UNITED STATES DISTRICT COURT WESTERN DISTRICT OF MICHIGAN

EVERETT HADIX, et al,

Plaintiffs,

v.

Case No. 4:92-CV-110

HONORABLE ROBERT J JONKER

PATRICIA CARUSO, et al,

Defendants.

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Corrected Sixth Report of the Independent Medical Monitor Dialysis Services for Prisoners at Ryan Correctional Facility

Robert L. Cohen, MD, Associate Monitor September 5, 2008

Corrected Sixth Report of the Office of the Independent Medical Monitor Dialysis Services for *Hadix* prisoners at Ryan Correctional Facility

The Court approved the Defendants' transfer plan (Dkt. No. 2465) June 5, 2007:

"...(granting) approval of the transfer because the transfer is not likely to endanger prisoners beyond the very significant dangers and failures of care present at the *Hadix* facilities. In saying so, the Court is not endorsing either the level of care at the *Hadix* facilities or the expected level of care at the Ryan Correctional Facility (RRF). The record specifies rather clearly that there are serious deprivations of medical care affecting dialysis patients, including, but not limited to, a failure by Defendants to provide timely chronic care, a failure to provide timely medication renewal of chronic medications, and a failure by Defendants to provide timely access to specialty care, among other problems. These problems, as recognized by the parties, are likely to continue upon transfer. ... The exercise of jurisdiction over the Ryan Facility and medical monitoring shall cease as soon as compliance with Eight Amendment standards is demonstrated by Defendants."

In the OIMM's first report on dialysis, Dr. Eric Gibney, OIMMs' consultant nephrologist, concluded "There is reason to be concerned about the health and safety of dialysis patients at Ryan Correctional." (Dkt. No. 2726)

This report will provide the Court with recent observation and objective data regarding the actual operation of the Michigan Department of Corrections (MDOC) dialysis program at RRF. The report will demonstrate continued critical failures with dialysis treatment, which shorten the life span and decrease the quality of life of persons with end stage renal disease (ESRD). These problems are remediable. They include:

- 1. Failure to maintain policies, procedures, a unit-specific infection control manual, and emergency guidelines on the dialysis unit.
- 2. Failure to provide adequate dialysis care:
 - a. Ordered thrice-weekly dialysis sessions are not being routinely provided to patients.
 - b. Documentation is of poor quality, inconsistent and of questionable veracity.
 - c. Inadequate dialysis repeatedly demonstrated by decreased levels of the serum Urea Reduction Ratio (URR).
 - d. Substantially elevated parathyroid hormone levels, which adversely affect bone and mineral metabolism.
 - e. Lack of advance care planning for end-of-life decisions.
- 3. Failure to correct a specialty care referral system:
 - a. Failure to provide accurate specialty care data in Defendants' Monthly Court Reports.
 - b. Substantial, continuing, and unacceptable delay of prisoner access to necessary consultation.
- 4. Failure to comply with the Court-approved dialysis transfer plan:
 - a. Staffing requirements
 - b. Permanent dialysis unit construction.

- 5. Failure to provide adequate and timely emergency care to critically ill patients.
- 6. Failure to evaluate prisoners for transplantation eligibility despite the fact that transplantation is the recommended treatment for ESRD, is cost efficient, and decreases mortality and morbidity from this disease.

1. Policies and Procedures and Standing Orders

Policies and Procedures

Every dialysis unit needs a set of policies and procedures outlining emergency care, water quality testing, dialysis medication administration, and infection control. Dr. Deon Middlebrook is the medical director of RRF's dialysis unit and the owner of Kidney Replacement Services (KRS). Dr. Middlebrook stated in his January 30, 2008 response to Dr. Gibney's report that this information was available in binders located at the dialysis unit. The OIMM staff asked the dialysis unit nurse to produce these binders on January 31, May 16, July 15, July 24, and August 15. Despite lengthy searches on five separate occasions, the putative binders were never found.

During our August 15 visit, another nurse who works in the dialysis unit only one shift per week was orienting a nurse on her first day. The nurse manager responsible for the orientation was not present in the facility, and written orientation material was not available for the new hire. This cavalier approach to training is dangerous for the functioning of the unit and for the complex medical care required for these fragile patients.

Standing Orders

During its review of dialysis, the OIMM noted that physician dialysis orders were not present in the medical record. These orders must include the length of treatment, dialyzer size, heparin dose and other information for the dialysis technician and nurse to allow them to administer safe dialysis patient care. Dialysis care is reviewed monthly by the nephrologist and, if necessary, adjustments are ordered.

On August 15, 2008, the Associate Monitor, Dr. Robert Cohen, asked the nurses to show him the standing orders used to develop the treatment plan for dialysis. The nurses could not locate standing orders in the chart. They said that they use the treatment plan on the previous dialysis flow sheet. This unsafe practice must cease immediately. Under this system, if a nurse incorrectly writes a treatment plan on a flow sheet, that error is continued indefinitely, placing the patient at great risk.

We audited all of the dialysis charts for standing orders signed and dated by a physician within the previous 12 months. Forty-two charts were reviewed on August 15. Only one chart had physician orders signed and dated in 2007. Ten orders were dated 2004, one was dated 2005, and twenty-eight charts had no orders.

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¹ Attachment 11, Spreadsheet 1. Patient Code Status, filed under seal.

2. Dialysis Care

This Court required Defendants to enroll in Michigan's ESRD Network 11 and participate in its quality assurance program (Dkt. No. 2465). Network 11 is one of the Network Coordinating Councils established by federal statute² to "ensure quality of care, encourage kidney transplantation and home dialysis, and increase program accountability." Defendants have consistently sought to minimize their participation in Network 11 and have refused to collect data that would identify serious failures in the dialysis program. This is not a trivial matter. Inadequate dialysis results in substantial, but preventable, increases in morbidity and mortality.

The OIMM monitored RRF dialysis using quality indices recommended by the ESRD Network 11 Medical Review Committee in February 2008.³ In addition, the provision of dialysis sessions, the water filtration system, and patient deaths were reviewed. The following quality indices were monitored:

- Provision of dialysis three times a week to each patient
- Dialysis adequacy measured by Urea Reduction Ratios (URR) serum levels (Network 11)
- Bone metabolism, serum phosphorus, and calcium levels (Network 11)
- Anemia management measured by hemoglobin levels (Network 11)
- Review of advance care planning (Network 11)
- Referral of patients for evaluation for transplantation eligibility (Network 11)

2.a. Provision of ordered dialysis sessions

The OIMM staff determined the number of dialysis sessions provided by reviewing the dialysis flow sheets for one week of each month from February through June 2008.⁴ With one exception, all ESRD patients in the MDOC dialysis program at RRF were scheduled for dialysis three times a week. A documented patient refusal or a hospital admission were counted as "session provided" in our analysis. If a patient missed a session because of another appointment or other reason, the patient should have received a "make-up" dialysis session the following day.

The low percentage of patients receiving dialysis three times a week was extremely disturbing and unexpected. Therefore, OIMM staff made an on-site visit to RRF. We looked for additional flow sheets that had not been provided to us and talked with dialysis staff to identify possible reasons for the unusually low number of dialysis sessions provided. Finally, we requested that MDOC staff determine if there were any additional against-medical-advice forms (AMAs) or any other reason that the flow sheets could not be located.

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² Section 2991 of Public Law 92-603 Rev. 8, Issued 12-07-07; Effective: 12-03-07; Implementation: 01-07-08.

³ Attachment 1. ESRD Network 11 Recommended Treatment Goals, February 2008.

⁴ Attachment 11, Spreadsheet 2, Patient Dialysis Days, filed under seal..

Dialysis Services for *Hadix* Prisoners at Ryan Correctional Facility

Page 4

The OIMM hosted a problem-solving session with the Parties on July 10, 2008 that reviewed these findings. In July 2008, Defendants reported that they had provided all dialysis patients thrice-weekly sessions. These results are summarized in Table 1.

<u>Table 1 Percent of patients receiving dialysis three times a week</u> Goal: 95% of the patients will have thrice-weekly dialysis sessions.

	Feb 2008	Mar 2008	Apr 2008	May 2008	June 2008	July 2008
Number patients reviewed	62	64	65	64	63	62
Number with dialysis three times/week	54	43	61	62	52	62
Percent with dialysis three times/week	87.1	67.2	93.8	96.8	82.5	100

Several possible explanations exist for the large number of patients not receiving three dialysis sessions per week. There could be insufficient dialysis stations and/or insufficient staff. The April 2008 dialysis forum meeting minutes documented that when a nurse is late to work or the bicarbonate solution is not mixed the patient's dialysis treatment is shortened because the unit must close at 6:30 p.m. in order to decrease costs. In addition, there is poor coordination of off-site specialty care appointments with scheduled dialysis. Patients miss dialysis if they are in the emergency room and sent back without admission because they are not rescheduled to receive dialysis later that day or the next day.

Finally, there has been inadequate attention to legitimate and predictable patient complaints of pain and discomforts of dialysis that cause patients to discontinue their sessions. Meeting minutes from April 2008 state: "Topical Lidocaine (a numbing medication) is normally used to decrease the pain of needle insertion and is not used in the dialysis unit because it is a nonformulated item and patients can get a "high." Topical lidocaine will not induce a feeling of euphoria. Similarly, diphenhydramine, an antihistamine, has not been available at the unit to treat the itching that often accompanies dialysis although this is a very common treatable complication of the procedure.

OIMM staff's review of specialty care appointments demonstrated that these scheduling conflicts adversely affected dialysis sessions. For example, Patient A was hospitalized during his scheduled dialysis session on March 3, 2008. The hospital discharged him on March 4, 2008 with a note entered into SERAPIS that he would be due for his next dialysis session on March 5, 2008. There is no documentation that Patient A received dialysis on March 5 and no explanation in the medical record for the missed session. Patient A waited three days between dialysis sessions. He resumed his usual schedule on March 7, 2008, missing a dialysis session that week. Subsequently, on March 24, Patient A was hospitalized for severe acidosis, fluid overload, uncontrolled hypertension, and pulmonary edema, all symptoms of missed dialysis. The

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⁵ Attachment 2. Dialysis Patient Forum Meeting Minutes, 4/21/08

⁶ ibid

physician who evaluated him at the Detroit Receiving Hospital Emergency Room noted that Patient A had missed a dialysis session, which probably contributed to his hospitalization.

Patient B entered the Reception and Guidance Center (RGC) on February 6, 2008 after a parole violation. On intake, it was noted that he required dialysis. He was sent to the emergency room at Duane Waters Health Center (DWHC). The nurse practitioner in the ER completed a history and physical documenting a graft in his left arm and noting that he was due for dialysis that day. Although DWHC notified Dr. Middlebrook and the RRF nursing supervisor, the patient did not receive dialysis until February 8, two days later.

2.b. Medical Record Documentation

The following are examples of discrepancies in the material the Defendants provided to the OIMM. We cannot understand how these discrepancies occurred in the normal course of clinical activity. We asked Defendants to provide an explanation at the July 10th meeting and they have not responded.

- Patient C has two dialysis flow sheets for March 3, 2008. According to these documents, he received dialysis at station 5 from 1045 to 1400 and on machine 9 from 1025 to 1330.
- Patient D also has two dialysis flow sheets for March 3, 2008. According to these documents, he received dialysis at station 4 from 0944 to 1245 and from 0940 to 1315 at the same station. However, his vital signs and other data are significantly different between the flow sheets.

The OIMM also found documents stating that dialysis was given when it should not have been scheduled and a document stating that dialysis was not given when a flow sheet stated that dialysis was provided.

- A SERAPIS note for Patient E explains that a social worker counseled him about why he refused dialysis on April 8, 2008. However, Patient E also has a dialysis flow sheet for April 8 that documents he received dialysis that day.
- Patient F has a dialysis flow sheet for February 9 and an AMA sheet stating that he refused dialysis that day. Although the date appears altered on the flow sheet, it documented that he received dialysis for almost 4 hours, removing 3979 ml of fluid.

The OIMM found multiple dialysis flow sheet records with incorrect patient identifiers, including incorrect names or prisoner numbers:

- On his April 9, 2008 flow sheet, Patient G has a completely wrong patient identifier number. This makes it difficult to determine whether Patient G received dialysis or prisoner #116272 listed on the flow sheet.
- On May 10, 2008, Patient H has two identical flow sheets with the exception of his patient identifier number. If the original flow sheet was copied, then the identifier numbers should be identical. These sheets appear as if the patient had two separate dialysis flow sheets for the same day at the same time.

Corrected Sixth Report of the OIMM Dialysis Services for *Hadix* Prisoners at Ryan Correctional Facility September 5, 2008 Page 6

In the preparation of this report, a list of possible missed dialysis days was submitted to Alex Glover, the KRS dialysis unit manager, requesting all "missing" dialysis records or, alternatively, an explanation for the missed sessions. Mr. Glover's response stated that dialysis was provided Patient I on March 4, 2008, and to Patients N, O, Q, T, U, V, and W on March 6, 2008. No contemporaneous records were provided by Mr. Glover. Mr. Glover stated that staff drew dialysis labs those days and, therefore, the dialysis sessions must have occurred.⁷ Our review of SERAPIS revealed that these dialysis labs were ordered that day but were not collected. We could not locate any dialysis flow sheet, AMA form, dialysis lab result or SERAPIS record confirming that dialysis had occurred.

Mr. Glover stated that Patient I received dialysis on March 4, 2008. However, they received dialysis March 3, 2008 and, therefore, would not have needed it the following day. Further, there is no documentation that Patient I received dialysis on March 5, 2008 when it was due; therefore he missed a dialysis session.

Mr. Glover also stated that Patient J did not receive dialysis on March 6, 2008 because he was in the hospital. A SERAPIS review indicates that Patient J returned to the facility on March 6, 2008 at 8:00 a.m. and would have been available for dialysis that day.

It is noteworthy that July records, reviewed by the OIMM after the July 10th meeting, were in better condition than prior months, with greater legibility and no discrepancies. It should also be noted that the OIMM had to request the July records on two separate occasions and was informed that the delay was caused by Defendants' need to "review" the dialysis run sheets before they provided them to us.8 The OIMM informed Defendants that they could review the original records, but should immediately provide us with copies. The OIMM remains concerned that the MDOC compliance monitor staff refused to provide us with contemporaneous records on request, and specifically indicated that they were involved with the "preparation" of records for submission to our office. These dialysis run sheet records are created at the time of dialysis, and we can think of no legitimate reason for MDOC's refusal to provide them to us when asked.

Quality Indices in Dialysis Care

"The mission of the ESRD Network 11 is to assess and improve the quality of care provided to individuals with end-stage renal disease. In keeping with this mission statement, the Medical Review Committee recommended nine treatment goals." The OIMM monitored 63 patients for five of these quality indices: hemodialysis adequacy, anemia management, bone and mineral metabolism, advance care planning, and transplant referral. The Network 11 goals are designed to move dialysis centers through a process of continuous quality improvement. This report provides baseline data and demonstrates the areas where improvement can be achieved. Failure to make successful attempts to improve dialysis quality indices directly compromises the lives of those enrolled in the dialysis program.

⁷ Attachment 3. Memo from Alex Glover to Leslie Jones, June 27, 2008.

⁸ Attachment 4. Email Info Request between Leslie Jones and Gail Bernth, July 27, 2008.

⁹ Attachment 1. ESRD Network 11 Recommended Treatment Goals, February 2008

Page 7

<u>Dialysis Services for Hadix Prisoners at Ryan Correctional Facility</u>

2.c. Hemodialysis Adequacy

The urea reduction ratio (URR) is a standard measurement used to determine the effectiveness of the dialysis session. Dialysis removes urea, a waste product normally removed by the kidneys. The URR is determined by measuring urea in the blood before and after dialysis. Low URR values for patients receiving dialysis are associated with a shorter life span. Low URR values can be the result of shortened dialysis sessions, blood flow problems due to inadequate vascular access (decreased blood flow through the patient's graft or fistula), and inadequate artificial kidneys (determined by the size of the filter prescribed by the nephrologist). The URR can be improved by lengthening a patient's dialysis session, increasing the blood flow through a patient's dialysis access site, or using a larger artificial kidney.

The treatment goal established by the ESRD Network 11 is for 80 percent of the dialysis patients receiving dialysis three times per week to have a mean URR of at least 65 percent. The mean value refers to the average of the first monthly value for each of three months.

The OIMM reviewed URR values for the months March through July 2008, calculating the mean based on three most recent measured URR's. Sixty-one patient records were reviewed. Only 65.6 percent of the patients met the goal of having an average URR over 65 percent. Nationally, in 2005, 88 percent of all Medicare recipients over 18 years of age had a URR over 65 percent.

Table 2. Urea Reduction Ratios

	Network Goal	
Number of patients reviewed		61
Number of patients with URR > 65%		40
Percentage of patients meeting goal	80%	65.6%

2.d. Bone and Mineral Metabolism

Parathyroid hormone (PTH) is a major hormone involved in the regulation of calcium and phosphate metabolism. Patients requiring dialysis are prone to developing elevated PTH and phosphorus levels in the blood. As the serum phosphorus level increases, it pulls calcium from the bones causing osteoporosis and calcium deposits in blood vessels, lungs, eyes, and heart. Maintaining PTH, phosphorus and calcium control is essential for minimizing morbidity and mortality among ESRD patients.

To promote optimum bone and mineral metabolism, the ESRD Network 11 established the following treatment goals that:

• Eighty percent of the patients have a mean Intact PTH between 150 and 300. The mean value refers to the average of the first monthly value for each of three months.

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¹⁰ Attachment 11, Spreadsheet 3. Patient URR Values and Means, filed under seal

¹¹ http://www.ahrq.gov/qual/nhqr07/Chap2a.htm,figure 2.12.

<u>Dialysis Services for Hadix Prisoners at Ryan Correctional Facility</u>

Page 8

- Seventy percent of dialysis patient have a mean serum phosphorous level less than 5.5 mg/dl and less than 10 percent of dialysis patients have a mean serum phosphorous greater than 8mg/dl.
- Eighty percent of dialysis patients have a mean corrected serum calcium concentration less than 10.2 mg/dl.

To determine whether RRF's dialysis patients have met this goal, the OIMM reviewed 63 patient records for PTH, phosphorus and calcium values in SERAPIS for the months of February through July 2008. A mean, using the three most recent months of laboratory results, was calculated for PTH, phosphorus and calcium.

Parathyroid Hormone (PTH)

Only 27 percent of the patients met the goal of PTH between 150-300. There are medical and surgical treatments for uncontrolled PTH levels in persons with ESRD which are not being appropriately used at RRF.

Table 3. Parathyroid Hormone

	Network Goal	
Number of patients reviewed		63
Number of patients with normal PTH		4
values		
(not used in calculating percent meeting		
goal)		
Number of patients with PTH 150-300		16
Percentage of patients meeting goal	80%	27.1% (16/59)

Phosphorus and Calcium

Sixty-five percent of the patients met the goal of having a phosphorus level less than 5.5mg/dl. Ninety-seven percent met the serum calcium goal. 14

¹² Attachment 11, Spreadsheet 4, Patient PTH Values and Means, filed under seal.

¹³ Attachment 11, Spreadsheet 5. Patient Phosphorus Values and Means, filed under seal.

¹⁴ Attachment 11, Spreadsheet 6, Patient Calcium Values and means, filed under seal.

Page 9

Dialysis Services for *Hadix* Prisoners at Ryan Correctional Facility

Table 4. Serum Phosphorus and Calcium Levels

	Network Goal	
Number of patients reviewed		63
Number of patients with a mean		41
Serum Phosphorus <5.5		
Number of patients with a mean		3
Serum Phosphorus >8		
Percent of patients meeting phosphorus goal	70%	65%
Number of patients with a mean		61
Serum Calcium < 10.2		
Percent of patients meeting calcium goal	80%	96.8%

Nephrologists have tools to control serum calcium and phosphorus. OIMM staff has noticed improvement with medication refills, keep-on-person medication dispensing, and overall tracking of medications administered at RRF. It is also worth noting that the medications lanthanum carbonate and calcium acetate, which are used to lower phosphate levels, no longer require RMO approval and that patients are obtaining these medications in a timely manner. KRS nephrologists have also sought to have additional ESRD specific medications placed on formulary status to prevent delays in administration of these important drugs.

Anemia Management

Healthy kidneys produce a hormone called erythropoietin (EPO) that stimulates bone marrow to produce the proper number of red blood cells needed to carry oxygen to vital organs. Patients on dialysis are especially prone to developing anemia. The ESRD Network 11 has established a goal that more than 80 percent of dialysis patients have a mean hemoglobin level greater than 11gm%. The mean value refers to the average of the first monthly value for each of three months. Dialysis patients' three most recent months of hemoglobin values were averaged together using lab results from the months of March through July 2008. Sixty-one patients were reviewed, and 77 percent of the patients met the goal of having an average hemoglobin level greater than 11gm%.

Table 5. Hemoglobin.

	Network Goal	
Number of patients reviewed		61
Number of patients with Hgb > 11		47
Percentage of patients meeting goal	80%	77%

¹⁵ Attachment 11, Spreadsheet 7. Patient Hemoglobin Values and Means, filed under seal.

Corrected Sixth Report of the OIMM
Dialysis Services for *Hadix* Prisoners at Ryan Correctional Facility

September 5, 2008 Page 10

Advance Care Planning

Patients with ESRD usually have multiple severe chronic illnesses and face a lifetime of spending 12-15 hours a week attached to a dialysis machine. They take multiple medications and suffer multiple, often painful side effects. They are encouraged to eat bland foods and avoid foods they enjoy. They have to restrict their fluid intake. They must undergo frequent, often painful surgical procedures to maintain a viable venous access site. They have shortened life spans. Understandably, many suffer from significant depression. They are at very high risk for sudden, acute, life-threatening medical crises, particularly strokes and heart attacks.

Because of their fragile medical conditions, these patients need advance care planning discussions to make decisions regarding the kind of end-of-life care they wish to receive. The ESRD Network 11 has established a goal that greater than 80 percent of dialysis patients have advance care planning discussion conducted within six months of initiating dialysis and that these issues are reviewed on an annual basis.

During the OIMM's August 15, 2008 tour of the dialysis unit, there was no documentation by KRS nursing or medical staff of any advance care planning discussions. There were no chart indicators stating the patients' preferences. Staff interviews with the nurses indicated that every patient would have CPR initiated because staff did not know which patients did not want to be resuscitated. The OIMM asked MDOC health administration staff to locate advance directives for the ESRD patients at the RRF medical clinic. The medical records clerk was able to locate only four patients who had advance directives, after looking through charts for 90 minutes. Charts were not labeled with DNR stickers, and the nurses stated they did not know where to find the DNR status in the patients' charts.

The OIMM urged the MDOC medical staff to undertake a systematic approach to help the ESRD patients at RRF establish their preferences for advance health care planning. Whenever possible, family members and identified medical proxies should be involved in these discussions.

Monthly Nephrology Meetings

The OIMM has noted that under the leadership of Dr. Haresh Pandya, MDOC Regional Medical Director, the monthly nephrology meetings required by the Court have been occurring and have begun to address some of the issues raised in this report. We support Dr. Pandya's efforts and urge him to utilize the structure and resources of Network 11 as the basis of his quality audits.

3. Specialty Care Services

The Second Report of the Office of the Independent Medical Monitor to the Court reviewed problems with access to specialty care services at the *Hadix* facilities (Dkt. No. 2608). The

 $^{\rm 16}$ Attachment 11, Spreadsheet 1. Patient Code Status, filed under seal.

report provided a detailed background of the Court's intervention in assuring timely access to specialty care and a description of how the specialty care system and the Defendants' monthly reporting works.¹⁷ At that time the OIMM demonstrated that Defendants were consistently providing incorrect information to the Court. This report, unfortunately, demonstrates that Defendants continue to provide incorrect data. The Court cannot rely on this data, nor can Defendants.

The Associate Monitor requested that Defendants provide specialty care information for RRF on multiple occasions (November 29, 2007, January 15, 2008, and February 13, 2008). Although these reporting requirements had been well established and the Court had specifically expressed concern over access of these prisoners to specialty care, Defendants delayed providing this information to the Court until March 2008.

These monthly status reports have demonstrated that the specialty care system at RRF is dysfunctional and is failing to provide necessary specialty care to these patients. In Defendants' July report on specialty care at RRF (Dkt. No. 2820), which covered data for June 2008, appointments were completed in their requested timeframes only 36 percent of the time. In Defendants' most recent report, which covered data for July, this reported percentage inexplicably shot up to 81 percent (Dkt. No. 2837). Although this report was submitted to the Court on September 5, we still have not received the underlying patient level information supporting this claim. Our analysis of the specialty care program will be limited to the five months for which we have received data: February through June 2008.

Table 6. -- RRF Patients Specialty Appointments Seen Within timeframe ¹⁸

2008	Feb.	March	April	May	June
	38%	45%	63%	54%	36%

For this report, the OIMM reviewed the accuracy of the Defendants' monthly reports through June, the functioning of the specialty care system, and the medical consequences of the Defendants' poor performance. As its findings will demonstrate, systemic problems ensure that appointments will continue to be delayed. These consultation delays have predictable, serious and painful consequences.

3.a. Statistical Concerns Regarding Defendants' Specialty Care Reports

The OIMM review uncovered many problems with the statistical accuracy of the Defendants' reports for the prisoners receiving dialysis at RRF. The two main problems are incorrect appointment information and underreporting.

Incorrect appointment information addresses the inaccuracy of the actual data submitted by the Defendants to the Court. Comparison of the spreadsheets to the available information in

¹⁷ Second Report of the OIMM (Dkt. No. 2608), page 1-6.

¹⁸ Defendants' Monthly Reports Regarding Specialty Care, (Dkt. Nos. 2749, 2764, 2785, 2810, 2822).

September 5, 2008

Page 12

SERAPIS, the OIMM found that the RRF reports remain largely unreliable, although they have improved over the past five months. Frequently, the date consultations are requested, the timeframes requested, and the dates of completion are incorrect on the spreadsheets. Some of the errors appear to be simple data-entry errors, but others suggest that these appointments are haphazardly tracked.

The following are examples of types of errors found that affect the statistical findings:

- An off-site gastrointestinal appointment for Patient K was incorrectly counted as having been completed February 29. There is no indication in SERAPIS that this visit, which was for a colonoscopy to precede a hernia repair, was completed. During a visit to RRF on July 16, OIMM staff reviewed Patient K's paper medical file and did not find this consultation either. The OIMM also asked the patient whether he received a colonoscopy in February, and he said he did not. The colonoscopy finally occurred in early August, six months after it was ordered, delaying surgery for a painful hernia.
- A vascular surgery appointment for Patient L was incorrectly listed once as a missed appointment on February 19 (when the patient refused the appointment) and listed a second time as a completed visit on February 19. There is no mention in SERAPIS that the patient completed or refused the appointment on February 19. It is very unlikely that both happened.
- An off-site gastrointestinal appointment for Patient M was incorrectly counted as "completed" on June 9, 2008. According to SERAPIS, the patient went to the colonoscopy appointment, but did not complete the appointment because his preparation was inadequate. The appointment was rescheduled for June 23 but was again cancelled because of inadequate preparation. Patient M finally received a colonoscopy August 11.
- A podiatry appointment completed June 6 for Patient N was inexplicably counted twice.
- A podiatry appointment for Patient O was incorrectly listed as having been completed on June 20. According to SERAPIS, the patient was not seen on June 20, and his appointment needed to be rescheduled. The podiatrist saw the patient on July 25.

A few clerical errors are expected. However, incorrectly stating that an appointment happened when it did not is not a clerical error and greatly skews the overall calculations. More importantly, it places the patient at risk for not being rescheduled and/or having the procedure completed. For tracking purposes and because appointments are rescheduled, the scheduler must know the outcome of all scheduled appointments.

The second major problem noticed by the OIMM was that data was underreported in the Defendants' monthly reports: consultations that were completed but never included in the Defendants' reports. In an attempt to quantify how many appointments are underreported, the OIMM compared the Defendants' June data to the specialty care appointment lists that the RRF scheduler provided to transportation and the dialysis unit on a weekly basis in June. Ideally, every appointment on the scheduler's list should be accounted for in the Defendants' reports as a completed appointment, missed appointment, or refused appointment. Additionally, because the scheduler writes in other urgent appointments, Defendants' spreadsheets would contain more completed and missed appointments than the scheduler's list. One would not expect that any appointments could be found in SERAPIS that are not accounted for in either of these records.

Dialysis Services for *Hadix* Prisoners at Ryan Correctional Facility

Page 13

However, the OIMM found wide discrepancies between these records. When Defendants' reports did not include accurate information about an appointment, the OIMM only looked at whether both records accounted for an appointment. For example, in the earlier example for Patient M, the scheduler's list includes the June 9 appointment and the rescheduled June 23 appointment. The Defendants' report includes only the June 9 appointment as completed, even though the procedure was not performed because of poor preparation. The June 9 appointment was counted as an appointment included on both documents; the June 23 appointment was counted as only being on the scheduler's list.

Table 7. Comparison: Defendants' Report, Scheduler's List, SERAPIS for June Appointments

	# of appts
# of appts on both the scheduler's list and Defendants' Court submission	26
# of appts only on the scheduler's list	17
# of appts only on the Defendants' Court submission	11
# of appts found only in SERAPIS	2

These findings are particularly helpful because they can be used to approximate how many specialty care appointments are completed each month and the prevalence of underreporting in the Defendants' reports.

Table 8. Estimated Underreporting in Defendants' June Report on Specialty Care

	# of appts
# of completed or missed appts included in Defs' June report ²⁰	36
Approximate # of completed or missed appts in June	56
Estimated percentage of appts included in Defs' June report	64.3%

Although the OIMM did not factor this into the analysis above, Defendants' reports also do not include the *Hadix* prisoners who receive dialysis at RRF but are temporarily housed at HVM for acute medical or psychiatric reasons. On July 15, five prisoners fell into this category. Logistically, Defendants should include these patients' specialty care appointments because the RRF scheduler will need to know what outstanding specialty care appointments these patients have when they return to RRF. These prisoners' specialty care appointments should be tracked in the Defendants' reports because they are *Hadix* prisoners.

Both of these problems — inaccurate data collection and underreporting — suggest that the Defendants' monthly specialty care reports are not being used to track specialty care consultations to their completion, identify systemic problems, and assure the delivery of

¹⁹ Attachment 13, RRF Scheduler's Appointment List, Defendants' Specialty Care Patients Seen and Comparison of Defendants' Reports and RRF Scheduler's List, June 2008, filed under seal.

²⁰ The podiatry appointment for Patient N counted twice in the Defendants' June report was only counted once for this purpose. Therefore, there were 35 completed appointments, and one missed appointment on Defendants' June report.

Corrected Sixth Report of the OIMM Dialysis Services for *Hadix* Prisoners at Ryan Correctional Facility

September 5, 2008 Page 14

specialty care services. Improving these reports' statistical accuracy is not just important because accurate reporting to the Court is required; it is important because it demonstrates whether the Defendants have a sustainable system in place that will assure ongoing necessary specialty care for members of the *Hadix* class.

3.b. Systemic Concerns Regarding Specialty Care

In addition to the statistical problems found in the Defendants' reports, the OIMM has several overall system concerns with regard to specialty care services. In particular, Defendants have not accurately estimated the amount of specialty care services that would be required by dialysis patients and the amount of support services necessary to provide the specialty care such as transportation and medical record keeping.

When the Defendants submitted to the Court their plan to transfer the dialysis unit at JMF to RRF, the Associate Monitor expressed concern about how the specialty care system at RRF would meet the needs of the dialysis patients. In response, the Defendants explained in their Fourth Supplement to the Dialysis Transfer Plan (Dkt. No. 2433) that once moved to Detroit, these prisoners would have new access to the more plentiful medical resources available in the Detroit and Ann Arbor areas as well as continued access to the Jackson area specialists. That supplement also reported that dialysis patients at JMF completed 78 specialty care appointments between January 2006 and May 2007, or approximately five appointments per month (Attachment A of Dkt. No. 2433-2). According to Defendant's monthly reports, the dialysis patients at RRF completed 229 specialty care appointments in the past six months, approximately 38 appointments per month.

On July 16, 2008, OIMM staff reviewed approximately one-third of the records waiting to be filed into patients' medical records, including 32 completed specialty care consultations for dialysis patients. One consultation dated back to February 21, 2008, and most dated back to May or June. The slow filing of records is not the fault of the medical records clerk. Rather, this is another symptom of the increased demand that the system at RRF is neither designed nor staffed to handle. The RRF specialty care scheduler explained to OIMM staff on July 16 that Defendants did not provide her a list of Detroit area specialists willing to accept prisoner patients. Accurately planning for the specialist care demands of RRF's dialysis patients is necessary and important for creating a system that can handle these demands. It was not apparent to the OIMM that any rational health planning process was involved in the decision to close JMF and to move the dialysis unit to RRF.

Sixteen months ago when Defendants announced that they were closing JMF, they said that closure was necessary in order to provide specialty care services that they could not provide in hospitals close to Jackson. They never provided any evidence to the Court that they had the capacity to provide specialty care for JMF patients at non-*Hadix* facilities. The specialty care crisis at RRF represents their failure to plan for the specialty care of the medically frail population of ESRD patients precipitously moved from JMF. The Court has every reason to be concerned that other patients transferred from JMF with complex medical problems are equally at risk of not receiving necessary care because the MDOC had never demonstrated the capacity or the interest to provide necessary and timely specialty care to its prisoner patients.

Additionally, the OIMM has noticed that Defendants' specialty care contractor, Correctional Medical Services (CMS), often delays approval of requests for specialty care appointments. In his January 25 report to the Court, Dr. Gibney noted this same problem and recommended that all consultations be reviewed by CMS and responded to within 24 to 48 hours.

Under the current procedure, when MSPs believe their patients need specialty care services, they submit requests to CMS. CMS must approve or deny those requests. The RRF scheduler told OIMM staff that she does not schedule appointments until she receives CMS approval via SERAPIS, largely because specialists will not schedule appointments unless they are sure CMS will pay them. In several cases, the OIMM has found specialty care requests in which CMS's slow response has caused significant delays:

- On March 18, Dr. Bahmini Sudhir, a KRS internist, requested an ophthalmology appointment to follow-up blurry vision possibly caused by herpes simplex keratitis, a painful condition, for Patient P, asking that the appointment be completed within two weeks. CMS did not respond until 15 days later. The patient then saw the ophthalmologist at DWH on April 15, four weeks after the request.
- On February 17, Dr. Sudhir requested a hematology appointment for Patient D to continue his necessary oncology treatment for his multiple myeloma, which had been diagnosed in 2005. The appointment was requested to be completed within two weeks. On March 25, CMS approved the appointment, 37 days after the request. As of July 25, there is no indication in SERAPIS that the patient went to see the hematologist. Additionally, this approved request has never appeared in the Defendants' reports, either as a pending or completed appointment.
- On March 5, Dr. Iad Naji, a KRS Internist, requested an orthopedic surgery appointment for Patient Q to be evaluated for possible right hip replacement for treatment of severe pain. He requested the appointment be completed within three weeks. CMS did not respond to this request until April 7, when it approved the consultation. The visit then took place on May 13, more than two months after the original request. The specialist recommended a hip replacement, but the patient is still waiting to receive this surgery.
- On June 19, Dr. James Sondheimer, a KRS nephrologist, requested a vascular surgery appointment for Patient L so the vascular surgeon could remove the patient's sutures and evaluate him for a permanent access site. Dr. Sondheimer requested the appointment within four days. CMS never responded in SERAPIS to this request. During the OIMM's visit to RRF on July 16, Patient L explained that he had not seen the vascular surgeon and had simply removed the sutures himself. The OIMM sent a memorandum to Defendants on July 23 that followed up on Patient L's complaint and asked that the vascular surgeon see him as soon as possible. The following day, OIMM staff also discussed his case with Health Unit Manager (HUM) Elizabeth Tate during a visit at the facility. A week later, on July 31, Dr. Sudhir submitted a request for Patient L to be seen within one week by the vascular surgeon. CMS approved the request on August 1, and Patient L saw the vascular surgeon on August 7.

No system is in place to follow up on specialty care requests if CMS fails to respond. MDOC has no system in place to hold CMS accountable for chronic excessive specialty care delays.

Corrected Sixth Report of the OIMM Dialysis Services for *Hadix* Prisoners at Ryan Correctional Facility

September 5, 2008 Page 16

Examples of clinical consequences of failures of specialty care system at RRF

A functioning program will assure requested consultations occur in a timely manner, facilitating diagnosis and treatment, and preventing adverse consequences from preventable delays in diagnosis and treatment. At RRF many dialysis patients are suffering significant pain and diagnostic delay because of this failed system.

Patient R — Bladder Cancer work-up

On January 16, 2008, Patient R complained to Dr. Sudhir that he had burning on urination and that he was urinating blood. He explained that in 1993 he was diagnosed with bladder cancer, for which he had received surgery and a couple of urology follow-ups. Hoping to rule out whether Patient R's symptoms were associated with a recurrence of his bladder cancer, Dr. Sudhir requested that a urology consultation be completed within one week. CMS approved the consultation the next day, but scheduled him to be seen on February 5 — almost three weeks after the request.

The urologist, Dr. Tony Pinson, saw Patient R as scheduled. He recommended that the patient receive a CT scan of his abdomen and pelvis without contrast and a cystoscopy with bilateral retrograde pyelogram. On February 18, Dr. Sudhir followed up Dr. Pinson's recommendations, requesting the CT scan be done in two weeks and the cystoscopy be done after that, in three weeks. CMS approved both of these requests on February 26.

Dr. Sudhir saw Patient R on February 27, noting the cystoscopy had been scheduled for May. She saw Patient R next on March 18 and noted that the CT had not been scheduled. That day, Dr. Sudhir wrote special nursing instructions that the CT was needed prior to the cystoscopy, which was scheduled for May 6, and that the RRF scheduler needed to make sure that the CT scan occurred before the cystoscopy appointment.

Two and a half months after Dr. Sudhir's request, Patient R went to Foote Hospital on May 6 to receive his cystoscopy.

According to SERAPIS, the patient refused the cystoscopy that day because he thought he was supposed to receive a CT scan first, which he had not. He also thought that the procedure was supposed to be performed at Harper Hospital, not Foote Hospital. During a visit to RRF, Patient R confirmed to OIMM staff that he refused the cystoscopy because he thought his tests were being done out of order. Contrary to these events, the Defendants' May specialty care data states the patient completed his appointment on May 6.

Dr. Naji saw Patient R on May 7, noting that the patient was still waiting for the abdominal CT and cystoscopy. No orders were written to direct nursing staff to resolve the problem. Patient R kited on May 11 asking about his medical procedures. In response, Dr. Sudhir saw him on May 12, noting that neither the cystoscopy nor the CT scan had been done and that she would discuss these appointments with the RRF scheduler. The CT scan was completed May 14.

Corrected Sixth Report of the OIMM Dialysis Services for *Hadix* Prisoners at Ryan Correctional Facility

September 5, 2008 Page 17

Since May 12, Drs. Naji, Sudhir, and Sondheimer have noted on four different occasions that Patient R still needs a cystoscopy. The most recent of these entries, by Dr. Sudhir on July 25, contains a special nursing instruction for the RRF scheduler to "please check on Patient R's appointment." However, almost six months after the urologist recommended he receive a cystoscopy, Patient R is still waiting to receive this procedure to determine if his bladder cancer has recurred.

Patient S – HIV care

Patient S waited 15 months before he received an ID consultation for treatment of his HIV infection. When he was finally see on July 11, 2008, the most recent laboratory studies were six months old, so old that they were completely useless in guiding and initiation or modification of therapy. Patient S had not been seen since April 18, 2007, despite repeated consultation requests, including a recommendation from OIMM consultant Dr. Gibney in his January 25 report. In the nearly 15 months it took to complete Patient S's ID consultation, at least six scheduled appointments were not kept, including appointments on July 31, 2007, September 18, 2007, November 5, 2007, December 3, 2007, January 3, 2008, and February 1, 2008.

Although the reason Patient S missed each of these appointments is not always clear in SERAPIS, several of his missed appointments are well documented. On September 18, a SERAPIS note by Dr. Craig Hutchinson, an ID specialist, states Patient S missed the appointment because he was being dialyzed and because his labs were not available. On November 5, Dr. Hutchinson noted that Patient S missed his appointment again because of a scheduling conflict. Similarly, on December 3, the patient waited for 40 minutes in health care for his telemedicine visit to begin before he became frustrated and returned to his housing unit. Finally, on February 1, Dr. Hutchinson noted that the RRF staff was not aware that Patient S had a scheduled appointment so the patient was again "not available."

This chaotic communications failure between the RRF scheduler, the dialysis unit, and Dr. Hutchinson's office resulted in a 15-month delay in necessary infectious disease follow-up. Defendants failed to arrange for consultation even after this patient was specifically identified tin OIMM's previous report. Further, Patient S has never appeared on the Defendants' monthly reports, even though he has had pending appointments since June 2007. Tracking and correcting long-standing delays like Patient S's is precisely the point of these reports.

Patient Q —Hip Replacement

Patient Q is a relatively new dialysis patient at RRF. He entered RGC on February 15, 2008 and transferred to RRF the same day so he could continue receiving dialysis, as he previously had before his incarceration.

Dr. Sudhir saw Patient Q on February 18, noting that he suffered from hypertension, diabetes, peripheral vascular disease with a history of stasis ulcers in the left lower extremity, and a history of osteomyelitis in his right hip. Dr. Sondheimer saw Patient Q on February 19, noting that the patient complained he was having problems with his right hip, which might require

replacement. During the next two weeks, Patient Q was in and out of the emergency room and hospital for opiate withdrawals and chest pain. His hip complaints went largely unaddressed.

On March 5, Dr. Naji noted the patient's chronic right hip pain and requested a consultation with Dr. Michael Fugle, the patient's orthopedic surgeon, regarding a hip replacement. He requested Patient Q be seen within three weeks. CMS did not respond to this request until April 7, when it approved the consultation.

Patient Q saw Dr. Fugle on May 13, 2008, more than a month after CMS's approval and more than two months after Dr. Naji's request. Dr. Fugle recommended that the patient receive a total hip replacement after he received a cardiac clearance for the surgery. The next day, Dr. Naji followed up on the Dr. Fugle's recommendation and requested that a cardiac stress test with myocardial perfusion imaging be done within two weeks. CMS approved the request two days later.

Patient Q saw a cardiologist on June 18, 2008, seven weeks later, who required the results of a persantine stress test and 2D echocardiogram before he could clear Patient Q for surgery. The cardiologist scheduled these tests for June 20, 2008, and Dr. Naji filed the necessary consultation request with CMS on June 18. CMS approved the tests on June 19.

On June 20, Patient Q went for the scheduled procedures. These tests could not be performed because they were unable to obtain vascular access. A peripherally inserted central venous catheter needed to be inserted so the stress test could be completed. On July 14, Dr. Sudhir requested that the PICC line be inserted within one week so the stress test could be performed on July 21. CMS approved the request on July 16.

According to Dr. Sudhir's SERAPIS consultation requests on August 12, the stress test results concerned the cardiologist, who requested an ABI test (for vascular adequacy) and a cardiac catherization. Dr. Sudhir requested that the ABI tests be completed within one week of August 12. The catherization is now scheduled in early September.

After waiting more than two months to see the orthopedic surgeon, another month to see the cardiologist, and another month to complete cardiac testing, Patient Q is now waiting for another cardiac procedure before he can undergo the hip surgery that Dr. Sondheimer suspected six months ago would be necessary. The indication for hip replacement is a hip joint that is diseased and is causing severe pain. Patient Q has endured six months of unnecessary pain because of the defective specialty care program at RRF.

Patient N — Hearing aid

Patient N experienced increased hearing loss in his left ear and kited about his problem on January 28. He was seen by nurse February 1, 2008, who noted that both ears were clear. He was scheduled to see Dr. Sudhir February 5. Dr. Sudhir saw him for his complaint on February 15. At his visit with Dr. Sudhir, Patient N explained that he had past problems with the hearing in his left ear but the problems suddenly worsened over the previous three weeks. Dr. Sudhir

requested an urgent ENT evaluation for Patient N's acute hearing loss, to be completed within one week.

On February 19, CMS denied Dr. Sudhir's urgent ENT request but approved an audiogram at DWHC for March 20, 2008. According to SERAPIS, Patient N was hospitalized on March 20 so this appointment was not completed. He completed his audiogram on April 10. Despite a kite from the patient on April 21, no one followed up on the audiology report until May 6, when Dr. Sudhir put in a consultation request for the patient to receive a hearing aid within one month. In a SERAPIS note on May 7, Dr. Sudhir clarified that the patient was seen in the audiology clinic, which stated he could receive a hearing aid without an ENT consultation.

CMS approved Dr. Sudhir's hearing aid request May 22, specifying that the patient needed ENT clearance. However, on May 27, Patient N's ENT consultation was cancelled for an unknown reason. Because of this cancellation, when the patient went to his audiology appointment on June 5 no service was performed since there was no ENT clearance.

During a review of Patient N's hard file on July 16, the OIMM found that his ENT consultation was subsequently rescheduled for June 10. However, according to a SERAPIS note by Dr. Sudhir on July 16, the appointment was cancelled because the patient was out on writ. When she saw the patient on July 24, Dr. Sudhir again noted that Patient N had not yet received his ENT consultation. She wrote a special nursing instruction for the RRF scheduler to check on the patient's ENT consultation.

On August 5, Patient N received his ENT consultation. According to a SERAPIS note that day by Dr. Sudhir, his appointment was scheduled on the same day as a vascular surgery consultation. Dr. Sudhir directed the RRF scheduler to send him to the ENT appointment and reschedule the vascular surgery appointment.

At his ENT appointment, Patient N was approved to receive his hearing aid. However, the ENT specialist also recommended that the patient receive a brain MRI to rule out acoustic neuroma, a possible cause of his acute hearing loss. CMS approved this consultation request on August 7 with the MRI occurring August 21, 2008. It took 6 months to complete an "urgent" ENT evaluation.

Lastly, it is also worth noting that only one of Patient N's appointments appeared on the Defendants' reports in the last five months. That appointment, the ENT consultation cancelled on May 27, incorrectly appeared as a completed appointment. MDOC's recording of a missed appointment as a completed appointment misleads the Court about the specialty care program at RRF.

Patient E — ID Clinic

On April 30, 2008, Patient E was diagnosed with a spinal abscess positive for staphylococcus. On May 8, 2008, DRH discharged Patient E to HVM, rather than back to RRF, because of his extensive medical needs. Patient E's discharge instructions stated that he needed to follow-up with the infectious disease clinic and the hospital scheduled the ID follow-up for June 4 at DRH.

On May 13, Dr. Muhammad Mustafa at HVM followed up on DRH's discharge instructions, requesting Patient E return for his ID consultation on the already scheduled date. CMS approved an ID consultation on May 20, however it denied Dr. Mustafa's request that the patient be seen at DRH as scheduled. Instead, CMS scheduled Patient E to see its contracted ID specialist, Dr. Hutchinson, at DWHC on June 4. It was specifically noted that Patient E needed to have "all pertinent outside medical records" with him.

Dr. Hutchinson saw the patient via telemedicine on June 12. Although CMS specifically noted that Dr. Hutchinson needed Patient E's complete medical records at that visit, these records were not available. In his consultation report, Dr. Hutchinson stated, "At this point I am unable to perform a meaningful ID consult as his dialysis days conflict with my on site clinics at DWHC so I am not able to see him in person and records pertinent to my evaluation are not immediately available to me today." The cardiology evaluation for bacterial endocarditis suggested by Dr. Hutchinson has not been documented in SERAPIS.

In this case, CMS cancelled an appointment with the ID specialist at DRH who had been following Patient E, only so the patient could be seen, without the necessary documentation, by its contracted specialist. Since Dr. Hutchinson did not have the DRH medical record, he could not perform the consultation.

4. Review of Defendants' Compliance with Dialysis Transfer Plan

4.a. Nurse Staffing

Defendants' Transfer Plan for Closing JMF (Dkt. No. 2397) stated, "Six added nursing FTEs will provide coverage for the additional medical needs of these prisoners transferred to RRF. Movement of 6 nurse FTEs has been put in place at RRF to cover these additional medical needs for the approximately 60 prisoners moving." Therefore, to determine the goal number of post-transfer nurse FTE's at RRF, OIMM reviewed the pre-transfer RRF nursing schedule from March 11 through April 21, 2007, which contained 9.5 FTE's, and added 6 to get 15.5 FTE's. A nurse scheduled 40 hours a week was considered full-time and was counted as one (1) while a nurse scheduled less than 40 hours a week was considered part time and counted as one-half (.5). The sum of these values equals the number of nurse FTE's for that schedule.

The OIMM's review indicates that Defendants are not providing the nursing coverage at RRF that they set forth in their Transfer Plan. Only 12.5 nurse FTE's were scheduled from March 23 through May 3, 2008, 13.5 from March 4 through June 14, and 15 from June 15 through July 26. Defendants fell short of the targeted 15.5 FTE coverage on all three schedules. However, the upward trend demonstrates movement in a positive direction. The 15.5 FTE coverage is only a minimum level of coverage for the dialysis transferees, and once reached, should be consistently maintained or exceeded.

Corrected Sixth Report of the OIMM Dialysis Services for *Hadix* Prisoners at Ryan Correctional Facility

September 5, 2008 Page 21

4.b. Construction of Permanent Dialysis Unit

Defendants agreed to first construct a temporary, six-station dialysis unit and later expand the unit into a permanent, 17-station unit with one isolation station. In June 2007, Defendants transferred the dialysis unit from JMF to RRF, estimating that the permanent unit would be completed sometime that fall. However, as Defendants explained in their March 24 Construction Progress Status Report on the Permanent RRF Dialysis Unit (Dkt. No. 2753), construction of this permanent unit was slow to start for a variety of reasons. Months behind schedule, construction began in early 2008, with a planned completion date of May 6, 2008.

The 17-station permanent dialysis unit began operation July 7, 2008. Thirteen stations are currently in use. One station was originally designed to provide some isolation and prevent cross contamination when a patient receiving dialysis had a contagious condition, such as Hepatitis B. Unfortunately, no locked space was allocated for medications or medical record storage so the isolation room is now being used for this purpose. No isolation stations are currently available.

Phase II of the project is supposed to replace much of what used to be the temporary dialysis unit with a new reverse osmosis water purification system and storage areas. During OIMM's July 24, 2008 visit to RRF, we were told that Phase II's expected completion date was August 8. As of our August 15 visit, the ceiling had been constructed in the new water room and the initial water pipes were in place. However, no reverse osmosis water equipment was present.

The OIMM has expressed concerns about the water quality at RRF multiple times in the past year. Dr. Gibney first raised his concerns about the water system in his January report, stating, "The absence of a problem to date at Ryan Correctional should not reassure prison officials."

The OIMM followed up on Dr. Gibney's concerns in a memorandum to Defendants on May 19, 2008. That memo raised concerns about using filtration tanks with expired labels, not dating the bicarbonate solution, and the adequacy of the temporary dialysis water system to meet the burden of the additional five dialysis chairs in the new unit, and the nine additional stations in the final unit.

Defendants responded to the OIMM's concerns on June 20, 2008. Lesley Jones, Administrative Assistant, Consent Decree Administration, provided a memorandum from Mr. Glover that stated that the water system is inspected by the Marco Water Company and that all tanks were functioning properly. In that memo, Mr. Glover also stated that the reverse osmosis system was working fine on both the one and two tanks the day of the visit. Our understanding is that the temporary water filtration system at RRF does not have reverse osmosis but is a series of deionization and carbon filter tanks. However, in the same memo, Mr. Early, the dialysis technician who usually tests and monitors the water system stated that the tanks on Bank #1 were working and the tanks on Bank #2 were turned off until the carbon tanks could be replaced. An additional pump was installed to maintain adequate water pressure with the increased number of dialysis machines currently used.

On August 15, Dr. Cohen and Gail Bernth MS, FNP, escorted by Deputy Warden Nobles, made an on-site visit to the dialysis water filtration room. The room was filthy. The floor had just

been mopped prior to our arrival but still had standing muddy water. The floor under the bicarbonate tank had many broken tiles and was covered with rust. The floor under the filtration tanks was so dirty that the tiles were not visible. The bicarbonate tank was open to the air with no cover to prevent contaminants from getting into the solution. However, a sticker stating that it had been mixed that morning was present. The hose entering the open bicarbonate tank was torn and rusted. Mr. Nobles took pictures of the water filtration room's condition; the pictures are attached to this report.²¹ These conditions represent a substantial failure of infection control and should be corrected immediately.

The charge nurse was asked to demonstrate how to check the water system because that would have been her responsibility if Mr. Early was not there. She said she would look for the green lights on the tank and pump. She was not familiar with testing the water for chloramines, a major toxic chemical in municipal water supplies that can cause large-scale morbidity and even death in dialysis patients. We asked Mr. Early to check the water for chloramines. He stated that he had tested the water two hours earlier but could not locate the testing strips. After a search, the testing strips were found in the filtration room's electrical circuit breaker box (neither of the two circuit breaker boxes had covers present). When the water was tested, it was allowed to flow directly onto the floor for the required 15 seconds. It was not mopped afterwards, as the mop cannot reach where the water flows.

The Northwest Renal Network published Monitoring Your Dialysis Water Treatment System in June 2005. This publication states, "One of the most critical tasks regarding patient safety in the day of a dialysis technician is checking the water treatment system for chlorine and chloramines." It discusses establishing procedures for periodic water analysis and culturing of dialysis machines for bacteria in the water lines. We recommend that these procedures be implemented at the RRF dialysis unit.

5. Emergency Care to Critically Ill Patients

The Court required Defendants to urgently report unexpected deaths and significant system failures to the OIMM.²³ Despite the Court's order, Defendants have never sent formal notice to the OIMM of a death involving a *Hadix* prisoner, urgently or otherwise. The OIMM's ability to objectively investigate a death is dependent upon the thoroughness of the information provided by Defendants. Until recently, OIMM requests for records pertinent to a death investigation were honored, although at times this occurred only after repeated requests. However, our effort to investigate the most recent unexpected death at RRF has been impeded by Defendants' recent refusal to produce portions of the appropriately requested information.²⁴

²¹ Attachments 5 and 6, RRF Water Filtration Room Pictures, August 15, 2008.

²² Attachment 7. Northwest Renal Network, Monitoring Your Dialysis Water Treatment System, June 2005.

²³ Finding of Fact and Conclusion of Law, 2006.12.07 (2233), 128 at page 58.

²⁴ Attachment 8. Email OIMM request 5/7/08 between Char Lowrie and Lesley Jones, August 20, 2008

Corrected Sixth Report of the OIMM Dialysis Services for *Hadix* Prisoners at Ryan Correctional Facility

September 5, 2008 Page 23

Patient A

Patient A was a 51-year-old man with ESRD secondary to diabetes mellitus and hypertension, and schizophrenia who died in DRH on May 1, 2008. He spent the last three months of his life at RRF, where his medical and mental health deteriorated and he failed to receive adequate treatment for his uncontrolled hypertension and congestive heart failure. The emergency care he received prior to his final hospitalization was extremely deficient.

Patient A was sent to RRF from Foote Hospital on January 22, 2008 after a 10-day hospitalization to treat congestive heart failure, fluid overload requiring emergency hemodialysis, and pneumonia. He was a new dialysis patient. After his arrival at RRF directly from Foote Hospital, he was evaluated by the psychiatrist, Dr. Kanwar Rana, on January 24, a nephrologist, Dr. Sondheimer, on January 25, and his primary care provider, Dr. Sudhir, on January 26, 2008.

On January 24, Dr. Rana reviewed Patient A's medical history and his recent start on dialysis. Dr. Rana renewed his psychiatric medications trihexyphenidyl 5 mg, aripiprazole 15 mg and sertraline 100 mg. Corresponding Medication Administration Records (MARs) indicate these medications were not given on January 25 or 26.

On January 25 Dr. Sondheimer, the KRS consultant nephrologist wrote his monthly nephrology note: "This is a new renal disease patient. He was started [on dialysis] at Foote last month. He is uncertain as to the etiology of his renal disease. Blood pressure is 174/78. He has no edema. His clearance (URR) is 19% which may represent lab error because he claims that he had a three hour treatment that day but he does not have much insight into his condition and I am not sure about some of his responses." Dr. Sondheimer did not know that Patient A had diabetes, congestive heart failure, or that he was schizophrenic. No change in his blood pressure medications was made. He did request a referral to the vascular surgeon to establish a vascular access for dialysis which was accomplished within three weeks.

The outpatient mental health team (OPMHT) met with Patient A on January 24, noting his lengthy mental health history and planning to monitor his adjustment. NP Edford met with Patient A on February 8, to monitor the patient's current mental health. A comprehensive treatment plan was established February 11 by Dr. Rana and NP Edford.

Dr. Sondheimer's February 27 monthly dialysis note again does not mention his diabetes or Patient A's congestive heart failure. The blood pressure was recorded as 183/84, but he did not recommend any change in anti-hypertension therapy.

Patient A was sent to the hospital by ambulance on March 2, after complaining of chest pain and shortness of breath. Upon arrival to the RRF medical unit, his blood pressure was 250/120, oxygen saturation 62% (representing life threatening respiratory failure), P 119 and R 24. He returned to RRF on March 4 after signing himself out against medical advice and without any hospital discharge information. SERAPIS notes indicate his last dialysis was March 3, with the next one due on March 5. Patient A did not receive his scheduled dialysis on March 5.

A late entry by Dr. Sudhir on March 8 states she was present with him from the time he arrived at the RRF ER on March 2 until he was sent to the hospital. She noted, "Patient was in flash pulmonary edema, patient's BP was lowered to about 25% from the initial and transported to the hospital". Dr. Sudhir's March 8 SERAPIS entry also states that Patient A reported that he had signed himself out of the hospital on March 4 "because he did not like being chained." Dr. Sudhir increased the blood pressure medication at this time.

Patient A was schizophrenic. The reason he signed out of DRH against medical advice was that he could not tolerate being chained down. When the Psychiatric Nurse Practitioner saw him on March 14 he reported that the hospital had diagnosed him as having an anxiety attack. He reported having had this on one prior occasion. The NP indicated she would refer the matter to the psychiatrist for consideration of the provision of lorazepam. The patient's coping mechanisms (walking, reading and writing poems) were discussed and the NP encouraged him to continue these activities. The relationship between his mental illness and his refusal of hospital-based medical care was not addressed.

Ten days later, on March 24, Patient A again came to the clinic with severe hypertensive crisis, shortness of breath, and chest pain. His blood pressure was 210/116, pulse 110, respirations 30. He was diaphoretic. No temperature was taken, no EKG was obtained, no nitroglycerin was given, and no emergency blood pressure treatment was provided. The patient was given oxygen and sent to the DRH emergency room. At the hospital, he was found to be in critical condition, with fluid overloaded, and in sepsis (Temp 102.2). He was severely acidotic (blood ph 7.14), and hypoxic (O2 saturation 81% on room air). The hospital record noted, "Missed dialysis (at RRF) unknown why." Patient A was intubated and sent to the intensive care unit.

One week later, on April 1, 2008, after an 8-day hospitalization, he was discharged back to his cell (at RRF) without CMS (Correctional Medical Services) knowledge. UM (Utilization Management) states physician wrote discharge order after business hours." He arrived back at RRF at 8:48 p.m. The RN noted he was on multiple psychiatric drugs. Patient A was evaluated by Dr. Sudhir who reviewed his medications and ordered them filled at an outside drugstore. When Patient A returned from the hospital on April 1, his next dialysis treatment was due April 4 with Vancomycin (antibiotic) to be administered at that time. The dialysis treatment and antibiotic administration did not occur; he was not dialyzed until April 7. This was the third dialysis session not provided within a five-week span.

The Psychiatric Nurse Practitioner saw him for a routine visit on April 4 and Patient A self-reported his recent hospitalization, once again noting that the hospital believed he was having anxiety attacks. The NP noted this information and referred the patient to the psychiatrist for evaluation for anti-anxiety medication.

On April 8, 2008, he was again sent to the DRH ER because of pulmonary edema secondary to life threatening uncontrolled hypertension. His blood pressure was 232/120. Dr. Sudhir provided emergency treatment at RRF (giving clonidine and labetalol) prior to Patient A's transport to the hospital.

Patient A returned from DRH on April 10, 2008 at 7:56 p.m. His blood pressure was dangerously uncontrolled at 207/87. Twenty minutes later, he was seen by Dr. Sudhir who noted his blood pressure as 171/78. Dr. Sudhir wrote: "After reviewing the discharge meds from the hospital, it is evident that patient's meds were no different than ones he was getting here, it proves the patient was probably not taking his meds as he should be. I have ordered for him to have all his meds nurse administered."

The psychiatrist saw Patient A April 17 and started clonazepam 0.5 mg at 5:00 p.m. for anxiety. The April 2008 Medication Administration Records indicates that the clonazepam ordered by the psychiatrist to begin on April 17 was not administered to Patient A until April 21 at 5 p.m., four days later.

Dr. Sudhir ordered blood pressure checks twice daily for two weeks beginning April 18. However, the blood pressure records suggest this occurred only once daily with readings on April 18 of 188/88, on April 19 of 199/90, and on April 20 of 200/91. Each of these readings was extremely high, but no KRS physician was notified.

On April 21, 2008 at 5:30 a.m. Patient A came to the RRF medical unit unable to talk, confused, sweating, and in respiratory distress. His blood pressure was 263/120. Again, he received no treatment other than oxygen by mask at RRF despite his life threatening hypertensive crisis. Dr. Shirley at DWHC ordered his transport to the hospital. He returned from DRH three hours later, having signed out of the emergency room against medical advice. When he returned to RRF, he had wet pants because he had urinated on himself. Once again, Patient A reported that he didn't want to be chained down. He was not seen by a physician after his return from the DRH ER. No change in treatment was ordered. No psychiatric evaluation occurred.

Four days later, on April 25, 2008 at 6:44 a.m. he again came to the RRF medical unit complaining of shortness of breath. At this time, his blood pressure was 170/80 and his pulse was 125 beats per minute. Prior to his transport to the hospital, Dr. Eggland (DWHC) ordered atroven/albuterol inhalation therapy. He was then given 50 mg of methylprednisolone, but refused the second dose. Around 11 a.m., he again signed out AMA from the DRH ER and returned to RRF. When he arrived back at RRF at 11:53 a.m., his blood pressure was 184/82. He was treated with methylprednisolone for chronic obstructive lung disease and referred to have his scheduled hemodialysis. He was seen by a physician upon return from DRH. Dr. Naji planned to titrate up the hypertension medications and wrote orders for labetalol 200mg 2 tabs BID. According to the MAR, Patient A received these meds as ordered on April 26 and 27, only in the evening on April 28 and only in the morning on April 29.

Patient A was also seen by Dr. Sondheimer in dialysis on April 25, who noted the patient's self-report that he had signed out of the hospital earlier that day after having an anxiety attack. Dr. Sondheimer reported a blood pressure of 198/90, a pulse of 80 and noted edema of 1+ on exam. He wrote, "Phosphorus is elevated at 5.9. He is on six PhosLo a day. We will increase to eight per day. His iron stores are low. We will reload him with Ferrlecit. Adequacy study was not complete. We will try to obtain stools guiac. Decrease his dry weight to 83.5 for blood pressure control. In addition, he is requesting and it is reasonable that he be given a diabetic snack. We will order that. Otherwise continue present regimen and monitor his falling hemoglobin."

September 5, 2008

Page 26

The blood pressure flow sheet indicates Patient A's blood pressure at 5:00 a.m. on April 26 was 176/84 and 183/93 at 8:00 p.m. On April 27 at 5:00 a.m. it was 227/109. Yet, the nurse did not refer the patient to see a physician. On April 28 at 5:00 a.m. it was 209/83; the nurse notified DWH ER and administered the breathing treatments ordered by the DWH ER physician. His blood pressure was 179/92 after the breathing treatment.

On April 28 at 6:01 a.m., he again complained of shortness of breath. His blood pressure was 179/92. The DWHC ER physician was contacted and ordered two inhalers used to treat asthma. He was not examined by an MSP during the day. At 2:59 a.m. on April 29, he came to the RRF medical unit complaining of chest tightness and shortness of breath. His blood pressure was 202/98. He was given two inhaler treatments (albuterol and atrovent) based on telephone orders from the DWHC Physician Assistant and was returned to his cell.

On April 29 at 5:00 a.m., Patient A's blood pressure was 201/90. At 4:46 p.m., he was seen by Dr. Sudhir who described Patient A as being short of breath with a blood pressure of 190/92. She added hydralazine to his blood pressure medications, ordered a wheelchair (since Patient A was unable to walk to meals), and scheduled no follow-up.

Twelve hours later Patient A had a cardio-respiratory arrest at RRF. According to the Critical Incident Report prepared by Captain Beard:

"At approximately 0345 hours prisoner Patient A of Housing Unit 00 came out of his room requesting to see healthcare staff. Patient A fell to the floor of the lower level. C/O Todd Campbell and C/O Patient A Cunningham reported to the area. C/O Campbell notified healthcare and spoke with Nurse Lola Nedd. C/O Campbell than notified Control Center. Lt. Tatton and C/O David Schuitt responded. Lt. Tatton spoke with prisoner Patient A; Patient A looked up at him without speaking or responding. Lt. Tatton instructed C/) Campbell and C/O Schuitt to escort Patient A to healthcare. C/O Campbell and C/O Schuitt placed Patient A into a wheelchair and took him to Healthcare. Upon arrival to Healthcare Nurse Nedd instructed staff to place Patient A on the ER stretcher/nursing table and began CPR. Nurse Bouey called Control Center and requested an ambulance with ALS (Advanced Life Support). Patient A was unresponsive and not breathing. C/O Schuitt began chest compressions. CPR continued with C/O Schuitt, C/O Daniel Townsend and C/) Randall Wyatt alternating the chest compressions. Nurse Nedd requested the ambulance service be called again. The ambulance was called a second time. The ambulance arrived at 0417 hours. CPR Continued. At approximately 0440 hours, Patient A #188104 was placed in ambulance and transported to Detroit Receiving Hospital. C/O JD McGee continued the chest compression in the ambulance."

Ms. Nedd, RN, noting that Patient A arrived at the RRF ER at 4 a.m., wrote: "Subjective: Officer called stating the inmate had fallen and will be brought to HC in a wheelchair." She continued: "Objective: Inmate arrived in HC in a wheelchair. The inmate was unresponsive to name. The inmate was placed on the ER stretcher. Vital sign checked, no pulse, not breathing and unable to obtain a blood pressure. Pupil was fixed and dilated. AED (Automatic

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Defibrillator) placed on the inmate chest wall and CPR started. CPR continued until the advance EMT staff placed the inmate in the ambulance with RRF staff assisting."

Patient A arrived at DRH at 5:00 a.m., over an hour after he collapsed. He was resuscitated and intubated at DRH. He died the next day.

Comments Regarding Care of Patient A

Emergency Care

Patient A was well known to the medical and nursing staff at RRF. He was receiving 17 medications directly from the nursing staff. He had been sent to the Emergency Room at DRH on four previous occasions during April, 2008 for life threatening hypertensive crises and pulmonary edema. Despite this, when he collapsed outside his cell and was unresponsive, correctional staff placed him in a wheelchair and brought him to the RRF medical unit, rather than have Nurse Nedd or Nurse Bouey run the short distance from the clinic to Building 200 to evaluate him where he had fallen. He was pulseless and not breathing when he arrived in the RRF medical unit. No attempt had been made to determine if he was breathing or had a pulse when he collapsed in Building 200, and we have received no documentation that any observations were recorded contemporaneously in the Building 200 Housing Log. More than one hour and 15 minutes elapsed from the time he collapsed until he arrived at the DRH Emergency Room, a facility located only 5.9 miles from the prison. Based upon the available information the emergency care provided to Patient A was grossly inadequate. His final encounter with RRF medical and correctional staff demonstrated a complete failure of basic emergency treatment.

OIMM staff visited Building 200 on May 19, 2008 and asked to see Patient A's cell and the housing log from the date of the incident. Neither the RRF administrative assistant nor the officers could find any mention of the incident in the housing unit log. At the July 10, 2008 problem solving session, Defendants' Council, Peter Govorchin was asked to provide the OIMM with a copy of the housing log for the date of this incident and refused. The OIMM's investigation of Patient A's death has been complicated by Defendants' refusal to supply detailed information about the emergency care provided, including the critically important housing unit logs and witness statements. Although Defendants have provided this information in other cases, they continue to deny the OIMM's request.

Mental Health Care

Patient A was schizophrenic and was being treated with multiple psychiatric medications (sertraline, trihexyphenidyl, and aripiprazole), and had suddenly developed ESRD requiring thrice weekly hemodialysis. He was followed regularly at RRF by Deborah Edford, a psychiatric Nurse Practitioner and by Dr. Kanwar Rana, a psychiatrist. He was clearly psychotic and delusional, occasionally disoriented. He told Dr. Rana on January 24 "that Free Masons who are the richest person and the president of USA covered the truth about Brenda Parsons. She was "Black" and had lot of wealth. She put all her money, businesses and home in his name but top masons covered it up. He likes to believe it but he does not have any papers."

Unfortunately, there was no communication between the psychiatric service providers and Patient A's medical providers. When Patient A repeatedly signed out AMA from DRH, there were no discussions between Dr. Sudhir and Dr. Rana. On two occasions Patient A said the reasons he had signed out from DRH was because they chained him down at the hospital.

Dialysis Care

The chronic dialysis and medical care received by Patient A was deficient. Although there is a SERAPIS terminal in the dialysis unit, it appears that Dr. Sondheimer did not know how to use it to review Patient A's medical record. No effort was made to coordinate care with psychiatric services even though the Patient A was often disoriented and delusional, and signed out AMA from DRH on multiple occasions when his medical condition was very unstable.

On several occasions when Patient A was having a life threatening hypertensive crisis, none of the KRS physicians were called, as required by the Court Order allowing transfer of JMF to RRF, and no treatment was administered. Patient A was known to have significant cardiomyopathy, but his chronic medical care failed to control his blood pressure, even on the multiple occasions when it was recorded as dangerously high. Patient A was not always compliant with his medications, but he was schizophrenic, and insufficient effort was made to mange his multiple complex problems. He was too sick to be housed at RRF, and should have been monitored and managed at DWHC or the HVM infirmary.

Conclusion

Patient A survived dialysis for less than four months. His death was premature, and his emergency care was unacceptable. Defendants have repeatedly denied the OIMM access to contemporaneous records regarding his emergency care in violation of the Court's order appointing the Associate Monitor and providing him with complete access to all records regarding medical care, including emergency care requiring coordination of medical and correctional staff.

6. Failure to evaluate ESRD Patients for Transplantation

The Associate Monitor recommended referral of prisoners with ESRD for transplantation when appropriate based on their medical condition (Dkt. No. 2451). Defendants did not respond to that filing. They continue to refuse to refer prisoners for transplantation because "Defendants believe that this is not the law or good social policy, and decline to spend limited public resources on solid organ transplants for prisoners when there are neither sufficient organs or money available to meet the demand by civilian patients." (Dkt No. 2414, p. 6).

Defendants' position is wrong on multiple grounds. Defendants have established a separate, unequal, and clearly inferior standard of care for prisoners with ESRD, which is substantially different from that available to all other persons in the United States. Correctional physicians do not treat leukemia differently in prisoners than in non-prisoners. Correctional physicians do not

treat coronary artery disease in prisoners differently than in non-prisoners.

Defendants cannot dispute the fact that ESRD is a serious medical need. ESRD is preferentially treated with kidney transplantation. Yet, in Defendants' Supplement to Dialysis Treatment Plan, they state: "To Defendants' knowledge no court within the Sixth Circuit has found that it is a violation of the Eighth Amendment of the US Constitution for a corrections department to decline to take a limited supply solid organ like a kidney and give it to a prisoner who had the foresight to rob a jewelry store." (Dkt. No. 2414, p. 6).

On the contrary, it is universally accepted medical opinion that the treatment of a person with ESRD must be based on that person's individual medical condition, and should include evaluation for eligibility for kidney transplantation. It is also federal policy, based on 40 years of extraordinarily successful medical practice and progress, that because transplantation is less expensive, improves quality years of life, and increases life expectancy, kidney transplantation should be encouraged. Transplantation of solid organs is available to prisoners in the Federal Bureau of Prisons, ²⁶ in New York State²⁷, Virginia²⁸, California²⁹, and in Washington state. ³⁰

It is a fundamental principle of correctional health care that our treatment be based on each prisoner's individual medical condition. We do not consciously choose a less effective treatment for a serious medical problem because we are treating a prisoner. We do not deny prisoners with HIV infection access to life saving anti-retroviral therapy because it is expensive. Defendants justifiably write about their high quality HIV care, and they appropriately utilize infectious disease specialists to direct every aspect of HIV care. We do not deny women prisoners with breast cancer necessary surgical, radiation and chemotherapy because it too expensive.

ESRD is unfortunately a too common medical problem. According to ESRD Network 11, there are over 12,000 men and women receiving dialysis in Michigan. There is no question that Defendants are choosing a "less efficacious treatment" in adhering to their present policy. Transplantation is now established as the standard of care for most ESRD patients in the United States. ESRD Regional Network 11 has stated an expectation that 75 percent of all ESRD patients receiving dialysis will be referred to a transplant center for assessment of eligibility for transplant. Congress enacted modifications of the Medicare ESRD Program on June 13, 1978 (PL 95-292) "to improve cost-effectiveness, ensure quality of care, *encourage kidney transplantation* and home dialysis, and increase program accountability (italics added)." The

²⁵ Section 2991 of Public Law 92-603 Rev. 8, Issued 12-07-07; Effective: 12-03-07; Implementation: 01-07-08,

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http://www.bop.gov/news/PDFs/legal_guide.pdf, p. 26, p. 27
 Attachment 10, New York State Department of Correctional Services, Division of Health Services Policy # 1.57 (9/7/04) "Organ Transplantation"

²⁸ Va. Dep't of Corrections Operating Procedure 734-4.0 (cited in MUST INMATES BE PROVIDED FREE ORGAN TRANSPLANTS?: REVISITING THE DELIBERATE INDIFFERENCE STANDARD, George Mason University Civil Rights Law Journal, Geo. Mason U. Civ. Rts. L.J. 341, FN 17

²⁹ http://www.cbsnews.com/stories/2002/01/31/health/main326305.shtml. Accessed August 30, 2008.

³⁰Email from Marc F. Stern, Associate Deputy Secretary for Health Care/Medical Director for the Washington State Department of Corrections, to author (Jan. 13, 2004) (on file with author), cited in MUST INMATES BE PROVIDED FREE ORGAN TRANSPLANTS?: REVISITING THE DELIBERATE INDIFFERENCE STANDARD, George Mason University Civil Rights Law Journal, Geo. Mason U. Civ. Rts. L.J. 341, FN 17

³¹ http://www.esrdnet11.org/assets/pdf/2007_annual_report_data_tables.pdf

number of transplants performed in Michigan has steadily increased, from 472 in 1997 to 623 in 2006.

Maintenance on dialysis is the "less efficacious treatment" for the starkest of reasons—the difference between life and death. The reason that transplantation is the standard of care is, quite simply, that people live significantly longer with transplants than with dialysis. The Canadian Society of Transplantation published its consensus guidelines on eligibility for kidney transplantation in 2005. Its first recommendation is based on the following statement:

"The development of ESRD is associated with a substantial reduction in health-related quality of life and premature death. Kidney transplantation is the treatment of choice for ESRD as it prolongs survival, improves quality of life and is less costly than dialysis.³³

Recommendation: All patients with end-stage renal disease should be considered for kidney transplantation provided no absolute contraindications exist. (Grade A)" ³⁴

Further, the longer ESRD patients remain on dialysis <u>before</u> transplantation, the shorter their expected survival will be should they receive a transplant. A study comparing transplantation and dialysis in Scotland demonstrated that there is an initial risk to transplantation, however, over time, the survival benefits proved to be dramatic, and the study found that a successful transplant triples the life expectancy of a patient compared with patients eligible for transplantation who remain on dialysis.³⁵

In addition to the dramatically decreased lifespan, the quality of life of dialysis patients is considerably worse than that of transplant patients. ESRD patients spend 10 to 15 hours each week on three separate days lying on their back, unable to move, connected to a noisy, constantly "beeping" machine that inefficiently "washes" their blood. In general, they feel chronically fatigued and dizzy. They suffer from frequent complications including anemia, rapidly progressive coronary artery disease, depression, failed vascular access with frequent hospitalizations for emergency repair, and don't feel healthy. Persons with ESRD who have received kidney transplantation do not require dialysis and can lead healthy productive lives for decades.

Defendants' argument that transplantation is not "good social policy" is not consistent with my experience as a correctional physician and expert in correctional health care. It has not been my experience that Courts have ever tolerated categorically denying life-saving medical care to persons solely because they are prisoners. It has not been my experience that the leadership of correctional medical programs has asked their physicians and other health workers to recommend an inferior treatment and deny a more efficacious treatment for a serious medical

³² http://www.esrdnet11.org/data/transplant_data.asp

Canadian Society of Transplantation: consensus guidelines on eligibility for Kidney transplantation, CMAJ • November 8, 2005; 173 (10). doi:10.1503/cmaj.1041588.

³⁴ Grade A refers to the quality of scientific evidence which supports the policy recommendation. Grade A is assigned only to recommendations based on the highest level and quality of scientific evidence.

Oniscu, G.C., Brown, H, and Forsythe, J.L.R, , Impact of Cadaveric Renal Transplantation on Survival in Patients Listed for Transplantation J Am Soc Nephrol 16: 1859-1865, 2005, © 2005 American Society of Nephrology

illness when they knew what the appropriate treatment should be. Further, the supposed basis of the Defendants' argument is erroneous. They cite "limited public resources"; but it is well established that kidney transplantation is *more* cost efficient than dialysis for treatment of ESRD. A significant number of kidneys transplanted in the United States are donated by relatives and others. There have been 9,356 kidney transplantations in Michigan over the past 20 years, of which 5,481 came from deceased donors and 3,875 from living donors.³⁶

A study published in Progress in Transplantation in 2001 compared the cost of dialysis with the cost of transplantation in New York City and found that transplantation was a more costeffective treatment than hemodialysis for the Medicare Program.³⁷ A study performed by the University of Maryland presented in 1999 showed that the "break-even point" where it becomes cheaper for patients to undergo kidney transplantation rather than remain on dialysis had decreased to 2.7 years. After that point, the cost of caring for the transplant patient was \$16,043 per year, compared with \$44,000 for dialysis.³⁸ A meta-analytic review of 13 studies in the medical and economic literature for economic evaluations of hemodialysis, peritoneal dialysis, and kidney transplantation showed that the cost effectiveness of hemodialysis was found to be between \$33,000 and \$50,000 per life year saved, while kidney transplantation has become more cost effective over time, approaching \$10,000 per life year saved.

The Defendants' assumption that prisoners should never be considered for transplantation because of the demand from civilian patients is contrary to accepted medical ethics, as articulated by the United Network for Organ Sharing (UNOS), the designated organization for allocating transplantation resources in the United States. In 1984, the National Organ Transplantation Act was passed (P.L. 98-507). In 1986, UNOS received the initial federal contract to operate the Organ Procurement and Transplantation Network. The UNOS Ethics Committee has published a "Position Statement Regarding Convicted Criminals and Transplant Evaluation." This position statement argues:

"The UNOS allocation system is based on the principles of equity and medical utility with the concept of justice applied to both access (consideration) as well as allocation (distribution). The UNOS Ethics Committee opines that absent any societal imperative, one's status as a prisoner should not preclude them from consideration for a transplant; such consideration does not guarantee transplantation. Acknowledged are medical and non-medical factors that may influence one's candidacy for transplant however prisoner status is not an absolute contraindication. Although one's status as a prisoner may evoke legitimate medical concerns (i.e., infectious diseases), as well as psychosocial issues (i.e., character disorders and substance abuse problems that may compromise compliance), judgments regarding these medical and non-medical factors are the

36 http://www.optn.org/latestData/rptData.asp, accessed August 20, 2008

Loubeau, PR, Loubeau, JM, Jantzen, R, The Economics of Kidney transplantation versus hemodialysis, in Prog Transplant. 2001 Dec;11(4):291-7.

Kalo, Z, Jaray, J, Nagy, J., Economic evaluation of kidney transplantation versus hemodialysis in patients with endstage renal disease in Hungary., Prog Transplant. 2001 Sep;11(3):188-93. http://www.uptodateonline.com/online/content/topic.do?topicKey=renltran/13302&selectedTitle=18~150&source=search result#25, accessed August 20, 2008.

http://www.unos.org/resources/bioethics.asp?index=3, accessed August 21, 2008

purview of individual transplant teams. Consideration of prisoners as well as others for transplantation includes evaluation of medical and non-medical factors relative to their impact on transplant outcome. Screening for all potential recipients should be done at the candidacy stage and once listed; all candidates should be eligible for equitable allocation of organs." 40

It should not be overlooked that Defendants' policy perpetuates the substantial racial disparity in access to kidney transplantation. Research has shown that nationally, African-Americans are less likely than whites to be considered as candidates for renal transplantation, and among those persons deemed appropriate, blacks were significantly less likely than whites to be referred for evaluation (90 versus 98 percent), placed on a waiting list (71 versus 87 percent), or transplanted (17 versus 52 percent). Michigan incarcerates African-Americans at more than five times the rate it incarcerate whites. Of the sixty-three men receiving dialysis at RRF one is Hispanic (2%), sixteen are white (25%), and forty-six are African-American (73%). ⁴³ Thus, the complete exclusion of prisoners serves only to exacerbate an already striking racial disparity.

Summary and Recommendations

There are serious, ongoing problems in the medical care at RRF that have harmed or have the potential to harm the prisoners receiving dialysis there. These problems include inadequate access to dialysis sessions, inadequate dialysis, poor management of basic medical/renal care as demonstrated by patients' low URR levels, elevated parathyroid hormone levels (PTH) levels, and chronic delayed access to necessary specialty care and inadequate emergency medical care. Defendants, by consistently denying access to assessment for eligibility for transplant, from either live donors or cadaver kidneys, demonstrate a conscious, deliberate and discriminatory commitment not to provide basic, efficacious, and cost effective comprehensive medical services to prisoners with ESRD. Underlying these clinical problems is a system that fails to accurately document medical care, provide the necessary and Court-required levels of staffing, and monitor problems and correct them as they arise.

Since the dialysis unit transferred to RRF more than a year ago, the OIMM has raised almost all of these issues with Defendants, either in its previously submitted report to the Court or in issuespecific memorandums to Parties. As noted above, Dr. Pandya has begun a quality assurance effort involving physicians, health administrators, nurses, dialysis administrators, and pharmacists. His efforts over the past year have not yet addressed most of the critical issues identified in this report. Defendants should immediately undertake the following remedial actions to prevent further unnecessary harm to *Hadix* class members with ESRD:

⁴⁰ Winkelmayer WC, Weinstein MC, Mittleman MA, Glynn RJ, Pliskin JS: Health economic evaluations: the special case of end-stage renal disease treatment. Medical Decision Making 2002; 22:417-430.

⁴¹http://www.uptodateonline.com/online/content/topic.do?topicKey=renltran/13302&selectedTitle=18~150&source=searc h result#25, accessed August 20, 2008
⁴² Racial designations were derived from the MDOC OTIS records online.

⁴³ In Michigan the incarceration rate is 412 Whites/100,000, while for African-Americans it is 2262/100,000. http://www.sentencingproject.org/Admin%5CDocuments%5Cpublications%5Crd_stateratesofincbyraceandethnicity.pdf, accessed August 21, 2008

Page 34 of 36

- Maintain a binder containing orientation material, dialysis schedules, and a daily checklist for dialysis nurses and technicians. Policies and procedures for patient care, water testing, and infection control need to be established and easily locatable.
- Monitor all ESRD Network 11 quality indicators on a quarterly basis and prepare quarterly corrective action plans when indicator goals are not met. Request support from the ESRD Network 11 when goals are repeatedly unmet. Provide these quarterly reports to the Court.
- Nephrologists should review dialysis orders and re-order dialysis as part of their monthly clinical review of each patient.
- Provide all ordered dialysis sessions to patients each week. Meeting this recommendation will require that Defendants reschedule patients who miss dialysis because of outside appointments, accurately document when patients refuse their sessions against medical advice, coordinate care between medical and custody, and maintain accurate, legible flow sheets of dialysis sessions. Include a report of compliance with this requirement with each quarterly report (see above).
- Develop a corrective action plan to assure that each ESRD prisoner patient develops an advanced health care directive. Provide necessary clinical, mental health, and social work support for this project. This process should include facilitation of family meetings to discuss different approaches to advanced directives and to identify and inform health care proxies of their responsibilities.
- Compile accurate specialty care data that tracks every appointment from the time an MSP requests it to its completion or outcome. Patients temporarily housed at HVM should be included in these reports. Defendants must provide a corrective action plan to assure that the specialty care data it provides the Court is accurate.
- Use the specialty care reporting system to discover individual delays and systemic problems that need correction. When there are questions about whether an out-oftimeframe appointment is clinically appropriate, the RRF scheduler should consult with a KRS physician at the time the appointment is requested. Do not "improve" the specialty care compliance rate by instructing clinicians to artificially extend consultation timeframes.44
- Maintain the staffing level of nurses promised by the Defendants in their previous Court submissions. Maintain at least two Registered Nurses per shift at all times.
- Complete the permanent dialysis unit, which is currently one year behind schedule. Report to the Court monthly on the status of this project. Provide at least one dialysis

⁴⁴ Attachment 9. Dialysis Nephrology Meeting Minutes, June 30, 2008.

Page 34

Page 35 of 36

Dialysis Services for *Hadix* Prisoners at Ryan Correctional Facility

station that is isolated for infection control purposes as indicated in the Defendants' Court submission.

- Immediately establish a water quality safety program that includes water analysis and machine surveillance cultures. Train staff to mix the bicarbonate solution and monitor the water quality on a regular basis. Create a safe and clean environment. Institute the monitoring criteria recommended by the Northwest Renal Network. Provide a corrective action plan to the Court that addresses all issues of water quality safety.
- Maintain a separate log of all ESRD patients who are sent to the emergency room. Review with RRF nursing staff the requirement that KRS nephrologists or internists be called directly when their patients are in crisis.
- Develop a corrective action plan to coordinate medical and psychiatric care of all prisoners with significant mental health problems
- Refer all prisoners with ESRD to a transplantation center where they will be evaluated for eligibility to receive a kidney transplant. Where possible, arrange for live donor kidney transplantation for transplant eligible prisoners. When no live donor is currently available for an eligible prisoner, enroll the prisoner patient in the regional cadaver donor transplantation program.
- Cooperate with the OIMM by providing all requested materials in a timely manner.

Corrected Sixth Report of the OIMM Dialysis Services for Prisoners at Ryan Correctional Facility

List of Attachments

Attachment 1	ESRD Network 11 Recommended Treatment Goals
	February 2008
Attachment 2	Dialysis Patient Forum Meeting Minutes
	April 21, 2008
Attachment 3	Memo from Alex Glover to Lesley Jones
	June 27, 2008
Attachment 4	Email Info Request between Lesley Jones and Gail Bernth
	July 27, 2008
Attachment 5	RRF Water Filtration Room Pictures – Set 1
	August 15, 2008
Attachment 6	RRF Water Filtration Room Pictures – Set 2
	August 15, 2008
Attachment 7	Northwest Renal Network, Monitoring Your Dialysis
	Water Treatment System, June 2005
Attachment 8	Email re OIMM request between Char Lowrie and Lesley Jones
	August 20, 2008
Attachment 9	RRF Dialysis Nephrology Meeting Minutes
	June 30, 2008
Attachment 10	New York State Department of Corrections
	Division of Health Services Policy 1.57
	Organ Transplantation, September 4, 2004
Attachment 11	OIMM Spreadsheets
	Filed under seal
Attachment 12	Patient Records
	Filed under seal
Attachment 13	Specialty Care Comparison Documents
	Filed under seal
Attachment 14	Patient Legend
	Filed under seal