled January 8<sup>th</sup> termination of Medicare participation will proceed.

If CMS and the hospital do execute a mutually-binding agreement prior to December 8, 2008, however, CMS may permit a further extension of the prospective termination date beyond January 8, 2009; CMS would then schedule an onsite survey in 2009 to verify that the improvements are effective in meeting all federal requirements. Should this later survey verify that the transplant program meets all CMS requirements for patient safety and quality of care, CMS may rescind the termination. However, if the re-survey finds that the hospital does not meet all federal Conditions of Participation, CMS would continue proceedings for the termination of the adult kidney transplant center's Medicare participation.

We look forward to further discussions and actions within the coming weeks to meet our common objective of high quality health care for transplant recipients in UMC's adult kidney transplant program. If you have any questions concerning this letter, please contact Ed Q Japitana at 415-744-by email at acceptance of the program of the p

Sincerely.

Deborah Romero Operations Manager

CMS Western Consortium

Reboral Romero

Enclosure

CC: Ms. Karen Watnem, Administrator, UMC Transplant Services
Mr. Glenn Krinsky, Attorney
Nevada State Department of Health
Commander Steve Chickering, Associate Regional Administrator, Survey & Certification
Thomas Hamilton, Director, Survey & Certification Group, CMS
Angela Brice-smith, Deputy Director, Survey & Certification Group, CMS
Karen Tritz, Technical Director, Transplant Program Survey & Certification, CMS
CMS Fiscal Intermediary/Medicare Administrative Contractor

# angeling of the specific positive and a Attachment of the control of the control

CMS' one-month extension of the termination date will permit UMC to provide additional information to CMS to demonstrate present readiness to provide safe transplantation services of high quality. CMS will engage with UMC in the next 2-3 weeks to consider recent actions by the hospital to improve quality of care, reduce mortality rates, and implement additional improvements that the hospital proposed to CMS on October 29, 2008.

In November CMS will review details of the hospital's improvement strategy. Should CMS determine that the improvement actions are not likely to enable fulfillment of the Medicare Conditions of Participation, then the scheduled termination of Medicare participation will proceed. If CMS and the hospital agree, however, CMS may permit a further extension of the prospective termination date beyond January 8, 2009 and would then schedule an onsite survey in 2009 to verify that the improvements are effective in meeting all federal requirements. Should this later survey verify that the transplant program meets all CMS requirements for patient safety and quality of care, CMS may rescind the termination.

While the outcome of these additional deliberations is not pre-determined, we are encouraged by the hospital's indicated willingness to make necessary improvements.

Below are certain actions and informational resources that we will need to begin the additional review.

	To be met
Actions and Information	by:
	and the same of th
A. Surgical Capabilities  We understand that UMC will execute contractual agreement(s) with qualified	Nov. 10, 2008
surgeons to maintain a fully operational surgical team that provides local surgical	
coverage 24 hours per day/ 7 days per week. If the agreements provide for	
rotational coverage, there must be significant protections and processes in the	:
agreement to ensure that the rotational coverage does not result in fragmented care	
for patients during the post-transplant period. Please describe such arrangements	
and the status for the surgical team to be licensed by the State of Nevada and to be	
credentialed by UMC.	
Provide CMS a copy of the written agreement(s) with such surgeons.	
Describe the specific nature and breadth of coverage by the surgical team during	
the transplant period to ensure continuity of care.	
B. Maintenance of an Effective Internal Quality Assessment and Performance	Nov. 10, 2008
Improvement (CAPI) program. UMC will sent to CMS:	-
- A copy of the written Quality Assessment and Performance Improvement program	
operational protocols, including protocols for:	
1. Regular review of all outcomes (patient and graft survival rates);	
2. Timely review of all 30-day readmission and complication events;	
3. Chart review to verify compliance with the blood type verification policies.	
* A list of the members of the Quality Assessment and Performance Improvement	
team and their fitles or description of primary responsibilities at the hospital;	 
A list of all of the objective performance measures currently tracked by the QAPI	

program.  Documentation that a full analysis was conducted of the adverse event that occurred in Spring 2008 in which a living donor's native kidney failed subsequent to the donation; a copy of the recommendations for policy or procedural changes to prevent a recurrence, and a description of the actions implemented to prevent a recurrence and to promote compliance with the hospital's own policies for donor selection and follow-up.	
<ul> <li>C. Administrative and Surgical Leadership:         <ul> <li>Provide a written plan that fully describes the implemented and planned changes to transform the key administrative and surgical leadership of the program. The plan must identify previous leadership, and current and future leadership which would include both interim steps (during the period of the agreement with the University of Utah) as well as long-range plans.</li> </ul> </li> <li>Describe specific commitments the hospital has made to support the development and proper administration and oversight of the program.</li> </ul>	Nov. 10, 2008

Provide individual name(s) and any additional description of changes that UMC will be making or has made in the administrative or surgical leadership to transform the program and ensure that these

efforts are sustained.

Position		Time Period	aganina manggaran na anggaranggaran ana ang anggaranggaran na anggaranggaran na anggaranggaran na anggaranggar	Description of other
January -	January - September 2008	Interim, During Agreement with Univ. of Utah	Long-range plans, following Univ. of Utah agreement	changes to these positions
Chief Executive	Commence Anna Anna Anna Anna Anna Anna Anna Ann			in the second
Officer				Carlo de Ca
Chief Operating				
Officer				and the state of t
Director of the	k.			
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Primary Transplant	::	-		
Surgeon	***************************************		-	
Other Transplant	-			
Surgeons			-	A CANALANT OF THE CONTRACTOR OF THE PROPERTY O
Primary Transplant			(dependence)	
Physician			<u> </u>	
Other Transplant				
Physician	<b>.</b>	li sana yani.mi	1	Sandaranin kaba kaka kaka kirin da

Please respond to the following question by November 12, 2008

# D. Questions Regarding the Agreement between the University Medical Center and surgeons from the University of Utah

- 1. What is the duration of the agreement between the surgeons from the University of Utah and the surgeons from the University Medical Center? What are the specific actions the hospital is taking to enlist and maintain a complete, local surgical team full-time beyond the interim rotational assignments?
- 2. Who are the four surgeons (and their qualifications) who will be serving in a rotating function? Are their primary responsibilities at the University of Utah to perform kidney transplants (i.e., they are part of the kidney transplant program at the University of Utah)?
- 3. Will these four surgeons also be recovering organs with the Organ Procurement Organization?

## E. Pre-Transplant

- 1. Who are the primary transplant surgeon and primary transplant physician designated to the OPTN for UMC? Have they been approved by the OPTN?
- 2. Who are the members of the multidisciplinary team for living donors and candidates? What are their roles?
- 3. Will a transplant surgeon see all potential candidates being evaluated for transplantation?
- 4. Who are the nephrologists(s) evaluating the patient? Are those individuals specifically trained in transplantation?
- 5. What was the average days/weeks needed for a patient to complete an evaluation prior to going inactive? Does the program expect that this will change?
- 6. If surgeons are coming in on a rotating basis, how will they evaluate the patients? For example, if the patient comes one week and requires more testing, will the patient have to wait until that surgeon who initially saw him or her rotates in again to review his/her follow up? What will be the arrangements to ensure continuity of care for the patients? What arrangements are in place or are being made to prevent delays in listing of the patients?
- 7. Will the transplant surgeon who evaluates the patient be the individual who participates in determining whether the program's selection criteria are met?
- 8. What is the process the program will use to decide when the patient is listed (meeting, discussion, paper review by the team)?

#### F. Transplant

1. We understand that there will be 2 Utah surgeons available onsite at University Medical Center at all times. Is this accurate or is another arrangement contemplated?

#### G. Post-Transplant

- 1. How will patient follow-up be maintained if the surgeons are serving on a rotating basis? What will be the arrangements to ensure continuity of care for the patients' follow up care?
- 2. Who is the transplant nephrologists(s) who will be following up with the patient immediately post-transplant and post-discharge? What will be the arrangements to ensure continuity of care for the patients? Will the nephrologist call the surgeon in Utah if he/she has a question with regard to a patient whose surgeon is off rotation and not available at the Nevada transplant hospital?
- 3. Will the surgeon from Utah have any access to patient medical records when they are not in Nevada?

From: Krinsky, Glenn < @ropesgray.com> Sent:

To:

Thursday, October 30, 2008 11:46 PM Kathy Silver @umcsn.com>

Subject:

Re: Tentative Resolution of UMC matter

I think it would be appropriate to say something like, "We are grateful to our Congressional members, who were instrumental in facilitating a constructive and collaborative dialogue with CMS that allowed both sides to achieve a result that puts the best interests of patients first." What do you think?

Glenn L. Krinsky **ROPES & GRAY LLP** 

T 415-315-4818

One Embarcadero Center, Sulte 2200 San Francisco, CA 94111-3711 @ropesgray.com

www.ropesgray.com

From: @umcsn.com

To: Krinsky, Glenn

Sent: Thu Oct 30 20:41:31 2008

Subject: Re: Tentative Resolution of UMC matter

Glen. How do we get this msg out so that we don't dismiss the importance of our political intervention but also respect the willingness of cms to negotiate an alternative with us?

Kathy Silver

CEO

**UMC** Administration

From: Krinsky, Glenn To: Kathy Silver

**Sent**: Thu Oct 30 17:36:31 2008

Subject: Re: Tentative Resolution of UMC matter

Het her know that you're no longer "interim" and she apologized and planned to delete the reference.

Glenn L. Krinsky **ROPES & GRAY LLP** 

T 415-315l M F 415-315-4818

One Embarcadero Center, Suite 2200 San Francisco, CA 94111-3711 @ropesgray.com

www.ropesgray.com

From: @umcsn.com

To: Krinsky, Glenn

Sent: Thu Oct 30 17:31:37 2008

**Subject:** Re: Tentative Resolution of UMC matter

Looks good except I am no longer -interim ceo. Also shelley berkley was just interviewed by tv

Kathy Silver

CEO

**UMC** Administration

From: Krinsky, Glenn

To: Gage, Larry S.; Luband, Charles A.; Kathy Silver

Sent: Thu Oct 30 15:50:20 2008

Subject: FW: Tentative Resolution of UMC matter

Your thoughts about this please?

Glenn L. Krinsky ROPES & GRAY LLP

T 415-315-4818

One Embarcadero Center, Suite 2200 San Francisco, CA 94111-3711

@ropesgray.com

www.ropesgray.com

From: Porter, Alanna [mailto: @mail.house.gov]

Sent: Thursday, October 30, 2008 3:44 PM

To: Krinsky, Glenn

Subject: RE: Tentative Resolution of UMC matter

What do you think about us sending this out?

From: Krinsky, Glenn [ @ropesgray.com]

Sent: Thursday, October 30, 2008 6:15 PM

To: Porter, Alanna

Subject: Tentative Resolution of UMC matter

#### Dear Alanna:

Thank you, once again, for your office's prodigious efforts on behalf of UMC. As we just discussed, CMS responded favorably to the settlement ideas we put forth yesterday and we have agreed to a process that will allow the transplant program at UMC to re-activate and continue its operations.

Here is a summary of what we have agreed to:

1) In the next couple of days, CMS will send a letter withdrawing its current decertification letter and issuing a new decertification date of January 8, 2009. Working backwards from that decertification date, the program would have an obligation to inform patients on its wait list approximately December 9, 2008, which is the date by which UMC needs to reactivate the program in order for wait listed patients not to lose accrued wait list time. This new decertification letter, however, is merely a "placeholder," pending the step described below.

- 2) Over the next 14-21 days, CMS and UMC will negotiate and execute a "System Improvement Agreement" that will incorporate representations from the hospital about its current state of readiness (especially the completion of the contract with the University of Utah physicians) and other elements that demonstrate its ability to operate the program safely. These elements will not be controversial, as UMC believes it can satisfy them now and UMC wishes to be held to a high standard. Upon execution of this agreement, CMS will withdraw the decertification date of January 8, 2009, and propose a new decertification date many months out in the future. This will allow the hospital to re-activate the program and begin to establish a successful track record. Sometime before the future decertification date, CMS will conduct an unannounced survey of the program. If UMC passes that survey, it will obtain new certification.
- 3) CMS and UMC will coordinate their announcements to the public, perhaps in the form of a joint press release. The message points will be that the program had an unacceptable track record as of the time of the survey was conducted in March 2008, that improvements have been implemented since the survey sufficient to allow the program to move forward, and that CMS and UMC worked together towards the singular goal of ensuring the best interests of the patients on the wait list and future Nevada patients. In this regard, CMS let UMC know that it is of the utmost importance that public statements not suggest that CMS was "browbeaten" into this agreement. I assured CMS that UMC would use its best efforts to ensure that all parties' public statements were positive and constructive, along the lines of, "All concerned parties worked constructively and collaboratively to reach a result that is in the best interests of current and future patients."

Please feel free to contact me with any comments or suggestions. We are deeply grateful for and appreciative of Congressman Porter's extraordinary efforts on behalf of UMC and its patients.

Best regards, Glenn

Glenn L. Krinsky ROPES & GRAY LLP

T 415-315-4818

One Embarcadero Center, Suite 2200 San Francisco, CA 94111-3711

@ropesgray.com

www.ropesgray.com

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From:

Krinsky, Glenn < @ropesgray.com>

Sent:

Thursday, October 30, 2008 6:48 PM

To:

Gage, Larry S. < @ropesgray.com>; Luband, Charles A.

@ropesgray.com>; Brody, Peter M. <

@ropesgray.com>;

Kathy Silver 4

@umcsn.com>

Subject:

Re: Tentative Resolution of UMC matter

Charlie and Kathy are contacting the other delegation members.

From: Gage, Larry S.

To: Krinsky, Glenn; Luband, Charles A.; Brody, Peter M.; Qumcsn.com'

Sent: Thu Oct 30 15:45:50 2008

Subject: Re: Tentative Resolution of UMC matter

Excellent outcome, Glenn. Let's make sure we coordinate with the delegation in any formal announcement (and also let them know we have agreed not to beat up on CMS). Larry

Larry S. Gage **ROPES & GRAY LLP** 

T 202-508- | F 202-383-9366

One Metro Center, 700 12th Street, NW, Suite 900

Washington, DC 20005-3948

@ropesgray.com

www.ropesgray.com

From: Krinsky, Glenn

To: Gage, Larry S.; Luband, Charles A.; Brody, Peter M.;

Sent: Thu Oct 30 18:16:31 2008

Subject: FW: Tentative Resolution of UMC matter

Please see below.

Glenn L. Krinsky **ROPES & GRAY LLP** 

T 415-315-F 415-315-4818

One Embarcadero Center, Suite 2200

San Francisco, CA 94111-3711

@ropesgray.com http://www.ropesgray.com/

From: Krinsky, Glenn

Sent: Thursday, October 30, 2008 3:15 PM

To: 'alanna.porter@mail.house.gov'

Tentative Resolution of UMC matter Subject:

#### Dear Alanna:

Thank you, once again, for your office's prodigious efforts on behalf of UMC. As we just discussed, CMS responded favorably to the settlement ideas we put forth yesterday and we have agreed to a process that will allow the transplant program at UMC to re-activate and continue its operations.

Here is a summary of what we have agreed to:

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- 3) CMS and UMC will coordinate their announcements to the public, perhaps in the form of a joint press release. The message points will be that the program had an unacceptable track record as of the time of the survey was conducted in March 2008, that improvements have been implemented since the survey sufficient to allow the program to move forward, and that CMS and UMC worked together towards the singular goal of ensuring the best interests of the patients on the wait list and future Nevada patients. In this regard, CMS let UMC know that it is of the utmost importance that public statements not suggest that CMS was "browbeaten" into this agreement. I assured CMS that UMC would use its best efforts to ensure that all parties' public statements were positive and constructive, along the lines of, "All concerned parties worked constructively and collaboratively to reach a result that is in the best interests of current and future patients."

Please feel free to contact me with any comments or suggestions. We are deeply grateful for and appreciative of Congressman Porter's extraordinary efforts on behalf of UMC and its patients.

Best regards, Glenn

Glenn L. Krinsky ROPES & GRAY LLP

T 415-315-4818

One Embarcadero Center, Suite 2200 San Francisco, CA 94111-3711

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11-0243\_0203

SYSTEMS IMPROVEMENT AGREEMENT	
<u>for</u>	
IMPROVING PATIENT SAFETY and HEALTH CARE OUTCOMES	
University Medical Center of Southern Nevada Transplant Program  and	
Centers for Medicare & Medicaid Services	

Tax Identification Number:
National Provider Identification No:
CMS Certification Number:

# SYSTEMS IMPROVEMENT AGREEMENT for IMPROVING PATIENT SAFETY and HEALTH CARE OUTCOMES University Medical Center of Southern Nevada Transplant Program

This Agreement (the "Agreement") is made between the University Medical Center of Southern Nevada (UMC), and the United States Department of Health and Human Services, Centers for Medicare and Medicaid Services ("CMS") (collectively, the "Parties") for the time period of December 1, 2008 through June 8, 2009, as affected by section C.4, as follows:

#### Recitals

Whereas, on March 12, 2008, CMS surveyors completed an onsite review of the UMC kidney transplant program and found non-compliance with several Medicare Conditions of Participation (CoP) which included significant deficiencies that affect the health and safety of transplant patients and living donors.

Whereas, the patient 1- year post-transplant survival outcomes were significantly lower than the risk-adjusted expected outcomes detailed in the January 2008 and July 2008 reports from the Scientific Registry of Transplant Recipients (SRTR), including patent deaths more than twice the number expected (a total of 5 compared to the expected 1.81).

Whereas, despite poor patient survival outcomes over an extended time period and despite requirements clearly delineated in regulation, there was no internal Quality Assessment and Performance Improvement (QAPI) system for the transplant program that provided a comprehensive identification and analysis of health and safety problems or adverse events in the transplant program;

Whereas, the UMC program did not have evidence that the blood type compatibility between recipients and donors had been properly verified;

Whereas, there was inadequate availability of the social worker throughout the transplantation and donation process, and the social worker was unaware that he/she was supposed to be providing these services to patients and living donors;

Whereas, the UMC program did not follow its own donor selection criteria and did not properly evaluate significant changes in a potential donor's physical condition followed by a subsequent adverse event for that living donor;

Whereas, the UMC had not analyzed the lower than expected outcomes reflected in the reports since January 2007 for areas needing improvement or changes made to the program as a result of an analysis;

Whereas, on May, 28, 2008, CMS provided notice to the UMC that the transplant program was not in compliance with Medicare's minimum requirements and would be terminated from Medicare

participation on (a) July 14, 2008 if the program did not meet those Medicare requirements unrelated to outcomes (subsequently extended to August 4, 2008), or on (b) October 13, 2008 if the program still did not meet Medicare's outcome requirements by that date. UMC did not come into compliance with Medicare's minimum requirements based on outcomes reported in the July 2008 SRTR report;

Whereas, an onsite re-survey on August 5, 2008, identified the program has having corrected all of the earlier cited deficiencies except for the proper verification of blood type and the outcomes;

Whereas, via letter, CMS further extended the effective date of the termination to November 20, 2008, December 3, 2008 and finally, January 8, 2008 to allow sufficient time for the program to provide proper notice to beneficiaries and to permit CMS opportunity to review the additional information provided to CMS on November 10, 2008 regarding UMC's recent actions for systemic improvements;

Whereas, the UMC kidney transplant program provided additional information on November 10 and 12, 2008 that indicates substantial systems improvements by UMC through:

- Additional administrative support including a designated full-time transplant administrator and a data coordinator,
- Development of a quality assessment and performance improvement system,
- Revised policies and procedures that conform with CMS' requirements;
- Substantial changes to surgical capability designed to promote skill improvements and increased depth of surgical coverage 24/7.

Whereas, the UMC has committed to making further improvements, including substantive personnel and resource investments, to establish the ability to both meet Medicare CoPs and improve systems of care so that the hospital is able to maintain compliance consistently over time;

**THEREFORE**, in response to a further request by the UMC for reconsideration of the effective date of termination and in consideration of the improvements made to the kidney transplant program, the parties agree to the following.

#### A. CMS Agrees to:

- 1. Amendment #1 to the Notice of Termination: CMS agrees to extend the termination date from January 8, 2009 to June 8, 2009, as affected by section C.4 of this document.
- 2. Revisit Survey: CMS will authorize an unannounced revisit survey prior to the June 8, 2009 termination date to determine whether the UMC kidney transplant program is in substantial compliance with all applicable Medicare CoPs.
- 3. Right of Termination: CMS reserves the right to immediately terminate the UMC kidney transplant program's participation in Medicare should CMS determine that the program's continuing noncompliance with applicable Medicare CoPs or this Agreement warrants such action.

#### B. University Medical Center Agrees to:

1. No Further Extensions: The UMC agrees that it will seek no further extensions of the termination date of the transplant program beyond June 8, 2009.

- 2. Commitments: The UMC agrees to abide by all commitments set forth in the November 10 and November 12, 2008, materials that were submitted to CMS and the subsequent conference call with CMS on November 20, 2008. There must be evidence that these commitments have been fulfilled prior to reactivation of the program. These commitments include, but are not limited to:
  - a. Comprehensive training of the UMC transplant staff in all protocols that will be adopted from the University of Utah;
  - b. Signed contracts between the UMC and four additional surgeons, proper credentialing by UMC, and licensure by the State of Nevada of all surgeons;
  - c. At least one surgeon in residence in Las Vegas, available 24/7, and all rotating surgeons in residence for at least one week per rotation, with overlapping rotations sufficient to permit in-person hand-offs between the departing and incoming surgeon;
  - d. Review by all surgeons participating in the agreement from the University of Utah of those UMC policies and procedures that will remain in place; and
  - e. Access to all surgeons participating in the agreement from the University of Utah, 24 hours a day, 7 days a week for discussion with the UMC staff regarding any patient care issues that arise;
  - f. Continuous monitoring and oversight of the ongoing care that is provided throughout the term of this Agreement, including monitoring and oversight of the thoroughness of the patient evaluation, communication with transplant recipients and living donors, operative techniques, post-operative care, and the quality and extent of follow-up visits.
- 3. Patient Notification: The hospital agrees to notify all beneficiaries on the waiting list of the agreement with the University of Utah surgeons no later than December 20, 2008. This notification must describe to beneficiaries that surgeons from the University of Utah will be rotating into the UMC on a weekly basis, and must outline the proposed length of this arrangement so that beneficiaries are aware they may receive services from several different surgeons during the pre-transplant, transplant and post-transplant follow-up period. The UMC agrees to submit to CMS the patient notification four calendar days in advance of sending it to the beneficiaries.
- 4. Surgical Leadership: Upon reactivation of the transplant program, the UMC shall ensure that the primary transplant surgeon shall participate in the weekly meeting of the UMC multidisciplinary meeting. When the primary transplant surgeon is not in residence at UMC, the surgeon shall make every reasonable and best effort to participate in these meetings by audio or videoconference to ensure that the primary surgeon's involvement in UMC's patient care is maintained. UMC shall also ensure that the monthly QAPI meeting is held at the time that the primary transplant surgeon is in residence at the UMC. UMC must also seek designation from the Organ Procurement and Transplantation Network (OPTN) for the primary transplant surgeon and notify CMS immediately upon approval of such designation from the OPTN.
- 5. Reporting Requirements: The UMC shall submit to CMS the following:
  - a. A <u>Baseline Measures Report</u> which is due to CMS no later than **January 15, 2009**. This report must contain information about all of the *specific* outcomes and process measures that the UMC will be tracking as part of its Quality Assessment and Performance Improvement program. This must include the specific clinical measures that are referenced more generally in the written QAPI plan. Such listing must reflect

measures that provide a *comprehensive* analysis of the program's performance as required by Medicare's regulations and must include measures that will provide a more current analysis of the program's outcomes and performance beyond waiting for the 1-year post-transplant period to have elapsed.

At a minimum, the report must include:

- The specific outcome or process measures that will be tracked;
- For each measure, the frequency with which that measure will be reviewed;
- The source data for each measure:
- The individual responsible for collecting and analyzing the source data for each measure:
- The performance benchmark with which actual data will be compared (e.g., expected survival rate at 1-year, percentage of patients with complications post-transplant); and
- The venue for review of the findings of each measure (e.g., discussion at QAPI monthly meeting, etc.)
- b. <u>Performance of Quality Assessment and Performance Improvement Program</u>
  Within 21 days after the end of each month, UMC agrees that the QAPI committee will meet at least monthly and will submit evidence of the performance of the Quality Assessment and Performance Improvement (QAPI) program for each month covered in this Agreement. Such evidence must include at a minimum:
  - The meeting date(s) and times;
  - The agenda, and
  - Actions taken by the transplant program as a result of that QAPI meeting.
  - Program changes adopted and implemented as a result of QAPI system analysis.

UMC further agrees that it will submit to CMS each month on the status of tracking measures, including:

- Number of Transplants performed
- Type of transplants performed
- Diagnoses for patients transplanted
- · Wait time
- Number of Living Donor operations performed
- Transplant patients with complications within 30-days post-transplant (included in this should be UMC's definition of the specific conditions that are considered a "complication")
- Living donors with complications within 30-days post-transplant
- Transplant patients with wound infection
- Transplant patients with an acute rejection episode
- Transplant patients that had unplanned return to operating room
- Transplant patients that required dialysis on day 7 post-transplant
- Transplant patients that required dialysis on day 30 post-transplant
- Transplant patients with re-admission rates within 90-days post-transplant: a) due to rejection, and b) for other reasons.
- Post-Transplant Graft Failure and Patient Death at 30 days
- Post-Transplant Graft Failure and Patient Death at 1-year
- Length of Transplant Admission (in days-range, mean, median)

- Length of Living Donor Admission (in days report the range, mean, and median)
- Length of stay by transplant patients in the intensive care unit (in days report the range, mean, and median)
- Readmission rate
- Comparison to national data
- General review of morbidity and mortality issues
- General review of selected program outcome issues
- New technology
- Evidence based measurement sets established by CMS and/or The Joint Commission
- National Patient Safety Goals
- Core Measures
- Patient Satisfaction
- c. <u>Status of Recruitment Efforts</u>: Insofar as recruitment of qualified, full-time dedicated staff is critical to the hospital's progress, UMC agrees that it will submit monthly progress reports describing recruitment and enlistment efforts for permanent transplant surgeons and transplant nephrologists.

#### C. The Parties Further Agree:

- 1. **Enforcement:** CMS retains the right to terminate the Medicare Approval for UMC's kidney transplant program in the event that the UMC fails to substantially comply with federal requirements at 42 C.F.R. Part 482 or fails to comply with any of the provisions of this Agreement including an inadequate responses by UMC to section B.5 of this document.
- 2. Agreement as Basis for Resolution: This Agreement sets forth the full and complete basis for the resolution of this matter by the parties. Each party shall be responsible for its own attorney fees associated with this Agreement.
- 3. **Binding Nature of Agreement**: This Agreement shall be final and binding upon the parties, their successors and assigns, upon execution by the undersigned, who represent and warrant that they are authorized to enter into this Agreement on behalf of the parties hereto.
- 4. Closure Contingency: In the event the UMC chooses to voluntarily cease operations, or fails to demonstrate compliance with federal participation requirements and has its Medicare approval for the kidney transplant program involuntarily terminated, the University Medical Center shall at least 30 days before the closure takes effect notify CMS and beneficiaries on the transplant waiting list.
- 5. Communications Contingency: If a new or revisit survey has been conducted but CMS has failed to issue a determination of the Hospital's compliance status prior to June 8, 2009, this Agreement and all terms of the Agreement shall automatically be extended for an additional but final 30 calendar days and be binding on all parties.
- 6. **Counterparts:** This Agreement may be executed in counterparts and by way of facsimile or electronic signature.

Agreement shall be forwarded to the following representatives: Steve Chickering, Consortium Survey Sherry Clark, Survey & Certification Group & Certification Officer Centers for Medicare & Medicaid Centers for Medicare & Medicaid Services Services 7500 Security Boulevard (5W) San Francisco, CA 94103-6707 Mailstop S2-12-25 Baltimore, MD 21244 415-744-410-786-@cms.hhs.gov @cms.hhs.gov

7. Contacts for Reporting Requirements: All documents and reports specified in this

Signed

n n	ate:	1	/	
Steve Chickering, Associate Regional Administrator		· ·		
Division of Survey & Certification				
Centers for Medicare & Medicaid Services				
(5W)				
San Francisco, CA 94103-6707				
415-744 @cms.hhs.gov				
D	ate:	/	/	

Kathy Silver, Chief Executive Officer
University Medical Center of Southern Nevada
1800 West Charleston Boulevard
Las Vegas, NV 89102



# DEPARTMENT OF HEALTH & HUMAN SERVICES CENTERS FOR MEDICARE & MEDICAID SERVICES CONSORTIUM FOR QUALITY IMPROVEMENT AND SURVEY & CERTIFICATION OPERATIONS

May 27, 2009

CMS Transplant Program Certification Number: 29-9800 CMS Hospital Certification Number: 29-0007

Ms. Karen Watnem University Medical Center Transplantation 1800 W. Charleston Boulevard Las Vegas, NV 89102

Dear Ms. Watnem:

This is to inform you that the Centers for Medicare & Medicaid Services (CMS) has reviewed the results of the second follow up survey of your hospital's transplant center conducted April 1, 2009 by Healthcare Management Solutions (HMS). Based on this review we have determined that UMC has satisfied the criteria established by the Systems Improvement Agreement made between CMS and University Medical Center of Southern Nevada, dated November 28, 2008, and is now in compliance with the Special Requirements for Transplant Centers at 42 C.F.R. §482.68. Accordingly the hospital's Adult Kidney (only) transplant program is hereby approved for Medicare participation effective May 19, 2009.

The following transplant program is approved, effective May 19, 2009, for participation in the Medicare program in accordance with the Conditions of Participation at 42 C.F.R. §482.68, Special Requirements for Transplant Centers:

#### Adult Kidney-Only (AKO)

Your facility has been issued the CMS certification number (CNN) shown above. This number is used for certification purposes only. Medicare claims should continue to use the national provider identification (NPI) number.

In receiving your CMS certification number, UMC has successfully met the criteria established by the Systems Improvement Agreement made between The Centers for Medicare and Medicaid Services and University Medical Center of Southern Nevada, dated November 28, 2008. If you believe that the effective date for any transplant program(s) listed is incorrect, you may request that CMS reconsider the decision, in accordance with 42 C.F.R. §498.22. Such a request must be filled in writing to this office no later than sixty (60) days from the receipt of this letter. Your request for reconsideration to CMS must identify the specific issues, or the findings of fact with which you disagree, and the reasons for the disagreement. 42 C.F.R. §498.22(e).

Denver Regional Office 1600 Broadway, Suite 700 Denver, CO 80202 San Francisco Regional Office 90 7th Street, Suite 5-300 (5W) San Francisco, CA 94103-6707 Seattle Regional Office 2201 Sixth Avenue, RX-48 Seattle, WA 98121 Please refer to our Web site for questions and answers, periodic program updates, and the requirements for notifying CMS (under 42 C.F.R. §482.74) of any significant changes to a transplant program:

7022078216

http://www.ems.hhs.gov/CertificationandComplianc/20\_Transplant.asp

We look forward to working with you in improving the quality of health care provided to beneficiaries through an efficient and effective administration of the Medicare program.

Please contact Ed Japitana of my staff at (415) 744- if you have questions.

Sincerely.

Deborah Romero, Operations Manager Division of Survey and Certification

**Denver Regional Office** 1600 Broadway, Suite 700 Denver, CO 80202

San Francisco Regional Office 90 7th Street, Suite 5-300 (5W)

San Francisco, CA 94103-6707

Seattle Regional Office 2201 Sixth Avenue, RX-

Seattle, WA 98121



Kathleen Silver Chief Executive Officer

May 18, 2010

«NAME» «ADDRESS\_1» «ADDRESS\_2» «CITY STATE ZIP»

Re: Notice of UMC's RFP No. 2010-18 for Nephrology Services

Dear Doctor:

University Medical Center of Southern Nevada (UMC), located in Las Vegas, Nevada, is soliciting proposals from qualified nephrology provider groups to provide nephrology services, including transplant nephrology services, at UMC in its surgery, trauma and emergency departments that will help the hospital exceed patient expectations, improve patient perception and provide patient with the best experience.

A copy of the RFP can be obtained by visiting the Clark County, Nevada website at <a href="https://www.accessclarkcounty.com/purchasing">www.accessclarkcounty.com/purchasing</a>. Click on "Current Contracting Opportunities", scroll to the bottom for UMC's Opportunities and locate appropriate document in the list of current solicitations. You may also request a copy, via email, from me at <a href="https://www.accessclarkcounty.com/purchasing">@www.accessclarkcounty.com/purchasing</a>. Click on "Current Contracting Opportunities", scroll to the bottom for UMC's Opportunities and locate appropriate document in the list of current solicitations. You may also request a copy, via email, from me at <a href="https://www.accessclarkcounty.com/purchasing">@www.accessclarkcounty.com/purchasing</a>. Click on "Current Contracting Opportunities", scroll to the bottom for UMC's Opportunities and locate appropriate document in the list of current solicitations. You may also request a copy, via email, from me at <a href="https://www.accessclarkcounty.com/purchasing">@www.accessclarkcounty.com/purchasing</a>.

If you are interested this invitation, please access the RFP documents from the website and fax the confirmation form (1<sup>st</sup> page of the RFP document) to the fax number provided at the bottom of the confirmation page.

Please let me know if you have any questions.

Sincerely,

#### Jim Haining, CPSM, C.P.M., A.P.P., MBA

Purchasing Administrator - Contracts Management Dept.
University Medical Center of Southern Nevada
1800 Charleston Blvd, Las Vegas, NV 89102
(702) 383
fax (702) 383

UMC's Bidding and RFP Opportunities can now be accessed online!

www.accessclarkcounty.com/purchasing > Current Contracting Opportunities, scroll to bottom for UMC's Contracting Opportunities

Interested in tracking UMC's and Clark County's contracting opportunities? Simply sign up for Twitter at no cost and then "follow" the County, which can be found at <a href="http://twitter.com/ClarkCountyNey">http://twitter.com/ClarkCountyNey</a>.

Board of Trustees

Lawrence Weekly, Chair · Chris Guinchigliani, Vice Chair · Susan Brager · Larry Brown · Tom Collins · Rory Reid · Steve Sisolak Virginia Valentine, PE, Clark County Manager

Notice	NAME	DEGRI	DEGRI Practice Name	ADDRESS 1	LICENSE	STATUS	SSUE DATE	EXPIRATION	ADDRESS	LICENSE (STATUS IISSUE DATE EXPIRATIVADORESSICITY STATE ZIP
Letter sent 5/18/10	ADAIMY, Mark J.	M.D.		2810 W. Charleston Blvd. Ste E47	10589 Active	Active	7/24/2003	7/24/2003 1/14/2011		Las Veoas NV 89102
Letter sent 5/18/10	ADEKILE, Ayoola	Ω. M.D.		6765 Tulip Falls Drive	13088 Active	Active	4/20/2009	6/30/2011	Unit 2070;	4/20/2009 6/30/2011 Unit 2070: Henderson NV 89011
Letter sent 5/18/10 Tetter sent	BARAMIDZE, George	M,D.		1905 Civic Center Drive, 2rld Floor	12926 Active	Active	10/17/2008	10/17/2008 6/30/2011		North Las Vegas NV 89030
5/18/10	BARNEY, Mark Herbert	M.D.		2810 W Charleston Blvd Ste E 47	0869	6980 Active	12/4/1993	12/4/1993 6/30/2011		Las Vegas NV 89102
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5/18/10	BOTLA, Venugopal	M.D.	u,	500 S Rancho Drive	11677 Active	Active	10/27/2005	10/27/2005 6/30/2011 Suite 12		Las Veges NV 89106
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5/18/10	CHU, Jay Koe	M.D.		500 S Rancho Dr Ste 12	13115 Active	Active	5/18/2009	5/18/2009 6/30/2011		Las Vegas NV 89106
Letter sent 5/18/10	DARBARI, Shabnam	M.D.		Ιŏ	10032 Active	Active	11/20/2001	6/30/2011		l as Venas NV 89138
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5/18/10	GUPTA, Arvin A,	M.D.		1750 E Desert Inn Rd Ste 200	12864 Active	Active	8/25/2008	8/25/2008 6/30/2011		Las Vecas NV 89169-3202
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5/18/10	KANTOR, Samuel Adam	M.D.		8017 Secret Harbor Ct	12391 Active	Active	7/24/2007	7/24/2007 6/30/2011		Las Vegas NV 89128-6887
5/18/10	KHANNA, Bindu	M.D.	3)	500 South Rancho Drive	11847 Active	Active	5/19/2006	5/19/2006 6/30/2011 Suite 12	Suite 12	Las Vegas NV 89106
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PRASAD, Darbha Rao	Clark		Nephrotogy
PRASAD, Rajeev	Clark	702-436	Nephrology
QAZI, Sayed Ziauddin	Clark	702-880	Nephrology
RAJU, Sujatha	Clark	702-818	Nephrology
RANAI, Ramchand B.	Clark	702-877	Nephrology
ROBERTSON, Cristy Ann	Clark	702-877	Nephrology
RUDNITSKY, Benjamin Sergei	Clark	702-732	Nephrology
RYU, Jeffrey Yong	Clark	702-732	Nephrology
SELA, Zvi	Clark	702-877	Nephrology
SHAH, Dipti R.	Clark	702-644	Nephrology
SHAH, Vipul Ashok	Clark	702-875	Nephrology
SHETE, Lata Kisanrao	Clark	702-877	Nephrology
TAKIEDDINE, Marwan	Clark	702-732	Nephrology
VISHNEPOLSKY, Mark	Clark	614-330	Nephrology
YARLAGADDA-JANGA, Radhika Rani	Clark	702-732-	Nephrology

### UNIVERSITY MEDICAL CENTER OF SOUTHERN NEVADA BOARD OF HOSPITAL TRUSTEES AGENDA ITEM

Issue:	Amendment One to Agreement for Physician Medical Directorship of the Nephrology Department and Related Professional Service with Kidney Specialists of Southern Nevada.	Back-up:
Petitioner:	Kathleen Silver, Chief Executive Officer, University Medical Center	Clerk Ref. #

#### Recommendation:

That the Board of Hospital Trustees approve Amendment One to Agreement for Physician Medical Directorship of the Nephrology Department and Related Professional Service between Kidney Specialists of Southern Nevada and University Medical Center of Southern Nevada; and authorize the Chief Executive Officer to sign the amendment.

#### FISCAL IMPACT:

Monthly rates to remain the same through December 31, 2010; funded by Operating Budget.

#### **BACKGROUND:**

On August 21, 2007, the Board awarded RFP 2007-18, Nephrology Services, to Kidney Specialists of Southern Nevada (another respondent was R.D. Prahbu-Lata K. Shete, M.D., Ltd. however their response was received late therefore it was rejected). This is to provide medical directorship of the Nephrology Department, 24-hours-a-day, 7-days-a-week including follow-up services. The contract term was from August 1, 2007 through July 31, 2010.

Amendment One requests to extend the contract term through December 31, 2010 with no monthly increase during the contract extension while staff completes the RFP process.

Respectfully submitted,

Kathleen Silver

Chief Executive Officer

Cleared for Agenda

Agenda Item #

UMC\_01771

11-0243\_0222

#### AMENDMENT ONE

### AGREEMENT FOR PHYSICIAN MEDICAL DIRECTORSHIP OF THE NEPHROLOGY DEPARTMENT AND RELATED PROFESSIONAL SERVICE

#### WITNESSETH:

WHEREAS, the parties entered into an Agreement entitled "Agreement For Physician Medical Directorship Of The Nephrology Department And Related Professional Service" dated August 21, 2007, (hereinafter referred to as "Agreement"); and

WHEREAS, the parties desire to amend the Agreement.

NOW, THEREFORE, the parties agree as follows:

- Section 5.5 Annual Increases. The following sentence shall be added to this section. "There shall be no annual increase for the extension term between August 1, 2010 and December 31, 2010."
- 2. Section 6.1 Term of Agreement. Replace July 31, 2010 with December 31, 2010.

-4₩

3. Except as expressly amended in this Amendment One, the Agreement shall remain in full force and effect.

HOSPITAL:

UNIVERSITY MEDICAL CENTER

OF SOUTHERN NEVADA

Chief Executive Officer

PROVIDER:

KIDNEY SPECIALISTS OF SOUTHERN NEVADA

Larry Lehrner, M.D.

President

APPROVED AS TO FORM:

DAVID ROGER, DISTRICT ATTORNEY

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#### Response to

# UNIVERSITY MEDICAL CENTER OF SOUTHERN NEVADA REQUEST FOR PROPOSAL

2010-18

#### **Nephrology Services**

From

Kidney Specialists of Southern Nevada



**Our Mission** 

To preserve kidney function

To minimize the complications of kidney dysfunction

To provide kidney replacement therapies- dialysis and kidney transplantation to patients with kidney failure

### **B.** Healthcare Experience

1. Document your organization's credentials, experience, and involvement with nephrology services.

Kidney Specialists of Southern Nevada has provided contract Nephrology services to the following organizations:

#### UMC

Since August 2000 we have been providing contract Nephrology services to UMC. Both Dr. Bernstein and Dr. Khanna have demonstrated exemplary Nephrology care to the patients at UMC while guiding the hospital with process based on KDOQI (Kidney Disease Outcomes Quality Initiative) and best demonstrated practice to improve the overall quality of patient encounters and disease management. Dr. Bernstein has been instrumental in lowering cost associated with the admission of undocumented dialysis patients to UMC. In cooperation with UMC Administration and the Emergency Department through policy development and implementation, Dr. Bernstein fronted the effort to help solve this costly issue for the hospital. As a direct result of Dr. Bernstein's streamlined protocols, acute admissions of the unfunded dialysis population have been substantially decreased saving the hospital large sums of money each year while continuing to provide necessary life saving treatment to patients presenting to the emergency room. Kidney Specialists of Southern Nevada have gone above and beyond the usual call of duty with this unfortunate situation, even hiring a full time Nurse Practitioner to streamline assessment of these patients as well as facilitate timely discharge avoiding acute admissions whenever possible.

#### **UMC Transplant Program**

For 10 years Kidney Specialists of Southern Nevada have provided a Transplant Nephrologist, currently Ayoola Adekile, MD, for the UMC Transplant program. Dr. Adekile works closely with the surgeons and the entire transplant team to provide optimal care and outcomes for patients receiving a transplant or donating a kidney at UMC. He serves on the transplant selection committee that is involved with evaluating patients for renal transplantation. He has actively assisted with the interviewing process in the search for a new transplant surgeon at UMC. Now, with the addition of Dr. Syed Shah to Kidney Specialists of Southern Nevada, we believe that we are the only nephrology group in Las Vegas with 2 UNOS certified transplant nephrologists, giving us the ability to provide the required coverage for the UMC Transplant Program within one group of physicians.

When UNOS threatened to decertify the UMC transplant program, Dr. Lehrner contacted the Nevada Congressional delegation, including Senator Harry Reid. The Nevada Congressional delegation was instrumental in the CMS decision to allow the program to continue. In addition, Dr. Bernstein went to great lengths to keep the transplant program running, including obtaining his UNOS Certification, working for UMC as the Interim Transplant Nephrologist, and attending numerous meetings as an advocate for the program. Kidney Specialist of Southern Nevada have demonstrated continuous strong support for and commitment to the Transplant Program and will continue to do so in the years to come.

#### Kindred Hospitals

Since July 2004 we have provided Nephrology and anemia management services to the Kindred Hospitals in Las Vegas.

### **University Medical Center Of Southern Nevada**

#### CONFIRMATION FORM for RECEIPT OF RFP NO. 2010-18 Nephrology Services

If you are interested in this invitation, immediately upon receipt please fax this confirmation form to the fax number provided at the bottom of this page.

Failure to do so means you are not interested in the project and do not want any associated addenda sent to you.

#### VENDOR ACKNOWLEDGES RECEIVING THE FOLLOWING RFP DOCUMENT:

PROJECT NO. RFP NO. 2010-18

DESCRIPTION: Nephrology Services

VENDOR MUST COMPLETE THE FOLLOWING INFORMATION:

Company Name: Lagrange Southern Nevar Howy Center

Company Address: 100 N. Green Valley PNWY # 110

City / State / Zip: Hen Glesson, NV 8 9074

Name / Title: TRAJEN FRASAD / President

Area Code/Phone Number: 702 436.

Area Code/Fax Number: 702 436
Email Address: On not mail com

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FAX THIS CONFIRMATION FORM TO: (702) 383-Or EMAIL TO: @umcsn.com TYPE or PRINT CLEARLY

### **University Medical Center Of Southern Nevada**

### CONFIRMATION FORM for RECEIPT OF RFP NO. 2010-18 Nephrology Services

If you are interested in this invitation, immediately upon receipt please fax this confirmation form to the fax number provided at the bottom of this page.

Failure to do so means you are not interested in the project and do not want any associated addenda sent to you.

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PROJECT NO. RFP NO. 2010-18

DESCRIPTION: Nephrology Services

VENDOR MUST COMPLETE THE FOLLOWING INFORMATION.
Kingou Sporialists of Southern Nevada
Company Name: 111011 Section 1
Company Name: 111011 OF EXPENSION SOUTH Rancho Drive Suite12
City/ State / Zin: L.V. DV. 89106
Name/Title: Bette Schnur Practice manager
Area Code/Phone Number: 702 877-
Area Code/Phone Number:
Area Code/Fax Number: 702 877-
Email Address: 6 KSOSn. Com

FAX THIS CONFIRMATION FORM TO: (702) 383-@umcsn.com Or EMAIL TO: TYPE or PRINT CLEARLY

#### REPORT OF RFP OPENING

PAGE \_\_\_OF\_\_\_

Date: June 22, 2010 Time: 2:00 pm

RFP NO. 2010-18	
PROJECT DESCRIPTION: Nephrology Services	
PURCHASING REPRESENTATIVE: Jim Haining	9
RFP'S RECEIVED BY: Rebekah Holder	
COMPANY NAME	RESPONSE RECEIVED (Yes)
Kidney Specialists of So. NV	les
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#### REPORT OF RECEIPT

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Due Date: June 22, 2010

Time: 2:00:00 pm

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RFP NO. 2010-18 PROJECT DESCRIPTION: Nephrology Services		
PURCHASING REPRESENTATIVE: Jim Haining		
RFP'S RECEIVED BY: Contracts Management		
COMPANY NAME	DATE / TIME RECEIVED	
Kidney Specialists of So. NV	6/18/10	11:00:33 am
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BID/REP NUMBER: 500 S. Grand Central Parkway, 4th Floor, Las Vegas, NV 89155-1217 ACCEPTED BY: RECEIVED FROM: (COMPANY NAME) 05/19/10 RM11:00:03 DC PURCHES CLARK COUNTY PURCHASING AND CONTRACTS (DATE/TIME STAMP IN THIS BOX) Clark County Purchasing and Contracts Receipt of Bid or Proposal Document PLEASE PRINT Nephology SINU nephrology Services KIDNEY SPECIALISTS OF SOUTHERN NEVADA 500 S. Rancho Dr., Suite 12 Las Vegas, NV 89106-4849

## **EXHIBIT 59**

## UNIVERSITY MEDICAL CENTER OF SOUTHERN NEVADA HOSPITAL ADVISORY BOARD AGENDA ITEM

Kidney Specialists of Southern Nevada.	
Petitioner: Kathleen Silver, Chief Executive Officer, University Medical Center Clerk Re	P. #

#### Recommendation:

That the Hospital Advisory Board award RFP No. 2010-18, Nephrology Services, to Bernstein, Pokroy & Lehrner, Ltd. d/b/a Kidney Specialists of Southern Nevada; and authorize the Chief Executive Officer to sign the Agreement for Physician Medical Directorship and Physician Professional Services.

#### FISCAL IMPACT:

Fund #: 5420,000

Fund Center: 3000719000

Fund Name: UMC Operating Fund

Amount: \$25,000 per year for Directorship services

\$713,720 per year for professional medical services

Additional Comments: Prices for professional services may be adjusted annually on anniversary date based on changes to the CPI – West Area.

#### BACKGROUND:

On May 23, 2010, RFP No. 2010-18 was published in the Las Vegas Review Journal for Nephrology Services. On June 22, 2010, only one (1) response was received and the sole respondent was Kidney Specialists of Southern Nevada.

An ad hoc committee reviewed the proposal submitted and recommends the selection of, and contract approval with Kidney Specialists of Southern Nevada. Provider shall provide the following:

- Provide nephrology services consultative coverage 24-hours-a-day, 7-days-a-week basis consisting
  of patient examination, diagnosis, medical/surgical intervention and follow-up care to all Hospital
  inpatients, outpatients, ER and Trauma Department patients.
- Provide consultative, diagnostic or medical service coverage at the outpatient nephrology clinic during the term of this contract at three (3) clinics per month for up to four (4) hours per clinic.
- Provide consultative, diagnostic or medical service coverage and training with a transplant nephrologist at the Transplant Center during the term of this contract at four (4) clinics per week for up to four (4) hours per clinic.

Cleared for Agenda December 8, 2010

Agenda Item #

9

 Provide service on an emergency and on-call basis to meet the needs of Hospital's inpatients and outpatients.

The term of this agreement is from January 1, 2011 through December 31, 2015 unless terminated with a 90-day written notice.

Staff has reviewed the proposed Agreement and costs associated, and found them equitable for the work to be performed.

Kidney Specialists of Southern Nevada currently holds a Clark County business license.

Respectfully submitted,

Kathleen Silver

Chief Executive Officer

Page Number

2

#### AGREEMENT FOR PHYSICIAN MEDICAL DIRECTORSHIP AND PHYSICIAN PROFESSIONAL SERVICES

This Agreement, made and entered into this \_\_\_\_\_\_\_ day of December, 2010, by and between University Medical Center of Southern Nevada, a publicly owned and operated hospital created by virtue of Chapter 450 of the Nevada Revised Statutes (hereinafter referred to as "Hospital") and Bernstein, Pokroy & Lehrner, LTD. d/b/a Kidney Specialists of Southern Nevada, a professional corporation, engaged in the practice of medicine specializing in nephrology services and existing under and by virtue of the laws of the State of Nevada, with its principal place of business at 500 South Rancho, Suite 12, Las Vegas, Nevada 89106 (hereinafter referred to as the "Provider");

WHEREAS, Hospital is the operator of a Nephrology Department located in Hospital which requires a Medical Directorship and professional medical services; and

WHEREAS, Hospital recognizes that the proper functioning of the Nephrology Department requires supervision and direction by a physician who has been properly trained and is fully qualified and competent to practice medicine as a nephrologist; and

WHEREAS, Provider desires to contract for and provide said Medical Directorship and professional medical services; and

WHEREAS, the parties desire to provide a full statement of their agreement in connection with the operation of Nephrology Department in Hospital during the term of this Agreement.

**NOW THEREFORE**, in consideration of the covenants and mutual promises made herein, the parties agree as follows:

#### I. DEFINITIONS

For the purposes of this Agreement, the following definitions apply:

- 1.1 <u>Provider.</u> Bernstein, Pokroy & Lehrner, LTD. d/b/a Kidney Specialists of Southern Nevada and all physicians associated with it who have privileges at Hospital to provide nephrology specialist services.
- 1.2 Principal Physician. Marvin J. Bernstein, M.D.
- 1.3 <u>Member Physicians</u>. Physicians associated with Provider who provide services pursuant to this Agreement. Unless the context requires otherwise, the term "Member Physicians" shall include the Principal Physician.
- 1.4 Allied Health Providers. Individuals other than a licensed physician, M.D., D.O. or dentist who exercise independent or dependent judgment within the areas of their scope of practice and who are qualified to render patient care services under the supervision of a qualified physician who has been accorded privileges to provide such care in Hospital.
- 1.5 <u>Department</u>. Unless the context requires otherwise, Department refers to Hospital's Department of Nephrology.
- 1.6 <u>Clinical Services</u>. Services performed for the diagnosis, prevention or treatment of disease or for assessment of a medical condition.

- 1.7 <u>Services to Patients</u>. Those services personally rendered by Provider's Member Physicians to the patient.
  - a. To qualify as "services to patients", services must, in general: (i) be personally furnished by Provider's Member Physicians; (ii) contribute directly to the diagnosis or treatment of the patient; and (iii) ordinarily require performance by a physician.
  - b. Services to patients include: (i) consultative services; and (ii) services personally performed by Provider's Member Physicians in the administration of procedures to an individual patient.
- 1.8 <u>Services to Hospital</u>. Those services which do not qualify as "services to patients" as herein defined, but which are services provided by Provider to Hospital and are related to the provision of patient care in Hospital; including, but not limited to, administrative and supervisory services. Clinical services which do not meet the requirements of "services to patients" shall be considered "services to Hospital."

#### II. PROVIDER'S OBLIGATIONS

- 2.1 <u>Coverage</u>. Provider, through its Member Physicians hereby agrees to perform the following services as requested by Hospital and in a manner reasonably satisfactory to Hospital:
  - a. Provider shall provide professional services in the best interests of Hospital's patients with all due diligence.
  - b. Provider will professionally staff Department during its normal operating hours so that a Physician is present when required for delivery of Services to Patients. Provider shall consult with the Medical Staff of Hospital when requested.
  - c. Provider shall provide Hospital with consultative coverage on a twenty-four (24) hour-aday, seven (7) day-a-week basis. For this purpose consultive coverage consists of patient examination/assessment, diagnosis, medical/surgical intervention and follow-up care. This coverage includes all Hospital inpatients, Hospital outpatients, Emergency Department patients and Trauma Department patients who are not designated patients of other physicians unless resident coverage has been assigned to another group or physician on a predetermined and agreed upon scheduled rotation.
  - d. Provider shall provide consultative, diagnostic or medical service coverage at the outpatient nephrology clinic during the term of this agreement at three (3) clinics per month for up to four (4) hours per clinic. Provider shall ensure that outpatient clinic patients shall not have to wait more than ten (10) calendar days for an urgent visit and no more than thirty (30) calendar days for an elective appointment. If appointment waiting times exceed these thresholds, Provider will staff additional clinics as required to reduce waiting times below these thresholds.
  - e. Provider shall provide consultative, diagnostic or medical service coverage and training with a transplant nephrologist at the Transplant Center during the term of this agreement at four (4) clinics per week for up to four (4) hours per clinic. The transplant nephrologist will provide medical examination and clearance for prospective transplant patients.

2

- e. Provider shall provide service on an emergency and on-call basis to meet the needs of Hospital's inpatients and outpatients.
- f. Provider shall coordinate the schedules and assignments of the physicians assigned to Department.
- g. Provider shall encourage the participation of other physicians in the community to assist Provider in the provision of the services outlined in this Agreement.

#### 2.2 Medical Staff Appointment.

- a. Physicians employed or contracted by Provider shall at all times hereunder, be members in good standing of Hospital's medical staff with appropriate clinical privileges and appropriate Hospital credentialing. Any of Provider's Member Physicians who fail to maintain staff appointment of clinical privileges in good standing will not be permitted to render services to Hospital's patients and will be replaced promptly by Provider. Provider shall replace a Member Physician who is suspended, terminated or expelled from Hospital's Medical Staff, loses his license to practice medicine, tenders his resignation, or violates the terms of this Agreement. In the event Provider replaces or adds a Member Physician, such new physician shall meet all of the conditions set forth herein, and shall agree in writing to be bound by the terms of this Agreement.
- b. It is expressly agreed that continuation of this Agreement is dependent upon the continued appointment of Marvin J. Bernstein, M.D. as Provider's Principal Physician.
- c. Provider shall be fully responsible for the performance and supervision of any of its Member Physicians, including its Principal Physician, or others under its direction and control, in the performance of services under this Agreement.
- d. Allied Health Providers employed or utilized by Provider, if any, must apply for privileges and remain in good standing in accordance with the University Medical Center of Southern Nevada Allied Health Providers Manual and Human Resource Policies as applicable to the Allied Health Provider.
- 2.3 <u>Medical Director</u>. Provider's Principal Physician, who has been appointed Medical Director of Department, shall assume medical responsibility for Department during the term of this Agreement. The Principal Physician shall at all times during the term of this Agreement;
  - a. be Board Certified;
  - b. hold an active license to practice medicine from the State of Nevada which is in good standing; and
  - c. not be subject to any agreement or understanding, written or oral, that the Principal Physician will not engage in the practice of medicine, either temporarily or permanently.

Hospital shall, in its discretion, have the right to terminate this Agreement if Principal Physician fails to meet any of the foregoing requirements in this section.

3

#### 2.4 Clinical Responsibilities of Principal Physician.

- a. Provide nephrology services;
- b. Provide clinical direction of Hospital's Department;
- c. Ensure clinical effectiveness by providing direction and supervision in accordance with recognized professional medical specialty standards and the requirements of local, state and national regulatory agencies and accrediting bodies;
- d. Provide consultations and documentation in accordance with the standards and recommendations of The Joint Commission and the Bylaws, Rules and Regulations of the Medical and Dental Staff, as may then be in effect;
- e. Provide ongoing patient contact as medically necessary and appropriate to include daily rounding on patients assigned to Nephrology Services, and consultative availability seven (7) days per week, fifty-two (52) weeks per year.
- f. Coordinate and integrate clinically related Department activities both inter and intra departmentally within Hospital and its affiliated clinics;
- g. Participate in scheduled clinical staff meetings and conferences;
- h. Provide training in nephrology to resident physicians at Hospital; and
- i. Perform such other clinical duties as necessary to operate the Department.

#### 2.5 Administrative Responsibilities of Principal Physician.

- a. Contribute to a positive relationship among Hospital's Administration, Health Care Providers (RN's, ancillary providers), Hospital's Medical Staff and the community;
- b. Promote the growth and development of the Department in conjunction with Hospital with special emphasis on expanding diagnostic and therapeutic services;
- c. Inform the Medical Staff of new equipment and applications;
- d. Recommend innovative changes directed toward improved patient services:
- e. Develop and implement guidelines, policies and procedures in accordance with recognized professional medical specialty standards and the requirements of local, state and national regulatory agencies and accrediting bodies;
- f. Recommend the selection and development of appropriate methods, instrumentation and supplies to assure proper utilization of staff and efficient reporting of results;
- g. Represent the Department on Hospital's medical staff committees and at Hospital department meetings as the need arises;

- h. Participate in Quality Assurance and Performance Improvement activities by monitoring and evaluating care; communicating findings, conclusions, recommendations and actions taken; and using established Hospital mechanisms for appropriate follow-up;
- i. Assess and recommend to Hospital's Administration a sufficient number of qualified and competent staff members to provide patient care;
- j. Assess and recommend to Hospital's Administration the need for capital expenditure for equipment, supplies and space required to maintain and expand the Department;
- k. Provide for the education of Medical Staff and Hospital personnel, residents and medical students in a defined organized structure and as the need presents itself;
- 1. Monitor the use of equipment and report any malfunction to Hospital Administration;
- m. Assist Hospital in the selection of outside sources for needed medical professional services;
- n. Assist Hospital in the appeal of any denial of payment of Hospital charges;
- o. Assist Hospital's Administration with the performance of such other administrative duties as necessary to operate the Department;
- p. Must see all patients that require follow-up visits in Provider's office regardless of patient's ability to make up-front payments or deposits; and
- q. Use best efforts to use Hospital's contracted anesthesiologists and hospitalists.
- 2.6 <u>Time Studies</u> Provider shall record in hourly increments time spent in teaching, administration and supervision. Provider shall choose to report a week he/she worked the entire week, ideally with a different week chosen each month, so there is an even distribution of weeks throughout the year. Provider shall submit such time studies to Hospital's Fiscal Services Department by the 12<sup>th</sup> of each month. Failure to submit the required time study by the 12<sup>th</sup> of each month will delay that month's payment until the time study is received. A copy of the PHYSICIAN'S TIME STUDY is incorporated herein as Attachment AA.@
- 2.7 Standards of Performance / Performance Expectations.
  - a. Provider promises to adhere to Hospital's established standards and policies for providing good patient care. In addition, Provider shall ensure that its Member Physicians shall also operate and conduct themselves in accordance with the standards and recommendations of The Joint Commission, all applicable National Patient Safety Goals, the Bylaws, Rules and Regulations of the Medical and Dental Staff, the CMS Conditions of Participation, and the Medical Staff Physician's Code of Conduct, as may then be in effect.
  - b. Hospital expressly agrees that the professional services of Provider may be performed by such physicians as Provider may associate with, so long as Provider has obtained the prior written approval of Hospital. So long as Provider is performing the services required hereby, its employed or contracted physicians shall be free to perform private practice at other offices and hospitals. If any of Provider's Member Physicans are

employed by Provider under the J-1 Visa waiver program, Provider will so advise Hospital, and Provider shall be in strict compliance, at all times during the performance of this Agreement, with all federal laws and regulations governing said program and any applicable state guidelines.

- c. Provider shall maintain professional demeanor and not violate Medical Staff Physician's Code of Conduct.
- d. Provider shall assist Hospital with improvement of customer satisfaction and performance ratings using results from Hospital's patient survey for Services performed in Hospital.
- e. Provider shall work in the development and maintenance of key clinical protocols to standardize patient care.
- f. Provider shall strive to improve morbidity and mortality rates among Hospital's nephrology and transplant nephrology patients.
- g. Provider shall provide a level of nephrology care to enhance and improve nephrology and transplant nephrology outcomes.
- h. Provider shall provide for the education of Medical Staff and Hospital personnel, residents and medical students in a defined organized structure and as the need presents itself.
- i. Provider shall provide a continuum of educational experience meeting all Graduate Medical Education (GME) standards.
- j. Provider shall provide scholarly activities that include, but are not limited to: 1) clinical research; 2) presentation of academic papers; and 3) lectures.
- k. Provider shall work with hospital staff and emergency department physicians to develop a protocol for emergent dialysis patients.
- 2.8 <u>Independent Contractor</u>. In the performance of the work duties and obligations performed by Provider under this Agreement, it is mutually understood and agreed that Provider is at all times acting and performing as an independent contractor practicing the profession of medicine. Hospital shall neither have, nor exercise any, control or direction over the methods by which Provider shall perform its work and functions.

#### 2.9 Industrial Insurance.

- a. As an independent contractor, Provider shall be fully responsible for premiums related to accident and compensation benefits for its shareholders and/or direct employees as required by the industrial insurance laws of the State of Nevada.
- b. Provider agrees, as a condition precedent to the performance of any work under this Agreement and as a precondition to any obligation of Hospital to make any payment under this Agreement, to provide Hospital with a certificate issued by the appropriate entity in accordance with the industrial insurance laws of the State of Nevada. Provider agrees to maintain coverage for industrial insurance pursuant to the terms of this

Agreement. If Provider does not maintain such coverage, Provider agrees that Hospital may withhold payment, order Provider to stop work, suspend the Agreement or terminate the Agreement.

#### 2.10 Professional Liability Insurance.

- a. Provider shall carry professional liability insurance on its Member Physicians and employees at its own expense in accordance with the minimums established by the Bylaws, Rules and Regulations of the Medical and Dental Staff. Said insurance shall annually be certified to Hospital's Administration and Medical Staff, as necessary.
- b. As Director of the Department described in this Agreement, Provider is covered for the performance of administrative duties under Hospitals=s current Directors and Officers Liability policy.
- 2.11 <u>Provider Personal Expenses</u>. Provider shall be responsible for all its personal expenses, including, but not limited to, membership fees, dues and expenses of attending conventions and meetings, except those specifically requested and designated by Hospital.

#### 2.12 Maintenance of Records.

- a. All medical records, histories, charts and other information regarding patients treated or matters handled by Provider hereunder, or any data or data bases derived therefrom, shall be the property of Hospital regardless of the manner, media or system in which such information is retained. Provider shall have access to and may copy relevant records upon reasonable notice to Hospital.
- b. Provider shall complete all patient charts in a timely manner in accordance with the standards and recommendations of The Joint Commission, CMS, and Regulations of the Medical and Dental Staff, as may then be in effect.

#### 2.13 Health Insurance Portability and Accountability Act of 1996.

- a. For purposes of this Agreement, "Protected Health Information" shall mean any information, whether oral or recorded in any form or medium, that: (i) was created or received by either party; (ii) relates to the past, present, or future physical condition of an individual, the provision of health care to an individual, or the past, present or future payment for the provision of health care to an individual; and (iii) identifies such individual.
- b. Provider shall use its reasonable efforts to preserve the confidentiality of Protected Health Information it receives from Hospital, and shall be permitted only to use and disclose such information to the extent that Hospital is permitted to use and disclose such information pursuant to the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d-1329d-8; 42 U.S.C. 1320d-2) ("HIPAA"), regulations promulgated thereunder ("HIPAA Regulations") and applicable state law. Hospital and Provider shall be an Organized Health Care Arrangement ("OHCA"), as such term is defined in the HIPAA Regulations.
- c. Hospital shall, from time to time, obtain applicable privacy notice acknowledgments and/or authorizations from patients and other applicable persons, to the extent required by

law, to permit the Hospital, Provider and their respective employees and other representatives, to have access to and use of Protected Health Information for purposes of the OHCA. Hospital and Provider shall share a common patient's Protected Health Information to enable the other party to provide treatment, seek payment, and engage in quality assessment and improvement activities, population-based activities relating to improving health or reducing health care costs, case management, conducting training programs, and accreditation, certification, licensing or credentialing activities, to the extent permitted by law or by the HIPAA Regulations.

- 2.14 <u>Voluntary Absence</u>. Provider's Principal Physician may require personal time away from Hospital for vacation, seminars and so forth. In such event, Principal Physician shall advise Hospital's Administration in a reasonable time prior to such absence, however, such absence shall not diminish the requirements for administration and supervision of the Department and Principal Physician shall arrange for administrative and supervisory coverage during his absence.
- 2.15 <u>UMC Policy #I-66</u>. Provider shall ensure that its staff and equipment utilized at Hospital, if any, are at all times in compliance with University Medical Center Policy #I-66, set forth in Attachment "B", incorporated and made a part hereof by this reference.

#### III. HOSPITAL'S OBLIGATIONS

- 3.1 Space, Equipment and Supplies.
  - a. Hospital shall provide space within Hospital for the Department (excluding Provider's private office space); however, Provider shall not have exclusivity over any space or equipment provided therein and shall not use the space or equipment for any purpose not related to the proper functioning of the Department.
  - b. Hospital shall make available during the term of the Agreement such equipment as is determined by Hospital to be required for the proper operation and conduct of the Department. Hospital shall also keep and maintain said equipment in good order and repair.
  - c. Hospital shall purchase all necessary supplies for the proper operation of the Department and shall keep accurate records of the cost thereof.
- 3.2 <u>Hospital Services</u>. Hospital shall, at its expense, furnish the Principal Physician with ordinary janitorial service, in-house messenger service and telephone service as may be required by the administrative duties of Principal Physician. Hospital shall also provide the services of other hospital departments including, but not limited to, Accounting, Administration, Engineering, Human Resources, Material Management, Medical Records and Nursing.
- Personnel. Other than Member Physicians and Allied Health Providers, all personnel required for the proper operation of the Department shall be employed by Hospital. The selection and retention of such personnel shall be in cooperation with Principal Physician, but Hospital shall have final authority with respect to such selection and retention. Salaries and personnel policies for persons within personnel classifications used in Department shall be uniform with other Hospital personnel in the same classification insofar as may be consistent with the recognized skills and/or hazards associated with that position, providing that recognition and compensation be provided for personnel with special qualifications in accordance with the personnel policies of Hospital.

3.4 <u>Annual Review.</u> Hospital and Provider shall initially conduct a quarterly review of Provider's performance of Services and to evaluate volume of vascular access surgery patients during that period. After one (1) year, parties will consider an amendment to the Agreement based on an increased volume of vascular access surgery patients.

#### IV. BILLING

#### 4.1 Direct Billing.

- a. Provider shall directly bill patients and/or third party payors for all professional components. Hospital shall provide, at Hospital's expense, usual social security and insurance information to facilitate direct billing. Unless specifically agreed to in writing or elsewhere in this Agreement, Hospital is not otherwise responsible for the billing or collection of professional components.
- b. Provider agrees to maintain a mandatory assignment contract with Medicare.
- c. Fees will not exceed that which is usual, reasonable and customary for the community. Provider shall furnish a list of these fees upon request of Hospital.
- d. Provider shall not bill patients or Hospital for Provider services rendered to patients deemed to be indigents by Clark County Social Service, or applicable law.
- e. Provider shall use best efforts to negotiate a contract with all payors with whom Hospital has a contract.

#### 4.2 Physician Billing/Compliance.

- a. Provider agrees to comply with all applicable federal and state statutes and regulations (as well as applicable standards and requirements of non-governmental third-party payors) in connection with Provider's submission of claims and retention of funds for Provider's services provided to patients at Hospital's facilities (collectively "Billing Requirements").
- b. In furtherance of the foregoing and without limiting in any way the generality thereof, Provider agrees:
  - 1. To ensure that all claims by Provider for Provider's services provided to patients at Hospital's facilities are complete and accurate;
  - 2. To cooperate and communicate with Hospital in the claim preparation and submission process to avoid inadvertent duplication by ensuring that Provider does not bill for any item or service that has been or will be appropriately billed by Hospital as an item or service provided by Hospital at Hospital's facilities;
  - 3. To keep current on applicable Billing Requirements as the same may change from time to time; and
  - 4. In addition to any other indemnification provision contained herein, to indemnify, defend, and hold harmless Hospital, its governing board members, officers,

employees, agents, successors and assigns from and against any and all claims, injuries, lawsuits, investigations, losses, damages, demands, expenses and liabilities, including, but not limited to, legal expenses and cost of settlements, of whatever nature, arising out of Provider's breach of the foregoing covenants.

#### V. COMPENSATION

- 5.1 Except as provided in Paragraphs 5.2, 5.3 and 5.4, hereinbelow, each of Hospital's patients receiving services from Provider shall be directly billed by Provider for such services.
- During the term of this Agreement and subject to paragraphs 7.6 and 7.15, hereinbelow, Hospital will compensate Provider twenty-five thousand dollars (\$25,000.00)per year at the rate of two thousand eighty-three dollars and thirty-three cents (\$2083.33)per month, on the third (3rd) Friday of each month, or if the third (3rd) Friday falls on a holiday, the following Monday, for the previous month's duties as Medical Director of the Department of Nephrology.
- During the first year of this Agreement and subject to paragraphs 7.6 and 7.15, hereinbelow, Hospital will compensate Provider seven hundred thirteen thousand seven hundred twenty dollars (\$713,720)per year at the rate of fifty-nine thousand four hundred seventy-six dollars and sixty-seven cents (\$59,476.67)per month, on the third (3rd) Friday of each month, or if the third (3rd) Friday falls on a holiday, the following Monday, for the previous month's services professional medical services rendered to Hospital's Nephrology Department, inpatient and outpatient services inclusive.
- Prices for professional services only may be adjusted annually upon the anniversary date. The first price adjustment request may be made 60 calendar days prior to the 1st anniversary of the Agreement. All price adjustment requests, including suitable proof, shall be submitted, at least 60 calendar days in advance of the anniversary date of the Agreement to the University Medical Center, Contracts Management, 1800 West Charleston Boulevard, Las Vegas, NV 89102. Price increases shall not be retroactive. A price adjustment can only occur if Provider has been notified in writing of UMC's approval of the new Price(s). Only one written price adjustment request(s) will be accepted from Provider each year. The reference months/period and indexes to be used to determine price adjustments will be the most recent published index between 14-16 months prior (using the final index) and 2-4 months prior (using the first-published index) to the anniversary date of the Agreement, using the Price Index specified below.

Suitable Proof: Print-out of index and calculated increase/decrease

#### Consuer Price Index:

The Consumer Price Index (CPI) - All Urban Consumers, Area - West Urban (Series ID = CUUR0400SA0). The price adjustment per annual request may be the lesser of percent of CPI change for the 12 month period or 3 percent whichever is less for an increase or decrease.

**Price Decrease:** Hospital shall receive the benefit of a price decrease for professional services during an annual period if the CPI decreases.

#### VI. TERM/MODIFICATIONS/TERMINATION

- 6.1 <u>Term of Agreement</u>. This Agreement shall become effective on the 1st day of January, 2011, and, subject to paragraphs 7.6 and 7.15, hereinbelow, shall remain in effect through the December 31, 2015.
- 6.2. <u>Modifications</u>. Provider shall notify Hospital in writing of:
  - a. Any change of address of Provider;
  - b. Any change in membership or ownership of Provider's group or professional corporation.
  - c. Any action against the license of any of Provider's Member Physicians;
  - d. Any action commenced against Provider which could materially affect this Agreement;
  - e. Any exclusionary action initiated or taken by a federal health care program against Provider or any of Provider's Member Physicians; or
  - f. Any other occurrence known to Provider that could materially impair the ability of Provider to carry out its duties and obligations under this Agreement.

#### 6.3 Termination For Cause.

- a. This Agreement shall immediately and automatically terminate, without notice by Hospital, upon the occurrence of any one of the following events:
  - 1. The exclusion of Provider from participation in a federal health care program:
  - 2. The expulsion, termination or suspension of Provider's Principal Physician by Hospital's Medical Staff or loss of Provider's Principal Physician's license to practice medicine unless Provider provides a substitute physician who is satisfactory to Hospital, as determined by Hospital's Administration in consultation with the Medical Executive Committee. [Hospital will not unreasonably withhold such acceptance/approval.]; or
  - 3. The conviction of Provider's Principal Physician of any crime punishable as a felony involving moral turpitude or immoral conduct unless Provider provides a substitute physician who is satisfactory to Hospital, as determined by Hospital's Administration in consultation with the Medical Executive Committee. [Hospital will not unreasonably withhold such acceptance/approval.].
- b. The Agreement may be terminated by Hospital at any time immediately, without notice by Hospital, upon the occurrence of any of the following events:
  - 1. Principal Physician loses Board Certification; or
  - 2. Principal Physician's license to practice medicine from the State of Nevada is suspended, revoked or otherwise looses good standing; or

- 3. The Principal Physician is subject to any agreement or understanding, written or oral, that the Principal Physician will not engage in the practice of medicine, either temporarily or permanently; or
- 4. Provider's or Principal Physician's business license has been suspended or revoked; or
- 5. The Principal Physician is subject to any court order that restricts or prohibits him/her from practicing medicine, either temporarily or permanently.
- c. This Agreement may be terminated by Hospital at any time with thirty (30) days written notice, upon the occurrence of any one of the following events which has not been remedied within thirty (30) days after written notice of said breach:
  - 1. Professional misconduct by any of Provider's Member Physicians as determined by the Bylaws, Rules and Regulations of the Medical and Dental Staff and the appeal processes thereunder;
  - Conduct by any of Provider's Member Physicians which demonstrates an inability
    to work with others in the institution and such behavior presents a real and
    substantial danger to the quality of patient care provided at the facility as
    determined by Hospital;
  - 3. Disputes among the Member Physicians, partners, owners, principals, or Provider's group or professional corporation that, in the reasonable discretion of Hospital, are determined to disrupt the provision of good patient care;
  - 4. Absence of Provider's Principal Physician, by reason of illness or other cause, for a period of ninety (90) days, unless adequate coverage is furnished by Provider. Such adequacy will be determined by Hospital's Administration; or
  - 5. Breach of any material term or condition of this Agreement.
- d. This Agreement may be terminated by Provider at any time with thirty (30) days written notice, upon the occurrence of any one of the following events which has not been remedied within said thirty (30) days written notice of said breach:
  - 1. The exclusion of Hospital from participation in a federal health care program;
  - 2. The loss or suspension of Hospital's licensure or any other certification or permit necessary for Hospital to provide services to patients;
  - 3. The failure of Hospital to maintain accreditation by The Joint Commission:
  - 4. Failure of Hospital to cooperate with Provider in the billing process as set forth in Section IV, above;
  - 5. Persistent and excessive referral of patients subject to Paragraph 4.1(d), above:
  - 6. Failure of Hospital to compensate Provider in a timely manner as set forth in Section V, above; or

- 7. Breach of any material term or condition of this Agreement.
- 6.4 <u>Termination Without Cause</u>. Either party may terminate this Agreement, without cause, upon ninety (90) days written notice to the other party.

#### VII. MISCELLANEOUS

- Access to Records. Upon written request of the Secretary of Health and Human Services or the Comptroller General or any of their duly authorized representatives, Provider shall, for a period of four (4) years after the furnishing of any service pursuant to this Agreement, make available to them those contracts, books, documents, and records necessary to verify the nature and extent of the costs of providing its services. If Provider carries out any of the duties of this Agreement through a subcontract with a value or cost equal to or greater than \$10,000 or for a period equal to or greater than twelve (12) months, such subcontract shall include this same requirement. This section is included pursuant to and is governed by the requirements of the Social Security Act, 42 U.S.C. 1395x (v) (1) (I), and the regulations promulgated thereunder.
- 7.2 <u>Amendments</u>. No modifications or amendments to this Agreement shall be valid or enforceable unless mutually agreed to in writing by the parties.
- Assignment/Binding on Successors. No assignment of rights, duties or obligations of this Agreement shall be made by either party without the express written approval of a duly authorized representative of the other party. Subject to the restrictions against transfer or assignment as herein contained, the provisions of this Agreement shall inure to the benefit of and shall be binding upon the assigns or successors-in-interest of each of the parties hereto and all persons claiming by, through or under them,
- Audits. The performance of this contract by the Provider is subject to review by the Hospital to insure contract compliance. The Provider agrees to provide the Hospital any and all information requested that relates to the performance of this contract. All requests for information shall be in writing to the Provider. Time is of the essence during the audit process. Failure to provide the information requested within the timeline provided in the written information request may be considered a material breach of contract and be cause for suspension and/or termination of the contract.
- 7.5 <u>Authority to Execute</u>. The individuals signing this Agreement on behalf of the parties have been duly authorized and empowered to execute this Agreement and by their signatures shall bind the parties to perform all the obligations set forth in this Agreement.
- 7.6 <u>Budget Act</u>. In accordance with NRS 354.626, the financial obligations under this Agreement between the parties shall not exceed those monies appropriated and approved by Hospital for the then current fiscal year under the Local Government Budget Act. Hospital agrees that this section shall not be utilized as a subterfuge or in a discriminatory fashion as it relates to this Agreement.
- 7.7 <u>Captions/Gender/Number</u>. The articles, captions, and headings herein are for convenience and reference only and should not be used in interpreting any provision of this Agreement.

  Whenever the context herein requires, the gender of all words shall include the masculine, feminine and neuter and the number of all words shall include the singular and plural.

- 7.8 <u>Confidential Records</u>. All medical records, histories, charts and other information regarding patients, all Hospital statistical, financial, confidential, and/or personnel records and any data or data bases derived therefrom shall be the property of Hospital regardless of the manner, media or system in which such information is retained. All such information received, stored or viewed by Provider shall be kept in the strictest confidence by Provider and its employees and contractors.
- 7.9 Corporate Compliance. Provider recognizes that it is essential to the core values of Hospital that its contractors conduct themselves in compliance with all ethical and legal requirements. Therefore, in performing its services under this contract, Provider agrees at all times to comply with all applicable federal, state and local laws and regulations in effect during the term hereof and further agrees to use its good faith efforts to comply with the relevant compliance policies of Hospital, including its corporate compliance program and Code of Ethics, the relevant portions of which are available to Provider upon request.
- 7.10 <u>Disagreements/Arbitration</u>. All matters involving the performance of Provider's duties, as set forth in this Agreement, shall be determined jointly by Provider and Hospital's Administration. Any disagreement between Provider and Hospital's Administration shall be resolved according to the following procedures:
  - a. In all matters concerning the reasonable adequacy of coverage and the performance of Provider's duties set forth in the Agreement, the decision of Hospital's Administration shall be initially binding upon both parties unless the same is appealed to the Board of Trustees within ten (10) days after the decision of Hospital's Administration is announced. Both parties shall have the right to arbitrate any matter in accordance with the procedures of paragraph 7.10 (c).
  - b. All disputed matters pertaining to the Medical and Dental Staff Bylaws, Rules and Regulations shall be addressed through the mechanisms and procedures adopted and established by the Bylaws, Rules and Regulations of the Medical and Dental Staff.
  - c. All other matters concerning the application, interpretation or construction of the provisions of this Agreement shall be submitted to binding arbitration. Arbitration shall be initiated by either party making a written demand for arbitration on the other party. Each party, within fifteen (15) days of said notice, shall choose an arbitrator, and the two selected arbitrators shall then choose a third arbitrator. The panel of three (3) arbitrators shall then proceed in accordance with the applicable provisions of the Nevada Revised Statutes, with the third arbitrator ultimately responsible for arbitrating the matter. Either party to the arbitration may seek judicial review by way of petition to the Eighth Judicial District Court of the State of Nevada to confirm, correct or vacate an arbitration award in accordance with the requirements of the Nevada Revised Statutes and the Nevada Rules of Civil Procedure.
- 7.11 Entire Agreement. This document constitutes the entire agreement between the parties, whether written or oral, and as of the effective date hereof, supersedes all other agreements between the parties which provide for the same services as contained in this Agreement. Excepting modifications or amendments as allowed by the terms of this Agreement, no other agreement, statement, or promise not contained in this Agreement shall be valid or binding.
- 7.12 False Claims Act.

- The state and federal False Claims Act statutes prohibit knowingly or recklessly a. submitting false claims to the Government, or causing others to submit false claims. Under the False Claims Act, a provider may face civil prosecution for knowingly presenting reimbursement claims: (1) for services or items that the provider knows were not actually provided as claimed; (2) that are based on the use of an improper billing code which the provider knows will result in greater reimbursement than the proper code: (3) that the provider knows are false; (4) for services represented as being performed by a licensed professional when the services were actually performed by a non-licensed person; (5) for items or services furnished by individuals who have been excluded from participation in federally-funded programs; or (6) for procedures which the provider knows were not medically necessary. Violation of the civil False Claims Act may result in fines of up to \$11,000 for each false claim, treble damages, and possible exclusion from federally-funded health programs. Accordingly, all employees, volunteers, medical staff members, vendors, and agency personnel are prohibited from knowingly submitting to any federally or state funded program a claim for payment or approval that includes fraudulent information, is based on fraudulent documentation or otherwise violates the provisions described in this paragraph.
- b. Hospital is committed to complying with all applicable laws, including but not limited to Federal and State False Claims statutes. As part of this commitment, Hospital has established and will maintain a Corporate Compliance Program, has a Corporate Compliance Officer, and operates an anonymous 24-hour, seven-day-a-week compliance Hotline. A Notice Regarding False Claims and Statements is attached to this Agreement as Attachment "C". Provider is expected to immediately report to Hospital's Corporate Compliance Officer directly at (702) 383- through the Hotline (888) 691- or the website at <a href="http://umcsn.alertline.com">http://umcsn.alertline.com</a>, or in writing, any actions by a medical staff member, Hospital vendor, or Hospital employee which Provider believes, in good faith, violates an ethical, professional or legal standard. Hospital shall treat such information confidentially to the extent allowed by applicable law, and will only share such information on a bona fide need to know basis. Hospital is prohibited by law from retaliating in any way against any individual who, in good faith, reports a perceived problem.
- 7.13 <u>Federal, State, Local Laws.</u> Provider will comply with all federal, state and local laws and/or regulations relative to its activities in Clark County, Nevada.
- 7.14 <u>Financial Obligation</u>. Provider shall incur no financial obligation on behalf of Hospital without prior written approval of Hospital or the Board of Hospital Trustees.
- 7.15 Fiscal Fund Out Clause. This Agreement shall terminate and Hospital's obligations under it shall be extinguished at the end of any of Hospital's fiscal years in which Hospital's governing body fails to appropriate monies for the ensuing fiscal year sufficient for the payment of all amounts which could then become due under this Agreement. Hospital agrees that this section shall not be utilized as a subterfuge or in a discriminatory fashion as it relates to this Agreement. In the event this section is invoked, this Agreement will expire on the 30<sup>th</sup> day of June of the current fiscal year. Termination under this section shall not relieve Hospital of its obligations incurred through the 30<sup>th</sup> day of June of the fiscal year for which monies were appropriated.
- 7.16 Force Majeure. Neither party shall be liable for any delays or failures in performance due to circumstances beyond its control.

7.17 Governing Law. This Agreement shall be construed and enforced in accordance with the laws of the State of Nevada.

#### 7.18 Indemnification.

- a. To the extent expressly provided in Chapter 41 of Nevada Revised Statutes, and any other statute, Hospital shall indemnify and hold harmless, Provider, its officers and employees from any and all claims, demands, actions or causes of action, of any kind or nature, arising out of the negligent or intentional acts or omissions of Hospital, its employees, representatives, successors or assigns. Hospital shall resist and defend at its own expense any actions or proceedings brought by reason of such claim, action or cause of action. Provider acknowledges Hospital is self-insured.
- b. Provider shall indemnify and hold harmless, Hospital, its officers and employees from any and all claims, demands, actions or causes of action, of any kind or nature, arising out of the negligent or intentional acts or omissions of Provider, its employees, representatives, successors or assigns. Provider shall resist and defend at its own expense any actions or proceedings brought by reason of such claim, action or cause of action.
- c. Each of the Party's obligation to indemnify and/or defend the other shall survive the termination of this Agreement if the incident requiring such indemnification or defense occurred during the Agreement term, or any extension thereof, and directly or indirectly relates to the Party's obligations or performance under the terms of this Agreement.
- 7.19 Interpretation. Each party hereto acknowledges that there was ample opportunity to review and comment on this Agreement. This Agreement shall be read and interpreted according to its plain meaning and any ambiguity shall not be construed against either party. It is expressly agreed by the parties that the judicial rule of construction that a document should be more strictly construed against the draftsperson thereof shall not apply to any provision of this Agreement.
- 7.20 <u>Non-Discrimination</u>. Provider shall not discriminate against any person on the basis of age, color, disability, sex, handicapping condition (including AIDS or AIDS related conditions), national origin, race, religion, sexual orientation or any other class protected by law or regulation.
- 7.21 Notices. All notices required under this Agreement shall be in writing and shall either be served personally or sent by certified mail, return receipt requested. All mailed notices shall be deemed received three (3) days after mailing. Notices shall be mailed to the following addresses or such other address as either party may specify in writing to the other party:

To Hospital:

Chief Executive Officer

University Medical Center of Southern Nevada

1800 West Charleston Boulevard

Las Vegas, Nevada 89102

To Provider:

President

Kidney Specialists of Southern Nevada

500 South Rancho, Suite 12 Las Vegas, NV 89106

- 7.22 <u>Publicity</u>. Neither Hospital nor Provider shall cause to be published or disseminated any advertising materials, either printed or electronically transmitted which identify the other party or its facilities with respect to this Agreement without the prior written consent of the other party.
- 7.23 Performance. Time is of the essence in this Agreement.
- 7.24 Severability. In the event any provision of this Agreement is rendered invalid or unenforceable, said provision(s) hereof will be immediately void and may be renegotiated for the sole purpose of rectifying the error. The remainder of the provisions of this Agreement not in question shall remain in full force and effect.
- 7.25 Third Party Interest/Liability. This Agreement is entered into for the exclusive benefit of the undersigned parties and is not intended to create any rights, powers or interests in any third party. Hospital and/or Provider, including any of their respective officers, directors, employees or agents, shall not be liable to third parties by any act or omission of the other party.
- 7.26 Waiver. A party's failure to insist upon strict performance of any covenant or condition of this Agreement, or to exercise any option or right herein contained, shall not act as a waiver or relinquishment of said covenant, condition or right nor as a waiver or relinquishment of any future right to enforce such covenant, condition or right.

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed on the day and year first above written.

17

Provider:

Hospital:

Berstein, Pokroy & Lehrner, LTD. d/b/a Kidney Specialists of Southern Nevada

University Medical Center of Southern Nevada

Larry Lehrner

President

Kathleen Silver

Chief Executive Officer

#### Attachment AA@

### MONTHLY PHYSICIAN TIME STUDY

Physician:						pt:				
Month:										
Time Study Conduc	cted From	1;				To:			*****	
(If on vacation or away during this week, please choose another week this month and change the dates accordingly)  Note: This form must be completed and returned by the 12th of the following month to prevent a delay in payment.										
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#### Attachment "B"

#### UNIVERSITY MEDICAL CENTER OF SOUTHERN NEVADA

SUBJECT: TEMPORARY STAFFING / THIRD-PARTY EQUIPMENT

**EFFECTIVE:** 9/96 REVISED: 6/99, 10/01, 04/07, 01/08

POLICY #: I-66

AFFECTS: Organization-wide

#### PURPOSE:

To assure that contractual agreements for the provision of services are consistent with the level of care defined by Hospital policy.

To ensure the priority utilization of contracted services, staffing and equipment.

#### POLICY:

- 1) All entities providing UMC with personnel for temporary staffing must have a written contract that contains the terms and conditions required by this policy.
- 2) All equipment provided and used by outside entities must meet the safety requirements required by this policy.
- 3) Contracts will be developed collaboratively by the department(s) directly impacted, the service agency and the hospital Contract Management Department.
- 4) Contracts directly related to patient care must be reviewed and evaluated by the Medical Executive Committee to ensure clinical competency.
- 5) The contract must be approved by the Chief Executive Officer prior to the commencement of services.
- A copy of the approved contract, along with initial contact information for the contractor, must be forwarded to Human Resources department for processing (Non-employee Orientation, ID Badge, background check etc..)

#### TEMPORARY STAFFING:

#### Contractual Requirements.

The contract must require the Contractor to meet and adhere to all qualifications and standards established by Hospital policies and procedures, by The Joint Commission and by all other applicable regulatory and/or credentialing entities with specific application to the service involved in the contract.

In the event a contractor contracts with an individual who is certified under the aegis of the Medical and Dental Staff Bylaws, Allied Health, the contract must provide that the contracted individuals applicable education, training, and licensure be appropriate for his or her assigned responsibilities. The contracted individual must fulfill orientation requirements consistent with other non-employee staff members. Records concerning the contracted individual shall be maintained by Hospital's Department of Human Resources (HR) and the clinical department directly impacted by the services provided under the contract. Human Resources will provide Employee Health and Employee Education with an on going list of these individuals and department in which they work.

#### Laboratory Services.

All reference and contracted laboratory services must meet the applicable federal regulations for clinical laboratories and maintain evidence of the same.

#### Healthcare Providers:

In the event a service agency employs or contracts with an individual who is subject to the Medical and Dental Staff Bylaws, or the Allied Health Providers Manual, the contract must provide that the assigned individual's applicable education, training, and licensure be appropriate for his or her assigned responsibilities. The assigned individual must have an appropriate National Provider Identifier (NPI).

#### Clinical Care Services:

The contractor may employ such allied health providers as it determines necessary to perform its obligations under the contract. For each such allied health provider, the contract must provide that the contractor shall be responsible for furnishing Hospital with evidence of the following:

- 1. The contractor maintains a written job description that indicates:
  - a. Required education and training consistent with applicable legal and regulatory requirements and Hospital policy.
  - b. Required licensure, certification, or registration, as applicable.
  - Required knowledge and/or experience appropriate to perform the defined scope of practice, services, and responsibilities.
- 2. The contractor has completed a pre-employment drug screen and a background check with UMC's contracted background check Vendor. Testing should include HHS Office of Inspector General (OIG), Excluded party list system (EPLS), sanction checks and criminal background. If there is a felony conviction found during the background check, UMC's HR department will review and approve or deny the Allied Health Practitioner access to the UMC Campus. University Medical Center will be given authorization to verify results on line by the contractor.
- 3. Double TB Skin Testing of the individual and, for individuals in Exposure Categories I and II, has offered the individual the option of receiving Hepatitis B vaccine or a signed declination if refused. Chicken Pox status must be established by either a history of chicken pox, a serology showing positive antibodies or proof of varivax and other required testing... Ensure these records are maintained and kept current at the agency and be made available upon request. Contractor will provide authorization to University Medical Center to audit these files upon request.
- 4. The contractor has completed a competency assessment of the individual, which is performed upon hire, at the time initial service is provided, when there is a change in either job performance or job requirements, and on an annual basis.
  - Competency assessments of allied health providers must clearly establish that the individual
    meets all qualifications and standards established by Hospital policies and procedures, by The
    Joint Commission and by all other applicable regulatory and/or credentialing entities with
    specific application to the service involved in the contract.
  - Competency assessments of allied health providers must clearly address the ages of the
    patients served by the individual and the degree of success the individual achieves in
    producing the results expected from clinical interventions.

- Competency assessments must include an objective, measurable system and be used periodically to evaluate job performance, current competencies, and skills.
- Competency assessments must be performed annually, allow for Hospital input and be submitted to Hospital's Department of Human Resources.
- The competency assessment will include a competency checklist for each allied health provider position, which at a minimum addresses the individual's:
  - Knowledge and ability required to perform the written job description;
  - Ability to effectively and safely use equipment;
  - Knowledge of infection control procedures;
  - d. Knowledge of patient age-specific needs;
  - e. Knowledge of safety procedures; and
  - f. Knowledge of emergency procedures.
- 5. The contractor has conducted an orientation process to familiarize allied health providers with their jobs and with their work environment before beginning patient care or other activities at UMC inclusive of safety and infection control. The orientation process must also assess each individual's ability to fulfill the specific job responsibilities set forth in the written job description.
- 6. The contractor periodically reviews the individual's abilities to carry out job responsibilities, especially when introducing new procedures, technology, and/or equipment.
- 7. The contractor has developed and furnishes ongoing in-service and other education and training programs appropriate to patient age groups served by Hospital and defined within the scope of services provided by the contractor's contract.
- 8. The contractor submits to Hospital for annual review:
  - a. The level of competence of the contractor's allied health providers;
  - b. The patterns and trends relating to the contractor's use of allied health providers; and
- 9. The contractor ensures that each allied health provider has acquired an identification badge from Hospital's Department of Human Resources before commencing services at Hospital's facilities. The contractor also ensures that the badge is returned to HR upon termination of service at the Hospital
- 10. The contract requires the contractor, upon Hospital's request, to discontinue the employment at Hospital's facilities of an allied health provider whose performance is unsatisfactory, whose personal characteristics prevent desirable relationships with Hospital's staff, whose conduct may have a detrimental effect on patients, or who fails to adhere to Hospital's existing policies and procedures. The supervising department will complete an exit review form and submit to Human Resources for the Individual's personnel file.

#### EQUIPMENT:

In the event Hospital contracts for equipment services, documentation of a current, accurate and separate inventory equipment list must be required by the contract and be included in Hospital's medical equipment management program.

All equipment brought into UMC by service contractor is required to meet the following criteria:

- 1. All equipment must have an electrical safety check which meets the requirements of Hospital's Clinical Engineering Department.
- 2. A schedule for ongoing monitoring and evaluation of the equipment must be established and submitted to Hospital's Clinical Engineering Department.
- 3. Monitoring and evaluation will include:
  - a. Preventive maintenance:
  - b. Identification and recordation of equipment management problems;
  - c. Identification and recordation of equipment failures; and
  - d. Identification and recordation of user errors and abuse.
- 4. The results of monitoring and evaluation shall be recorded as performed and submitted to Hospital's Department of Clinical Engineering.

The contractor must present information on each contractor providing medical equipment to assure UMC that the users of the equipment are able to demonstrate or describe:

- 1. Capabilities, limitations, and special applications of the equipment;
- 2. Operating and safety procedures for equipment use:
- 3. Emergency procedures in the event of equipment failure; and
- 4. Processes for reporting equipment management problems, failures and user errors.

The contractor must provide the following on each contractor providing medical equipment to assure that the technicians maintaining and/or repairing the equipment can demonstrate or describe:

- 1. Knowledge and skills necessary to perform maintenance responsibilities; and
- 2. Processes for reporting equipment management problems, failures and user errors.

MONITORING: The contractor will provide reports of performance improvement activities at defined intervals.

A contractor providing direct patient care will collaborate, as applicable, with Hospital's Performance Improvement Department regarding Improvement Organization Performance (IOP) activities.

#### Process for Allied Health Provider working at UMC Hospital Campus

- A. All Allied Health Provider personnel from outside contractors monitored by Human Resources (Non-credentialed/licensed) working at UMC will have the following documentation on file in Department of Human Resources.
  - Copy of the contract
  - Copy of the Contractor's liability Insurance
  - Job description and resume
  - Copy of Current driver's license <u>OR</u> One 2x2 photo taken within 2 years
  - · Specialty certifications, Basic Life Support (BLS), Advanced Cardiac Life Support (ACLS), etc

- Current license verification/primary source verifications
- Specialty Certifications
- Competency Statement/ Skills Checklist (Contractor's and UMC's)
- Annual Performance evaluations
- UMC Department Specific Orientation
- Attestation form/letter from Contractor completed for medical clearances
- Director/Manager approval sign off
- Completion of Non-Employee specific orientation, RN orientation
- B. Following documents can be maintained at the Contractor's Office:
  - Medical Information to include: History and Physical (H&P), Annual Tuberculosis (TB)/health clearance test or Chest -X-Ray, Immunizations, Hepatitis B Series or waiver Chicken Pox questionnaire, Health Card, Drug test results and other pertinent health clearance records as required. The results of these tests can be noted on a one page medical attestation form provided by University Medical Center.
  - Attestation form must be signed by the employee and the contractor. The form can be utilized to
    update information as renewals or new tests. The form must be provided to the Hospital each time
    a new employee is assigned to UMC. Once the above criteria are met, the individual will be
    approved to Orientation, receive identification badge and IS security.
  - Any and all peer references and other clearance verification paperwork must be maintained in the
    contractor's office and be available upon request.

#### Non-Employee Orientation-To be provided by Employee Education Department:

- Non-Employee orientation must occur prior to any utilization of contracted personnel.
- Orientation may be accomplished by attendance at non employee orientation; or by completion of the "Agency Orientation Manual" if scheduled by the Education Department
- Nurses must complete the RN orientation manual before working if Per Diem and within one
  week of hire if a traveler.
- Each contracted personnel will have a unit orientation upon presenting to a new area. This must
  be documented and sent to Employee Education. Components such as the PYXIS tutorial and
  competency, Patient Safety Net (PSN), Information Technology Services (IS), Glucose monitoring
  as appropriate and any other elements specific to the position or department.

#### Performance Guidelines

#### All Contractor personnel:

- Will arrive at their assigned duty station at the start of the shift. Tardiness will be documented on evaluation.
- Will complete UMC incident reports and/or medication error reports when appropriate using the PSN. The Contracted individual is to report to the Director of their employer all incidents and medication errors for which they are responsible. UMC will not assume this responsibility. UMC agrees to notify the Agency when their employees are known to have been exposed to any communicable diseases.

#### Assignment guidelines

#### All agency personnel:

- a. Will be assigned duties by the Physicians, Department Manager, Charge Nurse/Supervisor that matches their skill level as defined on the competency check list.
- b. Will administer care utilizing the standards of care established and accepted by UMC.
- c. Be responsible to initiate update or give input to the plan of care on their assigned patients,
  i. As defined in the job description.
- d. Will not obtain blood from the lab unless they have been trained by the unit/department to do so.

- i. This training must be documented and sent to Employee Education.
  e. Will administer narcotics as appropriate to position and scope of practice.

#### Attachment "C"

#### Notice of False Claims and Statements

UMC's Compliance Program demonstrates its commitment to ethical and legal business practices and ensures service of the highest level of integrity and concern. UMC's Compliance Department provides UMC compliance oversight, education, reporting and resolution. It conducts routine, independent audits of UMC's business practices and undertakes regular compliance efforts relating to, among other things, proper billing and coding, detection and correction of coding and billing errors, and investigation of and remedial action relating to potential noncompliance. It is our expectation that as a physician, business associate, contractor, vendor, or agent, your business practices are committed to the same ethical and legal standards.

The purpose of this Notice is to educate you regarding the federal and state false claims statutes and the role of such laws in preventing and detecting fraud, waste, and abuse in federally funded health care programs. As a Medical Staff Member, Vendor, Contractor and/or Agent, you and your employees must abide by UMC's policies insofar as they are relevant and applicable to your interaction with UMC. Additionally, providers found in violation of any regulations regarding false claims or fraudulent acts are subject to exclusion, suspension, or termination of their provider status for participation in Medicaid.

#### Federal False Claims Act

The Federal False Claims Act (the "Act") applies to persons or entities that knowingly and willfully submits, cause to be submitted, conspire to submit a false or fraudulent claim, or use a false record or statement in support of a claim for payment to a federally-funded program. The Act applies to all claims submitted by a healthcare provider to a federally funded healthcare program, such as Medicare.

Liability under the Act attaches to any person or organization who "knowingly":

- Present a false/fraudulent claim for payment/approval;
- · Makes or uses a false record or statement to get a false/fraudulent claim paid or approved by the government,
- Conspires to defraud the government by getting a false/fraudulent claim paid/allowed;
- Provides less property or equipment than claimed; or
- Makes or uses a false record to conceal/decrease an obligation to pay/provide money/property.

"Knowingly" means a person has: 1) actual knowledge the information is false; 2) acts in deliberate ignorance of the truth or falsity of the information; or 3) acts in reckless disregard of the truth or falsity of the information. No proof of intent to defraud is required.

A "claim" includes any request/demand (whether or not under a contract), for money/property if the US Government provides/reimburses any portion of the money/property being requested or demanded.

For knowing violations, civil penalties range from \$5,500 to \$11,000 in fines, per claim, plus three times the value of the claim and the costs of any civil action brought. If a provider unknowingly accepts payment in excess of the amount entitled to, the provider must repay the excess amount.

Criminal penalties are imprisonment for a maximum 5 years; a maximum fine of \$25,000; or both.

#### Nevada State False Claims Act

Nevada has a state version of the False Claims Act that mirrors many of the federal provisions. A person is liable under state law, if they, with or without specific intent to defraud, "knowingly:"

- presents or causes to be presented a false claim for payment or approval:
- makes or uses, or causes to be made or used, a false record/statement to obtain payment/approval of a false claim;

- conspires to defraud by obtaining allowance or payment of a false claim;
- has possession, custody or control of public property or money and knowingly delivers or causes to be
  delivered to the State or a political subdivision less money or property than the amount for which he receives
  a receipt;
- is authorized to prepare or deliver a receipt for money/property to be used by the State/political subdivision and knowingly prepares or delivers a receipt that falsely represents the money/property;
- buys or receives as security for an obligation, public property from a person who is not authorized to sell or pledge the property; or
- makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an
  obligation to pay or transmit money or property to the state/political subdivision.

Under state law, a person may also be liable if they are a beneficiary of an inadvertent submission of a false claim to the state, subsequently discovers that the claim is false, and fails to disclose the false claim to the state within a reasonable time after discovery of the false claim.

Civil penalties range from \$5,000 to \$10,000 for each act, plus three times the amount of damages sustained by the State/political subdivision and the costs of a civil action brought to recover those damages.

Criminal penalties where the value of the false claim(s) is less than \$250, are 6 months to 1 year imprisonment in the county jail; a maximum fine of \$1,000 to \$2,000; or both. If the value of the false claim(s) is greater that \$250, the penalty is imprisonment in the state prison from I to 4 years and a maximum fine of \$5,000.

#### Non-Retaliation/Whistleblower Protections

Both the federal and state false claims statutes protect employees from retaliation or discrimination in the terms and conditions of their employment based on lawful acts done in furtherance of an action under the Act. UMC policy strictly prohibits retaliation, in any form, against any person making a report, complaint, inquiry, or participating in an investigation in good faith.

An employer is prohibited from discharging, demoting, suspending, harassing, threatening, or otherwise discriminating against an employee for reporting on a false claim or statement or for providing testimony or evidence in a civil action pertaining to a false claim or statement. Any employer found in violation of these protections will be liable to the employee for all relief necessary to correct the wrong, including, if needed,:

- reinstatement with the same seniority; or
- · damages in lieu of reinstatement, if appropriate; and
- · two times the lost compensation, plus interest; and
- any special damage sustained; and
- punitive damages, if appropriate.

Reporting Concerns Regarding Fraud, Abuse and False Claims

Anyone who suspects a violation of federal or state false claims provisions is required notify UMC via a hospital Administrator, department Director, department Manager, or Angela Darragh, the Corporate Compliance Officer, directly at (702) 383 Suspected violations may also be reported anonymously via the Hotline at (888) 691 or <a href="http://umcsn.alertline.com">http://umcsn.alertline.com</a>. The Hotline is available 24 hours a day, seven days a week. Compliance concerns may also be submitted via email to the Compliance Officer at <a href="http://umcsn.com">@umcsn.com</a>.

Upon notification, the Compliance Officer will initiate a false claims investigation. A false claims investigation is an inquiry conducted for the purpose of determining whether a person is, or has been, engaged in any violation of a false claim law.

Retaliation for reporting, in good faith, actual or potential violations or problems, or for cooperating in an investigation is expressly prohibited by UMC policy.

# **EXHIBIT 60**

#### CONFIDENTIAL

Subject to the Nondisclosure Provisions of H. Res. 895 as Amended

## OFFICE OF CONGRESSIONAL ETHICS UNITED STATES HOUSE OF REPRESENTATIVES

#### **MEMORANDUM OF INTERVIEW**

IN RE: Physician #1, Kidney Specialists of Southern Nevada

REVIEW #(s): 11-0243

DATE: December 9, 2011

LOCATION: 500 South Rancho Drive

Las Vegas, Nevada

TIME: 2:33 PM to 3:20 PM (approximate)

PARTICIPANTS: Paul Solis

Scott Gast

<u>SUMMARY</u>: The witness is physician with Kidney Specialists of Southern Nevada ("KSSN") and worked extensively with the University Medical Center of Southern Nevada ("UMC"). The OCE requested an interview with the witness and she consented to an interview. The witness made the following statements in response to our questioning:

- 1. The witness was given an 18 U.S.C. § 1001 warning and consented to an interview. The witness signed a written acknowledgement of the warning, which will be placed in the case file in this review.
- 2. The witness is a nephrologist and partner in KSSN. He joined KSSN in 1977 as its second physician, and today the practice employs approximately 20 physicians, of whom 16 or 17 are partners. The witness began working with UMC probably in 1975.
- 3. According to the witness, UMC began a kidney transplant program in the late 1980s. KSSN hired a transplant nephrologist, Dr. Snyder, to work with this program. Dr. Snyder passed away a few years ago, and the witness began doing transplant nephrology for the UMC transplant program after his death.
- 4. At some point in 2008, CMS became involved with the UMC transplant program, and the hospital decided improvements in the program were necessary, including the hiring of a new transplant nephrologist. KSSN eventually recruited two transplant nephrologists to join the practice, and UMC also works with a third nephrologist at another practice.
- 5. The witness was not sure of the value of KSSN's contract with UMC to provide nephrology services, including transplant nephrology. The witness also was not sure what percentage of KSSN's total revenue came from the UMC contract, but he guessed that it was less than 15 percent. The amount paid to KSSN by UMC is augmented by payments from insurance providers and Medicare, but the witness noted that KSSN generally collects less than 50 percent of what it bills. He also noted that all kidney transplant patients are covered by Medicare. The witness indicated that financial affairs of the practice are handled by Dr. Larry Lehrner, KSSN's managing partner.

MOI - Page 1 of 3

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- 6. As the witness previously noted, KSSN has two physicians who spend about 80% of their time on transplant work.
- 7. The witness stated that KSSN was not doing many transplant cases, maybe 50-60 a year. So one case would have a big impact on the stats.
- 8. The witness stated that after UMC received notice of the CMS decision to decertify the kidney transplant program, he was involved in regular weekly meetings in which the CMS decision and UMC's response were discussed. He said that the UMC CEO, Kathy Silver, was primarily responsible for working with CMS, but that other administrators were also involved.
- 9. When asked if what assistance he provided in preparing responses to CMS, the witness said that he was mainly taking care of patients. He said that he was interviewed by an attorney from San Francisco as part of the drafting of UMC's request for approval based on mitigating factors.
- 10. The witness recalled that CMS denied UMC's request for approval, noting that he was worried and disappointed by that denial. He noted that some 250 current clients would have to find another home for transplant work.
- 11. When asked if he was disappointed about the impact on the practice, the witness responded "not so much" because he had plenty to do without transplants. When asked how the program's closure would have affected KSSN's recruiting, he said that maybe KSSN would not have recruited two transplant nephrologists, but they likely would have kept one because they were still taking care of transplant patients from other places.
- 12. When asked about the involvement of Nevada's elected officials in working with CMS, the witness thought it was a great idea to involve elected officials, but he stated that he was not a part of those decisions. He may have discussed the elected official involvement with CEO Kathy Silver after the fact.
- 13. The witness said he was not aware of the specific actions taken by members of the Nevada congressional delegation on this issue. He said he may have been aware of a letter sent by the delegation to the CMS Administrator after the fact, and he was not aware of any calls made by members of the delegation.
- 14. The witness suspected that other people at KSSN, meaning Dr. Lehrner, likely reached out to elected officials. The witness joked that "a Member of Congress sleeps over here [in Las Vegas] once a week." The witness said he may have talked to Dr. Lehrner about involving Rep. Berkley, but he could not recall specific times or dates. When asked who from KSSN would have reached out to elected officials, the witness responded that "Larry Lehrner is the Managing Partner."
- 15. Prompted by his attorney, the witness stated that throughout his time practicing in the region, it has not been unusual to reach out to elected officials, such as a mayor or county commissioners, for help with certain government issues. He said that elected officials may be contacted regarding government grants, for example.

MOI - Page 2 of 3

OFFICE OF CONGRESSIONAL ETHICS

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- 16. The witness stated that he was part of no discussion about a potential conflict between Dr. Lehrner's work with UMC and Rep. Berkley's advocacy to CMS.
- 17. The witness was asked about the KSSN response to a 2010 request for proposals from UMC for a new contract to provide nephrology services, including transplant nephrology. The witness stated that he thought he looked at the response at the time it was drafted, but he did not write it. The witness did not know why a statement was included in the response discussing Dr. Lehrner's contacts with Members of Congress regarding the CMS effort to decertify the UMC kidney transplant program.
- 18. The witness stated that the contract with UMC is "marginally profitable" and that there are pro bono reasons for staying in it including intellectual benefits, good will, and having a complete medical practice.

This memorandum was prepared on January 10, 2012 after the interview was conducted on December 9, 2011. I certify that this memorandum contains all pertinent matter discussed with the witness on December 9, 2011.

Paul Solis Investigative Counsel

## **EXHIBIT 61**

#### Elhawary, Katherine M. (Perkins Cole)

From:

Cherry, David

Sent:

Thursday, October 30, 2008 7:37 PM

To: Subject: Coffron, Matthew FW: Berkley UMC letter

Take a look below at the questions from this reporter.

----Original Message-

From: Marshall Allen [ @lasvegassun.com]

Sent: Thursday, October 30, 2008 4:18 PM

To: Cherry, David

Subject: Re: Berkley UMC letter

There are a few things I'd like to ask the Congresswoman.

- 1. Did she disclose to the CMS director that her husband is partners with the director of nephrology at UMC, who is over the transplant program? Does she consider it a conflict of interest for her to advocate for a program where she has a personal interest through her husband?
- 2. UMC failed to meet dozens of standards in its March review by Medicare. How much pressure has Berkley applied to the hospital to ensure it complies with patient safety standards at UMC?
- 3. Why does the hospital believe that a standard be applied to UMC that is not applied to other hospitals? Is the fact that UMC's is the only transplant center a reason to accept a lower standard of care?

Thanks for your help!

Marshall

@mail.house.cov> wrote: On 10/30/08 4:17 PM, "Cherry, David" > Thanks. > I will try and get back to you with an answer before your deadline > Friday on question below. What else are you looking at by way of story? > She has spoken to CMS Director personally and is encouraged by fact that > negotiations are now underway between CMS and UMC. > As the letter makes clear, the center is the only one in Nevada and its > closure would dramatically impact local patients. > > ----Original Message----@lasvegassun.com] > From: Marshall Allen [ > Sent: Thursday, October 30, 2008 4:07 PM > To: Cherry, David > Subject: Re: Berkley UMC letter > My deadline is tomorrow by noon. I do have a copy of the letter signed > by

```
> all three representatives.
>
> On 10/30/08 4:09 PM, "Cherry, David" <
                                                    @mail.house.gov>
> wrote:
>> What is your deadline Marshall?
>>
>> Also, do you have a copy of the letter signed by all three members of
>> the NV delegation, not just Rep. Berkley?
>>
>> Thanks
>>
>> ----Original Message-----
                                               @lasvegassun.com]
>> From: Marshall Allen [
>> Sent: Thursday, October 30, 2008 11:42 AM
>> To: Cherry, David
>> Subject: Berkley UMC letter
>>
>> Hi David, I'm writing a story about UMC losing its kidney transplant
>> program
>> and wanted to speak with you about it.
>> One of the things I wanted to ask is whether Congresswoman Berkley
>> have noted in her letter to CMS that her husband is a partner with the
>> director of nephrology at the hospital.
>>
>> Can you give me a call please? I'm at 702.259.
>>
>> Best,
>>
>> Marshall Allen
>> Las Vegas Sun
シシ
>
```

# **EXHIBIT 62**

Las Vegas Sun HEALTH CARE:

## Focus shifts to fixing kidney program's faults

#### Inspectors found many shortfalls at UMC

#### By Marshall Allen

Tuesday, Nov. 4, 2008 | 2 a.m.



The intense appeals to save University Medical Center's kidney transplant program from losing its Medicare funding have overshadowed fundamental patient safety problems revealed by inspectors.

Hospital Chief Executive Kathy Silver acknowledged failures in management of the program, even as she argued that it should remain open.

"I'll be the first to admit that over the years not enough resources have been applied to this program," Silver said.

Medicare surveys in March and August found that UMC failed to meet its conditions of funding because of too many patient deaths and other concerns connected to the transplant program. On Friday the federal agency postponed its process of taking away UMC's funding on the condition that UMC radically reform the program to improve patient safety.

Appeals for leniency for UMC did not mention that the kidney transplant center has more than twice the expected death rate and dozens of recent failures to meet announced standards of patient care.

The primary argument for leniency for the transplant program hinged on a sulcide included in the tally of patient deaths. Medicare counts transplant recipient deaths over a 30-month period to determine whether a hospital is meeting its standards.

UMC had five deaths in the time period, including the suicide, and hospital officials say they would have been within Medicare guidelines if there had been only four

Medicare officials say it's ridiculous for a hospital to pluck out the numbers it doesn't like, but that's been the straw grasped by UMC and its advocates who dismissed the suicide as out of the transplant program's control.

But that leaves out important context, including that a hospital social worker did not meet with the patient after the surgery, as Medicare requires. The patient committed suicide days after a May 2005 transplant, Medicare officials said.

Silver said UMC did a pre-surgical psychological assessment of the patient who committed suicide, and there was no indication of any problem.

"We felt that including that one death threw us out of compliance, and that this death should not have been included in the number," Silver said.

Medicare, however, found that UMC was lax in warning patients about the psychological risks of transplants.

Specifically, the March Medicare inspection found that in each of 15 cases reviewed, UMC failed to document that patients were informed of the psychosocial tisks of a transplant.

The inspection also said that in all seven cases reviewed there was no participation by a social worker. The social worker told Medicare inspectors that she did not know she should be involved in a patient's care through the transplant and discharge phases of the procedure.

UMC's transplant program had a host of other problems that were identified by Medicare during the March inspection. Among the dozens of deficiencies and four overarching failures to meet conditions of participation in Medicare:

- UMC failed to follow its established criteria to determine the suitability of living donors. One donor had a body mass index of 32, which is considered obese,
   and there is no documentation that explains the rationale for UMC deviating from its established standards.
- UMC failed to complete the verification of compatibility of donor and recipient blood type during organ recovery, after an organ's arrival at the center and before transplantation in all four living donor medical records and all seven recipient records reviewed.
- UMC failed to develop, implement and maintain a quality assessment/performance improvement program to evaluate its performance.

UMC became the only transplant option in the state after Sunrise Hospital & Medical Center shuttered its program in May. The Sunrise program was also about to have its Medicare funding taken away because of too many patient deaths, records show. But rather than correct its problems, Sunrise decided to merge with UMC.

Both UMC and Sumise blamed their poor performance on the low number of patients who receive transplants, depriving the hospitals of sufficient revenue to develop the program. Still, UMC was generating income from the program. From June 2007 to June 2008, the program made a net profit of \$202,000.

Officials of both hospitals also argued that because their programs had so few putients, even one death dropped their percentages below what's required for Medicare compliance.

These low-number arguments belie the fact that many like-sized or smaller programs in other states have high patient survival rates. For example, transplant programs in New Mexico and North and South Dakota are similar in volume to UMC but much better in terms of performance.

A Las Vegas performance improvement expert, who would speak only on the condition of that his name not be published, said it appears that UMC mismanaged the kidney transplant program. The hospital knew the rules for being reimbursed by Medicare, but it failed to live up to them, he said.

"I'm not really sure Medicare is being too hard on UMC," the expert said. "They're just holding their feet to the fire."

By Monday, UMC will have to improve its susgical capabilities, prove it has an effective quality assessment/performance improvement program and ensure there will be proper administration of the program. UMC will then be required to pass an unamounced inspection in the coming months to regain its certification.

The temporary reprieve is a victory for the hospital officials, congressional delegates and transplant advocates who lobbied against Medicare's plan to take away the hospital's funding. Closing UMC's kidney transplant program would mean the 200 people on the waiting list would have to travel hundreds of miles for transplant.

"It is critical that individuals who need an organ transplant get good quality of care," said Thomas Hamilton, director of Medicare's survey and certification group. "If that means that individuals need to travel a little bit further to get good quality of care, then we think that is a trade-off that should be made."

The political appeals for leniency included a lefter and personal conversations with the head of Medicare by Rep. Shelly Berkiey, D-Las Vegas, and Republican Reps. Jon Porter and Dean Helter.

Berkley's husband, Dr. Larry Lehmer, is a partner at Kidney Specialists of Southern Nevada, which has a \$588,200 annual contract to provide nephrology services at UMC, which includes the kidney transplant program. UMC officials said Lehmer handles the business aspects of the contract, not the medical services.

Officials from Citizens for Responsibility and Ethics in Washington said they do not consider Berkley's advocacy for UMC a conflict of interest because Lehmer does not have a direct financial tie to Medicare.

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## **EXHIBIT 63**

From:

Hamilton, Thomas E. (CMS/CMSO)

To:

Johnson, Donald N. (CMS/QL); Ransom, Robert S. (CMS/QA)

Cc:

Stoss, Douglas (CMS/OA); Chadwick, Alpheus K. (CMS/OL); Smith, Amelia I. (CMS/OL)

Subject:

RE: transplant center

Date: Attachments: Thursday, October 30, 2008 6:54:00 PM CMS Press Release-UMC-NV-draft-103008.doc

Note that I learned from a reporter today that Congresswoman Berkley is married to a physician (nephrologist) that has a personal financial interest in the success of UMC – so I was glad to be able to say that I'd had no conversation with her. So – perhaps you might want to suggest to one of the other congressional contacts that we want to inform, that they could let Rep Berkley know, so there is no contact and no appearance of any pressure or reacting to pressure.

Also -1 suggested to Herb and OEA that we do a press statement to get our story out. Attached is a starter kit. It is in the hands of Don McLeod.

Thomas E. Hamilton, Director Survey & Certification Group Centers for Medicare & Medicald Services

From: Johnson, Donald N. (CMS/OL)

Sent: Thursday, October 30, 2008 6:40 PM

To: Ransom, Robert S. (CMS/OA); Hamilton, Thomas E. (CMS/CMSO)

Cc: Stoss, Douglas (CMS/OA); Chadwick, Alpheus K. (CMS/OL); Smith, Amelia I. (CMS/OL)

Subject: RE: transplant center

Robert - OL will work with OA to do that. The outreach to Congresswoman Berkley will occur only after you let us know Kerry has successfully contacted Mr. Porter. Thanks.

From: Ransom, Robert S. (CMS/OA)

Sent: Thursday, October 30, 2008 6:34 PM

To: Hamilton, Thomas E. (CMS/CMSO); Johnson, Donald N. (CMS/OL)

Cc: Stoss, Douglas (CMS/OA) Subject: transplant center

Kerry wanted me to inform you that either he or someone needs to contact Congresswoman Berkley (After Congressman Porter is first notified) when a deal is struck in regards to the transplant center.

Thanks,

Robert Ransom

Robert S. Ransom
Centers for Medicare & Medicaid Services
U.S. Department of Health & Human Services
(202) 690-

@cms.hhs.gov

## **EXHIBIT 64**

## reviewjournal.com



# In hindsight, Berkley says she should have disclosed

BY STEVE TETREAULT
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Posted: Sep. 14, 2011 | 6:48 p.m.

WASHINGTON -- Rep. Shelley Berkley said Wednesday she should have more fully disclosed that her husband's medical practice held a contract for kidney services at University Medical Center when she used her influence with federal authorities to help rescue the threatened program.

Berkley, D-Nev., said she thought it was well-known that Dr. Larry Lehrner was involved with the Clark County public hospital, but she now would take further actions to publicize the connection.

Berkley said she saw at the time there could be a perceived conflict of interest but decided to act anyway. She insisted her actions on behalf of the kidney transplant program were motivated by its patients and not her husband's business.

"This was a tough decision for me, whether or not I would weigh in," Berkley said. "I recognized that it may not look great, but I would not have been able to live with myself" by not acting.

"What would I do differently? I thought everybody knew that Dr. Larry was a doctor. I have not exactly been shy about that," said Berkley, referring to her husband by his nickname. "I would make sure it was crystal clear, and I would make sure I would work doubly hard to ensure that everybody I was talking to knew the situation. I thought they did."

Berkley's remarks in a brief interview were her first comments after the publication of a story in the New York Times last week that reported actions she took as a House member aligned with the business interests of Lehrner, who runs a chain of dialysis clinics and kidney care centers in Nevada.

The seven-term lawmaker, who is running for the U.S. Senate, has received more than \$140,000 in campaign donations from kidney doctors, companies and

lobbyists, the newspaper reported. At least \$7,000 came from a political action committee representing renal physicians that her husband helped organize.

Berkley has co-sponsored at least five bills to expand federal assistance for kidney care and signed letters in 2008 and this year against cuts in Medicare reimbursements for dialysis providers, a cause sought by the doctors.

Berkley said she has co-sponsored more than 95 bills related to medical issues. She said she lobbied against changing reimbursements because it would have increased patient co-pays.

Berkley maintained Wednesday that patients "are always what is paramount in my mind." She said there have been instances where her health care advocacy has not been in sync with her husband. She said the federal veterans hospital she has championed and that is set to open within a year "will more than likely take business away from my husband" and that was "never relevant" to her work on the issue.

UMC officials sought help from Berkley and from then-Rep. Jon Porter, R-Nev., when its kidney transplant center -- the only one in the state -- was threatened with decertification in 2008. Lehrner's practice, Kidney Specialists of Southern Nevada, served as medical director of the kidney care unit.

Berkley, Porter and then-Rep. Dean Heller, R-Nev., signed a letter to the Centers for Medicare and Medicaid Services in support of the hospital's appeal. Berkley and Porter met further with federal officials to help broker an agreement that salvaged the hospital's certification.

"I recognized no matter what I chose to do, somebody would have thought it was not the right thing," Berkley said . "I recognize that it may not look great, but I recognized that the kidney transplant center was worth fighting for."

Kidney Specialists of Southern Nevada was the sole bidder when the UMC contract came up for renewal last year. Its current contract is worth \$738,000.

Berkley said she would continue to accept campaign donations from doctors groups, including nephrologists like her husband, saying contributions "have absolutely no bearing on my votes or my actions in any way or sense."

No organization or individual has publicly requested that the House Ethics Committee investigate allegations of conflict on Berkley. She said she has not been contacted by the panel.

Berkley stopped short of saying she would welcome scrutiny by the Ethics Committee to clear the matter. "That's up to Ethics (Committee)," she said. "My

life is pretty much an open book. That is not a decision I would make."

# Contact Stephens Washington Bureau Chief Steve Tetreault at @stephensmedia.com or 202-783-

#### Find this article at:

http://www.lvrj.com/news/in-hindsight-berkley-says-she-should-have-disclosed-129850673.html

Check the box to include the list of links referenced in the article.

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