2-9-05

To: My Dad's Pharmacist at VA

From: Nancy Lee Kay Nancy Lee Kay

Re: Pharmacist on Dialysis Team

I believe a pharmacist could be an integral member of the interdisciplinary dialysis team because of the special knowledge related to the complexities of drug interactions. Medications are often not filtered or processed in the normal manner for this client. Often the timing of the medications needs to be considered to optimize effectiveness. For example, Dad used ativan in the beginning months of dialysis. If he took it prior to the start of treatment, it did not carry through the 5 hours. It fact, it was filtered from his blood very quickly. Timing became important to gain the best effect from the drug so he could tolerate treatment. The same occurs with his quinine. Many dose alterations related to the dialysis may be better addressed with the expert pharmaceutical knowledge. The team benefits for the client seem evident. In the nursing home, a pharmacist is part of the psychoactive drug team meeting for the client. Other team members in the nursing home include the nurse care manager, social worker, and geropsych-nurse practitioner. Hope these thoughts help.

SCOTT & WHITE

Date: 02/09/2005
To: Centers for Medicare and Medicaid Services
From: Terri K. Oldham, MSW, LMSW
Regarding: Proposed 2005 CMS Conditions of Coverage

To Whom It May Concern:

I am a social worker in a health care setting, and work exclusively with dialysis clients and their families. My purpose for this letter is to convey my thoughts regarding the recently publicized 2005 CMS Conditions for Coverage—particularly as it relates to the profession of social work.

Since the onset of my work with dialysis clients, I have been concerned with the amount of clerical duties I find myself executing on a day-to-day basis. Many hours per week are spent facilitating admissions and coordinating transient and travel arrangements. In addition, copying, faxing, and other clerical duties consume numerous hours of my time each week.

I entered the profession of social work because of my passion for clinical work with clients. I recognize the importance of non-clinical tasks; however, because of the time I must allot to duties detailed above, I find myself unable to devote the time and attention needed to fulfill the role for which I was hired—clinical social worker. It is because of this concern that I would like to recommend that the Centers for Medicare and Medicaid Services require clerical support staff for social workers whose caseloads are above 75.

The Council of Nephrology Social Workers has deemed that 75 clients is a full caseload for one social worker. Many of us in the profession have well over 100 clients and lack clerical support. Please consider incorporating clerical support for social workers into the 2005 CMS Conditions of Coverage. In doing so, social workers will be able to more fully perform clinical work, which will result in better care of clients and further advancement of the profession.

Regards,

Terri K Oldham, MSW, LMSW.

Terri K. Oldham, MSW, LMSW
Scott & White Dialysis
2401 South 31st Street
Temple, TX 76508

"Things Are Different Here"

Dear SIRS: February 4, 2005

I am a dialysis social worker under the " grandfather clause "exempt from the master's degree requirement. I have worked all of my career in dialysis or chronic care and know my job inside out. Currently, I handle 150 patients and never have any problems assisting these people. I have attended some graduate school but could not continue due to finances. Every year I do attend many continuing education programs on my own time that relate to all aspects of the renal community. There are quite a few social workers across the country who are under the "grandfather clause " that are excellent and dedicated employees. If the proposal passes , we would all loose our jobs and it would be very difficult to obtain other employment due to our age and experience only working in the renal field. Personally, If I lost my job it would be devastating since I support my family and have two sons going to college. At that point, I will most likely be eligible for Medicaid and public assistance . PLEASE CONSIDER IN NOT PASSING THIS PROPOSAL BECAUSE THIS WOULD JEOPARDIZE OUR LIVES AND HURT PEOPLE WE SO TRULY CARE AND WORRY ABOUT IN THE DIALYSIS COMMUNITY. Thank You.

Joanne Harris

Very Truly Yours,
Joanne Harris,LCSW
A very concerned and dedicated social worker.

CMS-3818-P
Proposed 494.140(d)
405.2102(f)

Again, under rehabilitation status Proposed 494.90(A)(6), you mention rehabilitation status. You say on Page 100 that "The interdisciplinary team must provide the necessary care and services for the patient to achieve and maintain an appropriate level of productive activity, including vocation, that permits the patient to resume, to the extent feasible, activities engaged in prior to kidney failure." How, again, are we to gauge the rehabilitation of such a patient as concerns his prior work status? This is something that nephrologists generally have not been trained in measuring. I think it is reasonable to say that the patient should have the ability to be referred to a vocational rehabilitation specialist or agency. I think it is unfair to ask me and most other nephrologists to perform the task of evaluation when we have not been trained to do so.

On Page 126, you asked for comment on the provision of hemodialysis in a NF or SNF. I would simply say that perhaps you should allow nursing homes to have a dialysis unit on-site. The population is getting older and patients are going to wind up in these facilities, so why not allow a dialysis unit to be physically connected to such a facility.

Under Medical Director, which is Proposed Regulation 494.140(A), I think it is important to have a physician be a medical director who has completed a Board approved training program in nephrology with at least twelve months experience providing care to patients receiving dialysis. I think there are nephrologists in sufficient supply anywhere in this country to make that possible.

Under Proposed Regulation 494.90, I would also like to address transplantation referral tracking as mentioned on Page 273. I think that you need to make sure that each kidney transplant center readily provides its results for transplants. Also, you mention "The Team must communicate with the Transplant Center regarding patient transplant status at least quarterly, or more frequently if necessary." I think it is incumbent upon the transplant center to tell the dialysis center what information it needs in order to monitor the status and suitability of potential kidney transplant recipients.

Sincerely yours,

TEB

Thomas E. Burkart, M.D.

TEB/bj

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March 8, 2005

The Centers for Medicare
and Medicaid Services
Department of Health & Human Services
ATTN:CMS-3818-P
P. O. Box 8012
Baltimore, MD 21244-8012

Dear Sir:

I have reviewed the proposed change in Regulations for coverage for End Stage Renal Disease facilities and I would like to make some comments. What follows are my comments:

In Proposed 494.80(A) you mention evaluation of vocational and physical rehabilitation status and potential. I do not really see how that is appropriate since I am not a physician in that specialty. I think it would be more appropriate to say refer patients for vocational and physical rehabilitation status and potential. It is hard for me to say sometimes who can work and who cannot work because I have not had training in such evaluations.

In Proposed 494.10 you specify the definition of "interdisciplinary team" without including the facility medical director or the home dialysis physician. But then you say that "a physician is part of the interdisciplinary team." This I find confusing as to whether a physician is or should be part of the team.

In Proposed 494.90(A)(2) you asked for comments upon nutritional outcome measures other than serum albumin. I do not think any other measurements are as valid as the serum albumin in our patients. All of the other measures that you mention such as pre-albumin, or protein equivalent of total nitrogen appearance are very hard to measure accurately in the dialysis population. Therefore, we should simply stick with an evaluation by the dietitian and the serum albumin.

Again, under rehabilitation status Proposed 494.90(A)(6), you mention rehabilitation status. You say on Page 100 that "The interdisciplinary team must provide the necessary care and services for the patient to achieve and maintain an appropriate level of productive activity, including vocation, that permits the patient to resume, to the extent feasible, activities engaged in prior to kidney failure." How, again, are we to gauge the rehabilitation of such a patient as concerns his prior work status? This is something that nephrologists generally have not been trained in measuring. I think it is reasonable to say that the patient should have the ability to be referred to a vocational rehabilitation specialist or agency. I think it is unfair to ask me and most other nephrologists to perform the task of evaluation when we have not been trained to do so.

On Page 126, you asked for comment on the provision of hemodialysis in a NF or SNF. I would simply say that perhaps you should allow nursing homes to have a dialysis unit on-site. The population is getting older and patients are going to wind up in these facilities, so why not allow a dialysis unit to be physically connected to such a facility.

Under Medical Director, which is Proposed Regulation 494.140(A), I think it is important to have a physician be a medical director who has completed a Board approved training program in nephrology with at least twelve months experience providing care to patients receiving dialysis. I think there are nephrologists in sufficient supply anywhere in this country to make that possible.

Under Proposed Regulation 494.90, I would also like to address transplantation referral tracking as mentioned on Page 273. I think that you need to make sure that each kidney transplant center readily provides its results for transplants. Also, you mention "The Team must communicate with the Transplant Center regarding patient transplant status at least quarterly, or more frequently if necessary." I think it is incumbent upon the transplant center to tell the dialysis center what information it needs in order to monitor the status and suitability of potential kidney transplant recipients.

Sincerely yours,

TEB

Thomas E. Burkart, M.D.

TEB/bj

ACP | Sciences for Life

PHARMACY | PHARMACEUTICAL SCIENCES | BIOMEDICAL TECHNOLOGY

March 21, 2005

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
File Code: CMS-3818-P
PO Box 8012
Baltimore, MD 21244-8012

Dear Dr. McClellan:

I am writing to offer comments regarding Proposed § 494.140 ("Personnel Qualifications") within the proposed revisions to the Conditions for Coverage for End Stage Renal Disease Facilities. Within this document, CMS has invited comment regarding the role of the pharmacist within a dialysis clinic. I am pleased to have the opportunity to voice my support for this concept.

I have been involved in nephrology pharmacy for 21 years as a clinician, researcher and educator, and have developed a variety of skills and gained many experiences in that time. Currently, I am a full-time faculty member with responsibilities for the provision of student clinical experiences in dialysis. To that end, I oversee the medication management of some 30-40 chronic hemodialysis patients in two outpatient dialysis facilities. The patients that I follow have been selected by the dialysis staff as having special therapeutic needs, either because of regimen complexity, difficult in reaching the goal clinical outcome, lack of adherence to the regimen, or some other such issue.

In addition to care of individual patients, my experience has been requested to aid the production of guidelines that influence patients in a global setting. I have been asked to participate in a number of national and international initiatives pertaining to pharmacotherapy of dialysis patients. For example, I am currently a member of the Advisory Board for the National Kidney Foundation's (NKF) Kidney Disease Outcomes Quality Initiative (K/DOQI). In this capacity, I was a member of the NKF K/DOQI work group that produced the Clinical Practice Guidelines on HTN, and am currently a member of the NKF K/DOQI work group charged with updating the Clinical Practice Guidelines for Management of Anemia in CKD. I am also a member of the International Society of Peritoneal Dialysis (ISPD) work group that produces periodic updates to the ISPD's guidelines for the management of peritonitis in peritoneal dialysis patients. In each of these instances, I have been the sole pharmacist representative, and was sought out to complement the multidisciplinary teams, since I have a different skill set than theirs. Each of these guidelines has historically been widely used throughout the United States and abroad.

Pharmacists possess a unique skill set that can be of profound use for patients on dialysis. The focus of nephrology pharmacists encompasses pharmacotherapy, pharmacokinetics and pharmacoeconomics. Pharmacists are ideally trained to understand the complexities of variations in drug disposition during dialysis and between dialysis sessions. Given that the typical dialysis patient is prescribed an average of 12 medications and takes an additional two to four over-the-counter and herbal products, application of the concept of medication-related problems permits identification and resolution of problems of drug over- and underdosing, drug interactions, adverse event monitoring and reaching outcome goals, while at the same time ensuring the most cost-effective approach. Pharmacists are often the most appropriately placed to ensure compliance with many of the medication-related clinical practice guidelines.

Residents of long-term care facilities, who share many of the characteristics of dialysis patients in terms of multiple comorbidities and complex therapeutic regimens, enjoy review of their medication regimens at least once per month. There are compelling data demonstrating that pharmacists within dialysis units can identify potential drug-related problems and are typically successful in having the medication orders appropriately altered. Unfortunately, only a small proportion of dialysis facilities within the United States use the services of a suitably-trained nephrology pharmacist.

In summary, I feel that dialysis patients are currently disadvantaged in not having the routine services of pharmacists. Because of our unique training and skills, I suggest that pharmacists should become a routine part of the multidisciplinary team that cares for these individuals. There follows a brief bibliography that documents some of the activities of pharmacists in the dialysis setting.

Sincerely,

George R. Bailie, MSc, PharmD, PhD, FASN
Professor of Pharmacy

Annotated Bibliography

1. Bailie GR, Mason NA, Bragg-Gresham JL. Analgesic prescription patterns among hemodialysis patients in the DOPPS: potential for underprescription. Kidney Int 2004; 65:2419-2425.

   These authors demonstrated that 74% of patients in moderate to severe pain were prescribed no analgesics.

2. Mason NA, Bailie GR, Satayathum S, et al. HMG-Coenzyme A reductase inhibitor use is associated with mortality reduction in hemodialysis patients. Am J Kidney Dis 2005; 45:119-126.

   Analysis of data from the large DOPPS database showed that there was a large underuse of HMG-Coenzyme A reductase inhibitors (i.e., statins) with documented indications for use. Use of statins was associated with a 31% decrease in the overall relative risk for death and with a 23% lower risk of cardiac mortality.

3. Bailie GR, Mason NA, Elwell RJ, Sy FZ. Analysis of medication use in peritoneal dialysis patients in two units. Perit Dial Int (in press).

   The authors described the medication prescription practice patterns of PD patients in a prospective, observational study of patients from two outpatient PD clinics. Patients were prescribed a mean of 9.2 medications and took an additional 2.2 OTC medications/patient. Influenza and pneumococcal vaccines had been given to 81% and 38%, respectively. Most (60%) had received hepatitis vaccine, but about half had received the full course. While most patients (88%) had been prescribed phosphate binders, only 48% were on a vitamin D analogue, and the mean iPTH value was 485 pg/mL. There was a low (22%) use of ACE inhibitors. Only 7% of patients had ever had nasal swabs for *S. aureus* carrier status, and mupirocin was routinely used as prophylaxis by 33% of patients. Despite much emphasis placed on appropriate treatment of hemodialysis patients, this report is suggestive that more attention is needed for PD patients. This study has identified several areas of concern where there is opportunity to improve prescription patterns.

4. Drayer DK, Manley HJ. Providing free medications to dialysis patients. A description of a multidisciplinary team medication sampling and patient assistance program. Nephrol News Issues 2004; 18:25-29.

   Many hemodialysis patients are either not insured or are underinsured. These patients require several medications that collectively can cost over $16,000 per year. The authors describe efforts to decrease this burden to some patients through a pharmacist-coordinated multidisciplinary team approach to medication sampling and patient assistance programs at a dialysis facility. Over a 12-month period, 20 patients were provided 3,985 days and $12,751.31 of free medication.

5. Manley HJ, McClaran ML, Overbay DK, et al. Factors associated with medication-related problems in ambulatory hemodialysis patients. Am J Kidney Dis 2003; 41:386-393.

   In a review of 133 hemodialysis patients' medical records, medication-related problems were identified in 97.7% of patients. A total of 475 medication-related problems were identified, an average of 3.6 per patient. Diabetic patients had more medication-related problems identified than non-diabetic patients.

6. Manley HJ, Drayer DK, McClaran M, et al. Drug record discrepancies in an outpatient electronic medical record: frequency, type, and potential impact on patient care at a hemodialysis center. Pharmacotherapy 2003; 23:231-239.

Medication record discrepancies are a potential source of medication-related problems. In a prospective observational study, a pharmacist conducted a monthly medication interview of hemodialysis patients. During the interview, patient medication use was determined. Over the 5-month period, 215 medication interviews were conducted in 63 patients. One hundred thirteen medication record discrepancies were identified in 38 (60.3%) patients. The medication record discrepancies placed patients at risk for adverse drug events and medication dosing errors 49.6% and 34.5% of the time, respectively. Incorporation of a pharmacist in patient care may increase the accuracy of the electronic medical records and avoid unnecessary medication-related problems.

7. Kaplan B, Mason NA, Shimp LA, et al. Chronic hemodialysis patients. Part 1: Characterization and drug-related problems. Ann Pharmacother 1994; 28:316-319.

8. Kaplan B, Shimp LA, Mason NA, et al. Chronic hemodialysis patients. Part II: Reducing drug-related problems through application of the focused drug therapy review program. Ann Pharmacother 1994; 28:320-324.

9. Grabe DW, Low CL, Bailie GR, et al. Evaluation of drug-related problems in an outpatient hemodialysis unit and the impact of a clinical pharmacist. Clin Nephrol 1997; 47:117-121.

Grabe, et al also documented the occurrence of drug-related problems within a hemodialysis unit. Pharmacist interventions were significant and contributed to improved patient care.

South Dakota
GREAT FACES. GREAT PLACES.

DEPARTMENT OF HEALTH

SOUTH DAKOTA BOARD OF PHARMACY
4305 S. LOUISE AVE.
SUITE 104
SIOUX FALLS, S.D 57106
Phone: (605) 362-2737
FAX: (605) 362-2738

March 23, 2005

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
File Code: CMS-3818-P
PO Box 8012
Baltimore, MD 21244-8012

Dear Dr. McClellan:

I am writing to offer comments regarding the proposed revisions to the Conditions for Coverage for End Stage Renal Disease Facilities. Specifically I wish to comment on Proposed § 494.140 ("Personnel Qualifications") as this section addresses the possible role of a pharmacist within the dialysis facility. I appreciate that the Proposed Rule acknowledges the well-documented contributions a pharmacist can make to the safe and effective use of medications in the vulnerable dialysis patient population.

I am the Secretary of the South Dakota Board of Pharmacy and have practiced pharmacy for over thirty years, mainly in the hospital setting. As a hospital pharmacist, I was directly involved with helping to set up a dialysis unit in the hospital where I worked. Pharmacists work closely with nephrologists and nurses to make sure renal dialysis patient dialysate solutions contain the right electrolytes and do make recommendations and corrections to their concentrations. A pharmacist dispenses and monitors all other medications prescribed and used for dialysis patient treatments. The pharmacist is definitely one of the key players providing healthcare to dialysis patients and therefore should be included in any language regarding "Conditions for Coverage for End Stage Renal Disease Facilities"

I would like to emphasize the pharmacist medication knowledge and resource to the physicians treating dialysis patients:

- the complex nature of drug therapy in dialysis patients,
- the pharmacokinetic complexity of drugs during dialysis
- the vulnerability of these patients for adverse medication-related outcomes,
- the need for storage, preparation, and administration of medications within the dialysis unit,
- the need for cost effective drug therapy,
- the changing nature of drug therapy that will arise due to the MMA, and
- and the training of pharmacists that prepares them to serve as consultants to dialysis facilities.

I would like to make the following recommendations:

1. The multidisciplinary dialysis team should include a consultant pharmacist with experience or training in nephrology pharmacy.

2. The routine patient care assessment of dialysis patients should include a medication review by a pharmacist.
3. Medication reviews should be conducted at least monthly. This frequency is consistent with what is required in skilled nursing and intermediate care facilities.
4. Pharmacists should participate in the development and implementation of medication-related protocols within dialysis to assure cost-effective drug use.
5. Dialysis facilities should develop and maintain appropriate policies for the safe storage, preparation and administration of medications within the facility. These policies should be developed and maintained in consultation with a pharmacist.

Thank you for considering these comments and recommendations.

Dennis M. Jones
Executive Secretary,
South Dakota Board of Pharmacy
4305 S. Louise Ave., Suite 104
Sioux Falls, SD 57106 Phone 605-362-2737

3/23/05
%Pharmacy
VAMC Hot Springs,SD

http://www.cms.hhs.gov/regulations/ecomments
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3818-P
PO Box 8012
Baltimore, MD 21244-8012

Dear Sirs:

I have been a member OF an interdisciplinary dialysis team for many years. We at this facility thought it necessary to provide this service. Several years ago Dr. Birch became our nephrologist and requested a pharmacist be available for rounds once a month and quarterly reporting on each patient. Since I had been attending the quarterly reports I was selected to be the dialysis pharmacist.

I have had some dialysis training in which the VA sent me to a seminar in Minneapolis along with the rest of our team. Other than that my education has been thru working with our nephrologist and other members of the team. Our team includes a NP, social worker, dietician, dialysis nurse, and nephrologist.

I provide reports for rounds. I provide med sheets for both our VA patients and our community patients. I provide lab reports and medication history. I review all medication profiles each month. Since the VA has a great computer system, it's easy to get the information for our veterans. It's more difficult with our community patients. I visit them in dialysis once a month or on the phone to discuss current meds. Most of my medication teaching is during the dialysis rounds when our doctor is present. I've even helped a community patient get medication from a drug company. I'm the pharmacist who handles problems with any dialysis patient or a physician order.

I believe my presence is valuable since this year I had to be on medical leave for 8 weeks. We did not have enough pharmacists for someone to attend rounds. Although our acting supervisor did attend the multidisciplinary meetings. I was told by all of my dialysis teammates that I was missed greatly.

Therefore whenever possible, I believe a pharmacist should be available to dialysis for both rounds and other meetings.

Sincerely,

Janet Speirs

Janet Speirs R.Ph.

8

WILKES UNIVERSITY
The power of independent thinking

March 21, 2005

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
File Code: CMS-3818-P
PO Box 8012
Baltimore, MD 21244-8012

Dear Dr. McClellan:

I would like to voice my opinion regarding Proposed § 494.140 ("Personnel Qualifications") within the proposed revisions to the Conditions for Coverage for End Stage Renal Disease Facilities. Within this document, CMS has invited comment regarding the role of the pharmacist within a dialysis clinic. I am a strong proponent of this concept.

I am a pharmacist and pharmacy educator. My specialty is in nephrology with a particular interest in the dialysis population. Over the last 12 years I have seen first-hand the medication related problems in tis patient population. These patients are certainly some of our most vulnerable. An increasing age of the patient population and an increased use and complexity of the medications make these patients at high risk for so many problems.

The focus of nephrology pharmacists encompasses pharmacotherapy, pharmacokinetics and pharmacoeconomics. Pharmacists are ideally trained to understand the complexities of variations in drug disposition during dialysis and between dialysis sessions. Our ability to work with the whole health care team make us an excellent resource. Residents of long-term care facilities, who share many of the characteristics of dialysis patients in terms of multiple comorbidities and complex therapeutic regimens, enjoy review of their medication regimens at least once per month. There are compelling data demonstrating that pharmacists within dialysis units can identify potential drug-related problems and are typically successful in having the medication orders appropriately altered. Unfortunately, only a small proportion of dialysis facilities within the United States use the services of a suitably trained nephrology pharmacist.

In summary, I feel that dialysis patients are currently disadvantaged in not having the routine services of pharmacists. Because of our unique training and skills, I suggest that pharmacists should become a routine part of the multidisciplinary team that cares for these individuals.

Sincerely,

Edward F. Foote, PharmD, BCPS, FCCP
Associate Professor and Chair of Pharmacy Practice

Linda Lewandowski, R.D.
Dietitian, Commerce City Dialysis
6320 Holly Street
Commerce City , CO 80022

COMMENTS REFERRING TO FILE CODE CMS – 3818 – P
Titled "Conditions For Coverage for End Stage Renal Disease"

CARE PLAN

Elimination of the Long Term Care Plan is a good idea. It is already incorporated in the Care Plan and therefore is redundant.

Keep the requirement of the physician to review Advanced Directives yearly.

Agree that the Plan of Care for stable patients can be adequately addressed in a once–a–year plan.

PATIENT ASSESSMENTS 494.8

Perhaps the time frame of 3 months for New Patient Reassessment is too stringent as patients are often in and out of the hospital etc. and are not stable in 3 months. Unstable Assessments are already being done.

NUTRITIONAL STATUS 494.9

Throwing in an opinion – The SGA process is a waste of time. Anthropometric measurements are good for research, but only show dietitians what we already know. "Make-work" draws away from dietitian time with the patient.

Dietitian time with patients should be defined. There are dietitian ratios out there of 150-200 patients for full-time dietitian and that is not good care. I suggest that, at 90 – 100 patients there needs to be a full-time dietitian available.

Using total protein for protein status is not real helpful. I've not had experience with the pre-albumin to know if it can be more accurate. The albumin is useful as is the NPCR, but there are other indicators which are useful, as weight records and diet records, BUN and other subtle differences in chemistries. A dietitian uses a visual assessment and also culls information from patient and family.

Yearly measurement of height makes no sense. As a patient shrinks, his skeleton compresses but his bones and muscle mass change from other factors, not height. I.E., a male at 24 y/o still has the same bone structure as he has at 63 y/o, only bone density has changed, disc space and hip has compressed, etc, still not changing what his weight should be. What really affects that is age; as one ages, muscle/fat composition changes. The requirement to measure patients once a year should be discontinued.

ANEMIA

The standard of care of 33 or 11 Hgb has always been too low. Patients feel very tired and debilitated at Hct < 36. Nutrition and PTH also play a role in maintenance of desirable Hct. It is important to remain true to the goal of restoring health as much as possible so a patient can carry on a normal life, at work or in retirement, or retraining etc.

PERSONNEL QUALIFICATIONS

Dietitian – I do not agree that to have a Baccalaureate or advanced degree for ADA registration is enough. It is important for a dietitian to be experienced to go into this dialysis field.

Case loads should be defined for dietitians and social workers, to assure a better standard of care. The NKF years ago recommended 1 full time social worker for 75 patients and 1 full time dietitian for 90 – 100 patients.

Dialysis technicians – Requiring certification would be desirable. The 3 month training proposal sounds good.

Pharmacist coverage per unit might be expensive. Two points: 1) our physicians spend time each visit reviewing meds, 2) most HMO's have pharmacist review.
However, dialysis patients have a lot of meds prescribed by a lot of different physicians and some proposal for medicine reviews should be outlined.

Thank You for allowing/encouraging comments on the CMS proposal.
Linda Lewandowski

10

4/2/05

Mark B. McClellan, MD, PhD
Administrator Centers for Medicare & Medicaid Services
Department of Health and Human Services
File Code: CMS-3818-P
PO Box 8012
Baltimore, MD 21244-8012

Dear Dr. McClellan:

I am writing to offer comments regarding the proposed revisions to the Conditions for Coverage for End Stage Renal Disease Facilities. Specifically I wish to comment on Proposed § 494.140 ("Personnel Qualifications") as this section addresses the possible role of a pharmacist within the dialysis facility. I appreciate that the Proposed Rule acknowledges the well-documented contributions a pharmacist can make to the safe and effective use of medications in vulnerable dialysis patient population. I am a PharmD at the VA in Salt Lake City. I work as a clinical consultant for Home Based Primary Care program. A multidisciplinary team review patients weekly. We review patients Every 90 days. I am also the clinical pharmacist for the dialysis unit at the hospital. I was initially asked to solely review erythropoietic agents for the unit. However, that has evolved into a complete review all medications monthly with a multidisciplinary team. Prior to arriving at the VA in 2002, I was in Commissioned Corps. I worked for Indian Health Services in Sells, AZ. There were many diabetics & a dialysis unit that was part of pharmacy duties. So these professional experiences have clearly showed me the adjunct value of pharmacy in dialysis. I believe that consultant pharmacists should be included as part of the dialysis facility staff for the following reasons:

- the complex nature of drug therapy in dialysis patients,
- the pharmacokinetic complexity of drugs during dialysis,
- the vulnerability of these patients for adverse medication-related outcomes,
- the need for storage, preparation, and administration of medications within the dialysis unit,
- the need for cost effective drug therapy,
- the changing nature of drug therapy that will arise due to the MMA, and
- the training of pharmacists that prepares them to serve as consultants to dialysis facilities.

Specifically, I would like to make the following recommendations:

1. The multidisciplinary dialysis team should include a consultant pharmacist with experience or training in nephrology pharmacy.
2. The routine patient care assessment of dialysis patients should include a medication review by a pharmacist.
3. Medication reviews should be conducted at least monthly. This frequency is consistent with what is required in skilled nursing and intermediate care facilities.
4. Pharmacists should participate in the development and implementation of medication-related protocols within dialysis to assure cost-effective drug use.
5. Dialysis facilities should develop and maintain appropriate policies for the safe storage, preparation and administration of medications within the facility. These policies should be developed and maintained in consultation with a pharmacist.
6. Majority of dialysis patients have large numbers of chronic & prn medications that make patient compliance a major issue in dialysis & their other diseases.

Thank-you for your time & consideration,

Louis J. Riel, PharmD
VA Salt Lake City, UT
(801) 582-1565, X2169
(801) 339-2812

Centers for Medicare and Medicaid Services
Attention: CMS-3818-P
P.O. Box 8012
Baltimore, MD 21244-8012

March 21, 2005

To Whom It May Concern:

We are writing in response to File Code #**CMS-3818-P, Conditions of Coverage for End Stage Renal Disease Facilities; Proposed Rule.**

Item 1. Given the recent changes in verbiage to describe patients with End Stage Renal Disease, We would recommend that the title of the ESRD facilities (as well as this document title) be changed to 'Chronic Kidney Disease Facilities' so that the title is in line with these recent changes.

2. Re: Social worker to patient ratios: it would be beneficial to have specific numbers (possibly utilizing NASW guidelines), or, at least, a formula to determine ratios, which would create uniformity of caseload sizes among various centers, and would assist administrators in determining the number of social service hours necessary for each center based upon a national guideline from CMS.
3. Re: proposed 494.140 (d): We view the continuance of the existing requirement for a Master's level social worker as one of vital importance in the care of patients with chronic kidney disease. The issue of adding a licensure requirement in addition to the MSW in areas where social work licensure is available may be important to consider as well for the revised regulations.
4. RE: the comment that other "essential services including transportation and information on Medicare benefits, eligibility for Medicaid, housing and medications should be handled by other facility staff in order for the MSW to participate fully with the patient's interdisciplinary teams..." (494.140d) We feel that this should be expressly described elsewhere in the document (perhaps a section on Medical support/billing/clerical staff), and include the clerical duty of arranging transient trips as well. We feel that these clerical responsibilities are NOT in line with the counseling, education, rehabilitation, long-term behavioral/ adaptation therapy, and grief issues which must be addressed by the social workers. In fact, due to the immediacy of many transportation issues, and the amount of time needed for completion of forms for financial assistance, the primary counseling responsibilities may actually be impeded if social workers are continuously addressing clerical/billing needs of the patients.
5. Re: Interdisciplinary Care Plans (494.90), the changes in time frame seem appropriate so that the plan of care can be initiated as soon as possible. In addition, it is crucial that social work/psychosocial assessment continue to be included on the interdisciplinary care plans, and that the social workers fully participate in the development and implementation of these care plans.

6. We agree that: comprehensive rehabilitation efforts (both from the standpoint of emotional rehabilitation and "increased individual control over the effects of kidney disease and dialysis and the ability to maintain as active a lifestyle as possible") are important components of the social worker's role in assisting each patient.
7. Likewise, it is imperative that each social worker remains involved in addressing patient behavior that may become (or has become) challenging or disruptive. Social workers are also uniquely qualified to provide information/training re: psychosocial issues to other staff members, and provide facility staff counseling at times to enhance patient care. Again, for the reasons stated above, it is of fundamental importance that clerical and billing duties are specifically assigned to clerical and billing staff, and removed from the social service role.

Thank you for your consideration of the above comments.

We look forward to your response.

Renal Social Workers-Affiliated Hospitals Dialysis Centers, St. Louis Mo.
Suzie Welch, MSW, LCSW
Sue Brown, MSW, LCSW
Shelley Christiansen, MPH, MSW, LCSW

March 29, 2005

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
File Code: CMS-3818-P
PO Box 8012
Baltimore, MD 21244-8012

Dear Dr. McClellan:

I am writing to offer comments regarding Proposed § 494.140 ("Personnel Qualifications") within the proposed revisions to the Conditions for Coverage for End Stage Renal Disease Facilities. Within this document, CMS her invited comment regarding the role of a pharmacist within the dialysis facility. I am pleased to have the opportunity to show my support of the well-documented contributions a pharmacist can make to the safe and effective use of medications in the vulnerable dialysis patient population.

I have been involved in nephrology pharmacy for approximately 4 years as a clinician, researcher, and educator, and have developed a variety of skills and gained many experiences in that time. Currently, I am a full-time clinical pharmacist in five dialysis clinics caring for approximately 350 hemodialysis patients. My primary responsibilities include the provision of pharmaceutical care focusing on the management of cardiovascular risk factors. During this time, I have participated in multiple clinical research initiatives, identifying and resolving medication-related problems (MRPs) in dialysis patients.

In the dialysis population, MRPs are divided into nine categories: indication without drug therapy (IWD-patient has a medical problem requiring medication therapy, but is not receiving medication), drug without indication (DWI-patient is taking a medication for which no medically valid indication can be found), improper drug selection (IDS-patient has a medication indication, but is taking the wrong drug), sub-therapeutic dosage (UD-patient has a medical problem being treated with too little medication), overdosage (OD-patient has a medical problem being treated with too much medication), adverse drug reaction (ADR-patient has a medical problem that is the result of an adverse effect), drug interaction (DI-patient has a medical problem that is the result of a medication-medication, medication-laboratory, or medication-food interaction), failure to receive drug (FRD-patient has a medical problem that is the result of not receiving medication), and inappropriate laboratory monitoring (LAB - patient requires laboratory test(s) to either adequately monitor medication therapy, ensure that common comorbid conditions

are adequately identified and treated, or ensure that existing comorbid conditions are adequately treated)

Risk factors for the presence of MRPs in dialysis patients include: ≥3 concurrent disease states; medication regimen changed ≥4 times during the past 12 months; taking ≥5 medications or ≥12 doses per day; noncompliance history; drugs that require therapeutic monitoring; and presence of kidney disease or diabetes as a chronic condition. Virtually all dialysis patients have multiple risk factors for MRPs. Application of the concept of MRPs permits identification and resolution of problems of drug over- and underdosing, drug interactions, adverse event monitoring and reaching outcome goals, while at the same time ensuring the most cost-effective approach.

Compilation of published reports suggests that in the U.S. HD population, 1,052,406 MRPs can be identified at first MTM review and 165,477 MRP per month after 6 months continuous pharmacist MTM follow-up. Provision of MTM at the dialysis clinic will improve patient care and will result in considerable cost savings. A review of published reports demonstrated that for every $1 spent on pharmaceutical care (i.e., MTM) in ESRD patients, the healthcare system (i.e., CMS) will save approximately $4.

Pharmacists possess a unique skill set that can be of profound use for patients on dialysis. Pharmacists are uniquely qualified as we are specifically trained for medication review and assessment. The focus of nephrology pharmacists encompasses pharmacotherapy, pharmacokinetics and pharmacoeconomics. Pharmacists are ideally trained to understand the complexities of variations in drug disposition during dialysis and between dialysis sessions. Pharmacists are often the most appropriately placed to ensure compliance with many of the medication-related clinical practice guidelines. In the dialysis patient population, pharmacists also demonstrated to be better than nurses and physicians in obtaining medication use information.

Residents of long-term care facilities, who share many of the characteristics of dialysis patients in terms of multiple comorbidities and complex therapeutic regimens, enjoy review of their medication regimens at least once per month. There are compelling data demonstrating that pharmacists within dialysis units can identify potential MRPs and are typically successful in having the medication orders appropriately altered. Unfortunately, only a small proportion of dialysis facilities within the United States use the services of a suitably-trained nephrology pharmacist.

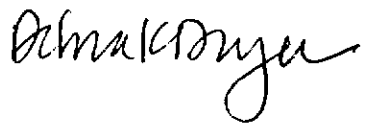
Specifically, I would like to make the following recommendations:

1. The multidisciplinary dialysis team should include a consultant pharmacist.
2. The routine patient care assessment of dialysis patients should include a medication review by a pharmacist.
3. Medication reviews should be conducted at least monthly. This frequency is consistent with what is required in skilled nursing and intermediate care facilities.
4. Pharmacists should participate in the development and implementation of medication-related protocols within dialysis to assure cost-effective drug use.

5. Dialysis facilities should develop and maintain appropriate policies for the safe storage, preparation and administration of medications within the facility. These policies should be developed and maintained in consultation with a pharmacist.

In summary, I feel that dialysis patients are currently disadvantaged in not having the routine services of pharmacists. Because of our unique training and skills, I suggest that pharmacists should become a routine part of the multidisciplinary team that cares for these individuals. There follows a brief bibliography that documents some of the activities of pharmacists in the dialysis setting.

Sincerely,



Debra Drayer, Pharm.D.
Clinical Nephrology Pharmacist
Dialysis Clinic, Inc.
6530 Troost Avenue, Suite B
Kansas City, MO 64131
816-363-8228

Annotated Bibliography

1. Manley HJ, Carroll C. The clinical and economic impact of pharmaceutical care in end-stage renal disease patients. Semin Dial. 2002 ;15(1): 45-9.

   A review of published reports demonstrated that for every $1 spent on pharmaceutical care (i.e., MTM) in ESRD patients, the healthcare system (i.e., CMS) will save approximately $4.

2. Manley HJ, Cannella CL, Bailie GR, St. Peter WL. Medication –related problems in hemodialysis patients: a pooled analysis of published reports. Submitted: American Journal of Kidney Diseases March 2005

   Compilation of published reports suggests that in the U.S. HD population, 1,052,406 medication related problems can be identified at first medication therapy management (MTM) review and 165,477 MRP per month after 6 months continuous pharmacist MTM follow-up

2. Manley HJ, McClaran ML, Overbay DK, et al. Factors associated with medication-related problems in ambulatory hemodialysis patients. Am J Kidney Dis 2003; 41:386-393.

   In a review of 133 hemodialysis patients' medical records, medication-related problems were identified in 97.7% of patients. A total of 475 medication-related problems were identified, an average of 3.6 per patient. Diabetic patients had more medication-related problems identified than non-diabetic patients.

3. Manley HJ, Drayer DK, McClaran M, et al. Drug record discrepancies in an outpatient electronic medical record: frequency, type, and potential impact on patient care at a hemodialysis center. Pharmacotherapy 2003; 23:231-239.

   Medication record discrepancies are a potential source of medication-related problems. In a prospective observational study, a pharmacist conducted a monthly medication interview of hemodialysis patients. During the interview, patient medication use was determined. Over the 5-month period, 215 medication interviews were conducted in 63 patients. One hundred thirteen medication record discrepancies were identified in 38 (60.3%) patients. The medication record discrepancies placed patients at risk for adverse drug events and medication dosing errors 49.6% and 34.5% of the time, respectively. Incorporation of a pharmacist in patient care may increase the accuracy of the electronic medical records and avoid unnecessary medication-related problems.

4. Bailie GR, Mason NA, Bragg-Gresham JL. Analgesic prescription patterns among hemodialysis patients in the DOPPS: potential for underprescription. Kidney Int 2004; 65:2419-2425.

   These authors demonstrated that 74% of patients in moderate to severe pain were prescribed no analgesics.

5. Mason NA, Bailie GR, Satayathum S, et al. HMG-Coenzyme A reductase inhibitor use is associated with mortality reduction in hemodialysis patients. Am J Kidney Dis 2005; 45:119-126.

   Analysis of data from the large DOPPS database showed that there was a large underuse of HMG-Coenzyme A reductase inhibitors (i.e., statins) with

documented indications for use. Use of statins was associated with a 31% decrease in the overall relative risk for death and with a 23% lower risk of cardiac mortality.

6. Bailie GR, Mason NA, Elwell RJ, Sy FZ. Analysis of medication use in peritoneal dialysis patients in two units. Perit Dial Int (in press).

   The authors described the medication prescription practice patterns of PD patients in a prospective, observational study of patients from two outpatient PD clinics. Patients were prescribed a mean of 9.2 medications and took an additional 2.2 OTC medications/patient. Influenza and pneumococcal vaccines had been given to 81% and 38%, respectively. Most (60%) had received hepatitis vaccine, but about half had received the full course. While most patients (88%) had been prescribed phosphate binders, only 48% were on a vitamin D analogue, and the mean iPTH value was 485 pg/mL. There was a low (22%) use of ACE inhibitors. Only 7% of patients had ever had nasal swabs for *S. aureus* carrier status, and mupirocin was routinely used as prophylaxis by 33% of patients. Despite much emphasis placed on appropriate treatment of hemodialysis patients, this report is suggestive that more attention is needed for PD patients. This study has identified several areas of concern where there is opportunity to improve prescription patterns.

7. Drayer DK, Manley HJ. Providing free medications to dialysis patients. A description of a multidisciplinary team medication sampling and patient assistance program. Nephrol News Issues 2004; 18:25-29.

   Many hemodialysis patients are either not insured or are underinsured. These patients require several medications that collectively can cost over $16,000 per year. The authors describe efforts to decrease this burden to some patients through a pharmacist-coordinated multidisciplinary team approach to medication sampling and patient assistance programs at a dialysis facility. Over a 12-month period, 20 patients were provided 3,985 days and $12,751.31 of free medication.

8. Kaplan B, Mason NA, Shimp LA, et al. Chronic hemodialysis patients. Part 1: Characterization and drug-related problems. Ann Pharmacother 1994; 28:316-319.

9. Kaplan B, Shimp LA, Mason NA, et al. Chronic hemodialysis patients. Part II: Reducing drug-related problems through application of the focused drug therapy review program. Ann Pharmacother 1994; 28:320-324.

10. Grabe DW, Low CL, Bailie GR, et al. Evaluation of drug-related problems in an outpatient hemodialysis unit and the impact of a clinical pharmacist. Clin Nephrol 1997; 47:117-121.

    Grabe, et al also documented the occurrence of drug-related problems within a hemodialysis unit. Pharmacist interventions were significant and contributed to improved patient care.

13

GAMBRO Healthcare

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Tel 202 581 9440
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March 30, 2005

To: Renee Bova- Collis/ Social Service Director

From: Linda E. Spencer- Patient Coordinator – Linda E Spencer

Subject: Call for Response for Proposed Condition of Coverage for Dialysis

Subpart A- General Provisions

My dialysis center is Gambro Healthcare Center. It is located on 3857 Pennsylvania Ave. SE, Washington, DC. My center provides what is needed for the patients.
The equipment is checked on a daily basis. Emergency equipment is also checked on a daily basis. The crash cart, oxygen tanks are all in an accessible location so it will be available to use in case of emergency. The staff works as a team. They know what to do, where to go and who to contact. As a patient you do not know what is going on until you see the ambulance crew come in. The ambulance crew comes into the unit and goes out so fast. You do not really know what is happening. The staff will come over and talk to you. They will always make you feel happy even when they feel upset.

Patient Safety- Subpart B

Myra Cruz, Center Director
When it snows Myra Cruz will be at my dialysis center clearing the snow and ice so the patients will have a safe path to come in to dialysis. Her husband who does not work for Gambro will come in with his wife to see that she gets there safe. They will come in as early as 4-5 am. To me that is dedication. The staff also shovels the walkways when they come in. Fairfex Village has people to shovel but they are slow.
The temperature is comfortable. Some clients are colder than others so there is a heater for those clients who would like heat and those who are warm have fans.
The machines are cleaned and sterilized after each patient's treatment. New bags of saline, new dialyzers, new needles, etc. are prepared for the next client.

Patient Care and Rights

Respect and dignity- their standards are very high for each client's individual and personal needs.

The privacy act- my center is very strict about this. I sometimes do not understand this.

At my center, we are a family. Morning, afternoon and evening patients, we are all ESRD patients. When someone gets sick we are concerned. When they die, we would like to pay our respects. But we know the privacy act is the law so we cannot break the law.

Administration- Personal qualifications

Nurse Manager- Myra Cruz, RN- She has been in dialysis for years. It is part of her life. She loves her patients and we love her.
Nelson, RN- He is a dedicated nurse. He shows his love for his patients.
Ester, RN- She is a dedicated nurse. She shows her love for her patients.
Flo, RN- She loves her job and the patients.
As you can see it is an honor to be a patient at my Gambro Healthcare center. The staff makes you feel like you are family. As a dialysis patient it is hard to accept the days of the week that you have to see the machine. The staff and the patients talk to each other and that is why we are a happy family. I thank God for each one of them.

The social worker- Roz will do anything to help you with any problem. She goes from patient to patient and asks if there anything she can do for you. She is always very pleasant.

The dietician- Mercy is very strict but pleasant. She checks with you once a week about the results of your blood work.

The secretary- Carla – she does everything. She is excellent with customer service. She is the first one you see in the morning. She is always pleasant. She helps out in an emergency.

I would like to say that the staff is outstanding. They meet all state government requirements.

The dietician- She is registered and meets the standards.

The social worker- She holds a masters degree and she meets the practice requirements for the state.

The technicians are outstanding.
Sharon, Gina, Yemi, Regina, Joe, Doretha, Myron are always there to please and serve their patients with a pleasant smile on their faces.
Patient care technicians meet all state requirements, practice certification and licensure. They have training programs that are approved by the medical director and governing body. The patient care technicians are supervised by the registered nurse. Technicians monitoring the water treatment system must complete a training program that has to be approved by the medical director and governing body.

Conditions and Governance
There are an adequate number of personnel for patients that are under going dialysis.

RN's are in the facility at all times. As a patient, if you have a grievance with the facility, you are free to write down your grievance. Myra and Richard, the regional director will have a meeting.

April 3, 2005

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
File Code: CMS-3818-P
PO Box 8012
Baltimore, MD 21244-8012

Dear Dr. McClellan:

I am writing to offer comments regarding the proposed revisions to the Conditions for Coverage for End Stage Renal Disease Facilities. Specifically I wish to comment on Proposed § 494.140 ("Personnel Qualifications") as this section addresses the possible role of a pharmacist within the dialysis facility. I appreciate that the Proposed Rule acknowledges the well-documented contributions a pharmacist can make to the safe and effective use of medications in the vulnerable dialysis patient population.

I am the Director of Pharmacy for Lifecare Hospitals of Milwaukee. Our facility is an Acute Long Term Care facility. We are a small specialty hospital in the heart of Milwaukee, Wisconsin providing care to medically complex patients. Many of our patients have end stage renal disease and require dialysis. Being a small hospital, I am intimately involved in the clinical as well as administrative practice of pharmacy at our hospital. I am submitting comments because I believe my contributions to the health care team in our setting are crucial and many potential medication use problems are avoided because of access to clinical pharmacy services.

I believe that consultant pharmacists **must** be included as part of the dialysis facility staff for the following reasons:

- Drug therapy in dialysis patients is extremely complex, requiring careful scheduling of medication administration times to avoid conflicts with dialysis including changes in patient vital signs during dialysis that may require a delay in administration of anti-hypertensive agents, as one example.
- The pharmacokinetic complexity of drugs during dialysis requires careful monitoring. In my facility, the pharmacist manages drug dosing and pharmacokinetic monitoring to assure desired therapeutic outcomes while avoiding drug accumulation or inadequate serum concentrations. We have many patients receiving vancomycin and other antibiotics for serious infections.
- The patients with end stage renal disease are vulnerable to adverse medication-related outcomes due to the unpredictability of drug handling within their bodies. The pharmacist provides a unique set of skills to assist the health care team in managing medication therapy.

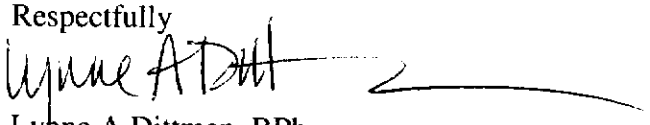
- The storage, preparation, and administration of medications within the dialysis unit should be under the supervision of a pharmacist. This doesn't necessarily mean a physical day to day presence; however, a pharmacist has a tremendous depth of knowledge regarding safe medication handling and professional standards for all distributive aspects of drugs.
- Obviously, cost effective drug therapy is every care giver's goal. I believe the pharmacist's focus on drug dosing, utilization, and monitoring enhances any organization's ability to control costs.
- The training of pharmacists prepares us serve as consultants to dialysis facilities. We routinely perform the above mentioned services in a variety of settings.

Specifically, I would like to make the following recommendations:

1. The multidisciplinary dialysis team should include a consultant pharmacist with experience or training in nephrology pharmacy.
2. The routine patient care assessment of dialysis patients should include a medication review by a pharmacist.
3. Medication reviews should be conducted at least monthly. This frequency is consistent with what is required in skilled nursing and intermediate care facilities.
4. Pharmacists should participate in the development and implementation of medication-related protocols within dialysis to assure cost-effective drug use.
5. Dialysis facilities should develop and maintain appropriate policies for the safe storage, preparation and administration of medications within the facility. These policies should be developed and maintained in consultation with a pharmacist.

I appreciate the opportunity to offer my comments. I am pleased that CMS acknowledges the complex nature of drug therapy required by dialysis patients and the potential for adverse outcomes if medications are not used appropriately. This patient population is medically complex and vulnerable. All of the dialysis patients I see are taking multiple medications for multiple medical conditions. Pharmacists are the natural partner for the medication related activities of dialysis centers. They will perform identified tasks more efficiently due to their background and training.

Respectfully



Lynne A Dittman, RPh
Director of Pharmacy,
Lifecare Hospitals of Milwaukee
(414) 447-3325
ldittmanedler@wi.rr.com

Form letter 15

DaVita™

Kidney Dialysis Care Units
3600 E. Martin Luther King Jr. Blvd.
Lynwood, CA 90262
Tel: (310) 639-6320
Fax: (310) 639-9071

March 28, 2005

Centers for Medicare & Medicaid Services
DEPARTMENT OF HEALTH AND HUMAN SERVICES
P.O. Box 8012
Baltimore, MD 21244-8012

To Whom It May Concern,

I am writing in response to the newly proposed changes in conditions of coverage for dialysis facilities. The following one is of particular concern: Section 494.140(d): The "Grandfather Clause". Having worked in the dialysis field since 2000 have come across several BSW's, B.A.'s M.A.'s, MFT's and PhD.'s in the work force. These professionals ave a wealth of information, skills, and experience that no degree can replace. These were the professionals that were in the "trenches" since at least 1976 and have weathered the storms of the dialysis world. Also they have always been monitored and supervised by an LCSW. What criteria is being used to now decide to change this law? It is my firm opinion that these few should remain "grandfathered in" until 2015 and allowed to continue to provide the high quality of service they have been doing since 1976. To eliminate this clause would be a detriment to the dialysis patients and a disregard for their contribution and years of service.

Please do not eliminate the "Grandfather Clause"!

Sincerely,

Lisa Greaves, BSW

Lisa Greaves, BSW
Kidney Dialysis Care Unit
Case Worker

Form letter-16

Carson Artificial Kidney Center

1309 East Carson Street
Carson, CA 90745

March 21, 2005

Centers for Medicaid & Medicare Services
Department of Health and Human Services
P.O. Box 8012
Baltimore, MD 21244-8012

Attention: CMS-3818-P

To Whom It May Concern:

Anne Reyhan is a Licensed Marriage and Family Therapist (LMFT) in the State of California and has been in the field of dialysis as a social worker for several years. I am the administrator of Carson Artificial Kidney Center and have worked with Anne Reyhan for over fifteen years.

I am writing this letter in response to the proposed changes in Conditions for Coverage for End Stage Renal Disease facilities, in particular, the proposed elimination of the grandfather clause" in Section 494.140(d). Anne is a very skilled social worker and is multifaceted in the service she is able to deliver to patients. She provides clinical interventions as well as assists with funding, transportation and other resources. Due to the many years she has served in the dialysis field, she would be a great loss to the clinics she serves.

The existing regulations require a renal social worker to have an MSW degree or be a Licensed Clinical Social Worker (LCSW). Based upon my experience with both disciplines, I have found LCSW's and LMFT's equally qualified and competent to function as renal social workers. Anne's training as an LMFT has prepared her well to function as a social worker in the dialysis setting and address the complex psychosocial issues that are often exhibited in these chronically ill patients. It is my hope that when the final decisions are made regarding the proposed changes, that LMFT's will be included in the regulations as qualified social worker.

Sincerely yours,

Angelita Tichachati

Angelita Tichachati, R.N
Administrator

Form letter #17

DaVita.

Doctors Dialysis Center of E. L.A.
950 S. Eastern Avenue
Los Angeles, CA 90022
Tel: (323) 262-2229 Fax: (323) 262-9418

March 26, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8012
Baltimore, MD 21244-8012

Attention: CMS-3818-P

To Whom It May Concern:

I have worked closely with Anne Reyhan in the field of dialysis for several years. In her capacity as social worker I have found her to be very professional and her skill level is excellent. Anne is one of the best social workers I have worked with over the years. Anne is well respected by her co-workers and the patients and their families seek her out. Our patients often present with many difficult issues and Anne is able to intervene and empower them to help facilitate movement towards a solution. In addition to excellent communication skills, her knowledge of community resources is invaluable and her documentation is thorough and reflects what is occurring with the patient.

I believe the MFT is as equally qualified as the MSW based on the educational process they undergo to become an MFT and therefore should be included as an eligible candidate for the role of nephrology social worker. The "grandfather clause" should be retained as it would be a great loss if a professional like Anne were to be forced out of the nephrology field. If you have any questions, please do not hesitate to contact me.

Sincerely,

Victor Carabello, M.D.

VIRGINIA PHARMACISTS ASSOCIATION

5501 Patterson Avenue, Suite 200 Richmond, Virginia 23226
Phone: (804) 285-4145 Fax: (804) 285-4227
E-Mail: vpha@vapharmacy.org http://www.vapharmacy.org

April 18, 2005

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
File Code: CMS-3818-P
PO Box 8012
Baltimore, MD 21244-8012

Dear Dr. McClellan:

I am writing on behalf of the Virginia Pharmacists Association, founded in 1881 representing the profession of pharmacy in Virginia, to offer comments regarding the proposed revisions to the Conditions for Coverage for End Stage Renal Disease (ESRD) Facilities. My comments will specifically address Proposed § 494.140 ("Personnel Qualifications") and the potential role of a pharmacist within the dialysis facility. While we are very pleased that the proposed rule recognizes the important contributions of a pharmacist in the care of dialysis patients, we feel the final rule should include a specific role for a pharmacist on the multidisciplinary dialysis team.

There are numerous reasons to support the inclusion of a pharmacist consultant in the dialysis facility staff. One primary reason is the complex nature of drug therapy in dialysis patients. These patients are on multiple medications and usually have a number of co-morbid conditions complicating their treatment. These conditions present an increased risk of drug interactions and adverse drug events. Pharmacists are well trained to review medication profiles and laboratory results to verify that the treatment plans achieve the best possible therapeutic outcomes while minimizing adverse events.

Many factors further complicate the care of dialysis patients. Kidney disease and dialysis greatly affect drug disposition and clearance in the body. This necessitates patient specific medication dosing which pharmacists are trained to manage. Other medications used in dialysis facilities for patients such as heparin, insulin, and intravenous electrolytes are high-alert medications requiring a great deal of caution. Oversight of the inventory and use of these medications is an area of expertise for pharmacists in a hospital setting and could easily translate to the dialysis facility.

Additionally, pharmacists are a valuable member of the healthcare team to contain the increasing cost of care for ESRD patients. Medication reviews by pharmacists in nursing facilities have been shown to decrease healthcare spending. Creation of therapy protocols and minimization of adverse events will also help provide dialysis patients with more cost-effective therapy.

Specifically, we would like to make the following recommendations:

1. The multidisciplinary dialysis team should include a pharmacist consultant with experience or training in nephrology pharmacy.
2. The routine patient care assessment of dialysis patients should include a medication review by a pharmacist.
3. Medication reviews should be conducted at least monthly. This frequency is consistent with what is required in skilled nursing and intermediate care facilities.
4. Pharmacists should participate in the development and implementation of medication-related protocols within dialysis to assure cost-effective drug use.
5. Dialysis facilities should develop and maintain appropriate policies for the safe storage, preparation and administration of medications within the facility. These policies should be developed and maintained in consultation with a pharmacist.

Your consideration of our recommendations and comments is greatly appreciated.

Sincerely,

James A. Pickral, Jr.
Director of Policy
Virginia Pharmacists Association

The University of Georgia

College of Pharmacy

Department of Clinical and Administrative Pharmacy

April 11, 2005

Mark B. McClellan, MD, PhD
Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
File Code: CMS-3818-P
PO Box 8012
Baltimore, MD 21244-8012

Dear Dr. McClellan:

I am writing to offer comments regarding the proposed revisions to the Conditions for Coverage for End Stage Renal Disease Facilities. Specifically I wish to comment on Proposed § 494.140 ("Personnel Qualifications") as this section addresses the possible role of a pharmacist within the dialysis facility.

As a pharmacist faculty member working in an academic medical center for nearly thirty years, I recognize the need for pharmacists to be more professionally involved at all levels of patient care, especially with patients requiring numerous daily medications.

Therefore, I certainly support the addition of medication management services for dialysis patients. I favor the role of pharmacists in all aspects of pharmaceutical care, especially the review and assessment of all medication regimens as a member of an interdisciplinary team. I am sure these patients will benefit from such services and am very excited about the likely addition of pharmacists to this specialized patient care group.

I look forward to a positive review by your agency and the improved patient outcomes realized through greater pharmacist participation in the care of these patients. Thank you for your work in this important area.

Sincerely,

A. Thomas Taylor, Pharm.D.
Assistant Dean and Associate Head
Clinical and Administrative Pharmacy
Clinical Professor
Medical College of Georgia School of Medicine

CJ-1020, The Medical College of Georgia, Augusta, Georgia 30912-2450
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Shasta Critical Care Specialists

Bruce G. Bartlow, MD
Jeffrey Krahling, MD, PhD
Rafael Lupercio, MD
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1555 East St., Suite 300
180 Northpoint
Redding, CA 96001
530-232-3047

To: Centers for Medicare & Medicaid Services
Department of Health Services
PO Box 8012
Baltimore, MD 21244-8012

16 April, 2005

Re: File Code CMS-3818p

Dear Sirs/Madams :

Thank you for the opportunity to respond to your Proposed Rules, ESRD Conditions of Participation. Much of the proposed changes, including efforts to reduce compliance burden and improve patient outcomes are excellent and worthy of support. I have the following concerns:

(1) None of my nephrology or Medical Director colleagues are aware of the proposed rule changes. Therefore, I hope you will take absence of response on their part not as assent or indifference, but unawareness.

(2) Patient Safety: CDC guidelines encourage Hepatitis C testing. Current practice offers no guidelines for change in management (isolation, reuse) for Hepatitis C or HIV patients. The current law refusing payment for HIV or Hepatitis C testing and no higher payment for the additional cost of isolation constitutes an "unfunded mandate" and should be changed.

(3) Patient Rights: As you'll see from the attached, I speak nationally with dialysis, community and other groups on end-of-life issues and Advance Directives (ADs). The PSDA, 1991 used the same language used here, requiring federally-funded healthcare institutions to "inform patients of their right to establish an AD." The PSDA had zero impact on patients' completing ADs.

I would recommend:

- encourage Networks or national dialysis organizations to develop guidelines for when, how, and through what means to encourage completion of ADs.
- Include re-evaluation of ADs at annual Assessments and updates.
- Develop a new, dialysis-specific AD which would provide clarity not evident in current ADs. The typical "do not resuscitate" clause states:

> "if I am in permanent coma, if I have an irreversible condition, or if the burden outweighs the benefit."

This provides no clear indication of "Do not resuscitate" in an emergency condition. It would not have saved Terri Schiavo had she completed it, and it would not tell a dialysis facility or EMTs whether or not to perform CPR in a patient who collapses in the dialysis facility. I've attached two ADs that could be used to provide clarity. The ESRD Workgroup of "Promoting Excellence in End-of-Life Care" offered a more specific AD and guidelines for dialysis providers in discussing end-of-life care with patients. Their recommendations are available at www.promotingexcellence.com, and have been previously reported to CMS.

- Funding for Social Worker time to address end-of-life issues could be linked to completion of ADs and end-of-life planning as part of intake and annual review.

The same ESRD Workgroup report includes careful testing of several Quality-of-life assessment tools.

(4) I applaud the inclusion of patient quality-of-life assessment and goals in annual or semi-annual reviews. These should be incorporated as well in the AD and be a component of end-of-life planning. A focus on patient goals, their feasibility and what is needed to achieve them are crucial in both dialysis and end-of-life planning. These could be incorporated in funded performance measures as crucial, if not more crucial, than biochemical tests.

(5) Nursing Service: Current funding makes provision of dialysis in SNFs an impossibility. Of greater concern, safe and high-quality dialysis care in those settings would require supervision by a nephrologists, availability of all the support available in the Acute Inpatient setting, and is in most cases not equivalent to home dialysis of a stable patient.

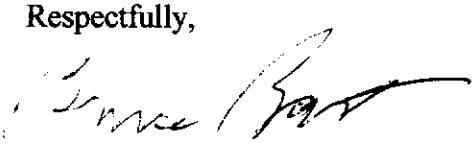
It's my feeling that SNF dialysis would require funding at the same level as acute inpatient dialysis, immediate access on-site to CPR, radiology, respiratory therapy and critical care response, and should demand no additional burden or financial demands of SNF personnel and facilities.

(6) Your intention to reduce administrative burden and not micro-manage is laudable, but not evident in the sum of your proposals. I would encourage you to examine the balance of reduced versus increased reporting, surveillance and demands. Unfunded mandates (hepatitis C testing, isolation, increased social worker time to deal with patient quality of life, end-of-life planning and goals, for example) should be replaced by additional funding for performance of such vital work. To the extent your desire is to improve

patient care, long experience has shown that unfunded mandates don't work, while funding based on performance measures is highly successful.

I hope these comments are helpful. I would be delighted to work with you in translating them into appropriate language, documents and guidelines.

Respectfully,



Bruce Bartlow, MD
Medical Director, Redding DaVita Dialysis

CURRICULUM VITAE

Bruce G. Bartlow, MD, FACP
22132 Lassen View Dr.
Palo Cedro, CA 96073
530-547-3617
beeper 530-226-7891
e.mail bgb@snowcrest.net

Born: Omaha, Nebr., Oct 2, 1947

SSN 327-42-6918

Present Academic Rank

Clinical Professor, Univ. of CA at Davis, Dept. of Family Practice
Chairman, Biomedical Ethics, Redding Med. Center, Redding, CA

Education

Northwestern University, Evanston, IL	9/65-6/67
Northwestern University Med., Chicago, IL	6/67-6/71
Internship, Chicago Wesley Memorial Hospital Chicago, IL	6/71-6/72
Residency, Internal Medicine, Rush-Presbyterian St. Luke's Med. Ctr., Chicago, IL	6/72-6/74
U.S.Army 3rd General Dispensary, Karlsruhe, W.Germany	8/74-8/76
Fellowship, Nephrology, Rush-Presbyterian St.Luke's Med. Ctr., Chicago, IL	9/76-6/78
Kidney Foundation Fellowship, Rush-Presbyterian St.Luke's Med. Ctr., Chicago, IL	6/78-6/79

Certification - Board Certified in:

Internal Medicine # 48410	June 19, 1974
Nephrology #48410	June 17, 1980
Critical Care # 48410	Nov 5, 1991

Medical Licensure

California G39299

Honors

Outstanding Clinical Instructor,
Children's Hospital, San Francisco 1981
UCSF Family Practice, San Francisco 1992

Military Service

US Army, 3rd General Dispensary, Karlsruhe, W.Germany 1974-76

Positions

Medical Staff
Children's Hospital SF 1979-83
Mt.Zion Hospital, SF 1979-95
Ralph K.Davies, SF 1979-95
Pacific Med. Ctr. Renal Transplant 1980-83
El Camino Hospital, Mountain View, CA 1983-84
St.Luke's Hospital, SF 1986-95
Pacific Med. Ctr. Nephrology 1987-95
Redding Med. Ctr., Redding, CA 1995-present
Mercy Med. Ctr., Redding, CA 1995-present
TRC/DaVita Dialysis 1995-present

Clinical Faculty, UCSF Medical 1991-95
UC Davis Medical 1999-present
Medical Director, Medical Volunteers International,
Tokar, Sudan 1984-86
Director, Intensive Care, St.Luke's Hospital, SF 1991-95
Director, St.Luke's Subacute Unit, SF 1992-95
Associate Director, TRC dialysis, Redding 1997-present

Teaching Positions

Anatomy, Northwestern University Med. 1968
Internal Medicine, Rush-Presbyterian St.Luke's 1972-74

Nephrology, Rush-Presbyterian	1978-79
Nephrology, Internal Medicine, Children's SF	1980-81
Nephrology, Internal Medicine, Valley Med. Ctr., Santa Clara, CA	1983-84
Family Practice (Critical Care), UCSF	1991-95
Family Practice (Primary Care), UC Davis	1998- present

Committee Memberships

Children's Hospital SF	Hemodialysis	1981-83
	Parenteral Nutrition	1981-83
	Antibiotic Utilization	1982-83
Pacific Med Center SF	Utilization Review	1982-83
El Camino, Mountain View	Hyperalimentation	1982-84
St.Luke's, SF	Medical Records	1987-95
	Special Care	1991-95
	Vice Chief of Staff	1991-92
	Board of Directors	1991-92
	Medical M&M Conference	1988-95
Redding Med. Ctr., Redding	Ethics	1995-
Mercy Med. Ctr., Redding	Ethics	1995-98

Vice President, Board of Directors, Transpacific Renal Network, 2004-

Other Committee Memberships

Infection Control
Ethics
Nutrition
Resource Management
Ethics Leadership, Catholic Healthcare West
Bay Area Network of Ethics Committees, San Francisco Med. Society
Infection Control
Critical Care
Credentials
TRC Dialysis CQI
Vice-Chair, Transpacific Renal Network, 2004-

Organizations

Alpha Omega Alpha

San Francisco Medical Society
American College of Physicians
AMA
CMA
Shasta County Medical Society
American Society of Nephrology
International Society of Law, Medicine and Ethics

Grants

Pillsbury Foundation Fellowship	1977-9
National Kidney Foundation, Research Fellow	1978-9
Rush-Presbyterian Institutional Grant	1978-9
Robert M. Kark Award, Clinical Research	1979
Nephrology Research Fund Grant, Pacific Med. Ctr.	1981
Medical Volunteers International, Medical Director	1983-4

Other

Chicago Maternity Center, home obstetrics, perinatal prenatal, Chicago	1969-70
Extern, Hopital Clinico de Madrid, Spain	1970
Development and Implementation of Maternal/Child Welfare Project, Tokar, Sudan	1985-86

Languages

Spanish, fluent
French, German, passable

Publications

Bartlow BG, Penn RD: Carotid-cavernous fistula presenting as a posterior fossa mass. J.Neurosurg 42:585-588, 1976

Bartlow BG, Oyama JH, Ing TS, Miller AW, Economou SG, Rennie IDB, Lewis EJ: Glomerular ultrastructural abnormalities in a patient with mixed IgG-IgM essential cryoglobulinemic glomerulonephritis. Nephron 14:309-319, 1975

Bartlow BG, Roberts JL, Lewis EJ: Identification of a non-immunoglobulin C3 nephritic factor

(C3NeF) with C3b-inactivator (C3bINA) accelerator (B1H). Clin Res 26:373A, 1978

Bartlow BG, Roberts JL, Lewis EJ: A non-immunoglobulin C3 activating factor in membranoproliferative glomerulonephritis. Kidney International 15:294-302, 1980

Roberts JL, Levy M, Chioros PG, Bartlow BG, Forristal J, West CD, Habib R, Lewis EJ: A serum C3-activating factor: its characterization and its presence in glomerular deposits. J Immunol 127:1131-37, 1981

El Camino Hospital Nutrition Support Manual, 1984

Bartlow BG: What next for famine-ravaged Africa? Chicago Sun-Times Jan 35, 1987

Bartlow BG: Sudan: coming of age in the disaster. Critique of America p. 16, Apr-May 1988

Bartlow BG: Microhematuria: Picking the fewest tests to make an accurate diagnosis. Postgraduate Medicine 88-4:138, 1990

Bartlow BG: We must start to ration life on the respirator. San Francisco Chronicle p.A-21, June 22, 1994

Futility Guidelines, Bay Area Network of Ethics Committees, San Francisco Med Society, 1994.

Bartlow BG: Who wants to stop futile care? San Francisco Med Society Journal Oct 1994

Bartlow BG: Leaving San Francisco. San Francisco Med Society Journal Oct 1996

Bartlow BG: Medical Care of the Soul. Johnson Books, Boulder, Colo. 2000

Bartlow BG: Healing the End of Life. Am Coll Chest Phys, ACCP-CA, Oct 2000

Bartlow, BG: Why Am I Here? Lastacts.com, Oct 1, 2000

Bartlow, BG: Final Gifts, American Kidney Fund on-line journal, 10/01

Bartlow, BG: Series on end-of-life issues, "The Valley News," Shingletown, CA

Bartlow, BG: Practical Applications of Palliative Care Guidelines Will Take Time, Effort. Nephrology News & Issues, p.53, March, 3003

Bartlow, BG: Final Journey: of Transplant, Love and Transfiguration. TBI Online, April, 03

Bartlow, BG: From Here to Eternity: How do Physicians Learn to Let Go? Nephrology News and Issues, July, 2003

Bartlow, BG: Parting Gifts. What Begins when Technology Ends. Nephrology News and Issues, Sep 2003

Bartlow, BG: A Death in the Island. Nephrology Incite. Feb, 2005

Bartlow, BG: The Spirit in the Empty Chair. IKidney, Feb, 2005

Bartlow, BG: Who Has Rights, Anyway? Neph News and Issues 19-5:45-48, Apr, 2005

Presentations

Am Kidney Association, "A non-IgG C3NeF", New Orleans 1979

Morbidity and Mortality Conference, St.Luke's Hospital SF, monthly 1989-1994

Bay Area Network of Ethics Committees, SF Med Soc, 7/22/94: "Futility of Care Guidelines."

St.Luke's Hospital, 1994: CPR Outcomes and the Realities of end-of-life support.

St.Luke's Hospital, 1994: Shock

Resuscitation III, IV, V Conference, Redding Med Center, Redding, CA Oct 1995: Realities and Practice of End-of-Life Decisions, 1995-97

Advance Directives. Multiple community groups, 1994-present

End-of-Life decisions, San Francisco Commonwealth Club, 1994

"Good Death/Bad Death," Mercy Medical Center, Redding, 1997

"A brief history and future of end-of-life discussions," Stanford University, 2/5/98

"Medical Care of the Soul," Bay Area Network of Ethics Committees, 2/4/98

"Medical Care of the Soul," Cal Pacific Med Center, San Francisco, 3/10/98

"Diabetic Renal Disease," Doubletree, Redding, CA 3/15/98

"Beyond Advance Directives," Mercy Hospice, Redding, CA 5/22/98

"Final Gifts," Stanford Ethics Conference, May 22, 1999

"Medical Care of the Soul,"
California Society of Respiratory and Cardiac Rehabilitation, Tahoe, CA, May 29, 1999
Medicine in the Mountains, Greenville, CA, 6/22/99
KARA Conference, VA Hospice, Palo Alto, CA, Feb 1999
Erskine Overnight radio, Oct 4, 2000
Jefferson Public Radio, Oct 10, 2000
Southern Oregon Public Television, Oct 10, 2000
Shreveport, LA radio, Oct 20, 2000
KUSP radio, Nov 27, 2000
1st International Conference on Men's and Women's Health at Midlife, Dec 2, 2001
Baptist Health Systems Ethics Symposium, San Antonio, Tx, May 2001
Brooks Army Medical Center, San Antonio, Tx, May 2001
Mercy Medical Center, Redding, CA 5/23/02
AMA Ethics and Legal Section, Chicago, IL, June 21, 2001
American Kidney Fund, Chicago, IL, Jun 22, 2001
Washington, DC, Sept 23, 2001
Atlanta, GA, 11/05/01
Sacramento, CA 5/22/02
New York, NY 9/13/02
Los Angeles, 11/6/03
Texas/Southeastern ESRD Network, Dallas, 10/20/02
Bay Area ESRD Network, Oakland, CA, 11/15/02
Southeastern ESRD Network, Tampa, FL, 11/22/02
NKF, San Francisco, CA and Sacramento, CA, 2/20-21/03
Transplant Bank of Northern CA, Redding, CA, 4/12/03
National Kidney Foundation, So. Cal, Los Angeles, 9/13/03
Swedish Medical Center, Seattle, WA, 10/22/03
Sacramento, CA ANNA 9/24/04 San Luis Obispo, CA 2/2/05
California Dialysis Council, 11/15/04
San Luis Obispo, CA 2/2/05

ESRD End-of-life Care, Sacramento, CA 3/31/04
Seattle, WA 3/18/04
ESRD Management of the Difficult Patient, Sacramento, CA 3/31/04

Additional Ethics Activities:

Established monthly multi-disciplinary ethics workshop at Redding Med Center for education, policy development and group ventilation.

Established Ethics Consultative Group, Redding Medical Center, 1995.

Outlined protocols for CQI-formatted investigation of institutional compliance with patients' advance directive wishes, leading toward mandatory AD inquiry and confirmation at time of admission. Ethics Leadership Group, Catholic Healthcare West, Sacramento, CA, 1996.

Guidelines for Institutional Response to Physician Refusal to treat HIV/HepC patients. Redding Medical Center, 1996.

UC San Diego Symposium on Futile Care, 2/20/98

Bereavement, Redding Medical Center, Jan, 2000

Access to Mental Health Services, Shasta/Trinity/Tehama County, Feb-June, 2001

Transpacific Renal Network Working Group, "Patients who Try Our Patience", Half-Moon Bay, CA, 10/05/02: Principal presentor/facilitator, Ethics of Termination of Dialysis for Dangerous Patients.

In Progress: "A Rose Garden," with Joni Walton: Experiences and writings of those who've been through end-of-life experiences – the dying, the surviving, the wounded and the transformed.

"Khadija, a Romance of Islam and the West"

"Mahmoud"

"Junkyard Dog"

WOODLAND DIALYSIS
SERVICES

35 WEST MAIN STREET • WOODLAND, CA 95695 • PHONE (530)668-4503 • FAX (530)668-4502

Centers for Medicare & Medicaid Services
Department of Health Services
PO Box 8012
Baltimore, Maryland 21244

RE: FILE CODE CMS 3818-P

To Whom It May Concern:

I object to the proposal that each dialysis unit must have an isolation chair for Hepatitis B patients. Our 13 station dialysis unit has **NO** Hepatitis B patients. It would be a huge financial burden to our business and a disservice to our community if we were unable to take six non-Hepatitis B patients for treatments because we were obligated to set aside a chair for a current non-event.

This proposal should be struck for dialysis units, as Hepatitis B in dialysis units represents an extremely low occurrence.

Sincerely,

Joseph (administrator) for M. Mezger.

Matthew Mezger, MD

DaVita

Doctors Dialysis Center of E. L.A.
950 S. Eastern Avenue
Los Angeles, CA 90022
Tel: (323) 262-2229 Fax: (323) 262-9418

March 5, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8012
Baltimore, MD 21244-8012

Attention: CMS-3818-P

To Whom It May Concern:

Anne Reyhan is a licensed Marriage and Family Therapist (LMFT) who I have supervised for the past four years in various dialysis units. I have been licensed as a Clinical Social Worker since 1995. In addition to the therapeutic interventions she provides, she completes psychosocial assessments, develops treatment plans and assists patients with such needs as insurance benefits, transportation, medications, housing, durable medical equipment.

Anne has a good understanding of how dialysis impacts family dynamics and the need for therapeutic intervention for optimal adjustment. She frequently assists with adjustment issues, relationship difficulties, and mood disorders (anxiety and depression) that often arise from the dialysis regimen. Anne is very skilled with her interventions with the patients and their families. They appear to have a good rapport with her and are comfortable with her approach. As an added bonus Anne has a thorough knowledge of community resources, which enables her to assist this population. Her documentation is thorough and paints a clear picture of the patient and/or family being discussed. I believe that with the education and experience Anne has she is perfectly capable of working without being supervised, however the current Medicare regulations require it since she does not have an MSW Degree.

As for the proposed changes in conditions for coverage, specifically regarding the "grandfather clause", I believe it should not be eliminated. Because of their experience, an individual such as Anne who has been employed in the dialysis setting for several years supports the argument that the "grandfather clause" should be retained. In addition, MFT's should be considered to be equal to a master's level social worker because of their similar education and training.

DaVita

Doctors Dialysis Center of E. L.A.
950 S. Eastern Avenue
Los Angeles, CA 90022
Tel: (323) 262-2229 Fax: (323) 262-9418

Anne is a definite asset to the dialysis community and it continues to be a pleasure supervising her. If you have any questions, please feel free to contact me.

Sincerely,

Deborah Gill, LCSW

Deborah Gill, LCSW
2421 North Brynwood Street
Santa Ana, CA 92705
Email: lcsw@adelphia.net
(714) 321-6474

March 5, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8012
Baltimore, MD 21244-8012

Attention: CMS-3818-P

To Whom It May Concern:

I am a licensed Marriage and Family Therapist (LMFT) in the State of California and have been employed in the dialysis field for the past several years. I have been retained in my current position under the grandfather clause and am supervised by an LCSW.

I am writing this letter in response to the newly proposed changes in conditions for coverage for End State Renal Disease facilities. I have concerns about these changes and they are as follows:

Section 494.140(d): The "grandfather clause" should be retained because there are those of us (a limited number of individuals) who have several years of experience in the dialysis field and are well equipped to provide for all facets of patient needs. What real purpose would it serve to eliminate this clause? What protection is there for those of us who, by virtue of longevity, are valuable experts in the field of dialysis?

The newly proposed regulations should include a clause that would protect the job security of the veteran social workers that are qualified to work under the existing "grandfather clause."

Rather than make this change specific to Masters in Social Work, why not include those holding Masters degrees in related fields (i.e., psychology, sociology, Marriage and Family Therapy). Training is similar and that, coupled with the experience in the dialysis field, makes for effective employees.

The existing regulation (405.2102(f)) requires a Licensed Clinical Social Worker and the new proposal suggests eliminating the clinical designation. I am wondering why the proposal to remove this position? Could it be there is a shortage of LCSW's available? If this is the reason, why not consider utilizing LMFT's in the same capacity since they are equally qualified. The LMFT like the LCSW is trained to meet the psychosocial needs of the dialysis patient. As an LMFT, I perform all the duties of an LCSW

including: psychosocial evaluations, development of treatment plans based on patient's needs, and direct social work interventions. As an LMFT I am able to function autonomously and provide therapeutic interventions around life changes and adaptation to the dialysis regimen and coping with grief and loss issues. Because dialysis affects the entire family system, an MFT is well qualified to provide family therapy as we receive much training in family therapy. We are able to treat a myriad of issues that often arise in this setting, including relationship difficulties due to change in roles, family conflicts, and the degree to which families adapt.

The existing expectation that social workers assist patients with transportation, insurance benefits, housing, medications, and other community resources is in line with their training in community work. Whether or not a change is made regarding delegating this role to nonprofessional facility staff does not affect the ability of an MFT to provide what is needed to assure optimal outcomes for the patient. Although MFT training does not focus on community work, I am an expert in this area due to my years of experience in various dialysis settings.

In conclusion, it is my belief that the "grandfather clause" should not be eliminated. LCSW's should be retained and LMFT's should be included in this category as the issues of the dialysis patients are complex and require clinical skills to provide the specialized care that is needed.

Enclosed is information regarding the qualification and licensure requirements for MSW's and MFT's to enable you to realize the similarities of these two disciplines. This information was obtained from www.bbs.ca.gov.

If you are in need of any additional information, please do not hesitate to contact me or the above-mentioned web site.

I will be anxiously awaiting your decision.

Sincerely,

Anne Reyhan, MFT
946 Sunny Hill Place
Diamond Bar, CA 91765
Email: areyhan@adelphia.net
(909) 964-2464

ISSUED BY:

BOARD OF BEHAVIORAL SCIENCES

LAWS AND REGULATIONS RELATING TO THE PRACTICE OF MARRIAGE AND FAMILY THERAPY, LICENSED CLINICAL SOCIAL WORK, AND LICENSED EDUCATIONAL PSYCHOLOGY

BOARD OF BEHAVIORAL SCIENCES
400 R STREET, SUITE 3150
SACRAMENTO, CA 95814-6240
WEBSITE ADDRESS: http://www.bbs.ca.gov

JANUARY 2005

PAUL RICHES
EXECUTIVE OFFICER

2005 LAWS - TABLE OF CONTENTS

BUSINESS AND PROFESSIONS CODE OF CALIFORNIA

CHAPTER 13. MARRIAGE AND FAMILY THERAPISTS

If those moneys transferred from the Behavioral Sciences Fund to the General Fund pursuant to the 1991 Budget Act are redeposited to the Behavioral Sciences Fund, the fees assessed by the board shall be reduced correspondingly.

Leg.H. (Added by Stats. 1995, ch. 839, sec. 4.)

ARTICLE 4. CLINICAL SOCIAL WORKERS

§4996. NECESSITY OF LICENSE; UNAUTHORIZED REPRESENTATION AS LICENSEE; MISDEMEANOR

(a) Only individuals who have received a license under this article may style themselves as "Licensed Clinical Social Workers." Every individual who styles himself or herself or who holds himself or herself out to be a licensed clinical social worker, or who uses any words or symbols indicating or tending to indicate that he or she is a licensed clinical social worker, without holding his or her license in good standing under this article, is guilty of a misdemeanor.

(b) It is unlawful for any person to engage in the practice of clinical social work unless at the time of so doing such person holds a valid, unexpired, and unrevoked license under this article.

(c) A clinical social worker licensed under this chapter is a licentiate for purposes of paragraph (2) of subdivision (a) of Section 805, and thus is a health care practitioner subject to the provisions of Section 2290.5 pursuant to subdivision (b) of that section.

Leg.H. (Added by Stats. 1985, ch. 820, sec. 1; Amended by Stats. 2003, ch.20, sec.5.)

§4996.1. ISSUANCE OF LICENSE

The board shall issue a clinical social worker license to each applicant who qualifies pursuant to this article and successfully passes a board administered written or oral examination or both examinations. An applicant who has successfully passed a previously administered written examination may be subsequently required to take and pass another written examination.

Leg.H. (Added by Stats. 1985, ch. 820, sec. 1; Amended by Stats. 2003, ch. 874, Section 13.)

§4996.2. QUALIFICATIONS OF LICENSES

Each applicant shall furnish evidence satisfactory to the board that he or she complies with all of the following requirements:

(a) Is at least 21 years of age.

(b) Has received a master's degree from an accredited school of social work.

(c) Has had two years of supervised post-master's degree experience, as specified in Section 4996.20, 4996.21, or 4996.23.

(d) Has not committed any crimes or acts constituting grounds for denial of licensure under Section 480. The board shall not issue a registration or license to any person who has been convicted of any crime in this or another state or in a territory of the United States that involves sexual abuse of children or who is required to register pursuant to Section 290 of the Penal Code or the equivalent in another state or territory.

(e) Has completed adequate instruction and training in the subject of alcoholism and other chemical substance

dependency. This requirement applies only to applicants who matriculate on or after January 1, 1986.

(f) Has completed instruction and training in spousal or partner abuse assessment, detection, and intervention. This requirement applies to an applicant who began graduate training during the period commencing on January 1, 1995, and ending on December 31, 2003. An applicant who began graduate training on or after January 1, 2004, shall complete a minimum of 15 contact hours of coursework in spousal or partner abuse assessment, detection, and intervention strategies, including knowledge of community resources, cultural factors, and same gender abuse dynamics. Coursework required under this subdivision may be satisfactory if taken either in fulfillment of other educational requirements for licensure or in a separate course. This requirement for coursework shall be satisfied by, and the board shall accept in satisfaction of the requirement, a certification from the chief academic officer of the educational institution from which the applicant graduated that the required coursework is included within the institution's required curriculum for graduation.

(g) Has completed a minimum of 10 contact hours of training or coursework in human sexuality as specified in Section 1807 of Title 16 of the California Code of Regulations. This training or coursework may be satisfactory if taken either in fulfillment of other educational requirements for licensure or in a separate course.

(h) Has completed a minimum of seven contact hours of training or coursework in child abuse assessment and reporting as specified in Section 1807.2 of Title 16 of the California Code of Regulations This training or coursework may be satisfactory if taken either in fulfillment of other educational requirements for licensure or in a separate course.

Leg.H. (Amended by Stats. 1988, ch. 1091, sec. 3; Stats. 1993, ch. 1234; Stats. 1994, ch. 474; Stats. 2001, ch. 728, sec. 45; Stats. 2002, ch. 481, Sec. 8.)

§4996.3. APPLICATION AND EXAMINATION FEES; DEPOSIT

(a) Each application for the standard written examination received on or after January 1, 1999, shall be accompanied by an application fee of one hundred dollars ($100) and a fee of up to one hundred fifty dollars ($150), including the standard written examination fee and related administrative costs for the standard written examination. After successfully passing the standard written examination, each applicant shall submit one hundred dollars ($100) for the clinical vignette written examination. Applicants failing to appear for any examination, once having been scheduled, shall forfeit any examination fees paid. Effective January 1, 2005, the examination fees for the standard written and clinical vignette written examinations shall be based on the actual cost to the board of developing, purchasing, and grading of each examination, plus the actual cost to the board of administering each examination. The written examination fees shall be adjusted periodically by regulation to reflect the actual costs incurred by the board.

(b) The fee for rescoring any written examination shall be twenty dollars ($20).

(c) The fee for issuance of the initial license shall be a maximum of one hundred fifty-five dollars ($155).

(d) With regard to all license, examination, and other fees, the board shall establish fee amounts at or below the maximum amounts specified in this chapter.

Leg.H. (Amended by Stats. 1990, ch. 547, sec. 3; Stats. 1995, ch. 839, sec. 4.5; Stats. 1996, ch. 829, sec 95; Stats. 1998, ch. 879, sec 17; Amended by Stats. 2004, ch. 909, sec. 16.)

§4996.4. FEE FOR REEXAMINATION

Notwithstanding Section 4996.3, an applicant who has failed any standard or clinical vignette written examination may apply for reexamination upon payment of the fee of up to one hundred fifty dollars ($150) including the examination fee and related administrative costs. An applicant who fails a standard or clinical vignette written examination may within one year from the notification date of failure, retake that examination as regularly scheduled, without further application, upon payment of the required examination fees. Thereafter, the applicant shall not be eligible for further examination until he or she files a new application, meets all current requirements, and pays all fees required. Applicants failing to appear for reexamination, once having been scheduled, shall forfeit any reexamination fees paid.

experience during the time the accredited school or department was in candidacy status by the Commission on Accreditation of the Council on Social Work Education.

(h) An applicant for registration or licensure trained in an educational institution outside the United States shall demonstrate to the satisfaction of the board that he or she possesses a master's of social work degree that is equivalent to a master's degree issued from a school or department of social work that is accredited by the Commission on Accreditation of the Council on Social Work Education. These applicants shall provide the board with a comprehensive evaluation of the degree and shall provide any other documentation the board deems necessary. The board has the authority to make the final determination as to whether a degree meets all requirements, including, but not limited to, course requirements regardless of evaluation or accreditation.

Leg.H. (Amended by Stats. 1988, ch. 1091; Stats. 1992, ch. 1308, sec 2; Stats. 1995, ch. 839, sec. 7; Stats. 1998, ch. 589, sec 14.; Amended by Stats. 2000, ch. 836, sec 50; Stats. 2001, ch. 728, sec. 46; Amended by Stats. 2003, ch. 607, sec. 20; Amended by Stats. 2004, ch. 695, sec. 46.)

§4996.19. LICENSED CLINICAL SOCIAL WORKERS' CORPORATION; APPLICATION OF ARTICLE

Nothing in this article shall prohibit the acts or practices of a licensed clinical social workers' corporation duly certificated pursuant to the Moscone-Knox Professional Corporation Act, as contained in Part 4 (commencing with Section 13400) of Division 3 of Title 1 of the Corporations Code and Article 5 (commencing with Section 4998), when the corporation is in compliance with (a) the Moscone-Knox Professional Corporation Act; (b) Article 5 (commencing with Section 4998); and (c) all other statutes and all rules and regulations now or hereafter enacted or adopted pertaining to the corporation and the conduct of its affairs.

Leg.H. (Added by renumbering Section 4996.18 by Stats. 1987, ch. 826, sec. 8.)

§4996.20. SUPERVISED POST-MASTER'S EXPERIENCE CRITERIA PRIOR TO JANUARY 1, 1999

The experience required by subdivision (c) of Section 4996.2 shall meet the following criteria:

(a) An applicant shall have at least 3,200 hours of post-master's experience, supervised by a licensed clinical social worker, in providing clinical social work services consisting of psychosocial diagnosis; assessment; treatment, including psychotherapy and counseling; client-centered advocacy; consultation; and evaluation as permitted by Section 4996.9. For persons applying for licensure on or after January 1, 1992, this experience shall have been gained in not less than two nor more than six years and shall have been gained within the six years immediately preceding the date on which the application for licensure was filed.

(b) Notwithstanding the requirements of subdivision (a) that 3,200 hours of experience shall be gained under the supervision of a licensed clinical social worker, up to 1,000 hours of the required experience may be gained under the supervision of a licensed mental health professional acceptable to the board.

For purposes of this section, "supervision" means responsibility for and control of the quality of social work services being provided. Consultation shall not be considered to be supervision. Supervision shall include at least one hour of direct supervision for each week of experience claimed. Not less than one-half of the hours of required supervision shall be individual supervision. The remaining hours may be group supervision. "Individual supervision" means one supervisor meets with one supervisee at a time. "Group supervision" means a supervisor meets with a group of no more than eight supervisees at a time.

(c) For purposes of this section, a "private practice setting" is any setting other than a governmental entity, a school, college or university, a nonprofit and charitable corporation or a licensed health facility. Employment in a private practice setting shall not commence until the applicant has been registered as an associate clinical social worker. A registrant employed in a private practice setting shall not:

(1) Pay his or her employer for supervision, and shall receive fair remuneration from his or her employer.

(2) Receive any remuneration from patients or clients and shall only be paid by his or her employer.

(3) Perform services at any place except where the registrant's employer regularly conducts business.

(4) Have any proprietary interest in the employer's business.

(d) A person employed in a setting other than a private practice setting may obtain supervision from a person not employed by the registrant's employer if that person has signed a written contract with the employer to take supervisory responsibility for the registrant's social work services.

(e) This section shall apply only to persons who apply for registration on or before December 31, 1998.

Leg.H. (Amended by Stats. 1991, ch. 654, sec. 47.5; Stats. 1998, ch. 589, sec 15; Amended by Stats. 2004, ch. 695, sec. 47.)

§4996.21. SUPERVISED POST-MASTER'S EXPERIENCE CRITERIA EFFECTIVE JANUARY 1, 1999

The experience required by subdivision (c) of Section 4996.2 shall meet the following criteria:

(a) On or after January 1, 1999, an associate shall have at least 3,200 hours of post-master's degree experience in providing clinical social work services as permitted by Section 4996.9. At least 1,700 of these hours shall be gained under the supervision of a licensed clinical social worker. The remaining hours of the required experience may be gained under the supervision of a licensed mental health professional acceptable to the board as defined in a regulation adopted by the board. Experience shall consist of the following:

(1) A minimum of 2,000 hours in psychosocial diagnosis, assessment, and treatment, including psychotherapy or counseling.

(2) A maximum of 1,200 hours in client-centered advocacy, consultation, evaluation, and research.

(3) Experience shall have been gained in not less than two nor more than six years and shall have been gained within the six years immediately preceding the date on which the application for licensure was filed.

(b) Supervision means responsibility for and control of the quality of clinical social work services being provided.

(c) Consultation or peer discussion shall not be considered to be supervision.

(d) Supervision shall include at least one hour of direct supervisor contact for a minimum of 104 weeks and shall include at least one hour of direct supervisor contact for every 10 hours of client contact in each setting where experience is gained. Of the 104 weeks of required supervision, 52 weeks shall be individual supervision, and of the 52 weeks of required individual supervision, not less than 13 weeks shall be supervised by a licensed clinical social worker. For purposes of this section, "one hour of direct supervisor contact" means one hour of face-to-face contact on an individual basis or two hours of face-to-face contact in a group setting of not more than eight persons.

(e) The supervisor and the associate shall develop a supervisory plan that describes the goals and objectives of supervision. These goals shall include the ongoing assessment of strengths and limitations and the assurance of practice in accordance with the laws and regulations. The associate shall submit to the board the initial original supervisory plan upon application for licensure.

(f) (1) Experience shall only be gained in a setting that meets both of the following:

(A) Lawfully and regularly provides clinical social work, mental health counseling, or psychotherapy.

(B) Provides oversight to ensure that the associate's work at the setting meets the experience and supervision requirements set forth in this chapter and is within the scope of practice for the profession as defined in Section 4996.9.

(2) Experience shall not be gained until the applicant has been registered as an associate clinical social worker.

(3) Employment in a private practice as defined in paragraph (4) shall not commence until the applicant has been registered as an associate clinical social worker.

(4) A private practice setting is a setting that is owned by a licensed clinical social worker, a licensed marriage and family therapist, a licensed psychologist, a licensed physician and surgeon, or a professional corporation of any of those licensed professions.

(5) If volunteering, the associate shall provide the board with a letter from his or her employer verifying his or her voluntary status upon application for licensure.

(6) If employed, the associate shall provide the board with copies of his or her W-2 tax forms for each year of experience claimed upon application for licensure.

(g) While an associate may be either a paid employee or a volunteer, employers are encouraged to provide fair remuneration to associates.

(h) An associate shall not do the following:

(1) Receive any remuneration from patients or clients and shall only be paid by his or her employer.

(2) Have any proprietary interest in the employer's business.

(i) An associate, whether employed or volunteering, may obtain supervision from a person not employed by the associate's employer if that person has signed a written agreement with the employer to take supervisory responsibility for the associate's social work services.

Leg.H. (Added by Stats. 1998, ch. 589, sec 16; Added by Stats. 1999, ch. 657, sec. 15; Stats. 2001, ch. 728, sec. 47; Stats. 2003, ch. 607, sec. 21)

§4996.22. CONTINUING EDUCATION EFFECTIVE JANUARY 1, 2004

(a) (1) Except as provided in subdivision (c), on and after January 1, 2000, the board shall not renew any license pursuant to this chapter unless the applicant certifies to the board, on a form prescribed by the board, that he or she has completed not less than 36 hours of approved continuing education in or relevant to the field of social work in the preceding two years, as determined by the board.

(2) For those persons renewing during 1999, the board shall not renew any license pursuant to this chapter unless the applicant certifies to the board, on a form prescribed by the board, that he or she has completed not less than 18 hours of approved continuing education in or relevant to the field of social work, as determined by the board. The coursework of continuing education described in this paragraph may be taken on or after the effective date of the continuing education regulations adopted by the board pursuant to the other provisions of this section.

(3) The board shall not renew any license of an applicant who began graduate study prior to January 1, 2004, pursuant to this chapter unless the applicant certifies to the board that during the applicant's first renewal period after the operative date of this section, he or she completed a continuing education course in spousal or partner abuse assessment, detection, and intervention strategies, including community resources, cultural factors, and same gender abuse dynamics. On and after January 1, 2005, the course shall consist of not less than seven hours of training. Equivalent courses in spousal or partner abuse assessment, detection, and intervention strategies taken prior to the operative date of this section or proof of equivalent teaching or practice experience may be submitted to the board and at its discretion, may be accepted in satisfaction of this requirement. Continuing education courses taken pursuant to this paragraph shall be applied to the 36 hours of approved continuing education required under paragraph (1).

(b) The board shall have the right to audit the records of any applicant to verify the completion of the continuing education requirement. Applicants shall maintain records of completion of required continuing education coursework for a minimum of two years and shall make these records available to the board for auditing purposes upon request.

(c) The board may establish exceptions from the continuing education requirement of this section for good cause as defined by the board.

(d) The continuing education shall be obtained from one of the following sources:

(1) An accredited school of social work, as defined in Section 4990.4, or a school or department of social work that is a candidate for accreditation by the Commission on Accreditation of the Council on Social Work Education. Nothing in this paragraph shall be construed as requiring coursework to be offered as part of a regular degree program.

(2) Other continuing education providers, including, but not limited to, a professional social work association, a licensed health facility, a governmental entity, a continuing education unit of an accredited four-year institution of higher learning, and a mental health professional association, approved by the board.

(3) The board shall establish, by regulation, a procedure for approving providers of continuing education courses, and all providers of continuing education, as described in paragraphs (1) and (2), shall adhere to the procedures established by the board. The board may revoke or deny the right of a provider to offer continuing education coursework pursuant to this section for failure to comply with the requirements of this section or any regulation adopted pursuant to this section.

(e) Training, education, and coursework by approved providers shall incorporate one or more of the following:

(1) Aspects of the discipline that are fundamental to the understanding, or the practice, of social work.

(2) Aspects of the social work discipline in which significant recent developments have occurred.

(3) Aspects of other related disciplines that enhance the understanding, or the practice, of social work.

(f) A system of continuing education for licensed clinical social workers shall include courses directly related to the diagnosis, assessment, and treatment of the client population being served.

(g) The continuing education requirements of this section shall comply fully with the guidelines for mandatory continuing education established by the Department of Consumer Affairs pursuant to Section 166.

(h) The board may adopt regulations as necessary to implement this section.

(i) On and after January 1, 1997, the board shall, by regulation, fund the administration of this section through continuing education provider fees to be deposited in the Behavioral Science Examiners Fund. The fees related to the administration of this section shall be sufficient to meet but shall not exceed the costs of administering the corresponding provisions of this section. For purposes of this subdivision, a provider of continuing education as described in paragraph (1) of subdivision (d), shall be deemed to be an approved provider.

(j) This section shall become operative on January 1, 2004.

Leg.H. (Added by Stats. 2002, ch. 481, sec. 11, operative January 1,2 004. ; Amended by Stats. 2003, ch. 607, sec. 22, operative January 1, 2004)

§4996.23 SUPERVISED POST-MASTER'S EXPERIENCE CRITERIA EFFECTIVE JANUARY 1, 2002

The experience required by subdivision (c) of Section 4996.2 shall meet the following criteria:

(a) All persons registered with the board on and after January 1, 2002, shall have at least 3,200 hours of post-master's

degree supervised experience providing clinical social work services as permitted by Section 4996.9. At least 1,700 hours shall be gained under the supervision of a licensed clinical social worker. The remaining required supervised experience may be gained under the supervision of a licensed mental health professional acceptable to the board as defined by a regulation adopted by the board. This experience shall consist of the following:

(1) A minimum of 2,000 hours in clinical psychosocial diagnosis, assessment, and treatment, including psychotherapy or counseling.

(2) A maximum of 1,200 hours in client-centered advocacy, consultation, evaluation, and research.

(3) Of the 2,000 clinical hours required in paragraph (1), no less than 750 hours shall be face-to-face individual or group psychotherapy provided to clients in the context of clinical social work services.

(4) A minimum of two years of supervised experience is required to be obtained over a period of not less than 104 weeks and shall have been gained within the six years immediately preceding the date on which the application for licensure was filed.

(5) Experience shall not be credited for more than 40 hours in any week.

(b) "Supervision" means responsibility for, and control of, the quality of clinical social work services being provided. Consultation or peer discussion shall not be considered to be supervision.

(c) (1) Prior to the commencement of supervision, a supervisor shall comply with all requirements enumerated in Section 1870 of Title 16 of the California Code of Regulations and shall sign under penalty of perjury the "Responsibility Statement for Supervisors of an Associate Clinical Social Worker" form.

(2) Supervised experience shall include at least one hour of direct supervisor contact for a minimum of 104 weeks. In addition, an associate shall receive an average of at least one hour of direct supervisor contact for every week in which more than 10 hours of face-to-face psychotherapy is performed in each setting experience is gained. No more than five hours of supervision, whether individual or group, shall be credited during any single week. Of the 104 weeks of required supervision, 52 weeks shall be individual supervision, and of the 52 weeks of required individual supervision, not less than 13 weeks shall be supervised by a licensed clinical social worker. For purposes of this section, "one hour of direct supervisor contact" means one hour of face-to-face contact on an individual basis or two hours of face-to-face contact in a group of not more than eight persons receiving supervision.

(d) The supervisor and the associate shall develop a supervisory plan that describes the goals and objectives of supervision. These goals shall include the ongoing assessment of strengths and limitations and the assurance of practice in accordance with the laws and regulations. The associate shall submit to the board the initial original supervisory plan upon application for licensure.

(e) Experience shall only be gained in a setting that meets both of the following:

(1) Lawfully and regularly provides clinical social work, mental health counseling, or psychotherapy.

(2) Provides oversight to ensure that the associate's work at the setting meets the experience and supervision requirements set forth in this chapter and is within the scope of practice for the profession as defined in Section 4996.9.

(f) Experience shall not be gained until the applicant has been registered as an associate clinical social worker.

(g) Employment in a private practice as defined in subdivision (h) shall not commence until the applicant has been registered as an associate clinical social worker.

(h) A private practice setting is a setting that is owned by a licensed clinical social worker, a licensed marriage and family therapist, a licensed psychologist, a licensed physician and surgeon, or a professional corporation of any of those licensed

professions.

(i) If volunteering, the associate shall provide the board with a letter from his or her employer verifying his or her voluntary status upon application for licensure.

(j) If employed, the associate shall provide the board with copies of his or her W-2 tax forms for each year of experience claimed upon application for licensure.

(k) While an associate may be either a paid employee or volunteer, employers are encouraged to provide fair remuneration to associates.

(l) Associates shall not do the following:

(1) Receive any remuneration from patients or clients and shall only be paid by his or her employer.

(2) Have any proprietary interest in the employer's business.

(m) An associate, whether employed or volunteering, may obtain supervision from a person not employed by the associate's employer if that person has signed a written agreement with the employer to take supervisory responsibility for the associate's social work services.

(n) Notwithstanding any other provision of law, associates and applicants for examination shall receive a minimum of one hour of supervision per week for each setting in which he or she is working.

Leg.H. (Added by Stats. 2001, ch. 728, sec 48; Amended by Stats. 2003, ch. 607, sec. 23)

§4996.25 ADDITIONAL COURSEWORK

(a) Any applicant for licensure as a licensed clinical social worker who began graduate study on or after January 1, 2004, shall complete, as a condition of licensure, a minimum of 10 contact hours of coursework in aging and long-term care, which could include, but is not limited to, the biological, social, and psychological aspects of aging.

(b) Coursework taken in fulfillment of other educational requirements for licensure pursuant to this chapter, or in a separate course of study, may, at the discretion of the board, fulfill the requirements of this section.

(c) In order to satisfy the coursework requirement of this section, the applicant shall submit to the board a certification from the chief academic officer of the educational institution from which the applicant graduated stating that the coursework required by this section is included within the institution's required curriculum for graduation, or within the coursework, that was completed by the applicant.

(d) The board shall not issue a license to the applicant until the applicant has met the requirements of this section.

(Added by Stats. 2002, ch. 541, Sec. 8.)

§4996.26 ADDITIONAL CONTINUING EDUCATION REQUIREMENTS

(a) A licensee who began graduate study prior to January 1, 2004, shall complete a three-hour continuing education course in aging and long-term care during his or her first renewal period after the operative date of this section, and shall submit to the board evidence acceptable to the board of the person's satisfactory completion of the course.

(b) The course shall include, but is not limited to, the biological, social, and psychological aspects of aging.

(c) Any person seeking to meet the requirements of subdivision (a) of this section may submit to the board a certificate evidencing completion of equivalent courses in aging and long-term care taken prior to the operative date of this section,

(b) In order that the board, the educational institutions, and the supervisors who monitor the education and experience of applicants for licensure may develop greater cooperation, the board shall do all of the following:

(1) Apply a portion of its limited resources specifically to the task of communicating information about its activities, the requirements and qualifications for licensure, and the practice of marriage and family therapy to the relevant educational institutions, supervisors, professional associations, applicants, trainees, interns, and the consuming public.

(2) Develop policies and procedures to assist educational institutions in meeting the curricula requirements of Section 4980.40 and any regulations adopted pursuant to that section, so that those educational institutions may better provide assurance to their students that the curriculum offered to fulfill the educational requirements for licensure will meet those requirements at the time of the student's application for licensure.

(3) Notify applicants in the application procedure when applications are incomplete, inaccurate, or deficient, and inform applicants of any remediation, reconsideration, or appeal procedures that may be applicable.

(4) Undertake, or cause to be undertaken, further comprehensive review, in consultation with educational institutions, professional associations, supervisors, interns, and trainees, of the supervision of interns and trainees, which shall include, but not be limited to, the following, and shall propose regulations regarding the supervision of interns and trainees which may include, but not be limited to, the following:

(A) Supervisor qualifications.

(B) Continuing education requirements of supervisors.

(C) Registration or licensing of supervisors, or both.

(D) Responsibilities of supervisors in general.

(E) The board's authority in cases of noncompliance or negligence by supervisors.

(F) The intern's and trainee's need for guidance in selecting well-balanced and high quality professional training opportunities within his or her community.

(G) The role of the supervisor in advising and encouraging his or her intern or trainee regarding the necessity or value and appropriateness of the intern or trainee engaging in personal psychotherapy, so as to enable the intern or trainee to become a more competent marriage, family, and child counselor.

Leg.H. (Added by Stats. 1986, ch. 1365, sec. 4; Stats. 1993, ch. 1054; Amended by Stats. 2002, ch. 1013, Sec. 18.)

§4980.37. DEGREE PROGRAM; COURSE OF STUDY AND PROFESSIONAL TRAINING

(a) In order to provide an integrated course of study and appropriate professional training, while allowing for innovation and individuality in the education of marriage and family therapists, a degree program which meets the educational qualifications for licensure shall include all of the following:

(1) Provide an integrated course of study that trains students generally in the diagnosis, assessment, prognosis, and treatment of mental disorders.

(2) Prepare students to be familiar with the broad range of matters that may arise within marriage and family relationships.

(3) Train students specifically in the application of marriage and family relationship counseling principles and methods.

(4) Encourage students to develop those personal qualities that are intimately related to the counseling situation such as integrity, sensitivity, flexibility, insight, compassion, and personal presence.

(5) Teach students a variety of effective psychotherapeutic techniques and modalities that may be utilized to improve, restore, or maintain healthy individual, couple, and family relationships.

(6) Permit an emphasis or specialization that may address any one or more of the unique and complex array of human problems, symptoms, and needs of Californians served by marriage and family therapists.

(7) Prepare students to be familiar with cross-cultural mores and values, including a familiarity with the wide range of racial and ethnic backgrounds common among California's population, including, but not limited to, Blacks, Hispanics, Asians, and Native Americans.

(b) Educational institutions are encouraged to design the practica required by subdivision (b) of Section 4980.40 to include marriage and family therapy experience in low-income and multicultural mental health settings.

Leg.H. (Added by Stats. 1986, ch. 1365, sec. 4; Stats. 1993, ch. 1054; Amended by Stats. 2002, ch. 1013, Sec. 19.)

§4980.38. NOTIFICATION TO STUDENTS OF DESIGN OF DEGREE PROGRAM; CERTIFICATION OF FULFILLMENT OF REQUIREMENTS

(a) Each educational institution preparing applicants to qualify for licensure shall notify each of its students by means of its public documents or otherwise in writing that its degree program is designed to meet the requirements of Sections 4980.37 and 4980.40, and shall certify to the board that it has so notified its students.

(b) In addition to all the other requirements for licensure, each applicant shall submit to the board a certification by the chief academic officer, or his or her designee, of the applicant's educational institution that the applicant has fulfilled the requirements enumerated in Sections 4980.37 and 4980.40, and subdivisions (d) and (e) of Section 4980.41.

(c) An applicant for an intern registration who has completed a program to update his or her degree in accordance with subdivision (i) of Section 4980.40 shall furnish to the board certification by the chief academic officer of a school, college, or university accredited by the Western Association of Schools and Colleges, or from a school, college, or university meeting accreditation standards comparable to those of the Western Association of Schools and Colleges, that the applicant has successfully completed all academic work necessary to comply with the current educational requirements for licensure as a marriage and family therapist.

Leg.H. (Amended by Stats. 1987, ch. 738, sec. 1; Stats. 1993, ch. 1054; Stats. 2001, ch. 435, sec. 13; Amended by Stats. 2002, ch. 1013, Sec. 20.)

§4980.39. ADDITIONAL COURSEWORK

(a) Any applicant for licensure as a marriage and family therapist who began graduate study on or after January 1, 2004, shall complete, as a condition of licensure, a minimum of 10 contact hours of coursework in aging and long-term care, which could include, but is not limited to, the biological, social, and psychological aspects of aging.

(b) Coursework taken in fulfillment of other educational requirements for licensure pursuant to this chapter, or in a separate course of study, may, at the discretion of the board, fulfill the requirements of this section.

(c) In order to satisfy the coursework requirement of this section, the applicant shall submit to the board a certification from the chief academic officer of the educational institution from which the applicant graduated stating that the coursework required by this section is included within the institution's required curriculum for graduation, or within the coursework, that was completed by the applicant.

(d) The board shall not issue a license to the applicant until the applicant has met the requirements of this section.

(Added by Stats. 2002, ch. 541, Sec. 6.)

§4980.40. QUALIFICATIONS

To qualify for a license, an applicant shall have all the following qualifications:

(a) Applicants applying for licensure on or after January 1, 1988, shall possess a doctor's or master's degree in marriage, family, and child counseling, marital and family therapy, psychology, clinical psychology, counseling psychology, or counseling with an emphasis in either marriage, family, and child counseling or marriage and family therapy, obtained from a school, college, or university accredited by the Western Association of Schools and Colleges, or approved by the Bureau for Private Postsecondary and Vocational Education. The board has the authority to make the final determination as to whether a degree meets all requirements, including, but not limited to, course requirements, regardless of accreditation or approval. For purposes of this chapter, the term "approved by the Bureau for Private Postsecondary and Vocational Education" shall mean unconditional approval existing at the time of the applicant's graduation from the school, college, or university. In order to qualify for licensure pursuant to this subdivision, a doctor's or master's degree program shall be a single, integrated program primarily designed to train marriage and family therapists and shall contain no less than 48 semester or 72 quarter units of instruction. The instruction shall include no less than 12 semester units or 18 quarter units of coursework in the areas of marriage, family, and child counseling, and marital and family systems approaches to treatment.

The coursework shall include all of the following areas:

(1) The salient theories of a variety of psychotherapeutic orientations directly related to marriage and family therapy, and marital and family systems approaches to treatment.

(2) Theories of marriage and family therapy and how they can be utilized in order to intervene therapeutically with couples, families, adults, children, and groups.

(3) Developmental issues and life events from infancy to old age and their effect upon individuals, couples, and family relationships. This may include coursework that focuses on specific family life events and the psychological, psychotherapeutic, and health implications that arise within couples and families, including, but not limited to, childbirth, child rearing, childhood, adolescence, adulthood, marriage, divorce, blended families, stepparenting, and geropsychology.

(4) A variety of approaches to the treatment of children. The board shall, by regulation, set forth the subjects of instruction required in this subdivision.

(b) (1) In addition to the 12 semester or 18 quarter units of coursework specified above, the doctor's or master's degree program shall contain not less than six semester or nine quarter units of supervised practicum in applied psychotherapeutic techniques, assessment, diagnosis, prognosis, and treatment of premarital, couple, family, and child relationships, including dysfunctions, healthy functioning, health promotion, and illness prevention, in a supervised clinical placement that provides supervised fieldwork experience within the scope of practice of a marriage and family therapist.

(2) For applicants who enrolled in a degree program on or after January 1, 1995, the practicum shall include a minimum of 150 hours of face-to-face experience counseling individuals, couples, families, or groups.

(3) (A) Supervised practicum hours, as specified in this subdivision, shall be evaluated, accepted, and credited as hours for trainee experience by the board.

(B) The practicum hours shall be considered as part of the 48 semester or 72 quarter unit requirement.

(c) As an alternative to meeting the qualifications specified in subdivision (a), the board shall accept as equivalent degrees, those master's or doctor's degrees granted by educational institutions whose degree program is approved by the Commission on Accreditation for Marriage and Family Therapy Education.

(d) All applicants shall, in addition, complete the coursework or training specified in Section 4980.41.

(e) All applicants shall be at least 18 years of age.

(f) All applicants shall have at least two years' experience that meets the requirements of this chapter in interpersonal relationships, marriage and family therapy and psychotherapy under the supervision of a licensed marriage and family therapist, licensed clinical social worker, licensed psychologist, or a licensed physician certified in psychiatry by the American Board of Psychiatry and Neurology. Experience shall not be gained under the supervision of an individual who has provided therapeutic services to that applicant. For those supervisorial relationships in effect on or before December 31, 1988, and which remain in continuous effect thereafter, experience may be gained under the supervision of a licensed physician who has completed a residency in psychiatry. A person supervising another person pursuant to this subdivision shall have been licensed or certified for at least two years prior to acting as a supervisor, shall have a current and valid license that is not under suspension or probation, and shall meet the requirements established by regulations.

(g) The applicant shall pass a board administered written or oral examination or both types of examinations, except that an applicant who passed a written examination and who has not taken and passed an oral examination shall instead be required to take and pass a clinical vignette written examination.

(h) The applicant shall not have committed acts or crimes constituting grounds for denial of licensure under Section 480. The board shall not issue a registration or license to any person who has been convicted of a crime in this or another state or in a territory of the United States that involves sexual abuse of children or who is required to register pursuant to Section 290 of the Penal Code or the equivalent in another state or territory.

(i) (1) An applicant applying for intern registration who, prior to December 31, 1987, met the qualifications for registration, but who failed to apply or qualify for intern registration may be granted an intern registration if the applicant meets all of the following criteria:

(A) The applicant possesses a doctor's or master's degree in marriage, family, and child counseling, marital and family therapy, psychology, clinical psychology, counseling psychology, counseling with an emphasis in marriage, family, and child counseling, or social work with an emphasis in clinical social work obtained from a school, college, or university currently conferring that degree that, at the time the degree was conferred, was accredited by the Western Association of Schools and Colleges, and where the degree conferred was, at the time it was conferred, specifically intended to satisfy the educational requirements for licensure by the Board of Behavioral Sciences.

(B) The applicant's degree and the course content of the instruction underlying that degree have been evaluated by the chief academic officer of a school, college, or university accredited by the Western Association of Schools and Colleges to determine the extent to which the applicant's degree program satisfies the current educational requirements for licensure, and the chief academic officer certifies to the board the amount and type of instruction needed to meet the current requirements.

(C) The applicant completes a plan of instruction that has been approved by the board at a school, college, or university accredited by the Western Association of Schools and Colleges that the chief academic officer of the educational institution has, pursuant to subparagraph (B), certified will meet the current educational requirements when considered in conjunction with the original degree.

(2) A person applying under this subdivision shall be considered a trainee, as that term is defined in Section 4980.03, once he or she is enrolled to complete the additional coursework necessary to meet the current educational requirements for licensure.

(j) An applicant for licensure trained in an educational institution outside the United States shall demonstrate to the satisfaction of the board that he or she possesses a qualifying degree that is equivalent to a degree earned from a school, college, or university accredited by the Western Association of Schools and Colleges, or approved by the Bureau of Private Postsecondary and Vocational Education. These applicants shall provide the board with a comprehensive

evaluation of the degree performed by a foreign credential evaluation service that is a member of the National Association of Credential Evaluation Services (NACES), and shall provide any other documentation the board deems necessary.

Leg.H. (Added by Stats. 1995, ch. 758, sec. 6.5; Amended by Stats. 1996 ch. 829, sec 86; Stats. 1998, ch. 879, sec 4.5.; Stats. 2001, ch. 728, sec. 36; Stats. 2002, ch. 1013, Sec. 21; Amended by Stats. 2003, ch. 874, sec. 7; Amended by Stats. 2004, ch. 909, sec. 10.)

§4980.41. ELIGIBILITY TO SIT FOR LICENSING EXAMINATIONS; COURSEWORK OR TRAINING

All applicants for licensure shall complete the following coursework or training in order to be eligible to sit for the licensing examinations as specified in subdivision (g) of Section 4980.40:

(a) A two semester or three quarter unit course in California law and professional ethics for marriage and family therapists, which shall include, but not be limited to, the following areas of study:

(1) Contemporary professional ethics and statutory, regulatory, and decisional laws that delineate the profession's scope of practice.

(2) The therapeutic, clinical, and practical considerations involved in the legal and ethical practice of marriage and family therapy, including family law.

(3) The current legal patterns and trends in the mental health profession.

(4) The psychotherapist/patient privilege, confidentiality, the patient dangerous to self or others, and the treatment of minors with and without parental consent.

(5) A recognition and exploration of the relationship between a practitioner's sense of self and human values and his or her professional behavior and ethics.

This course may be considered as part of the 48 semester or 72 quarter unit requirements contained in Section 4980.40.

(b) A minimum of seven contact hours of training or coursework in child abuse assessment and reporting as specified in Section 28 and any regulations promulgated thereunder.

(c) A minimum of 10 contact hours of training or coursework in human sexuality as specified in Section 25, and any regulations promulgated thereunder. When coursework in a master's or doctor's degree program is acquired to satisfy this requirement, it shall be considered as part of the 48 semester or 72 quarter unit requirement contained in Section 4980.40.

(d) For persons who began graduate study on or after January 1, 1986, a master's or doctor's degree qualifying for licensure shall include specific instruction in alcoholism and other chemical substance dependency as specified by regulation. When coursework in a master's or doctor's degree program is acquired to satisfy this requirement, it shall be considered as part of the 48 semester or 72 quarter unit requirement contained in Section 4980.40.

(e) For persons who began graduate study during the period commencing on January 1, 1995, and ending on December 31, 2003, a master's or doctor's degree qualifying for licensure shall include coursework in spousal or partner abuse assessment, detection, and intervention. For persons who began graduate study on or after January 1, 2004, a master's or doctor's degree qualifying for licensure shall include a minimum of 15 contact hours of coursework in spousal or partner abuse assessment, detection, and intervention strategies, including knowledge of community resources, cultural factors, and same gender abuse dynamics. Coursework required under this subdivision may be satisfactory if taken either in fulfillment of other educational requirements for licensure or in a separate course. The requirement for coursework shall be satisfied by, and the board shall accept in satisfaction of the requirement, a certification from the chief academic officer of the educational institution from which the applicant graduated that the required coursework is included within the institution's required curriculum for graduation.

(f) For persons who began graduate study on or after January 1, 2001, an applicant shall complete a minimum of a two

semester or three quarter unit survey course in psychological testing. When coursework in a master's or doctor's degree program is acquired to satisfy this requirement, it may be considered as part of the 48 semester or 72 quarter unit requirement of Section 4980.40.

(g) For persons who began graduate study on or after January 1, 2001, an applicant shall complete a minimum of a two semester or three quarter unit survey course in psychopharmacology. When coursework in a master's or doctor's degree program is acquired to satisfy this requirement, it may be considered as part of the 48 semester or 72 quarter unit requirement of Section 4980.40.

(h) The requirements added by subdivisions (f) and (g) are intended to improve the educational qualifications for licensure in order to better prepare future licentiates for practice, and are not intended in any way to expand or restrict the scope of licensure for marriage and family therapists.

Leg.H. (Added by Stats. 1986, ch. 1365, sec. 4; Amended by Stats. 1987, ch. 738, sec. 3; Stats 1993, ch. 1234, sec. 9; Stats. 1999, ch. 406, sec.1; Stats. 2001, ch. 435, sec. 14; Stats. 2002, ch. 481, sec. 4; Stats. 2003, ch. 874, sec. 8)

§4980.42. TRAINEES' SERVICES

(a) Trainees performing services in any work setting specified in subdivision (e) of Section 4980.43 may perform those activities and services as a trainee, provided that the activities and services constitute part of the trainee's supervised course of study and that the person is designated by the title "trainee." Trainees may gain hours of experience outside the required practicum. Those hours shall be subject to the requirements of subdivision (b) and to the other requirements of this chapter.

(b) On and after January 1, 1995, all hours of experience gained as a trainee shall be coordinated between the school and the site where the hours are being accrued. The school shall approve each site and shall have a written agreement with each site that details each party's responsibilities, including the methods by which supervision shall be provided. The agreement shall provide for regular progress reports and evaluations of the student's performance at the site. If an applicant has gained hours of experience while enrolled in an institution other than the one that confers the qualifying degree, it shall be the applicant's responsibility to provide to the board satisfactory evidence that those hours of trainee experience were gained in compliance with this section.

Leg.H. (Added by Stats. 1993, ch. 1054, sec. 8.)

§4980.43. PROFESSIONAL EXPERIENCE; INTERNS OR TRAINEES

(a) For all applicants, a minimum of two calendar years of supervised experience is required, which experience shall consist of 3,000 hours obtained over a period of not less than 104 weeks. Not less than 1,500 hours of experience shall be gained subsequent to the granting of the qualifying master's or doctor's degree. For those applicants who enroll in a qualifying degree program on or after January 1, 1995, not more than 750 hours of counseling and direct supervisor contact may be obtained prior to the granting of the qualifying master's or doctor's degree. However, this limitation shall not be interpreted to include professional enrichment activities. Except for personal psychotherapy hours gained after enrollment and commencement of classes in a qualifying degree program, no hours of experience may be gained prior to becoming a trainee. All experience shall be gained within the six years immediately preceding the date the application for licensure was filed, except that up to 500 hours of clinical experience gained in the supervised practicum required by subdivision (b) of Section 4980.40 shall be exempt from this six-year requirement.

(b) All applicants, trainees, and registrants shall be at all times under the supervision of a supervisor who shall be responsible for ensuring that the extent, kind, and quality of counseling performed is consistent with the training and experience of the person being supervised, and who shall be responsible to the board for compliance with all laws, rules, and regulations governing the practice of marriage and family therapy. Experience shall be gained by interns and trainees either as an employee or as a volunteer in any allowable work setting specified in this chapter. The requirements of this chapter regarding gaining hours of experience and supervision are applicable equally to employees and volunteers. Experience shall not be gained by interns or trainees as an independent contractor.

(c) Supervision shall include at least one hour of direct supervisor contact for each week of experience claimed. A trainee shall receive an average of at least one hour of direct supervisor contact for every five hours of client contact in each setting. A person gaining postdegree experience shall receive an average of at least one hour of direct supervisor contact for every 10 hours of client contact in each setting in which experience is gained. For purposes of this section, "one hour of direct supervisor contact" means one hour of face-to-face contact on an individual basis or two hours of face-to-face contact in a group of not more than eight persons. The contact may be counted toward the experience requirement for licensure, up to the maximum permitted by subdivision (d). All experience gained by a trainee shall be monitored by the supervisor as specified by regulation. The 5 to 1 and 10 to 1 ratios specified in this subdivision shall be applicable to all hours gained on or after January 1, 1995.

(d) (1) The experience required by Section 4980.40 shall include supervised marriage and family therapy, and up to one-third of the hours may include direct supervisor contact and other professional enrichment activities.

(2) "Professional enrichment activities," for the purposes of this section, may include group, marital or conjoint, family, or individual psychotherapy received by an applicant. This psychotherapy may include up to 100 hours taken subsequent to enrolling and commencing classes in a qualifying degree program, or as an intern, and each of those hours shall be triple counted toward the professional experience requirement. This psychotherapy shall be performed by a licensed marriage and family therapist, licensed clinical social worker, licensed psychologist, licensed physician and surgeon certified in psychiatry by the American Board of Psychiatry and Neurology, or a licensed physician and surgeon who has completed a residency in psychiatry.

(e) (1) A trainee may gain the experience required by subdivision (f) of Section 4980.40 in any setting that meets all of the following:

(A) Lawfully and regularly provides mental health counseling or psychotherapy.

(B) Provides oversight to ensure that the trainee's work at the setting meets the experience and supervision requirements set forth in this chapter and is within the scope of practice for the profession as defined in Section 4980.02.

(C) Is not a private practice owned by a licensed marriage and family therapist, a licensed psychologist, a licensed clinical social worker, a licensed physician and surgeon, or a professional corporation of any of those licensed professions.

(2) Experience may be gained by the trainee solely as part of the position for which the trainee volunteers or is employed.

(f) (1) An intern may gain the experience required by subdivision (f) of Section 4980.40 in any setting that meets both of the following:

(A) Lawfully and regularly provides mental health counseling or psychotherapy.

(B) Provides oversight to ensure that the intern's work at the setting meets the experience and supervision requirements set forth in this chapter and is within the scope of practice for the profession as defined in Section 4980.02.

(2) An applicant shall not be employed or volunteer in a private practice, as defined in subparagraph (C) of paragraph (1) of subdivision (e), until registered as an intern.

(3) While an intern may be either a paid employee or a volunteer, employers are encouraged to provide fair remuneration to interns.

(4) Except for periods of time during a supervisor's vacation or sick leave, an intern who is employed or volunteering in private practice shall be under the direct supervision of a licensee enumerated in subdivision (f) of Section 4980.40. The supervising licensee shall either be employed by and practice at the same site as the intern's employer, or shall be an owner or shareholder of the private practice. Alternative supervision may be arranged during a supervisor's vacation or sick leave if the supervision meets the requirements of this section.

(5) Experience may be gained by the intern solely as part of the position for which the intern volunteers or is employed.

(g) All persons shall register with the board as an intern in order to be credited for postdegree hours of experience gained toward licensure, regardless of the setting where those hours are to be gained. Except as provided in subdivision (h), all postdegree hours shall be gained as a registered intern.

(h) Except when employed in a private practice setting, all postdegree hours of experience shall be credited toward licensure so long as the applicant applies for the intern registration within 90 days of the granting of the qualifying master's or doctor's degree and is thereafter granted the intern registration by the board.

(i) Trainees, interns, and applicants shall not receive any remuneration from patients or clients, and shall only be paid by their employers.

(j) Trainees, interns, and applicants shall only perform services at the place where their employers regularly conduct business, which may include performing services at other locations, so long as the services are performed under the direction and control of their employer and supervisor, and in compliance with the laws and regulations pertaining to supervision. Trainees and interns shall have no proprietary interest in the employer's business.

(k) Trainees, interns, or applicants who provide volunteered services or other services, and who receive no more than a total, from all work settings, of five hundred dollars ($500) per month as reimbursement for expenses actually incurred by those trainees, interns, or applicants for services rendered in any lawful work setting other than a private practice shall be considered an employee and not an independent contractor. The board may audit applicants who receive reimbursement for expenses, and the applicants shall have the burden of demonstrating that the payments received were for reimbursement of expenses actually incurred.

(l) Each educational institution preparing applicants for licensure pursuant to this chapter shall consider requiring, and shall encourage, its students to undergo individual, marital or conjoint, family, or group counseling or psychotherapy, as appropriate. Each supervisor shall consider, advise, and encourage his or her interns and trainees regarding the advisability of undertaking individual, marital or conjoint, family, or group counseling or psychotherapy, as appropriate. Insofar as it is deemed appropriate and is desired by the applicant, the educational institution and supervisors are encouraged to assist the applicant in locating that counseling or psychotherapy at a reasonable cost.

Leg.H. (Added by Stats. 1986, ch. 1365, sec. 4; Amended by Stats. 1987, ch. 738, sec. 5; Stats. 1989, ch. 772, sec. 1; Stats. 1990, ch. 1086, sec. 2; Stats. 1992, ch. 890, sec. 2; Stats. 1993, ch. 1054., sec. 9; Stats. 1994, ch. 116, sec. 1; Stats 1996, ch. 739, sec. 1.; Stats 1997, ch. 196, sec 1.; Stats. 2000, ch. 836, sec. 30; Stats. 2002. ch. 1013, sec. 22; Stats. 2003, ch. 607, sec. 14; Amended by Stats. 2004, ch. 204, sec. 3.)

§4980.44. UNLICENSED INTERN; QUALIFICATIONS; NOTICE TO CLIENT OR PATIENT

(a) An unlicensed marriage and family therapist intern employed under this chapter shall:

(1) Have earned at least a master's degree as specified in Section 4980.40.

(2) Be registered with the board prior to the intern performing any duties, except as otherwise provided in subdivision (e) of Section 4980.43.

(3) File for renewal of registration annually for a maximum of five years after initial registration with the board. Renewal of registration shall include filing an application for renewal, paying a renewal fee of seventy-five dollars ($75), and notifying the board whether he or she has been convicted, as defined in Section 490, of a misdemeanor or felony, or whether any disciplinary action has been taken by any regulatory or licensing board in this or any other state, subsequent to the issuance of the initial registration or the registrant's last renewal.

(4) Inform each client or patient prior to performing any professional services that he or she is unlicensed and under the supervision of a licensed marriage and family therapist, licensed clinical social worker, licensed psychologist, or a licensed physician and surgeon certified in psychiatry by the American Board of Psychiatry and Neurology.

YEAR LIMITATION ON WRITTEN EXAMINATION

(a) Every applicant who meets the educational and experience requirements and applies for a license as a marriage and family therapist shall be examined by the board. The examinations shall be as set forth in subdivision (g) of Section 4980.40. The examinations shall be given at least twice a year at a time and place and under supervision as the board may determine. The board shall examine the candidate with regard to his or her knowledge and professional skills and his or her judgment in the utilization of appropriate techniques and methods.

(b) The board shall not deny any applicant, who has submitted a complete application for examination, admission to the licensure examinations required by this section if the applicant meets the educational and experience requirements of this chapter, and has not committed any acts or engaged in any conduct that would constitute grounds to deny licensure.

(c) The board shall not deny any applicant, whose application for licensure is complete, admission to the standard written examination, nor shall the board postpone or delay any applicant's standard written examination or delay informing the candidate of the results of the standard written examination, solely upon the receipt by the board of a complaint alleging acts or conduct that would constitute grounds to deny licensure.

(d) If an applicant for examination who has passed the standard written examination is the subject of a complaint or is under board investigation for acts or conduct that, if proven to be true, would constitute grounds for the board to deny licensure, the board shall permit the applicant to take the clinical vignette written examination for licensure, but may withhold the results of the examination or notify the applicant that licensure will not be granted pending completion of the investigation.

(e) Notwithstanding Section 135, the board may deny any applicant who has previously failed either the standard written or clinical vignette written examination permission to retake either examination pending completion of the investigation of any complaints against the applicant. Nothing in this section shall prohibit the board from denying an applicant admission to any examination, withholding the results, or refusing to issue a license to any applicant when an accusation or statement of issues has been filed against the applicant pursuant to Sections 11503 and 11504 of the Government Code, respectively, or the applicant has been denied in accordance with subdivision (b) of Section 485.

(f) Notwithstanding any other provision of law, the board may destroy all examination materials two years following the date of an examination.

(g) On or after January 1, 2002, no applicant shall be eligible to participate in a clinical vignette written examination if his or her passing score on the standard written examination occurred more than seven years before.

(h) An applicant who has qualified pursuant to this chapter shall be issued a license as a marriage and family therapist in the form that the board may deem appropriate.

Leg.H. (Added by Stats. 1986, ch. 1365, sec. 4; Amended by Stats. 1987, ch. 738, sec. 8; Stats. 1990, ch. 1086, sec. 3; Stats. 2000, ch. 836, sec. 32; Stats. 2001, ch. 728, sec .38; Stats. 2002, ch. 1013, Sec. 27; Stats. 2003, ch. 874, sec. 9; Amended by Stats. 2004, ch. 909, sec. 11.)

§4980.54. CONTINUING EDUCATION

(a) The Legislature recognizes that the education and experience requirements in this chapter constitute only minimal requirements to assure that an applicant is prepared and qualified to take the licensure examinations as specified in subdivision (g) of Section 4980.40 and, if he or she passes those examinations, to begin practice.

(b) In order to continuously improve the competence of licensed marriage and family therapists and as a model for all psychotherapeutic professions, the Legislature encourages all licensees to regularly engage in continuing education related to the profession or scope of practice as defined in this chapter.

(c) (1) Except as provided in subdivision (e), on and after January 1, 2000, the board shall not renew any license pursuant to this chapter unless the applicant certifies to the board, on a form prescribed by the board, that he or she has completed

not less than 36 hours of approved continuing education in or relevant to the field of marriage and family therapy in the preceding two years, as determined by the board.

(2) For those persons renewing during 1999, the board shall not renew any license pursuant to this chapter unless the applicant certifies to the board, on a form prescribed by the board, that he or she has completed not less than 18 hours of approved continuing education in or relevant to the field of marriage and family therapy, as determined by the board. The coursework of continuing education described in this paragraph may be taken on or after the effective date of the continuing education regulations adopted by the board pursuant to the other provisions of this section.

(d) The board shall have the right to audit the records of any applicant to verify the completion of the continuing education requirement. Applicants shall maintain records of completion of required continuing education coursework for a minimum of two years and shall make these records available to the board for auditing purposes upon request.

(e) The board may establish exceptions from the continuing education requirements of this section for good cause, as defined by the board.

(f) The continuing education shall be obtained from one of the following sources:

(1) An accredited school or state-approved school that meets the requirements set forth in Section 4980.40. Nothing in this paragraph shall be construed as requiring coursework to be offered as part of a regular degree program.

(2) Other continuing education providers, including, but not limited to, a professional marriage and family therapist association, a licensed health facility, a governmental entity, a continuing education unit of an accredited four-year institution of higher learning, or a mental health professional association, approved by the board.

(3) The board shall establish, by regulation, a procedure for approving providers of continuing education courses, and all providers of continuing education, as described in paragraphs (1) and (2), shall adhere to procedures established by the board. The board may revoke or deny the right of a provider to offer continuing education coursework pursuant to this section for failure to comply with the requirements of this section or any regulation adopted pursuant to this section.

(g) Training, education, and coursework by approved providers shall incorporate one or more of the following:

(1) Aspects of the discipline that are fundamental to the unde rstanding or the practice of marriage and family therapy.

(2) Aspects of the discipline of marriage and family therapy in which significant recent developments have occurred.

(3) Aspects of other disciplines that enhance the understanding or the practice of marriage and family therapy.

(h) A system of continuing education for licensed marriage and family therapists shall include courses directly related to the diagnosis, assessment, and treatment of the client population being served.

(i) On and after January 1, 1997, the board shall, by regulation, fund the administration of this section through continuing education provider fees to be deposited in the Behavioral Sciences Fund. The fees related to the administration of this section shall be sufficient to meet, but shall not exceed, the costs of administering the corresponding provisions of this section. For purposes of this subdivision, a provider of continuing education as described in paragraph (1) of subdivision (f) shall be deemed to be an approved provider.

(j) The continuing education requirements of this section shall comply fully with the guidelines for mandatory continuing education established by the Department of Consumer Affairs pursuant to Section 166.

Leg.H. (Added by Stats. 1986, ch. 1365, sec. 4; Amended by Stats. 1987, ch. 738, sec. 9; Stats. 1995, ch. 839, sec. 2, Stats. 1997, ch 196, sec. 2; Stats. 2002, ch. 1013, Sec. 28; Stats. 2003, ch. 874, sec. 10)

§4980.55. STATEMENTS OF EXPERIENCE, EDUCATION, SPECIALTIES, ETC.

As a model for all therapeutic professions, and to acknowledge respect and regard for the consuming public, all marriage and family therapists are encouraged to provide to each client, at an appropriate time and within the context of the psychotherapeutic relationship, an accurate and informative statement of the therapist's experience, education, specialties, professional orientation, and any other information deemed appropriate by the licensee.

Leg.H. (Added by Stats. 1986, ch. 1365, sec. 4; Amended by Stats. 2002, ch. 1013, Sec. 29.)

§4980.57. CONTINUING EDUCATION FOR SPOUSAL OR PARTNER ABUSE

(a) The board shall require a licensee who began graduate study prior to January 1, 2004, to take a continuing education course during his or her first renewal period after the operative date of this section in spousal or partner abuse assessment, detection, and intervention strategies, including community resources, cultural factors, and same gender abuse dynamics. On and after January 1, 2005, the course shall consist of not less than seven hours of training. Equivalent courses in spousal or partner abuse assessment, detection, and intervention strategies taken prior to the operative date of this section or proof of equivalent teaching or practice experience may be submitted to the
board and at its discretion, may be accepted in satisfaction of this requirement.

(b) Continuing education courses taken pursuant to this section shall be applied to the 36 hours of approved continuing education required under paragraph (1) of subdivision (c) of Section 4980.54.

(c) This section shall become operative on January 1, 2004.

Leg.H. (Stats. 1993, ch. 1234; Repealed by Stats. 2002, ch. 1013, sec. 30; Added by Stats. 2002, ch. 481, sec. 5; Amended by Stats. 2003, ch. 607, sec. 16)

§4980.60. RULES AND REGULATIONS

The board may adopt those rules and regulations as may be necessary to enable it to carry into effect the provisions of this chapter. The adoption, amendment, or repeal of those rules and regulations shall be made in accordance with Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.

The board may, by rules or regulations, adopt, amend, or repeal rules of advertising and professional conduct appropriate to the establishment and maintenance of a high standard of integrity in the profession, provided such rules or regulations are not inconsistent with Section 4982. Every person who holds a license to practice marriage and family therapy shall be governed by the rules of professional conduct.

Leg.H. (Added by Stats. 1986, ch. 1365, sec. 4.; Amended by Stats. 2002, ch. 1013, sec. 31)

§4980.70. ADDITIONAL PERSONNEL

Except as provided by Section 159.5, the board may employ whatever additional personnel is necessary to carry out the provisions of this chapter.

Leg.H. (Repealed and added by Stats. 1986, ch. 1365, sec. 4.)

§4980.80. RECIPROCITY; EQUIVALENT REQUIREMENTS; PAYMENT OF FEES; FURTHER CONDITIONS

The board may issue a license to any person who, at the time of application, has held for at least two years a valid license issued by a board of marriage counselor examiners, marriage therapist examiners, or corresponding authority of any state, if the education and supervised experience requirements are substantially the equivalent of this chapter and the person successfully completes the board administered licensing examinations as specified by subdivision (g) of Section 4980.40

April 12, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O.Box 8012
Baltimore, MD 21244-8012

Re: CMS-3818-P

To Whom It May Concern:

I am writing in response to the newly changes of coverage for dialysis facilities. The following are my comments regarding different regulations.

ASSESSMENT

CMS-3818-P82
20 calendar days to complete assessments is not long enough to do a thorough assessment. We have to be aware that most of the new patients' conditions are not stable during the first two weeks. They are weak and fragile. Sometimes they have to go back to the hospital. I personally believe 30 calendar days should be a reasonable timeframe for every member in the team. There should not be any change.

CMS-3818-P85
The proposed annual comprehensive reassessment of stable patients is reasonable. This will help the team members minimize the facility burden for unstable patients we should do the monthly care plan.

REHABILITATION

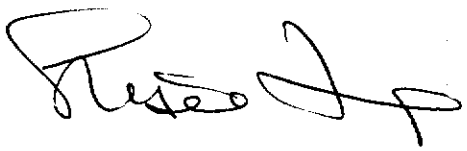
I strongly believe rehabilitation –related activities is ultra important for patients' self image and independency. To help patients to re-enter the workforce will help patients to maintain a active life style which in a way to add positive effects on their outlook in life.

SOCIAL WORK QUALIFICATIONS

The proposed 494.140(d) is not clearly defined. The social workers without a master's degree, already employed in the dialysis or transplantation setting as of 1975 should be allowed to work until they retire. As for the new recruits, we should require them to have a master's degree due to the complex of nature in the field. In order to meet the many and varied psychosocial needs of this patient population, I believe qualified master's degree social worker (MSW) trained to function autonomously are essential.

If additional information is necessary, please do not hesitate to contact the undersigned.

Sincerely,



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Mitchell E. Daniels, Jr.
Governor

Judith A. Monroe, M.D.
State Health Commissioner

Indiana State Department of Health

An Equal Opportunity Employer

April 5, 2005

Centers for Medicare and Medicaid Services (CMS)
Department of Health and Human Services
Attention: CMS-3818-P
PO Box 8012
Baltimore, MD 21244-8012

Re: Comments on proposed ESRD 42 CFR Parts 400, 405, 412, 413, 414, 488, and 494

Dear Regulatory Comments Review Committee:

This response is from Indiana, a State Agency (SA) that contracts with CMS to conduct the ESRD federal surveys in Indiana. Please consider Indiana State Department of Health (ISDH) Acute Care Program area comments on the proposed rules at 42 CFR Parts 494.
III Provision of Proposed Part 494 Subpart A-General Provisions:

A. Basis and Scope (Proposed 494.1)
"Basis" Several patients' safety can be compromised with an error in treatment; because the patient care is highly risky and technological; ESRDs regulation *should include* regulations mandating the frequency of End Stage Renal Disease (ESRD) surveys at least every three (3) years and follow up surveys annually for two (2) years where the facility is non-compliant to one or more of the Conditions of Participation (CoP).
"Basis" Money *should be allocated* to conduct federal ESRD surveys to ensure surveys are conducted as mandated and to ensure patient safety.
"Basis" Language *should* address sanctions to ESRD clinics that restrict admission or if ESRD clinics discharge patients based on patient requiring higher skill care issues (vent dependent patients), mobility issues (bed-bound, or obesity) where the patient is unable to get dialysis at an outpatient ESRD. This practice cost the patient significantly in quality of life and is costly when the patient can only secure help at the hospital in an emergency situation.

B. Definitions (Proposed 494.10)
Definitions *should be* cross referenced to ensure inconsistencies do not exist within the regulations proposed.
"Definition" Interdisciplinary team *should be* the same definition throughout the regulations. Refer to proposed definition at Plan of Care section (propose494.80) that states, "The interdisciplinary definition proposed states, "the interdisciplinary team consist of, at a minimum, the patient (if he or she desires) or his/her designee, a registered nurse, a nephrologists or physician treating the patient for ESRD, a social worker, and a dietitian" The definition at Plan of Care is the desired definition.

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Definitions *should* reflect abbreviations and terms that have been expanded such as dialysis technician, AAMI, AAMI, Certification organizations such as BONENT, etc. if they are to be used in the regulations.

"Definition" *should be* specific when defining home dialysis that extends from the patients residence and extends into a variety of managed owned residents such as nursing homes, residential centers, group homes, assistive living etc. The federal government *may want to limit* dialysis care going into "homes" managed by facilities that are only regulated federal facilities. We *would oppose* the regulations allowing dialysis being offered in home environments that are not federally regulated.

C. Compliance with Federal, State, and Local Laws and Regulations (Proposed 494.20)

"Compliance with Laws and Regulations" *should* have a statement that compliance with laws and regulations may be cited as deficient practice if a referral has been made by the SA even if action has not yet occurred. The citation would remain until action was taken or removed by the SA or federal agency that receives the referral.

IV. Provisions of Proposed Part 494 Subpart B (Patient Safety)

A. Infection Control (Proposed 494.30)

"Infection Control" Agree with using the Centers for Disease Control and Prevention (CDC) "Recommended Infection Control Practices for Hemodialysis Units At a Glance" with the exception of Hepatitis C and infection control proposals for handling waste, oversight of facility infections, and policies will also help decrease risk of infections.

B. Water Quality (Proposed 494.40)

"Water Quality" Water quality is essential to the health and safety of all dialysis patients. Agrees with updating the water standards by using American National Standards Institute) AAMI as proposed is essential for improving outcomes, staying current, decreasing risk and reducing cost related to complications.

"Water Quality" CMS *should further amend* this section to strengthen Water Quality by adding that CMS Central Office staff may approve and mandate future AAMI or International Standards by Program Memorandum provided a process is in place to involve the regulatory commission over the Department of Health and Human Services (DHHS).

Reuse of Hemodialyzers and Bloodlines (Proposed 494.50)

"Reuse of hemodialyzers and bloodlines" increases several risk to dialysis patient with the current regulations as many inconsistencies occur among facilities when cleaning dialyzers. Agree with the proposal *to maintain the existing regulations and to adopt the more current AAMI guidelines and manufactures recommended guidelines* as care in this area must be current with national and international standards.

"Reuse of hemodialyzers and bloodlines" CMS *should further amend* this section to strengthen reuse standards by adding that CMS Central Office staff may approve and mandate future AAMI or International standards by Program Memorandum provided a process is in place to involve the regulatory commission over the Department of Health and Human Services (DHHS) provided a process is in place to involve the regulatory commission over the Department of Health and Human Services (DHHS).

"Reuse of hemodialyzers and bloodlines" The new proposals *should have* stronger penalties for facilities that violate cleaning recommendations and prohibit facilities from performing reuse when unsafe practices are repeatedly cited as deficient practices.

C. Physical Plant (Proposed 494.60

"Physical Environment" Agree with adopting the National Fire Protection Associations (NDPA) Life Safety Code (LSC).

"Physical Environment" Support the use of life safety surveys for ESRD facilities; however, the *mandate needs to include funding* to conduct life safety inspections.

"Physical Environment" Agree with *adding* fire safety language, equipment maintained by manufactures recommendations and standards.

"Physical Environment" Agree with *additions* for emergency preparedness and disaster plans, monitoring, and training staff on use of emergency equipment since many ESRD facilities employ unlicensed nonprofessionals to provide health care.

Proposed Part 494 Subpart C (Patient Care)

A. Patients' Rights (Proposed 494.70)

"Patients' Rights" Agree with informing patients of their rights prior to beginning treatment.

"Patients' Rights" ESRD facilities frequently make patients sign a leaving against medical advice (AMA) form when they "break" a facility policy of eating or drinking while being dialyzed or request to go to the restroom. Patient rights *should propose* protection for patients when the patient is forced to sign AMA forms before the patient may be disconnected, especially when the patient is noncompliant to policies that may be violating a persons right or dignity.

"Patients' Rights" Stronger language *should be added* to require the ESRD facility to provide and post the different ways a patient may file a complaint with the State Agency (SA) and Network. Current and accurate telephone numbers and hours of operation should be posted in legible print.

"Patients' Rights" The public statement *should state* the patient or family may file a complaint directly with the SA or Network prior to filing the grievance with the facility.

"Patients' Rights" Many ESRD patients fear retaliation, so the proposed rules *should have* language addressing this.

"Patients' Rights" A statement *should be* included in patient rights regarding the patient has a right to be free from sexual, verbal or physical abuse, intimidation and harassment.

"Patients' Rights" A statement *should be* included that prohibits the ESRD facilities from discriminating against patient when admitting or discharging related to disability or the need for more skilled care such as ventilator dependent, cart bound, and severe obesity. Hospitals emergency rooms should not have to treat ESRD patients on a routine basis.

Patient Assessment (Proposed 494.80)

"Patient assessment" Agree with the statement in the proposed rules regarding the importance of comprehensive patient assessment by a group of professionals (physician, registered nurse, social worker, and dietitian) and the areas that should be addressed.

"Patient assessment" The proposed language *should also state* that routine patient assessments and reassessments that are performed prior to initiating care and when complications arise during treatment be performed by a professional registered nurse. Most State Nursing Practice Acts have the registered nurse performing assessment and reassessments not licensed practical nurses or unlicensed technicians.

"Patient assessment" *Would strongly oppose to any regulatory language in the ESRD proposed rules that would expand the practice of medicine or the practice of nursing to licensed practical nurses and unlicensed technician. CMS ESRD regulations should use*

caution and not interfere with other State regulatory bodies (Federal and State) that have authority to establish practice standards and rules.

Patient Plan of Care (Proposed 494.90)

"Plan of Care" Current regulations were confusing with two plans of care, we support one plan of care that meets all the patients ESRD needs based on the comprehensive assessment by professionals. However, the definition of "Interdisciplinary Team" *should be consistent at this section and the definitions section.*

"Plan of Care" We *would support* the definition for interdisciplinary team to read, "The interdisciplinary team consist of, at a minimum, the patient (if he or she desires) or his/her designee, a registered nurse, a nephrologists or physician treating the patient for ESRD, a social worker, and a dietitian."

"Plan of Care" The plan of care *should address* issues that the facility wishes to restrict such as toileting, eating and drinking if the facility is planning to restrict these activities while being dialyzed. However, the plan of care should not violate individual's rights to choose and be involved in care regardless if the decision is not in the best interest of the patient.

1. Development of the Patient Plan of Care (Proposed 494.90(a)(1))
   a. Dose of Dialysis (Proposed 494.90(a)(1))

   "Plan of Care -Dose of dialysis" The proposed rules *should reflect* an assessment by the registered nurse or physician and a change in order by a physician prior to changing flow rates, run time, or treating and administering medications, fluids or treatments for changes in the patient medical status.

   "Plan of Care-dose of dialysis" Frequently ESRD facilities have allowed unlicensed technicians to perform patient assessments and perform treatments without the involvement of professional interdisciplinary team member or physician order. The proposed language *should restrict this practice.*

   "Plan of Care-dose of dialysis" The proposed rules on nutrition are detailed; the patient care plan of care *should include* more detail.

   b. Nutritional Status (Proposed 494.90(a)(2))

   "Plan of Care-Nutritional Status" We agree with proposed recommendations for nutritional status.

   c. Anemia (Proposed 494.90(a)(3))

   "Plan of Care-Anemia" We agree with proposed recommendations. Anemia management is crucial to dialysis patient outcomes.

   d. Vascular Access (Proposed 494.90(a)(4))

   "Plan of Care-Vascular Access" The vascular access is the lifeline to the dialysis patient. The proposed regulations *should address* issues associated to patient outcomes.

   "Plan of Care-Vascular Access" Currently access is being performed by unlicensed personnel, many without proper training or the professional knowledge to assess for potential complications until it is too late. Language *should be included* that promotes the professional registered nurse as responsible for assessment, accessing and initiating treatment, and monitoring care.

   "Plan of Care-Vascular Access" Vascular access is a national concern and Fistula's First is just one initiative. Vascular Access is a concern for patients as found on the CMS Webb site, "Evaluation of the Content of the Dialysis Facility Compare Website: Final Report" April 2004, page 45-48. Surveyors frequently site issues related to training, care,

and issues with vascular access. CMS *should* consider consumers concerns regarding care issues.

e. Transplantation Status (Proposed 494.90(a)(5)
"Plan of Care-Transplantation status." We agree with proposed rules that include planning for transplantation where appropriate.

f. Rehabilitation Status (Proposed 494.90(a)(6))
"Plan of Care-Rehabilitation Status" We agree with proposed language that are addressed under rehabilitation status.

g. Social Services (494.80(a) as part of plan of care)
"Plan of Care-Social Services" Agree that social services should be included in the plan of care.

2. Implementation of the Patient Plan of Care (Proposed 494.90(b))
"Plan of Care- Implementation of Patient Plan of Care" The dialysis patient and care is highly technical and complicated. The reassessment and comprehensive plan of care *should be* completed at a minimum of every six (6) months for stable patients and monthly for unstable patients with addendums to care for changes. Would *oppose* any regulatory language increasing the time for comprehensive assessment to annual because the dialysis patient's needs change and it is reasonable that the professional team, that is onsite most days, have the opportunity to conduct the comprehensive assessment.

3. Transplantation Referral Tracking (Proposed 494.90(c))
"Plan of Care- Transplantation Referral Tracking" Agree with this proposal as some form of tracking is needed to ensure the list is maintained and current.

4. Patient Education and Training (Proposed 494.90(d))
"Plan of Care- Patient Education and Training" Patient education and training is essential to positive patient care outcomes. The proposals language *should be expanded* especially for dialysis that is being performed in the home setting or nursing home environment.

B. Condition: Care at Home (Proposed 494.100)
"Care at Home" Proposed rules *should reflect* the professional staff such as the registered nurse, should evaluate, maintain the plan of care and educate the patient on home dialysis care in conjunction with the physician, dietician and social worker.
"Care at Home" Trained assistants *should be* defined in the definitions and *should not* be unlicensed staff *employed by* ESRD facility or nursing home. Trained assistants *should be* those individuals that are either family members or significant others or that the patient is hiring or using to assist them with home dialysis.

1. Dialysis of the ESRD Patient in the Home Setting
"Care at Home-Dialysis of the ESRD Patient in the Home Setting" We agree with proposal that the same standards apply in the home setting as the outpatient setting.
"Care at Home-Dialysis of the ESRD Patient in the Home Setting" Strongly agree that the facility *should be involved and provide all* of the support services, regardless of whether the dialysis supplies are provide by the dialysis facility or a durable medical company.

2. Dialysis of ESRD Patients in Nursing Facilities and Skilled Nursing Facilities

a. Delineation of Responsibility
"Care at Home-Delineation of Responsibility" The ESRD facility *must maintain responsibility* for the dialysis of patients in Nursing Facilities and Skilled Nursing

Facilities and a written agreement *should be* in place delineating services and responsibilities.

b. Applicable ESRD Conditions of Coverage
"Care at Home-Applicable ESRD Conditions of Coverage" All of the Conditions of Coverage should apply to care provided at the NF and SNF that apply to ESRD facilities.

c. Nursing Coverage
"Care at Home-Nursing Coverage" Dialysis is highly technical and is constantly changing. Extensive training is required for experienced registered nurses when transferring to work in ESRD facilities. The nursing coverage in the proposed rules *should mandate and define* an experienced ESRD registered nurse to be on duty at the NF and SNF while patients are receiving dialysis. In most State Nursing Practice Acts, the licensed practical nurse is a delegated nursing service and therefore should not be responsible for the supervision of care provided at NF and SNF. The licensed practical nurse should work *under the on-site* direction of an experienced ESRD registered nurse. Patients in the NF and SNF typically have multiple co-morbidities and require even more skill to assess and reassess, so the patients in NF ands SNF should not receive care from staff with less expertise and knowledge.

d. Training
"Care at Home-Training" Agree with any proposed language where the certified ESRD facility staff is completely responsible for all training of ESRD and dialysis care completed in the NF and SNF to patients, family or staff.

e. Monitoring
"Care at Home-Monitoring" Agree that the certified ESRD facility staff *should be* responsible for monitoring of the ESRD patient's care related to dialysis and dialysis related issues.

E. Condition: Quality Assessment and Performance Improvement (QAPI) (Proposed 494.110)
"QAPI" Agree with the proposed requirements for the ESRD facility to have a QAPI and to perform.

1. Program Scope (Proposed 494.110 (a))
"QAPI" Agree with the areas proposed, *may want to consider* adding language regarding equipment problems, staffing problems, other errors, etc.
"QAPI" May want to *add language* regarding the facility should initiate action to QA issues found and will measured for improved outcomes.
2. Monitoring Performance (Proposed 494.110(b))
"QAPI" Agree with proposed recommendations.
3. Prioritizing Improvement Activities (Proposed 494.110(c))
"QAPI"Agree with proposed recommendations under prioritizing improvement activities.
4. Facility Specific Standards for Enforcement (Proposed 494.110(d))
"QAPI" *Agree with issues* identified by the OIG *but disagree that with issues* raised by the facilities. ESRD facilities *should be* held accountable to standards for care and *should have* an understanding and expectations that minimal standards that must be maintained.

Condition: Clinical Standards

"Clinical Standards" Agree with having a condition for clinical standards. A condition is needed to ensure clinical standards are maintained and a means to enforce deficient practice when it occurs. *The rules should propose this section.*

Standard: Performance Expectations

(a) "Clinical Standards- Dose of dialysis" The proposed rules *should reflect* an assessment by the registered nurse or physician prior to changing flow rates, run time or treating and administering treatments for changes in the patient's medical condition. Frequently, ESRD facilities allow unlicensed renal technicians to perform patient assessments and treatments without the involvement or direct supervision of professional registered nurse or physician and without physician orders. The proposed rules on nutrition are detailed; the clinical standards section *requires more detail.*

(b) "Clinical Standards- Anemia" Agree with proposals.

(c) "Clinical Standards- Additional clinical standards" Agree somewhat; however, CMS *should seek input* for clinical standards for nursing and the delegation of nursing from the National Council State Boards of Nursing, State Nursing Boards, and the National Nursing Associations and National Nursing Associations Specialties.

"Clinical Standards- Additional clinical standards" CMS *should use caution and not* suggest ESRD regulations that contradict State Nurse Practice Acts and Medical Practice Acts by introducing language of unlicensed renal technicians to perform nursing. The use of unlicensed personnel for the performance of nursing care may not enhance the quality of patient care in technical and critical areas that require advanced knowledge and judgment.

(d) "Clinical Standards- Notification" Agree that proposals should be published in the federal register for comment.

C. Conditions: Special Purpose Renal Dialysis Facilities (Proposed 494.120)
"Special Purpose Renal Dialysis Facilities" Agree with proposal, this was especially helpful with the disaster in the state of Florida.

D. Laboratory Services (Proposed 494.130)
"Laboratory Services" Agree with proposal to regulations.

VI. Provision of Proposed Subpart D: Administration

A. Personnel Qualifications (Proposed 494.140)
"Personnel Qualifications"

1. Medical Director (Proposed 494.140(a))
"Personnel Qualifications-Medical Director" Agree with proposed changes.

2. Nursing Services (Proposed 494.140(b))
"Personnel Qualifications-Nursing Service" Agree with having four distinct categories defined for nursing responsibility based on duties of the registered nurse.
"Personnel Qualifications" #1. Nurse responsible for nursing services at the facility: Agree with the qualifications that each facility employ a full time registered nurse with the proposed experience.
"Personnel Qualifications" For numbers # 2 and # 3, nurse responsible for training in self care and in charge of the unit: agree with a professional being responsible each shift; agree the nurse *should be* a registered nurse. *Disagree that the nurse could be a licensed practical nurse* as the proposal may violate individual State Nurse Practice Acts. CMS *should use caution* when introducing regulatory language that may introduce conflicting

standards/rules that are enforced and regulated by other State and Federal entities and rules. The nursing shortage should not justify the use of unqualified staffs.
"Personnel Qualifications"# 4. Care on the unit for nursing service: Agree that licensed practical nurses may be able to provide care on the unit under the direct onsite supervision of a registered nurse provided the regulations do not introduce care that is direct conflict with individual State Practice Acts.

3. Dietitian (Proposed 494.140 (c))
"Personnel Qualifications-Dietitian" Agree provided the rules do not overstep the boundaries of the dietitian and regulatory body that govern individual State Dietitians Practice Acts.
4. Social Worker (Proposed 494.140(d))
"Personnel Qualifications-Social Worker" Agree with proposed regulations. A masters degree is already expected, *oppose grandfathering*. CMS should also seek input from entities that regulate Social Work.
4. Dialysis Technicians (Proposed 494.140(e))
"Personnel Qualifications-Dialysis Technicians" *Opposed to* any regulatory language that suggest the use of unlicensed personnel for the practice of nursing or the practice of medicine. CMS should use caution when introducing regulatory language in the ESRD regulations that could conflict with individual State Nurse Practice Acts and Medical Practice Acts. CMS is not the regulatory body over individual State Practice Acts and introducing conflicting regulations will create unnecessary issues. Regardless that ESRD facilities use renal technicians for care, the use of unlicensed personnel in lieu of registered nurses is extremely dangerous and has had documented negative outcomes.
5. Other Personnel
"Personnel Qualifications- Other personnel" Agree with pharmacy being a part of the interdisciplinary team where applicable.

B. Condition: Responsibilities of Medical Director (Proposed 494.150)
"Responsibilities of Medical Director" Agree with keeping medical director as a separate condition as suggested by the Office of Inspector General (OIG).
"Responsibilities of Medical Director" We agree with the medical director being assigned over quality assessment and performance improvement (QAPQ) programs and best practice.
"Responsibilities of Medical Director" Agrees with maintain the requirement of responsibility of the unit having adequate trained staff.
"Responsibilities of Medical Director" We agree that the medical director should be responsible and involved with ESRD facility policy oversight and compliance.
"Responsibilities of Medical Director" Agree the medical director oversee the interdisciplinary team follows the policies and procedures.

C. Relationship With ESRD Network (494.160)
"ESRD Network" Agree that The Network *should not* be included in the regulations and at times question the role of ESRD Networks. Patient care complaints *should be* sent to the SA regulatory body that conducts surveys and not the Network.

D. Condition: Medical Records (494.170)
"Medical Records" *Agree* with the proposal to maintain complete medical records for all patients under the ESRD facilities supervision including home patients and durable medical equipment.

"Medical Records" *Disagree* that CMS does not establish some standardization of what should minimally contained in the medical records, CMS should not assume a facility will maintain standardize records unless CMS describes what they would want to have in the medical records.

"Medical Records" *Agree* with retaining the language to safe guard medical records against loss and destruction.

"Medical Records" *Disagree* with eliminating written policies and procedure for recordkeeping. Policies and procedures establish written guidelines for all staff to follow.

E. Condition: Governance (Proposed 494.180)

"Governance" Comments are given under each subcategory under governance.

1. "Governance- Existing Requirements for Governing Bodies" *Agree* with current language under the existing requirements.
2. "Governance- Overview of the Proposed Governance Requirements" *Agrees* with proposal that requires necessary minimum administrative features that are responsive to patients and that strengthen the accountability of the governing body.
3. "Governance- Governance Condition" (Proposed 494.180) *Agrees* with the proposed language that the governing body be under control of an identifiable governing body, or designated person(s) so function, with full legal authority and responsibility for the governance and operation of the facility.

   "Governance- Governance Condition" Would *suggest adding* "the governing body must notify the State Agency (SA) or surveying entity of any administrative or medical director staff changes or any changes in location/telephone numbers, management, governing body members or Clinical management staff".
4. "Governance- Designation of a Chief Executive Officer or Administrator" (Proposed 494.180(a)) *Agrees* with proposed language regarding the CEO/administrators role.
5. "Governance- Adequate Number of Qualified and Trained Staff" (Proposed 494.180(b)) *Agrees with having minimum staffing ratios;* however, stronger language regarding the ratios for registered nurse to renal technician should be given since ESRD is highly technical.

   "Governance- Adequate Number of Qualified and Trained Staff" *Propose* that the registered nurse not just be available, but that the registered nurse is a directed patient care giver and provides the direct supervision of care. *Propose* the administrative registered nurse be responsible for the overall operations and not the daily direct care supervision.

   "Governance- Adequate Number of Qualified and Trained Staff" *Agree* that renal technicians need regulatory language if the renal technicians role is expanding to patient care, nursing and clinical areas. However, documentation proves that individual states do not agree on the renal technician's role, practices, and the training program because technician roles are crossing over into the practice of nursing and the practice of medicine. CMS should use caution when introducing "standards" for unlicensed personnel into regulatory language when other State rules promulgate the practice of nursing or unlicensed personnel performing under nursing. The nursing shortage should not be exploited to substitute substandard care and non-professional staff such as technicians to perform the duties of nursing in a highly technical medical area that requires knowledge, judgment, and constant assessment with nursing interventions. The proposed language is suggesting that CMS supports the use of

unlicensed personnel for nursing and steps into proposing changes in the practice of nursing and the practice of medicine.
"Governance- Adequate Number of Qualified and Trained Staff" *Propose* that CMS introduce language that allows for renal technicians only where they are nationally certified and where State laws clearly allow this practice.
"Governance- Adequate Number of Qualified and Trained Staff" *Further propose* language that addresses caution where state law does not regulate unlicensed personnel for nursing or where state law is noncommittal to the issue. Any language regarding technicians should support current national standards as outlined by the certification groups for renal technicians. Renal technicians should have limited responsibilities in the clinical setting unless they are nationally certified, and evidence of extensive training, and where State law supports unlicensed personnel.
"Governance- Adequate Number of Qualified and Trained Staff" *Oppose any* language where ESRDs are allowed to police their own training programs.

6. "Governance-Medical Staff Appointments" (Proposed 494.180(c)) Agree with proposed language.
7. "Governance-Furnishing Services" (Proposed 494.180(d)) We agree with proposed language; however, *propose additional* language regarding home dialysis.
8. "Governance-Internal Grievance Process" (Proposed 494.180(e)) We agree with proposal; however, *propose additional language* regarding the expectation with timely investigation, documentation, and resolution to grievance along with QA to prevent future issues or reoccurrence.
9. "Governance-Discharge and Transfer Policies and Procedures" (Proposed 494.180(f)) Agrees with some of the proposed language. *Proposed* the adding of language for admission policy that discourages discrimination.
"Governance-Discharge and Transfer Policies and Procedures" Also, the regulations *should address* procedures regarding the ESRD making arrangements and paying for services provided at a local hospital for treatment they refuse to provide when they wish to discontinue a disruptive patient. The payment and arrangements should continue until an internal or external hearing can be conducted and/or a mental health evaluation to evaluate if the behavior was related to a disability, medication, dialysis, etc. and could be treated. Based on findings, the facility could then provide discharge with notice and assist with transfer to another facility. Discharging to hospital emergency room for care is not acceptable for managing this disease.
10. "Governance-Emergency Coverage" (Proposed 494.180(g)) Agree with proposed suggestions.
11. "Governance-Furnishing Data and Information for ESRD Program Administration" (Proposed 494.180(h)) Agree that data and information from ESRD programs *should be* mandatory instead of voluntary.
"Governance-Furnishing Data and Information for ESRD Program Administration" Provisions *should be* available to make the data public such as home health compare etc. so the public may make informed consent when choosing an ESRD facility.
"Governance-Furnishing Data and Information for ESRD Program Administration" *Propose* that regulations contain language to allow for audits by The Networks regarding accuracy of data that has been submitted since the data submitted is self

reported. Many ESRDs have data available directly from their computerized systems with machines and documentation.

12. "Governance- Disclosure of Ownership" (Proposed 494.180(i)) Agrees with proposal, *consider adding* language where the facility must report all administrative changes to the State surveying agency, including administration, changes in address, and telephone numbers.

VII. Other Proposed Changes and Issues

A. Proposed Cross-Reference Changes

"Cross-Reference Changes" agrees with moving references to the appropriate sections when the new rules are implemented to make the regulations read easily.

B. Proposed Additions to Part 488

"Part 488" agrees with adding Subpart H to Part 488 that included the existing sanction provisions, termination procedures, alternative sanctions denial of payment, notice procedures, and rights of suppliers.

VIII. Reference Materials

A. New Provisions of Part 494

"Part 494 - new provisions" agrees with format, but please refer to comments above regarding infection control, water quality, physical environment, patient rights, patient assessment, patient plan of care, care at home, quality assessment and performance improvement, special purpose renal dialysis facilities, personnel qualifications responsibilities of the medical director, and governance.

Thank you for the opportunity to comment. If you desire further clarification, feel free to contact me at the address and telephone numbers below.

Sincerely,

Lana K Richmond MSN, RNBC

Lana K. Richmond, MSN, RN, BC
Public Health Nurse Surveyor Supervisor/Program Director
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Work: (317) 233-7742

April 15, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-3818-P
P.O. Box 8012
Baltimore, Maryland 21244-8012

Re: CMS-3818-P

To Whom It May Concern:

I am a renal social worker who has been working in the field of dialysis for almost 10 years and in the field of social work for over 30 years. Therefore, I feel qualified to comment on your proposals, especially as they relate to the social work areas.

First, I would like to express my sincere appreciation for all the hard work and the insight that is evidenced in the document. Because dialysis has changed greatly over the almost 30 years since the first regulations were enacted, it is so important to ensure that the dialysis companies are actually *providing* quality care to our patients. The following are my comments, suggestions and concerns.

494.60(d)(1)(ii) I would like you to specify that ONLY staff who provide direct medical care to patients be required to have CPR certification. I have strong objections to being required by my company to be certified for CPR. I did not go into direct patient care and do not feel that I should be held responsible for life and death medical treatment.

494.70(b)(1) and (2) I strongly support your stand on giving a unit the right to discharge a disruptive/dangerous patient in order to protect the rights of other patients and the safety of other patients as well as staff members. Having worked in the inner city of Baltimore, I know that there are times when discharging a patient is the only thing that can be done.

494.80(a) It is quite essential for social workers to be an intergral part of the patient plan of care. Nephrology social work interventions have been shown to successfully:

- Enhance/facilitate social support networks of patients and their families (Brady & Lawry, 2000; Johnstone, 2003; Spira, 1996)
- Help patients and their families cope with ESRD and the treatment regime (Brady & Lawry, 2000; Frank, Auslander & Weissgarten, 2003)
- Help patients improve dialysis adequacy (Callahan, Moncrief, Wittman & Maceda, 1998)

- Help improve patient outcomes, including anemia status (Spira, 1996; Vourlekis & Rivera-Mizzoni, 1997
- Help patients minimize nonadherence to ESRD treatment regime (Beder, Mason, Johnstone, Callahan & LeSage, 2003; Callahan, Moncrief, Wittman & Maceda, 1998; Johnstone, 2003).
- Reduce patient missed treatments by 50% (Medical Education Institute, 2004)
- Help patients reduce their interdialytic weight gains between dialysis treatments (Auslander & Buchs, 2002; Root, 2005)
- Achieve up to a 48% improvement in fluid adherence Johnstone & Halshaw, 2003)
- Improve ESRD patients' blood pressure (Beder, Mason, Johnstone, Callahan & LeSage, 2003)
- Increase ESRD patients' medication compliance (Beder, Mason, Johnstone, Callahan & LeSage, 2003)
- Reduce anxiety in CKD patients (Iacono, 2005; Sikon, 2000)
- Improve ESRD patient quality of life (Callahan, Moncrief, Wittman & Maceda, 1998; Chang, Winsett, Gaber & Hathaway, 2004; Christensen, Smith, Turner, Holman, Gregory & Rich, 1992; Frank, Auslander & Weissgarten, 2003; Fukunishi, 1990; Johnstone, 2003; MacKinnon & MacRae, 1996; Sloan & Rice, 2000; Spira, 1996)
- Decrease patient morbidity and mortality via: increasing dietary adherence, enhancing patient coping and adaptation to ESRD and its treatment regimes, decreasing depression, increasing ESRD patient satisfaction and increasing patients' rehabilitation potential (Cummings, Kirscht & Levin, 1981; Erickson, LeSage, Johnstone & Parsonnet, 1991 ; Evans, 1990; Korniewicz & O'Brien, 1994; Lenart, 1998; LeSage, 1998; Parsonnet, 1991)
- Reduce patient hospitalizations and emergency room visits (Dobrof, Dolinko, Lichtiger, Uribarri & Epstein, 2000)
- Improve patient adherence, improve functional status and assist the patient and family in coping with and adapting to changes brought about by ESRD and its treatment regimes. (Berkman, Bonander, Rutchik, Silverman, Marcus & Isaacson-Rubinger, 1990; Parsonnet 1991)
- Mediate conflicts in dialysis settings (Johnstone, Seamon, Halshaw, Molinair & Longknife, 1997).
- Increase advance directives completion (Yusack, 1999)
- Encourage patients to get a kidney transplant (Rosen, 2002) and may decrease racial disparity in transplantation (Wolfe, 2003 & Wolfe & Toomey, 2004)

- Help patients stay employed and reduce hospitalizations that may inhibit employment (Raiz, 1996, Grumke & King, 1994, Rasgon, Schwankovsky, James-Rogers, Widrow, Glick & Butts, 1993)

Therefore, I recommend that there be a social work portion in the care plan to address the same issues as other disciplines with an additional area left for other comments on issues not covered by those disciplines

494.90(1)(6) Returning a patient to the highest level of functioning is important to the emotional well-being of that patient. Psychosocial education and support can help patients stay employed and reduce hospitalizations that may inhibit employment (Raiz, 1996, Grumke & King, 1994, Rasgon, Schwankovsky, James-Rogers, Widrow, Glick & Butts, 1993. It can also improve patient activity level and rehabilitation status for those who are unable to return to work or who are retired. (Beder, Mason, Johnstone, Callahan & LeSage, 2003; Callahan, Moncrief, Wittman & Maceda, 1998; Ericson & Riordan, 1993; Institute on Rehabilitation Issues, 2001; Raiz, 1999).

490.140(d) I highly endorse your proposal for retaining the requirement for a master's level social worker for the following reasons:

- The nephrology social worker must be skilled in assessing for psychosocial influences and their interrelatedness in predicting treatment outcomes. The nephrology social worker must also be able to design interventions with the patient, the family, the medical team, and community systems at large to maximize the effectiveness of ESRD treatment. The additional training received by masters-prepared social workers enable them to perform these complex professional tasks and ensure effective outcomes that have a direct relationship to morbidity and mortality.
- Masters-prepared social workers are trained to utilize validated tools, such as the SF36 and KDQOL, to improve care and to monitor the outcomes of directed interventions, assess the complex variables that these instruments measure (Ellstrom-Calder & Banning, 1992; Lenart, 1998; National Association of Social Workers, 1994), and continually redesign a plan of care to achieve outcome goals. The masters-prepared social worker provides the interdisciplinary team with a biopsychosocial view of the patient's strengths and needs (Berkman, 1996) through use of patient-perceived quality of life measures and the person-in-environment model of assessment (Monkman, 1991).
- Most nephrology social workers provide psychosocial services autonomously as primary providers without social work supervision or consultation. Autonomous practice in an ESRD setting demands highly developed social work intervention

skills obtained in a master's level curriculum. MSWs are trained to autonomously provide diagnostic, preventive and treatment services for individuals, families and groups in the context of their life situations (Harris, 1995). These interventions assist ESRD patients in developing adaptive behaviors and perceptions necessary to cope with the changes brought about by chronic illness and hospitalization.

- Nephrology social workers must be prepared to contribute to the development of clinical pathways to enhance treatment outcomes. Nephrology social workers must have outcome evaluation skills and must understand the interaction among individual systems, the social system, and the medical system as each impacts patients and families. Nephrology social workers must be able to distinguish between normal adjustment reactions and more debilitating and potentially self-destructive emotional reactions, as well as tailor interventions to the individual coping styles of the ESRD patient (Christensen, Smith, Turner, et al., 1994)
- The masters in social work degree (MSW) provides an additional 900 hours of specialized training beyond a baccalaureate degree in social work. An MSW curriculum is the only curriculum which offers additional specialization in the Bio-Psycho-Social-Cultural, Person-in-Environment model of understanding human behavior. Undergraduate (B.S.W.) degrees, or other mental health credentials (M.A. in counseling, sociology, psychology or Ph.D. in Psychology, etc.) do not offer this specialized and comprehensive training in bio-psycho-social assessment and interaction between individual and social systems.
- The National Association of Social Workers Standards of Classification considers the Baccalaureate degree as a basic level of practice (Bonner & Greenspan, 1989; National Association of Social Workers, 1981). Under these same standards, the Masters in Social Work degree is considered a specialized level of professional practice and requires a demonstration of skill or competency in performance (Anderson, 1986).
- Masters-prepared social workers are trained in conducting empirical evaluations of their own practice interventions (Council on Social Work Education). Empirically, the training of a masters-prepared social worker appears to be the best predictor of overall performance, particularly in the areas of psychological counseling, casework and case management (Booz, Allen, & Hamilton, Inc., 1987; Dhooper, Royse & Wolfe, 1990)
- Masters-prepared social workers are identified as major mental health service providers in both urban and rural areas (Hiratsuka, 1994).
- The additional 900 hours of specialized, clinical training prepares the MSW to work autonomously in the ESRD setting, where supervision and peer support is not readily available. This additional training in the biopsychosocial model of understanding human behavior also enables the masters-prepared social worker to provide cost-effective interventions such as assessment, education, individual, family and group therapy and to independently monitor the outcomes of these interventions to ensure their effectiveness.

> Renal patients present with highly complex needs on an individual as well as systems level. Social workers are trained to intervene within both areas of need that are essential for optimal patient functioning, and help facilitate congruity between individuals and their environments' resources, demands and opportunities (Coulton, 1979; McKinley & Callahan, 1998; Morrow-Howell, 1992; Wallace, Goldberg, & Slaby, 1984). Social workers have an expertise of combining social context and utilizing community resource information along with knowledge of personality dynamics.

I heartily approve of the overall approach in the preamble to include social workers in the team process. A multidisciplinary approach (including a Master's level social worker) to CKD care has been shown to be effective in improving patient outcomes, and is the recommended method of providing CKD patient care (Corsini & Hoffman, 1996, Dunn & Janata, 1987; Gitlin, Lyons, & Kolodner, 1994; Goldstein, Yassa, Dacouris & McFarlane, 2004; Houle, Cyphert, & Boggs, 1987; Warady, Alexander, Watkins, Kohaut & Harmon, 1999).

494.140(d) I was so encouraged by your recognition that we have been used for many tasks and services that are not in keeping with the intent of having a master's level social worker. The suggestion that the essential services of providing information on transportation, Medicare/Medicaid benefits, housing, medications (and I might add transient arrangements, insurance issues) should be assigned to "other facility staff" was welcomed. However, until a specific regulation is included in the COC, large dialysis companies, like mine, will continue to use us as glorified clerks. It is my belief that they hire us ONLY because we are required by your regulations. However, they choose to require us to do anything but attending to the biopsychosocial needs of our patients. Please refer to the following:

- Russo (2002) found that 100% of nephrology social workers surveyed felt that transportation was not an appropriate task, yet 53% of respondents were responsible for making transportation arrangements
- Russo (2002) found that 46% of nephrology social workers were responsible for making transient arrangements, yet only 20% were able to do patient education
- Tasks such as clerical duties, admissions, billing and insurance matters prohibit effective nephrology clinical social work intervention to patients (Callahan, Witten & Johnstone, 1997; Russo, 2002)
- Promoting Excellence in End-of-Life Care (2002), a national program office of The Robert Wood Johnson Foundation recommends that dialysis units discontinue using Master's level social workers for clerical tasks (such as arranging transportation) in order to ensure that nephrology social workers have sufficient time for clinical service provision to their patients and their families
- Merighi & Ehlebracht (2004b; 2004c; 2005) in an exhaustive survey of 809 national nephrology social workers found that:

- 94% of social workers did clerical work (faxing, copying), and that 87% of those respondents found these tasks to be outside the scope of their social work training
- 61% of social workers were solely responsible for arranging patient transportation
- 57% of social workers were responsible for making transient arrangements, taking 9% of entire social work time
- Only 34% of the social workers thought that they had enough time to sufficiently address patient psychosocial needs
- 26% of social workers were responsible for initial insurance verification
- 43% of social workers tracked Medicare coordination periods
- 44% of social workers are primarily responsible for completing admission packets
- Alarmingly, 18% of social workers were involved in collecting fees from patients. This can negatively affect the therapeutic relationship and decrease patient trust
- The more that nephrology social workers are involved with insurance/billing, the lower their job satisfaction, particularly among social workers who collect fees from patients
- Nephrology social work job satisfaction is related to amount of time spent counseling and patient education (significantly higher job satisfaction) and insurance-related, clerical tasks (significantly lower job satisfaction)
- Respondents spent 38% of their time on insurance, billing and clerical tasks vs. 25% of their time counseling and assessing patients
- Nephrology social workers who spend more time doing insurance, billing and clerical activities report more emotional exhaustion.
- Nephrology social workers who spend more time doing counseling and patient education report less emotional exhaustion. The authors indicate that these correlations may be indicative of the fact that providing education and direct counseling to patients and family members are activities that are commensurate with the professional training and education of master's-level social workers (unlike billing, insurance and clerical tasks).

494.180(b)(1) Finally, it is my very strong belief that there is a pressing need to include the issue of social work ratios in these regulations. Until this is done, the large dialysis companies will continue to raise the patient-social worker ratios. In the region of the company in which I work, the minimum ratio has been set at 140 to 1. It is my opinion that this minimum will only continue to rise unless CMS sets a standard. Only last year I had a patient load of over 150 patients and covered 3 clinics. Obviously, I could do nothing but triage and put out fires. Please review the following:

- CNSW recommends 75 patients per full-time social worker (Council of Nephrology Social Workers, 1998)
- Texas mandates that nephrology social workers have a patient ratio of 75 to 100 patients per full time social worker
- Nevada has a mandated ratio of one full time social worker per 100 dialysis patients
- Oregon Council of Nephrology Social Workers recommends a ratio of 100 patients to one full time social worker
- Social workers report that high case loads result in a lack of ability to provide adequate clinical services (Merighi, & Ehlebracht, 2002)
- Merighi, & Ehlebracht, (2004a) in a national survey of dialysis social workers, found that only 13% of full time social workers had caseloads of 75 or fewer, 40% had caseloads of 76-100 patients, 47% had caseloads of more than 100 patients
- High nephrology social work caseloads result in lower patient satisfaction and less successful patient rehabilitation outcomes (Callahan, Moncrief, Wittman & Maceda, 1998)
- Estrada & Hunt (1998) recommend that increased time is needed for social workers to fully assess patients' psychosocial status
- Merighi & Ehlebracht (2005) found that nephrology social workers spend more time providing counseling to patients when they have lower patient caseloads
- In one study of nephrology social workers (Bogatz, Colasanto & Sweeney, 2005) 68% of all social workers did not have enough time to do casework or counseling; 62% did not have enough time to do patient education; 36% spent excessive time doing clerical, insurance and billing tasks. One participant stated: 'the combination of a more complex caseload and greater number of patients to cover make it impossible to adhere to the federal guidelines as written. I believe our patients are being denied access to quality social work services.' (P.59). Social workers had caseloads as high as 170 patients, 72% of social workers had a median caseload of 125 patients.
- Social workers have indicated that large caseloads hinder their ability to provide clinical interventions (Bogatz, Colasanto & Sweeney, 2005)

I hope that this research and my comments have been helpful to you in making further decisions before coming out with the final regulations. Thank you for your openness to listen and consider all the input that you will be receiving.

Sincerely,

C. Betty Grandison, LCSW-C

April 10, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3818-P
P.O. Box 8012
Baltimore, MD 21244-8012

To Whom It May Concern:

I am writing in response to the proposed revisions to the Conditions for Coverage for End Stage Renal Disease Facilities. This lengthy and detailed document shows thorough study of this field and a genuine effort to guarantee quality care for people being treated for ESRD. Since I am a clinical social worker who has worked in dialysis centers for 19 years, I am focusing my comments on the issues about social workers, as these are the ones I know the most about.

The section in the preamble about social workers not spending their time doing clerical tasks is most welcome, but I fear that unless it becomes part of the Conditions for Coverage it will not be effective. I have contact with dialysis social workers throughout the country and find that many of us are spending much of our time collecting records for patients visiting or transferring to our centers, sending records for our patients who are visiting or transferring to other centers, checking insurance and Medicare/Medicaid status, arranging transportation or performing other tasks that can be performed by clerical staff. In the meantime, there is no one else available to help patients and their families adjust to ESRD, understand Advanced Directives and choices in treatment modalities, make decisions concerning possible need for changes in their lives, access community resources or cope with other issues in their lives that impact doing what they need to do to maintain health. Some of our patients are mentally ill, demented, have substance abuse problems or are developmentally disabled so require special skill to take them through the process of adjusting to and working with the dialysis team. It takes time to gain a patient's trust so that he shares personal or embarrassing information that may be very important to know. It takes time to establish a working relationship with a patient. Usually we are just expected to do it all, but deadlines on the paperwork often give that priority. I know some excellent social workers who have left the field of dialysis because they feared that their clinical skills would atrophy from disuse.

Recently I had two patients whose spouses had just died. I am trained to help them with their grief work, tolerate the emotional pain and think through changes that they may have to make in having adequate care at home. Instead, I spent much time making sure that records got to other centers so two of our patients would have dialysis on trips. Travel is important for dialysis patients but secretaries could have sent the records. Secretaries didn't step in to help the patients facing a tragic loss.

If patients and their families are to receive the social work assistance described in the Conditions of Coverage the social workers have to be given the time to do this kind of work. I have six years of college, passed a rigorous written and oral exam to get my California license, take courses and read relevant literature to build my skills and meet a strict code of professional ethics. My patients and the people who are trying to help them deserve to benefit from this training.

Thank you for your consideration.

Sincerely,

Ruth Sugerman, MSW, ACSW, LCSW, BCD

Reference: "Case Study: Defining the Impact of High Patient/Staff Ratios on Dialysis Social Workers by Steve Vogatz, Rebecca Colasanto and Lisa Sweeney in Nephrology News & Issues, January 2005, pages 55--60.

April 8, 2005

Department of Health and Human Services
Attention: CMS-3818-P
P.O. Box 8012
Baltimore, MD 21244-8012

RE: Proposed Rule for Medicare Program; Conditions for Coverage for End Stage Renal Disease Facilities; File Code CMS-3818-P

To Whom It May Concern:

I am a nephrology social worker writing to comment on the proposed Conditions for Coverage as published in the Federal Register. In general, I support the revisions and commend the writers of the proposal on their detailed review of regulations that are now almost 30 years old. In particular, I would like to offer specific comments on the sections noted below:

Patient Rights: 494.70

I feel that it is very important that facilities inform patients of their right to have Advance Directives. The company I am employed with has been informing patients of this right for the past five years. I have noticed, however, that many facilities refuse to honor Do-Not-Resuscitate orders. This is largely because they are uncomfortable dealing with death in the dialysis clinic. I feel that this practice is unethical and that the regulations should include language about honoring the wishes of patients who choose not to be resuscitated, should they suffer cardiac or respiratory arrest during dialysis.

Patient Assessment: 494.80

I recognize the importance of completing a comprehensive psychosocial assessment in a timely manner, but feel that completion of this document within 20 days would be difficult for those social workers with large caseloads, or those covering more than one unit. The company I am employed with expects full time social workers to carry 140-150 patients. I do not believe that a social worker carrying this caseload could complete a psychosocial assessment on a new patient within 20 days, especially if s/he were covering two facilities. Unless CMS intends to recommend caseload limits to less than 100, I feel retaining the 30-day timeline for psychosocial assessments is more realistic.

I like the proposal for a 3-month reassessment to review the patient's ability to adhere to the renal treatment regimen. I do not feel that this should be a lengthy assessment, but perhaps a short form to note patient adjustment and list the obstacles preventing the patient from adhering to the recommended treatment.

Monthly reassessments for unstable patients would certainly benefit the patient, but again I am concerned about those social workers with large caseloads and many unstable patients. Certainly these patients need to be assessed monthly if they are unstable, but hopefully a brief reassessment will suffice.

Plan of Care: 494.90

I endorse the incorporation of transplant planning and referral tracking into the Plan of Care. However, I feel that it is important for patients to also demonstrate their motivation and involvement in the transplant referral process. Social workers can provide education and referral assistance regarding transplant evaluation, but the ultimate responsibility for follow through remains with the patient.

I applaud the emphasis that the proposed regulations place on interdisciplinary team meetings, which include the patient. Too many facilities continue to do care planning in isolation without setting aside time to meet together as a team with the patient.

Social workers welcome the inclusion of Rehabilitation Status in the Plan of Care. Certainly research shows that patients who participate in clinic rehabilitation programs show better adherence to treatment. Rehabilitation interventions, such as providing education and encouragement to patients, are at the core of social work values. However, most dialysis providers hold social workers responsible for maintaining patients' commercial insurance and arranging patient travel. A recent study in Nephrology News and Issues found that almost 94% of the 809 nephrology social workers surveyed perform clerical duties which they perceive as inappropriate use of their clinical training and skills (Merighi and Ehlebracht, May, 2004). Only 34% of social worker reported having sufficient time to counsel patients and families regarding psychosocial needs. I very much appreciate the language in the preamble stating "We recognize that dialysis patients also need other essential services including transportation and information on Medicare benefits, eligibility for Medicaid, housing and medications, but these tasks should be handles by other facility staff in order for the MSW to participate fully with the patient's interdisciplinary teams so that optimal outcomes of care may be achieved" (p. 157-158). Could some of this language be incorporated into the actual regulations to encourage dialysis providers to appropriately use their social workers?

I would welcome the use of an outcome-based tool, such as a Quality of Life instrument, to assist in the measurement of social work outcomes. Quality of Life tools could help measure depression and predict patient mortality and morbidity (DeOreo, 1997). I would recommend a short instrument, such as the SF-12 Version 2.0. Such a tool could target high-risk patients for clinical social work intervention.

Personnel Qualifications – 494.16

I recommend that a timeline be established for elimination of the grandfather clause for those non-MSW social workers who were working in the field prior to 1976. The Los Angeles area has four non-MSW social workers who were grandfathered into the field. They are now in their mid-fifties to early sixties and starting to think about retirement. If the grandfather clause were eliminated now, these individuals would have to seek employment in other fields near the end of their careers. I recommend that they be allowed to finish their careers in nephrology social work. Therefore, I propose that the grandfather clause be eliminated in 2015.

I wholeheartedly support maintaining the MSW as a requirement for "qualified social worker". The ESRD patient population has become increasingly more complex, from both the medical and psychosocial perspectives. In order to meet the needs of this population, I feel that nephrology social workers should have a minimum of a master's degree. I do not feel that the social worker requires specialization in advanced clinical practice, but I do feel that the social worker should be either licensed or registered in the state practicing. While this is already the

case in most states, much confusion about social work credentialing exists in California. As opposed to most states, where tiered licensing exists, California has only one licensing level. The LCSW in California is largely regarded as an advanced clinical practice license. It requires that the MSW be supervised for at least two years and pass two written examinations, one of which dealing exclusively on clinical vignettes. Because of the difficulty obtaining a social work license in California, only approximately 50% of nephrology social workers are licensed in this state (Merighi and Ehlebracht, April, 2004). Of the remaining social workers, some are registered with the state as Associate Clinical Social Workers and are being supervised by LCSW's. The rest practice without being licensed or registered with the state social work board. This situation has caused much confusion among social workers, DHS surveyors and dialysis providers alike. To end this confusion in California, I recommend that the Conditions of Coverage define a qualified social worker as an individual who "is licensed or registered for social work practice in the State in which he or she is employed."

Governance – 494.180

I support the strengthening of requirements that facilities make efforts to mediate problems between patients and staff before discharging patients. I would especially support incorporating language into the regulations stating that patients not be discharged from facilities for non-compliance with the treatment regimen. I feel that patients have the right to self-determination. They should be educated regarding the risks of non-compliance, but ultimately, if patients choose to disregard medical advice, this is their right. I feel that dialysis facilities should continue to accommodate these patients to the best of their ability, even if it negatively affects the clinic's outcomes.

Thank you for allowing me the opportunity to provide feedback on regulations that will probably be affecting patients and staff for many years to come. I wish you luck in your analysis of all the comments you will receive.

Sincerely,

Maureen McKinley

Maureen McKinley, MSW, LCSW
24132 Minnetonka Lane
Lake Forest, California 92630

References:

DeOreo, PB. Hemodialysis Patient-Assessed Functional Health Status Predicts Continued Survival, Hospitalization and Dialysis-Attendance Compliance. *American Journal of Kidney Disease* 1997. 30(2): 204-212.

Merighi, J. and Ehlebracht, K. Workplace Resources, Patient Caseloads, and Job Satisfaction of Renal Social Workers in the United States. *Nephrology News and Issues* April, 2004. 58-63.

Merighi, J. and Ehlebracht, K. Issues for Renal Social Workers in Dialysis Clinics in the United States. *Nephrology News and Issues* May, 2004. 67-73.

Aida dela Cerna, R.N.
33782 Channel St., Temecula, CA 92592
Tel. # (951) 302-9894

April 07, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8012
Baltimore, MD 21244-8012

Attention: CMS-3818-P

Re: Social Worker (Proposed Sec. 494.140 (d)

To Whom It May Concern:

Since 1990 until the present, Susie Fong has worked as a social worker for DaVita, a dialysis company. I had worked with her for 10 years as a past Facility Administrator of Los Angeles Dialysis Center, Los Angeles, CA.

She had demonstrated superior judgment and initiatives in solving complex psychosocial issues of dialysis patients. She had proven her skills in utilizing and coordinating available community resources to resolve problems. Her long experience in the field has given her a deep and broad understanding of the medical issues of patients on dialysis. This enables her to work well with the doctors and the rest of the staff. Her regular attendance to conferences and seminars always update and prepare her to new challenges and changes in the field of social services.

I strongly believe that her length of experience, vast knowledge, and qualification deserve the retention of the "grandfather clause".

Sincerely,

Aida dela Cerna, R.N.

DaVita™

Los Angeles Dialysis Center
2250 S. Western Ave Suite 300
Los Angeles, CA 90018
Tel: (323) 733-2260
Fax: (323) 733-4088

April 6, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8012
Baltimore, MD 21244-8012

Re: CMS-3818-P

To Whom It May Concern:

I am writing this letter in support of retaining Los Angeles Dialysis Center's, social worker, Susie Fong. Susie has been our social worker for the past 15 years and before that she worked at another dialysis unit for nearly 10 years. This gives her almost a quarter of a century's experience in dealing with hemodialysis patients and their problems.

Susie has a BSW, but that in no way has diminished her capacity in performing excellently as our unit's social worker. I have been the Medical Director of 2 hemodialysis units and Susie is clearly the best social worker I have known.

This is evident by the fact that both patients and their families seek her out to help them with dialysis related problems. She is able to resolve an overwhelming number of their problems and when she cannot, she gives them options that they were not aware of in attempt to resolve whatever issues these patients may have. As a result she is an integral part in the smooth functioning of our unit.

Although she is not a MSW, she performs her job as well as any MSW I know. She is able to handle complex psychological issues that arise in patients on hemodialysis who are chronically ill have.

It is my hope that the "grandfather clause" be retained so we are not forced to lose Susie. It is important for you to understand it not the degree that matters, rather it is the performance of the person in her job performance that matters. In that respect, Susie Fong has no equal in her field and her lose would be devastating to our unit and its patients.

If you have any questions, please contact me at the address above.

Sincerely yours,

Jack E. Rubin, M.D.,

Medical Director

April 10, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3818-P
P.O. Box 8012
Baltimore, MD 21244-8012

To Whom It May Concern:

I am writing in response to the proposed revisions to the Conditions for Coverage for End Stage Renal Disease Facilities. This lengthy and detailed document shows thorough study of this field and a genuine effort to guarantee quality care for people being treated for ESRD.

I have some concern however, with the proposal in 494.140(d) requirements for social workers at 405.2101(f) to eliminate the "grandfather clause" that allows those with "at least two years of experience as a social worker, one year of which was in a dialysis unit or transplant program prior to Sept 1, 1976 and has established a consultative relationship with a social worker who qualifies under paragraph (f)(1) of this definition." I don't know anyone who feels more strongly than I that the serious and complex issues facing dialysis patients require a well trained professional social worker. I don't see how eliminating that clause will improve the quality of social work services available. I have been supervising Susie Fong, BSW, for over 13 years and have found her to be very professional and ethical and to be dedicated to providing quality care to her patients. She worked in Hong Kong in both dialysis and transplant before Sept 1, 1976, as an MSW wasn't required there then. I think it would be unfair to social workers who have been working in the field for over 29 years to tell them they must leave and to do so would deprive their patients of their services.

Thank you for your consideration.

Sincerely,

Ruth Sugerman, MSW, ACSW, LCSW, BCD

Ruth Sugerman, MSW, ACSW, LCSW, BCD

DaVita™

Los Angeles Dialysis Center
2250 S. Western Ave Suite 300
Los Angeles, CA 90018
Tel: (323) 733-2260
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April 6, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O.Box 8012
Baltimore, MD 21244-8012

Attention: CMS-3818-P

To Whom It May Concern:

Susie Fong has been working as a Nephrology Social Worker with Los Angeles Dialysis Center since 1990 under the "Grandfather Clause". She has had 25 years of experience in the dialysis field. With her years of service in the field she could be considered as one of the pioneers. I am the facility administrator of DAVITA Los Angeles Dialysis Center and I have had the pleasure of working with Susie for the past three years.

I am writing this letter in response to the proposed changes in condition for coverage for End State Renal Disease facilities, in particular, the proposed elimination of the "Grandfather Clause" in Section 494.140(d). Susie is a very devoted social worker, she goes extra mile for the patients. The patients find her very helpful and supportive. She is well loved by the patients. She provides clinical interventions as well assistance with funding, insurance, transportation and other resources. Susie is a great asset in the facility.

It is my opinion that the "Grandfather Clause should be retained so we will not have to lose an experienced social worker. I believe experience is as valuable as academic qualification. To eliminate the "Grandfather Clause" will be a detriment to the dialysis industry. If you have any question, please do not hesitate to contact me.

Sincerely,

SunHee Park, R.N.
Facility Administrator

Centers For Medicare & Medicaid Services
Department of Health $ Human Services
P.O. Box 8012, Baltimore, MD 21244-8012

April 6, 2005

File code CMS 3818-P

TO WHOM IT MAY CONCERN

I am writing this letter to express my disagreement with the proposed Sec. 494.140 (d). I believe that the social workers that have been hired into the dialysis center since 1975 under the "grandfather clause" should be allowed to continue with their current employment until their regular retirement age.

I received my Bachelor Degree in Social Work from Chinese University in Hong Kong. Upon graduation I joined Queen Mary Hospital in Hong Kong as a medical social worker and worked there from 1965 to 1984. Among those nineteen years of service there I spent nine years working with renal patients. Since 1990, I have been employed as a nephrology social worker at Los Angeles Dialysis Center under the "Grandfather Clause" based on my previous work experience in the dialysis field.

After working so many years in the dialysis field, I possess good working knowledge of individual behavior, family dynamics, and the psychosocial impact of chronic illness and treatment on the patients and their families. I have extensive experience working with dialysis patients and am familiar with my patients' needs. With the experience I am capable of providing comprehensive services to the needy patients. In addition, I am also experienced in providing counseling and long-termed behavioral, adaptation and grieving therapy. For the past 15 years at the Los Angeles Dialysis Center I have proven to be an effective and competent social worker.

I believe there are some other social workers under "Grandfather Clause". They are as valuable as the social workers with the master degree. Their

experience in the field should be recognized.

Please do not eliminate the "Grandfather Clause".

Sincerely,

Susie Fong, B.S.W.
312 S. Clark Drive
Beverly Hills
Ca 90211
E-mail: susiefong@davita.com

March 29, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8012
Baltimore, MD 21244-8012

Attention: MS-3818P

To Whom It May Concern:

I am a licensed Marriage and Family Therapist (MFT) in the State of California and have been employed as a medical social worker in dialysis since 1975. I have been retained in my current position under the grandfather clause and am supervised by an LCSW.

I am writing this letter in response to the newly proposed changes in conditions for coverage for End Stage Renal Disease facilities. I have concerns about these changes and they are as follows:

Section 494.140(d): The "grandfather clause" should be retained because there are those of us (a limited number of individuals) who have several years of experience in the dialysis field and are well equipped to provide for all facets of patients needs. What real purpose would it serve to eliminate this clause? What protection is there for those of us who, by virtue of longevity, are valuable experts in the field of dialysis?

The newly proposed regulations should include a clause that would protect the job security of the veteran social workers that are qualified to work under the existing "grandfather clause."

Rather than make this change specific to Masters in Social Work, why not include those holding Masters degrees in related fields (i.e., psychology,

sociology, Marriage and Family Therapy). Training is similar and that, coupled with the experience in the dialysis field, makes for effective employees.

The existing regulation (405.2102(f) requires a Licensed Clinical Social Worker and the new proposal suggests eliminating the clinical designation. I am wondering why the proposal to remove this position? Could it be there is a shortage of LCSW's available? If this is the reason, why not consider utilizing MFT's in the same capacity since they are equally qualified. The MFT like the LCSW is trained to meet the psychosocial needs of the dialysis patient. As an MFT, I perform all the duties of an LCSW including: psychosocial evaluations, development of treatment plans based on patient's needs, and direct social work interventions. As an MFT I am able to function autonomously and provide therapeutic interventions around life changes and adaptation to the dialysis regimen and coping with grief and loss issues. Because dialysis affects the entire family, an MFT is well qualified to provide family therapy as we receive much training in family therapy. We are able to treat a myriad of issues that often arise in this setting, including relationship difficulties due to change in roles, family conflicts, and the degree to which families adapt.

The existing expectation that social worker assist patients with transportation, insurance benefits, housing, medications, and other community resources is in line with their training in community work. Whether or not a change is made regarding delegating this role to nonprofessional facility staff does not affect the ability of an MFT to provide what is needed to assure optimal outcomes for the patient. Although MFT training does not focus on community work, I am an expert in this area due to my years of experience in various dialysis settings, since 1995. Also, I worked for Los Angeles County for 6 years as a case worker prior to my master degree.

In conclusion, it is my belief that the "grandfather clause" should not be eliminated. LCSW's should be retained and MFT's should be included in this category as the issues of the dialysis patients are complex and require clinical skills to provide the specialized care that is needed.

Enclosed is information regarding the qualifications and license requirements of LCSW's and MFT's to enable you to realize the

similarities of these two disciplines. This information was obtained from www.bbs.ca.gov.

If you are in need of any additional information, please do not hesitate to contact me or the above mentioned web site.

I will be anxiously awaiting your decision.

Sincerely,

Ingrid Scribner

Ingrid Scribner, MFT
157 Elkins Place
Arcadia, CA 91006
E-mail: IngridHS@adelphia.net
(626) 355-0346

March 25, 05

Department of Health and Human Services
Centers for Medicare and Medicaid Services
Service Attn: File Code CMS-~~3835~~ 3818
P.O. Box 8013
Baltimore, MD 21244-8013

Dear Centers for Medicare and Medicaid:

In the thirty years I have been a dialysis social worker, I have seen the enormity of business side grow. More and more individuals are diagnosed with ESRD and therefore receive hemodialysis treatments three times a week largely funded by Medicare and Medical dollars. As dialysis companies focus on their profits, their temptations lie in reducing costs like the social worker who usually is a masters level person well educated and equipped to treat and counsel patients undergoing a chronic disease. Let's make sure to keep this vital human function in place.With the ability to talk to a professional social workers, dialysis patients function better and are more able to contribute to society. For example, I have counseled people with job conflicts related to dialysis that has helped patients keep their jobs. I have also counseled patients in vocational directions that have led to dialysis patients obtaining jobs and thus, ceasing their dependence on government monies like SSI. Additional long term therapy and emotional support as well as assistance with concrete problem solving is vital to anyone undergoing a chronic disease. I therefore urge you to sustain proposal 494.14(proposal for dialysis centers. We want to keep a master's level social worker-preferably a social worker licensed by state, to assist the abundance (and ever growing numbers) of hemodialysis patients receiving treatments paid for by Medicare and Medical in dialysis centers all over the country.

Thanks for your attention to this.

Sincerely,

Susan F. Levine,L.C.S.W
221 Mira Mar Ave.
Long Beach, Calif. 90803

Form letter 36

NENYSHP

April 28, 2005

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
File Code: CMS-3818-P
PO Box 8012
Baltimore, MD 21244-8012

Dear Dr. McClellan:

I am writing to offer comments regarding the proposed revisions to the Conditions for Coverage for End Stage Renal Disease Facilities. Specifically I wish to comment on Proposed § 494.140 ("Personnel Qualifications") as this section addresses the possible role of a pharmacist within the dialysis facility. I appreciate that the Proposed Rule acknowledges the well-documented contributions a pharmacist can make to the safe and effective use of medications in the vulnerable dialysis patient population.

I am a member of the New York State Council of Health-system Pharmacists- Northeast Chapter and believe that consultant pharmacists should be included as part of the dialysis facility staff for the following reasons: the complex nature of drug therapy in dialysis patients, the pharmacokinetic complexity of drugs used during dialysis, the vulnerability of these patients for adverse medication-related outcomes, the need for cost effective drug therapy and the training of pharmacists that prepares them to serve as consultants to dialysis facilities.

Specifically, I would like to make the following recommendations:

1. The multidisciplinary dialysis team should include a consultant pharmacist with experience or training in nephrology pharmacy.
2. The routine patient care assessment of dialysis patients should include a medication review by a pharmacist.
3. Medication reviews should be conducted at least monthly. This frequency is consistent with what is required in skilled nursing and intermediate care facilities.
4. Pharmacists should participate in the development and implementation of medication-related protocols within dialysis clinics to assure cost-effective drug use.

Pharmacists are an integral part of the health care team and can make dramatic, positive contributions in the safe and effective use of medications in all patients and most especially within the dialysis population. Again, I wish to strongly voice my support for the role of pharmacists within dialysis facilities.

Respectfully submitted,

Member of the New York State Council Health-system Pharmacists- Northeast Chapter

April 25, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3818-P
P.O. Box 8012
Baltimore, MD 21244-8012

Dear CMS Team,

I am writing on behalf of the Physician Assistants in the Renal-Electrolyte Division at the University of Pittsburgh Medical Center (UPMC). We are a rather large division of the department of medicine with 17 attending Nephrologists, 13 Renal Fellows, 3 Physician Assistants, one Nurse Practitioner and two outpatient dialysis centers. We would like to comment on the CMS Program: Conditions for Coverage for the End Stage Renal Disease / Proposed Rules. These proposals cover 42 CFR parts 400, 405, 410, 413, 414, 488, and 494.

As a vital part of the dialysis patient care team, we are concerned that Physician Assistants are not mentioned anywhere is this document. We function as an MD / PA team in daily care of our dialysis patients in the outpatient facilities. These physician services provided by PAs are currently reimbursed through CMS. This will lead to problems with reimbursement for physician services that are provided by PAs. There could also be concerns about liability and regulatory issues.

Our patient population is rapidly growing and we are starting new dialysis patients every week. We recently started a local professional group, Southwestern Pennsylvania Society of Renal Physician Assistants and Nurse Practitioners, due to the large number of mid level practitioners in the area that have filled new Renal / Dialysis positions. With our population aging and new dialysis centers opening throughout the area more Nephrologists will consider hiring PAs to help with the patient care.

The most particular area of concern is CFR 494.9 "Plan of Care: where specifically it states:

Proposed Sec.494.90(b)(4) would specify that the facility must ensure every patient is seen at least monthly by a physician providing the ESRD care as evidenced by a monthly progress note that is either written in the beneficiary's medical record by the physician or communicated from the physician's office and placed in the beneficiary's medical record.

This proposal has excluded the Physician Assistant from seeing the patient for the purpose of the monthly progress note. We PAs from UPMC urge the Centers for Medicare and Medicaid Services to amend Proposed Sec. 494.90(b)(4) to read:

"The facility must ensure every patient is seen at least monthly by a physician or physician assistant providing the ESRD care as evidenced by a monthly progress note that is either written in the beneficiary's medical record by the physician/ or physician assistant or communicated from the physician's office and placed in the beneficiary's medical record.

Please consider this change of language within this document as our Nephrologists depend on us for assisting in quality outpatient dialysis care. It would be to our patients' disadvantage to eliminate PAs from this vital health care team.

Sincerely,

Joan C. Marszalek, MMS, PA-C
Renal-Electrolyte Division
F-1149 Terrace Street
Pittsburgh, PA 15216

(412)647-9511

April 25, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3818-P
P.O. Box 8012
Baltimore, MD 21244-8012

Dear CMS Team,

I am writing on behalf of the Physician Assistants in the Renal-Electrolyte Division at the University of Pittsburgh Medical Center (UPMC). We are a rather large division of the department of medicine with 17 attending Nephrologists, 13 Renal Fellows, 3 Physician Assistants, one Nurse Practitioner and two outpatient dialysis centers. We would like to comment on the CMS Program: Conditions for Coverage for the End Stage Renal Disease / Proposed Rules. These proposals cover 42 CFR parts 400, 405, 410, 413, 414, 488, and 494.

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Please consider this change of language within this document as our Nephrologists depend on us for assisting in quality outpatient dialysis care. It would be to our patients' disadvantage to eliminate PAs from this vital health care team.

Sincerely,

Joan C. Marszalek, MMS, PA-C
Renal-Electrolyte Division
F-1149 Terrace Street
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(412)647-9511

April 29, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn CMS-3818-P
PO Box 8012
Baltimore, MD 21244-8012

Dear CMS,

The proposed conditions of coverage for ESRD patients are certainly a welcome contribution for the renal community. The scope of the coverage was thoroughly covered and the changes highlight your intent on improving patient care for this cohort of patients. However, we feel it necessary to comment on several aspects of the proposal.

494.90 (b)(4) suggests that each patient be "seen by a physician providing the ESRD care....". Physician assistants provide an integral component of patient care in the dialysis facility. Specific language including both the physician and physician assistant should be used throughout the proposed changes to eliminate the possibility of non-reimbursement for physician services provided by the PA.

494.30 No one can argue that infection control is a welcome area as a separate condition of coverage. Infections should be monitored as part of any CQI process. But, the language that this should be done by an appointed RN should be eliminated. The issue is the tracking of the infections, not who does the tracking.

494.40 The water quality proposal, specifically 494.40 (c) (2), suggests that water samples be taken every 4 hours or prior to each patient shift, which ever is shorter. We feel that testing the water on a regular 4-hour basis will not be practical. And, it goes without saying that the water should be tested for chlorine/chloramines on this schedule. Ensuring that a center once daily is chlorine/chloramines free does not account for possible surges in these potentially fatal contaminants. Thus, a test performed prior to each shift would be the most effective strategy

494.60 Specifically in 494.60(d)(1)(ii) that a defibrillator is specifically mentioned as essential emergency equipment. AEDs are perhaps a better term. In order for a defibrillator to be used the facility will need to ensure all personnel are current in aspects of its use. Please specify an AED is an alternative to the debrillator.

494.90 The proposals of the patient plan of care are indeed an integral part of any ESRD program. However, listing specific targets (ex. 494.90(a) (1) dose of dialysis and 494.90(a)(3)-anemia) should be avoided. We propose a process by which current industry targets are reviewed and implemented rather than listing specific targets that may only be applicable in 2005. Vascular access is another welcome condition that you draw attention to. However, the routine monitoring of an AVG or and AVF for stenosis is too ambiguous. To date, no one is sure

what is the best surveillance for these accesses. Again, may we suggest that we continue to develop a process by which we monitor vascular access.

494.90(c) Tracking the results of each kidney transplant center referral is certainly an important aspect of ensuring transplantation in our patients. However, at many transplant facilities the results may be better followed by the transplant center itself. Which "results" should be tracked? We feel that this may lead to poor communication amongst the members of the dialysis and transplant teams which are often separate entities. An issue of "I thought someone else took care of it" may arise. The issue of tracking by the dialysis unit should be eliminated.

494.180 (b)(2) An RN with training in dialysis therapy should be on the premises whenever a hemodialysis patient is being treated. But, this requirement should be omitted for patients maintained on CPD therapy. Language that the NF/SNF should be within or adjoined to the ESRD facility do not apply to patients maintained on CPD.

494.110(b) It has always been the policy of the networks not to require a dialysis facility to participate in ESRD network activities and pursue Network goals. The word "requires" should be changed to "suggests".

Again, the standards that are used should be determined by a process of continuous review during. The specific Kt/V requirements and anemia standards outlined should not be the goal.

Lastly, we propose that the conditions of coverage are reviewed on a regular 5-year basis. We feel that this approach will allow the community to address current conditions as well as new conditions more timely.

Taken these suggestions for the proposed conditions of coverage the care of the ESRD patient will benefit.

Respectfully submitted,

Laura Troidle, PA-C, member AANPA
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PRACTICE LIMITED TO
RENAL DISEASES
HYPERTENSION

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5/2/05

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Att CMS-3818-P
P.O. Box 8012
Baltimore, MD 21244-8012

Dear Sirs,

As a member of the American Academy of Nephrology Physician Assistants (ANNPA), I was recently made aware of the excellent work on the revisions made on the "Conditions of Coverage for End Stage Renal Disease." After reviewing the proposed revisions, I felt compelled to express my opinion on CFR 494.90 9 (b)(4) - "Plan of Care". The present wording specifically only mentions that a physician provides a monthly note for adequate end stage renal disease (ESRD) care. As you are aware, physician assistants (PA) have been in practice for over 25 years in United States, working under physician supervision. There is, at present, a shortage of nephrologists, and to possibly worsen in the ensuing years. It is thus clear that we will require PA's to help manage patients with ESRD. There are many PA's working in the nephrology field and specifically in the dialysis unit. The PA in the dialysis unit has been shown to improve the quality of care. The nephrologist is required to write a monthly note is not in question, rather that the proposed amendment does not include physician assistants and that reimbursement should be included for the work that they provide in the dialysis units in order to achieve adequate end stage renal disease care for these ill patients. I suggest that a statement should include, that in addition to the minimum of a monthly visit by the physician, the physician or physician assistant are able do the additional monthly visits.

Thank you for your kind attention,

Sincerely yours,

Peter Juergensen, PA -C

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April 29, 2005

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
File Code: CMS-3818-P
PO Box 8012
Baltimore, MD 21244-8012

Dear Dr. McClellan:

We are writing to offer comments regarding the proposed revision to the Conditions for Coverage for End Stage Renal Disease Facilities as published in the February 4, 2005 Federal Resister. Specifically we wish to comment on Proposed § 494.140 ("Personnel Qualifications") as this section addresses the possible role of a pharmacist within the dialysis facility. We appreciate the acknowledgement in the Proposed Rule of the well-documented contributions a pharmacist can make to the safe and effective use of medications in a vulnerable dialysis patient population and are writing in support of requiring pharmacists in dialysis centers.

At the University of Wisconsin Hospital and Clinics (UWHC), the second largest kidney transplant center in the world, our pharmacists take care of numerous dialysis patients. We understand the complexity that these patients pose to our medical staff and the key role our pharmacists play in managing their complex medication regimens and unique pharmacokinetic profiles. As an institution we have aggressively utilized pharmacists to improve patient outcomes and contain drug costs. Pharmacists review every medication order on all our units, complete admission histories on every patient and counsel each patient at discharge. This past February UWHC was honored twice; first, as one of 15 academic medical centers in Solucient's top 100 hospitals in terms of clinical, operational and financial performance and second, by the Leapfrog Group as one of the top 50 hospitals in terms of patient safety and quality of care. Our model of intense pharmacist involvement is spreading across the country because of its ability to control costs. Since FY 2003, drug expenditures have increased 8.5% at UWHC while the national average during the same timeframe was a 21.6% increase. Our experience has demonstrated that whenever pharmacists are actively a part of the prescribing and medication management process this results in improved care and reduced costs. Therefore, we support the rule that pharmacists be included as part of the dialysis facility staff.

Additional reasons to include consultant pharmacists as a part of the dialysis facility include:

- Dialysis patients frequently see many physicians and are typically on 10 – 12 medications with varying routes of administration and doses per day. Subsequently duplicate therapy from different providers and non-adherence to therapy is common especially as these medications can cost over $16,000 per year. Pharmacists are uniquely trained to counsel and provide practical solutions to patients to improve compliance and to obtain free medication through drug company patient assistance programs.

- Dialysis units stock, prepare and administer medications for use at the time of dialysis. In hospitals, pharmacists are required by regulatory agencies to check all medication orders. This is not a requirement in dialysis centers where the patients are more vulnerable to overdoses due to the multitude of additional variables that kidney failure and dialysis treatment engenders. Some of these medications administered such as heparin, insulin and intravenous electrolytes are well-known as high-risk, high alert medications. CMS is currently supporting studies on pharmacists' roles in reducing these errors. Pharmacists are the ideal health care provider to supervise inventory, oversee sterile medication preparation, document medication administration and reduce medication errors.
- Despite the increase of pharmacists in hospitals nationwide there is infrequent participation by a pharmacist in medication-related activities on dialysis units. Additionally, free-standing facilities represent 84% of all dialysis clinics and a majority of these have no pharmacists present. In fact in 1998, only 110 pharmacists were identified as working with dialysis patients This deprives patients from the benefit of a medication review conducted by a professional trained specifically to detect and address medication-related problems.
- Studies of dialysis patients find medication-related problems are frighteningly common. Ninety-seven percent of patients have medication-related problems with an average of 3.6 problems per patient. Medication-related problems are implicated in 16.1% of all hospital admissions to medical units. Of these admissions, 58.9% could definitely or possibly have been avoided. Having a medication expert in this environment is essential to prevent costly and life-threatening hospitalizations. Studies demonstrate having a pharmacist involved in dialysis patient care reduces medication-related problems by 72%. Additionally, the likelihood that patients would experience optimal drug related outcomes increases from 42% to 60% with pharmacist involvement.
- Selection of appropriate medications is another way pharmacists can prevent hospitalizations and improve overall care. Antibiotic resistance is a concern to every health care provider and threatens to become a public health crisis. Currently, dialysis patients' initial antibiotic choices are inappropriate approximately 35% of the time. Pharmacists can improve appropriateness o f antibiotics as well as improve rates of immunization. At UWHC pharmacists screen all patients for appropriateness for vaccines and have increased the rates of vaccination 10-fold.

There are also multiple cost control interventions which offset a pharmacist's salary in their role in dialysis centers:

- Economic evaluations of pharmaceutical care programs in dialysis centers suggest that for every $1 spent on pharmacist salary you save the healthcare system $3.98.
- Studies done in nursing facilities confirm that every $1 spent on medications consumes $1.77 in medication-related problems, morbidity and mortality. Federally mandated reviews by pharmacists in this setting reduce healthcare expenditures by $3.6 billion annually. Dialysis patients represent a growing population and therefore, a growing opportunity to control costs using pharmacist labor.
- Medications to control anemia are costly and difficult to manage. Veterans Affairs hospitals have found that pharmacists are as effective as physicians in managing anemia and can do so at a lower overall cost to the system. This has lead many authors to recommend multidisciplinary teams for the management of medications because of pharmacists' position to understand the pharmacoeconomics of medication use and comparative drug costs.

Specifically, we would like to make the following recommendations:

1. The multidisciplinary dialysis team should include a consultant pharmacist with experience or training in nephrology pharmacy.
2. The routine patient care assessment of dialysis patients should include a medication review by a pharmacist.
3. Medication reviews should be conducted at least monthly. This frequency is consistent with what is required in skilled nursing and intermediate care facilities.
4. Pharmacists should participate in the development and implementation of medication-related protocols within dialysis centers to assure cost-effective drug use.
5. Dialysis facilities should develop and maintain appropriate policies for the safe storage, preparation and administration of medications within the facility. These policies should be developed and maintained in consultation with a pharmacist.
6. There are reasonable ways to pay for pharmacist services by either incorporating their costs in the composite rate, which may then need to be increased, or by allowing for billing under medication therapy management services on a per claim basis through Medicare part D.

In summary, UWHC has pioneered the use of pharmacists in all settings where medications use occurs and it has succeeded in lowering cost and improving patient outcomes. Pharmaceutical care is a right that is mandated federally for nursing home residents, who are at less risk than dialysis patients are for medication-related problems. Increased pharmacist participation in complex dialysis patients improves utilization and subsequently reduces cost while also reducing hospital admissions, morbidity and mortality. We strongly support a requirement for a pharmacist position in the care of dialysis patients.

Sincerely,

Thomas S. Thielke, M.S., R.Ph., FASHP
Vice President of Professional and Support Services
University of Wisconsin-Hospital and Clinics

Steve S. Rough, M.S., R.Ph.
Director of Pharmacy
University of Wisconsin – Hospital and Clinics

Fresenius Medical Care

April 25, 2005

Medicare and Medicaid Services
Dept of Health and Human Services
Attn: CMS-3818-P
P. O Box 8012
Baltimore, MD 21244-8012

Re: Conditions of Coverage, proposed dialysis regulations.

I am a renal social worker who has been in this field for almost 11 years. I have reviewed the proposed regulation changes that affect the renal social worker and how we do our job. The renal population has change quite a bit over the years. Some of the proposed changes are a welcome change but some are not. I am in favor of keeping the 30 day time line for conducting initial psychosocial assessments. I am in favor of eliminating the Long Term Care Plan. I oppose eliminating the grandfather clause for social workers. I am in favor of keeping the MSW requirement for nephrology social workers. I would like to also add that the ratio for social workers and patients be based on their needs not necessarily a set number. For example, this unit has numerous new admissions from the Ventura County. With new admissions bring many social services needs, psychosocially and resource and referral related. This is time consuming and the new patient should be given adequate social service time in order to adjust and stabilize. I request that this be taken into consideration. Thank you for your attention to this matter.

Sincerely,

Mavis E. Laughlin, MSW, LCSW

Mavis E. Laughlin, MSW, LCSW
CNSW member
NASW member

University of Pittsburgh

Celebrating 215 years

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April 27, 2005

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
PO Box 8012
Baltimore, MD 21244-8012

Reference File Code: CMS-3818-P

Dear Dr. McClellan:

I am writing to offer comments regarding the proposed revisions to the Conditions for Coverage for End Stage Renal Disease Facilities, CMS-3818-P. Specifically I wish to comment on Proposed § 494.140 ("Personnel Qualifications") as this section addresses the role of a pharmacist within the dialysis facility. I greatly appreciate that the Proposed Rule acknowledges that a pharmacist can make significant contributions to the safe and effective use of medications in patients with chronic kidney disease especially those who require life-sustaining chronic dialysis therapy.

I have been actively involved in the renal and pharmacy communities for over 25 years. During that time I have provided direct patient care for individuals with end stage kidney disease (ESKD) in institutional and ambulatory dialysis environments while serving on the faculty of Wayne State University, the University of Minnesota and the University of North Carolina at Chapel Hill. During the mid 1990s while on the faculty of the University of Pittsburgh I spearheaded the development of a model program for the provision of clinical pharmaceutical care services for individuals with ESKD who required chronic dialysis as well as the integration of research into the patient care arena. [Joy MS, Cleary DJ, Matzke GR. Effect of clinical pharmacy services on epoetin utilization in a university dialysis center, *Pharmacotherapy* 1994;14:352; Alexander ACM, Matzke GR, Rault R. Individualized dosing of intravenous iron dextran for chronic hemodialysis patients. *J Am Soc Nephrol* 1994;5:430; Matzke GR, Alexander Cadogan ACM, Kim JJ, Rault RM. Pharmaceutical care in a university medical center-affiliated ambulatory dialysis center. *Pharmacother* 1999; 19(4):518-519, and Matzke GR, Comstock T, Frye RF, Weiner M, Carter W. Computerized bayesian pharmacodynamic modeling for erythropoietin dosage

individualization. *J Am Soc Nephrol* 1994;5:464.] These experiences lead to the collaborative development and conduction of a multi-center clinical trial (750 patients at 33 centers) to ascertain the influence of the provision of pharmaceutical care to hemodialysis patients on established clinical endpoints and quality of life. [Joy MS, Matzke GR, Comstock TJ, Coons SJ, Mapes DL. Development and implementation of a multicenter renal pharmaceutical care evaluation. *Int Pharmaceutical Abstracts* 1995; 32:2389 and Matzke GR, Comstock TJ, Coons SJ, Carter WB, Mapes D. A multi-center optimization of anemia management trial: The hospital pharmacy cooperative study. *J Am Soc Nephrol 2000*]

I have also developed a Nephrology Pharmaceutical Care Preceptorship program in collaboration with colleagues from VCU, Rutgers, and the University of Minnesota, to train over 150 pharmacists from 1993-1996, from throughout the United States how to develop this type of program in their institution. The impact of this program on the patients cared for by these individuals has been evaluated and the results were published in 2000. [Matzke GR, St. Peter WL, Comstock TJ, Foote EF. Nephrology pharmaceutical care preceptorship: a programmatic and clinical outcome assessment. *Ann Pharmacother* 2000;34:593-99]

Finally the results of pharmacokinetic studies in patients with renal disease which I have directed during my career have provided the scientific basis for FDA labeling for drug dosing in patients with renal insufficiency as well as those on dialysis for over 30 medications. I understand the complexities of medication management of patients with kidney disease and have seen the adverse consequences that are associated with prescribing of inappropriate medication doses and regimens, and polypharmacy. I strongly support the inclusion of pharmacists, who understand the complexities of kidney disease and resultant alterations in drug pharmacokinetics and pharmacodynamics, in either an employed or consultative capacity as integral members of the patient care team within Medicare-approved dialysis facilities.

I believe that pharmacists should be included as an integral member of the dialysis facility patient care team for the following reasons:

- Dialysis patients are prescribed medication regimens that are highly complex. They are prescribed an average of 10-12 medications and thus must take as many as 70 tablets or capsules daily, almost twice the number of the average Medicare patient who is documented to be at high risk for adverse medication outcomes. Several publications including ours document non-adherence to prescribed medications and the improvements that have been associated with pharmacist interventions.
- Dialysis patients must have their dosage regimens individualized based on their dialysis prescription since it can significantly impact the dosage of drug they need. Pharmacists have published much of the original research in this area and have written many of the review articles that are utilized to guide drug dosing in these patients.
- Dialysis patients also typically require frequent inpatient hospital admissions and have fluctuating biochemistry profiles that further complicate drug therapy regimens and place these patients at risk for adverse medication outcomes.

- Positive clinical and financial outcomes have been reported when pharmacists are involved in the management of anemia, metabolic bone disease, and diabetes mellitus. The provision of pharmacist directed drug therapy management for individual patients and hospital affiliated dialysis units has been reported to result in $4 of cost-savings in healthcare expenditures for every $1 spent on pharmaceutical care.
- The role of pharmacists in providing medication therapy management for at risk Medicare beneficiaries, such as dialysis patients, is recognized within the new Part D drug benefit. This policy and benefit should logically be incorporated within the framework of the proposed revisions to the Conditions of Coverage for End Stage Renal Disease facilities since this is where the facilities healthcare team responsibilities for patient care are defined.

Based on my personal experience and that of colleagues who provide pharmaceutical care for patients with a multiplicity of acute and chronic medical conditions in institutional and ambulatory environments I propose the following recommendations regarding the role of the pharmacists as a member of the dialysis facility staff.

1) **A medication review for each dialysis patient should be conducted by a pharmacist at the initiation of dialysis and at relevant intervals thereafter based on the patient's clinical status.** Documentation of this interaction should include generation of an updated list of medications including drug name, dose, frequency, and special instructions. All medication-related problems should be documented and a plan of action to prevent or correct the problems should be recommended to the medical director of the unit and counseling provided to patients to optimize adherence with their new medication regimens.

2) **A monthly review of laboratory studies should be conducted by a pharmacist to evaluate the appropriateness of prescribed medication regimens, such as erythropoeitin and modify the medication therapy accordingly based on the patient's individual needs and the policies in the individual dialysis units.** Examples of laboratory review procedures as they relate to medication therapy management protocols have been proposed in the literature and should be implemented for ESKD patients.

3) **All protocols / guidelines which incorporate medication should be developed in consultation with the dialysis unit's pharmacist to assure patient safety and cost-effective drug use.** In addition, a continuous quality improvement program should be implemented and administered by the pharmacist for such protocols / guidelines to evaluate the outcomes of the protocols.

4) **The pharmacist affiliated with the dialysis facility should coordinate that medication management for dialysis patients that is delivered within the facility with other community based disease and medication management programs.**

5) **Pharmacists should review prescribed medications for consistency with the proposed Medicare reform rules.**

6) **Pharmacists should be responsible for the safe storage, preparation and administration of dialysis center medications.**

In addition to these specific recommendations concerning the role of the pharmacist, I encourage CMS to evaluate and revise as necessary the payment policies affecting ESRD facilities to assure that payment levels are appropriate to support the activities of pharmacists described in these recommendations. Given the substantial body of evidence demonstrating the effectiveness of pharmacists' interventions in promoting safer and more cost-effective medication use, such payment policy adjustments would likely produce net savings to Medicare as a result of reductions in rates of hospitalization and consumption of other health care services that are known to occur in patients whose medication regimens are ineffectively managed.

Sincerely,

Gary R. Matzke, Pharm.D., FCP, FCCP

CATHOLIC HEALTH INITIATIVES

Franciscan
Health System

April 29, 2005

Mark B. McClellan, MD, PhD, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
File Code: CMS-3818-P
PO Box 8012
Baltimore, MD 21244-8012

RE: **Proposed Revisions to Conditions for Coverage for End Stage Renal Disease Facilities**

Dear Dr. McClellan:

I am writing to offer comments regarding the proposed revisions to the Conditions for Coverage for End Stage Renal Disease Facilities. Specifically I wish to comment on Proposed § 494.140 ("Personnel Qualifications") as this section addresses the possible role of a pharmacist within the dialysis facility. I appreciate that the Proposed Rule acknowledges the well-documented contributions a pharmacist can make to the safe and effective use of medications in vulnerable dialysis patient population.

We have a large hospital-based dialysis unit here at St. Joseph Medical Center in Tacoma, WA. We've had the luxury of a pharmacist assigned to the dialysis unit for over 15 years. We've seen a tremendous value to this addition and so have our patients. Who else is better qualified to review medications? What about medication safety, protocol development, staff education about new medications—just to name a few.

I believe that consultant pharmacists should be included as part of the dialysis facility staff for the following reasons:

Specifically, I would like to make the following recommendations:

1. The multidisciplinary dialysis team should include a consultant pharmacist with experience or training in nephrology pharmacy.
2. The routine patient care assessment of dialysis patients should include a medication review by a pharmacist.
3. Medication reviews should be conducted at least monthly. This frequency is consistent with what is required in skilled nursing and intermediate care facilities.
4. Pharmacists should participate in the development and implementation of medication-related protocols within dialysis to assure cost-effective drug use.
5. Dialysis facilities should develop and maintain appropriate policies for the safe storage, preparation and administration of medications within the facility. These policies should be developed and maintained in consultation with a pharmacist.]

J. Kelly Martin, BPharm, PharmD
Pharmaceutical Care Manager

American Society of Pediatric Nephrology

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April 27, 2005

Mark McClellan, M.D., Ph.D. Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW Room 314G
Washington, DC 20201

Re: Conditions for Coverage for End Stage Renal Disease Facilities (CMS-3818-P)

Dear Administrator McClellan:

On behalf of the American Society for Pediatric Nephrology (ASPN), I am writing to provide comment on the proposed Conditions for Coverage for End Stage Renal Disease (ESRD) Facilities.

Founded in 1969, the American Society for Pediatric Nephrology (ASPN) is a professional society composed of pediatric nephrologists whose goal is to promote optimal care for children with renal disease and to disseminate advances in the clinical practice and basic science of pediatric nephrology. The ASPN currently has over 500 members, making it the primary representative of the pediatric nephrology community in North America. From this perspective the Society has the following comments:

Proposed 494.80, Condition: Patient Assessment:

a6) Evaluation of nutritional status should also include growth assessment for pediatric patients less than 18 years of age. This should include height, length and weight measurements every 6 months for all, and head circumference assessment every 6 months for patients less than 3 years of age. In addition, the evaluation of psychosocial needs for pediatric patients less than 18 years of age should include the entire family.

a7) The evaluation of vocational and physical rehabilitation should also include the evaluation of developmental progress and educational needs for pediatric patients less than 18 years of age.

Proposed 494.110, Condition: Quality Assessment and PI:

a2) Quality indicators to be tracked by dialysis facilities should also include assessment of growth and development for pediatric patients less than 18 years of age.

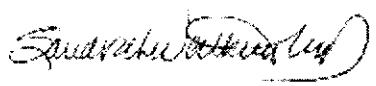
Proposed 494.150, Condition: Responsibilities of Medical Director:
ASPN recommends that the medical director also be responsible for assuring pediatric patients less than 18 years of age have regular assessment by a pediatric nephrologist, dietitian, and social worker with pediatric expertise. This will ensure that the pediatric ESRD patient receives the appropriate expertise that encompasses the understanding of pediatric drug dosages and nutritional requirements, and the unique aspects of dialysis and transplantation in infants, children and adolescents.

Proposed 494.120, Condition: Special Purpose Renal Dialysis Facilities:
c1) ASPN is pleased to see specific mention made for scope of requirements for vacation camps, which are especially helpful in the rehabilitation of pediatric patients. However, the vacation camps should be certified as a safe environment for the campers.

Proposed 100 percent participation for CPM Project Data: ASPN supports the proposed 100 percent participation for CPM project data. Full reporting will be more useful for assessing the actual status of CPMs in the small population of pediatric patients, as well as identifying where need for improvement exists.

Overall the proposed Conditions for Coverage for ESRD Facilities are a positive step forward in improving and modernizing the Medicare ESRD Program. ASPN stands ready to work with CMS in an effort to strengthen the conditions for coverage to ensure pediatric ESRD patients receive quality care. Please contact me at 206-987-2524, or by email sandra.watkins@seattlechildrens.org, if I can provide additional information or clarification regarding ASPN's above comments.

Sincerely,



Sandra L. Watkins, M.D.
President

CC: Dr. Barry Straube
Brady Augustine

4/5

BDO Seidman, LLP
Accountants and Consultants

A Report on Shortfalls in Medicaid Funding for Nursing Home Care

PREPARED BY
BDO SEIDMAN, LLP
ACCOUNTANTS AND CONSULTANTS

FOR THE
AMERICAN HEALTH CARE ASSOCIATION

April 2005

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REPORT HIGHLIGHTS

- The average shortfall in Medicaid nursing home reimbursement was $12.58 per Medicaid patient day in 2002.
- The daily reimbursement shortfall increased by about 9% from 2001 to 2002 (about 39% in the 4 years from 1999 to 2002).
- Unreimbursed Medicaid allowable costs were estimated at $4.5 billion nationally in 2002.
- Since 1999, cost increases have exceeded rate increases by 2%.
- Provider taxes are increasingly being relied upon by states to fund nursing home reimbursement.
- Greater use of provider taxes is limited since many states are at or near the regulatory limit.
- Greater adoption of Section 1115 waivers will likely lead to higher cost per diems in nursing homes and increasingly endanger the financial stability of the Medicaid funding stream for nursing home care.
- Medicare cross-subsidization of Medicaid will continue to play an important role in sustaining nursing home care, particularly as the Medicaid annual shortfall continues to grow.

MEDICAID 2002 NURSING HOME SHORTFALL STUDY SUMMARY

For the fourth consecutive year, BDO Seidman, LLP (BDO) was engaged by the American Health Care Association (AHCA) to work with its state affiliates and other sources to compile information on the shortfall between Medicaid reimbursement and allowable Medicaid costs in as many states as feasibly possible.[1] The compilation was derived from 2002 rate and cost data, the latest year in which audited or desk-reviewed cost report information was available for most states. The data from over 60% of the states reporting was based upon audited or desk-reviewed cost reports, or some blend of both. As-filed cost reports were used for the remaining states.[2]

The results, based upon data from 36 states, representing over 86% of the Medicaid patient days in the country, indicate that nationwide, the average shortfall in Medicaid reimbursement was $12.58 per Medicaid patient day.[3] This average shortfall is 9% higher than last year's average shortfall of $11.55 per Medicaid patient day, and has increased over 39% since 1999.

However, not all the states in the previous years' analyses were able to provide comparable data this year and some states provided data this year for the first time. When comparing the shortfall in those states providing data for all four years, the average shortfall climbed 5% from 2001 to 2002, and 36% from 1999. Figures I and II, on the next page, illustrate this comparison and Table I on page 3 depicts the rates, costs and shortfalls in Medicaid reimbursement by state.

In total for 2002, unreimbursed Medicaid allowable costs exceeded $3.8 billion for these 36 states and almost $4.5 billion when the results are extrapolated for all 50 states. If all costs of

[1] Medicaid operates as a joint federal-state program to finance health care services including nursing home services. Medicaid is the single largest funding source for nursing home services. According to CMS's actuarial estimates, Medicaid is the payer for about one-half of total expenditures for these services, paying at least in part for services provided to approximately two-thirds of residents nationwide.

[2] As-filed cost reports were the only available reports in many states where rates were not based upon the most current cost report. In this situation, the state may not have audited the report since it was not used in the rate setting process. These cost reports, however, already excluded non-allowable costs per cost report instructions although additional adjustments would typically be made if audited by the state agency or its contractor.

[3] Applying an estimated audit adjustment factor of 1.9% to the costs in those states where as-filed reports were utilized still resulted in a shortfall of $11.14 per Medicaid patient day. The 1.9% factor was a weighted average of the historical difference between audited or desk-reviewed cost reports and as-filed reports in these states. The information was obtained from the AHCA state affiliate in each of these states.

operations were considered, not just Medicaid allowable costs, the $4.5 billion shortfall would be significantly greater. The charts on pages 10 and 11 reflect the per diem shortfall and the fiscal impact of the shortfall in each state, respectively.

FIGURE I
Shortfall Per Medicaid Patient Day
All States In Each Year

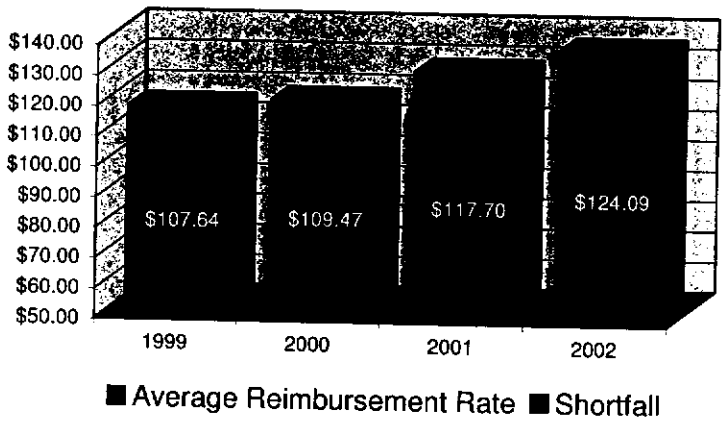


FIGURE II
Shortfall Per Medicaid Patient Day
Comparable States In Each Year

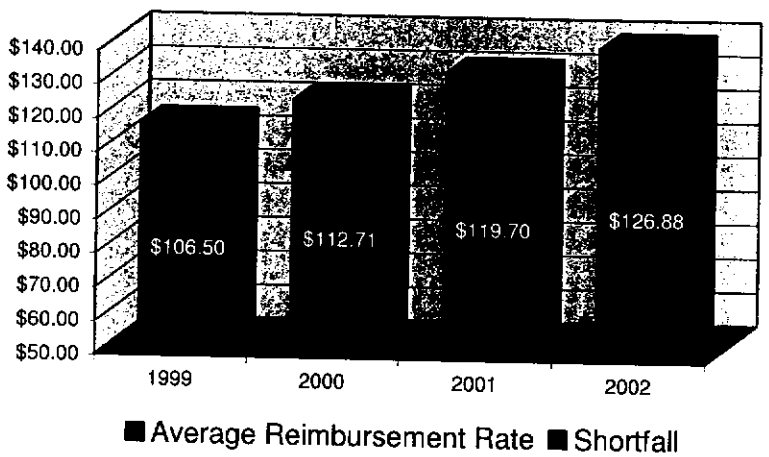


TABLE I
STATE-BY-STATE COMPARISON OF RATES AND COSTS

State	Rate	Cost	Difference
Arizona	$ 112.43	$ 135.62	$ (23.19)
Arkansas	$ 94.48	$ 94.74	$ (0.26)
California	$ 113.20	$ 123.17	$ (9.97)
Colorado	$ 125.51	$ 141.66	$ (16.15)
Connecticut	$ 162.81	$ 178.48	$ (15.67)
Delaware	$ 165.33	$ 185.00	$ (19.67)
Florida	$ 135.40	$ 143.47	$ (8.07)
Georgia	$ 99.73	$ 102.69	$ (2.96)
Illinois	$ 93.45	$ 109.77	$ (16.32)
Indiana	$ 103.65	$ 112.14	$ (8.49)
Iowa	$ 93.09	$ 99.08	$ (5.99)
Kansas	$ 97.20	$ 108.53	$ (11.33)
Maine	$ 133.37	$ 144.16	$ (10.79)
Maryland	$ 154.14	$ 161.83	$ (7.69)
Massachusetts	$ 139.31	$ 159.89	$ (20.58)
Michigan	$ 124.73	$ 135.71	$ (10.98)
Missouri	$ 97.17	$ 119.98	$ (22.81)
Nebraska	$ 121.15	$ 127.48	$ (6.33)
New Hampshire	$ 125.63	$ 154.61	$ (28.98)
New Jersey	$ 142.41	$ 170.26	$ (27.85)
New Mexico	$ 108.57	$ 122.02	$ (13.45)
New York	$ 173.55	$ 194.78	$ (21.23)
North Carolina	$ 106.20	$ 116.20	$ (10.00)
North Dakota	$ 125.27	$ 127.33	$ (2.06)
Ohio	$ 146.52	$ 153.13	$ (6.61)
Oklahoma	$ 93.51	$ 97.90	$ (4.39)
Oregon	$ 112.26	$ 127.10	$ (14.84)
Pennsylvania	$ 145.04	$ 159.72	$ (14.68)
Rhode Island	$ 132.92	$ 154.01	$ (21.09)
South Dakota	$ 90.69	$ 107.02	$ (16.33)
Tennessee	$ 101.71	$ 112.07	$ (10.36)
Texas	$ 95.68	$ 98.38	$ (2.70)
Utah	$ 102.87	$ 119.75	$ (16.88)
Virginia	$ 103.58	$ 115.22	$ (11.64)
West Virginia	$ 131.06	$ 139.74	$ (8.68)
Wisconsin	$ 118.27	$ 133.45	$ (15.18)

THE NURSING HOME REIMBURSEMENT ENVIRONMENT IN 2002

In 2002, nursing homes experienced a much slower growth in expenditures than in the prior year reflecting the slowdown in the economy subsequent to the events of September 11, 2001. Nursing home costs, on average, increased 5.8% in 2002 compared to 8.4% in 2001. Medicaid rates also followed this pattern, with average increases of 5.4% in 2002, compared to 7.5% in 2001.

Though the economy was slowing down in 2002, most states did not freeze or reduce rates with only one state in the study reducing rates from the prior year. This is consistent with the findings of the Kaiser Commission on Medicaid and the Uninsured (Kaiser Commission) in Reports issued by them on Medicaid spending growth in 2002.[4] According to the Kaiser Commission, it became apparent to states later in 2002 that their fiscal situation was deteriorating to a greater extent than anticipated. Thus, state budgetary problems in 2002 did not translate to rate reductions or lower increases until after 2002. In addition, in 2002, states relied heavily on alternative funding sources such as intergovernmental transfers (IGTs) and provider taxes to balance their budgets. In 2002, 15 states were using IGTs as a revenue enhancement strategy while 17 states utilized provider tax programs.

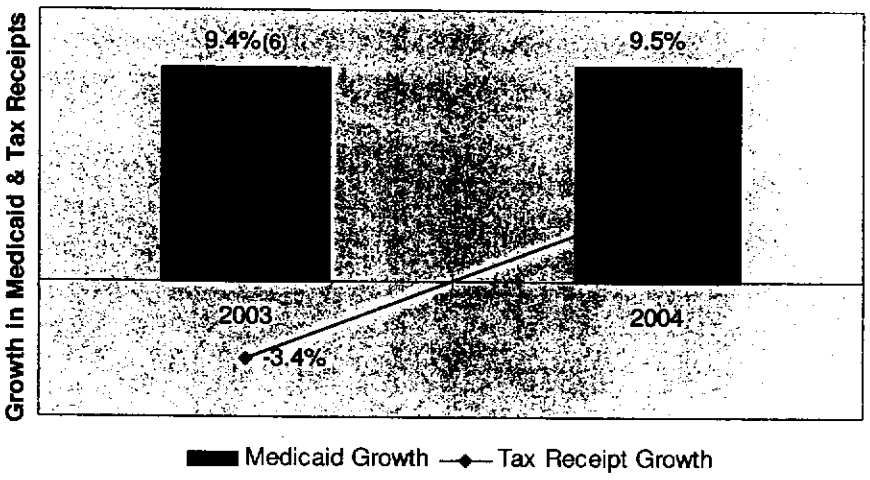
These findings are supported in an October 2003 Government Accounting Office Report (GAO) on Medicaid nursing home payments. The GAO Report indicates that irrespective of increasing fiscal pressures by states, modifications to nursing home payment methods had not resulted in widespread rate reductions to nursing homes. However, as indicated in this shortfall study, each year the rate increases have fallen short of nursing home cost increases resulting in increased Medicaid shortfalls.

[4] Kaiser Commission on Medicaid and the Uninsured, "State Budgets Under Stress: How are States Planning to Reduce The Growth in Medicaid Costs?" July 20, 2002; and
Kaiser Commission on Medicaid and the Uninsured, "Medicaid Spending Growth: A 50-State Update for Fiscal Year 2003" January 2003

NURSING HOME REIMBURSEMENT TRENDS SINCE 2002

The Medicaid shortfall continues to increase every year because rate increases have not kept pace with nursing home cost inflation. In the four years we have done this study, cost increases have exceeded rate increases by 2% over this time period. Since the time frame of this study (2002), the situation does not appear to have greatly improved. The Kaiser Commission reports that Medicaid expenditures continued to far outpace state tax revenue receipts in 2003 and 2004, resulting in all states implementing cost containment measures in these years. Figure III below reflects the trends in Medicaid expenditures and revenue growth over the past two years as reported by the Kaiser Commission.[5]

FIGURE III
MEDICAID GROWTH AND TAX RECEIPT TRENDS



Source: Kaiser Commission on Medicaid and the Uninsured, Rockefeller Institute of Government, Bureau of the Census, Bureau of Economic Analysis, National Association of State Budget Officers

Federal fiscal relief through enhanced federal matching rates did, however, help states meet Medicaid shortfalls in FY 2004. According to the Kaiser Commission, the temporary increase of 2.95% in the federal matching rate from April 2003 through June 2004 reduced the states' share of Medicaid spending from 9.5% to 4.8%[5]. Even with the enhanced federal match, four states

[5] Source: Kaiser Commission on Medicaid and the Uninsured, "The Continuing Medicaid Budget Challenge: State Medicaid Spending Growth and Cost Containment in Fiscal Years 2004 and 2005," October 2004.
[6] As reported later in this study, CMS determined Medicaid expenditure growth at 7.1% in 2003.

still cut and 18 others froze nursing home rates in FY 2004. In FY 2005, rates were reduced in two states and frozen in 11 others[5]. While the majority of states granted rate increases in the last two years, many of these increases, especially those commensurate with nursing home cost increases, were funded through new or increased provider taxes.

THE ROLE OF PROVIDER TAXES IN FINANCIAL STABILITY

In FY 2004 and FY 2005, many states used provider taxes and corresponding federal matching funds to increase Medicaid rates to nursing homes. Prior to FY 2004, we identified 20 states assessing provider taxes on nursing homes. Now, in FY 2005, 33 states have either implemented nursing home tax programs or are awaiting CMS approval of their tax programs. Based upon survey responses from 33 AHCA state affiliates on FY 2005 rate increases, provider taxes funded the rate increase in 13 of the 28 states reporting increases. The weighted average rate increase for these states was 5.2%. For the other 20 states, the average rate increase was only 1.8%.

States are, however, limited in the amount of provider taxes that can be assessed and matched by federal funds. The current limitation is 6% of annual patient revenues received by providers. We estimate that as of the end of FY 2005, 22 of the 33 states with provider taxes on nursing homes will be at that limit, thereby limiting this avenue of revenue enhancement in many states in FY 2006.

THE EXPECTED ROLE OF 1115 WAIVERS IN LIMITING GROWTH IN MEDICAID NURSING HOME EXPENDITURES

As it relates to nursing home services, many states are doing more than just limiting rate increases. Many are attempting to reduce nursing home utilization by diverting potential nursing home-eligible individuals to home and community-based services. In fact, some states are now turning to Medicaid 1115 Research and Demonstration Waivers in an attempt to better manage costs and allocate limited Medicaid resources. Vermont and Maryland are two examples of states that have filed, or will be filing, 1115 Waivers with CMS to implement more of a managed care approach to delivery of long term care services. Vermont will use a service prioritization strategy

based upon client need while Maryland will follow the Arizona 1115 Waiver model of using managed care companies and strategies to control the rate of growth in its Medicaid program.

A fundamental strategy in these waiver programs to achieve slower growth in Medicaid expenditures is a reduction in nursing home utilization. For example, over the five-year waiver period, Vermont projects a 10% reduction in nursing home utilization over the anticipated growth rate without implementation of the waiver. New Hampshire's proposed "GraniteCare" waiver program initially projected a 30% reduction in nursing home utilization.

Implementation of 1115 Waivers will likely result in increased Medicaid shortfalls for providers, at least in the short run. If nursing home utilization declines, fixed costs associated with empty beds will increase until the market can sort itself out as to the optimum bed supply. Lower occupancy in nursing homes will increase per diem costs in areas such as property costs, utilities, maintenance and administration. If prospective nursing home admissions that have lower care needs are diverted to home and community-based programs, the medical, physical, and psychosocial needs of those actually admitted to nursing homes will be greater, resulting in higher nursing costs. These factors are not being taken into account in states' cost projections. In Vermont's waiver application, for example, the state projects Medicaid rate increases for nursing homes at only 2% during the waiver period.

NURSING HOME REIMBURSEMEMENT OUTLOOK FOR THE REMAINDER OF FY 2005 AND THROUGH FY 2006

As the Kaiser Commission indicates, state Medicaid officials expect lower growth rates for Medicaid enrollment and spending and anticipate that revenues will continue to rebound. In fact, CMS indicates in the January/February 2005 issue of "Health Affairs" that Medicaid spending sharply decelerated in 2003 – the first drop in growth since 1997. According to CMS, spending growth slowed from 12.1% in 2002 to 7.1% in 2003. By tightening eligibility and restricting benefits, states were able to reduce spending on Medicaid.

In spite of their successful cost containment efforts and a slower rate of Medicaid growth, many states still project significant budget deficits for the remainder of FY 2005. States also express concern that the clawback provision in the Medicare Modernization Act, requiring states to make payments to the federal government to help finance the Medicare drug benefit, will more than offset any potential savings. Most states believe this provision will actually result in a net increase in drug costs to the state when the Part D Medicare drug benefit begins in 2006.

All of these factors point to future Medicaid payment increases that cannot keep pace with nursing home inflation, thereby widening the gap between Medicaid payment and cost. The only likely exceptions will be those states that implement new provider tax programs or those that have existing tax programs with room to increase the tax.

Our findings demonstrate that nursing home providers in most states will have to continue to rely on Medicare prospective payment and other payers to compensate for increasing Medicaid shortfalls. That is a troubling proposition considering the Bush Administration's FY06 budget proposal to reduce Medicare nursing home payments by $1.5 billion. According to an April 2005 Industry Update from Friedman, Billings, Ramsey & Co., Inc.[7], these Medicare reductions would decrease skilled nursing net income by some 29% in 2006 at a time when current net margins are at 2.8%. In addition, we calculate that further restrictions on provider taxes proposed in the budget would reduce federal Medicaid funds to states by over $1.7 billion. As a result, many of the 33 states would have no recourse but to reduce Medicaid payments to providers if this happens.

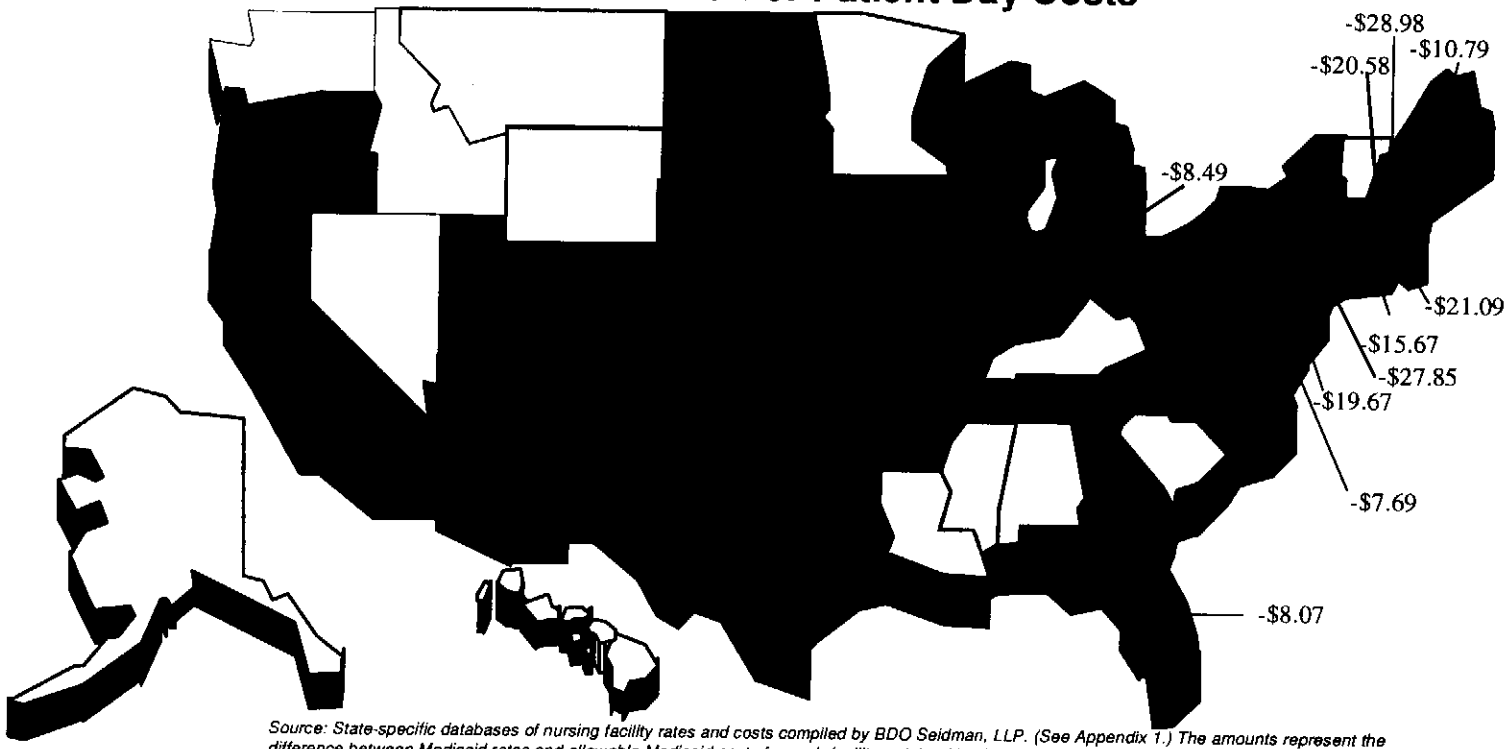
[7] Friedman, Billings, Ramsey & Co., Inc. Research, "Senior Moments: Medicare RUGs Refinement Outlook Varies Widely, but Current Budget Could Disproportionately Hurt Nursing Homes," April 4, 2005.

Charts

CHART 1

In 2002, on Average, the Shortfall in Medicaid Reimbursement Was $12.58 Per Medicaid Patient Day

Average Disparity By State Between Medicaid Rates and Allowable Medicaid Per Patient Day Costs



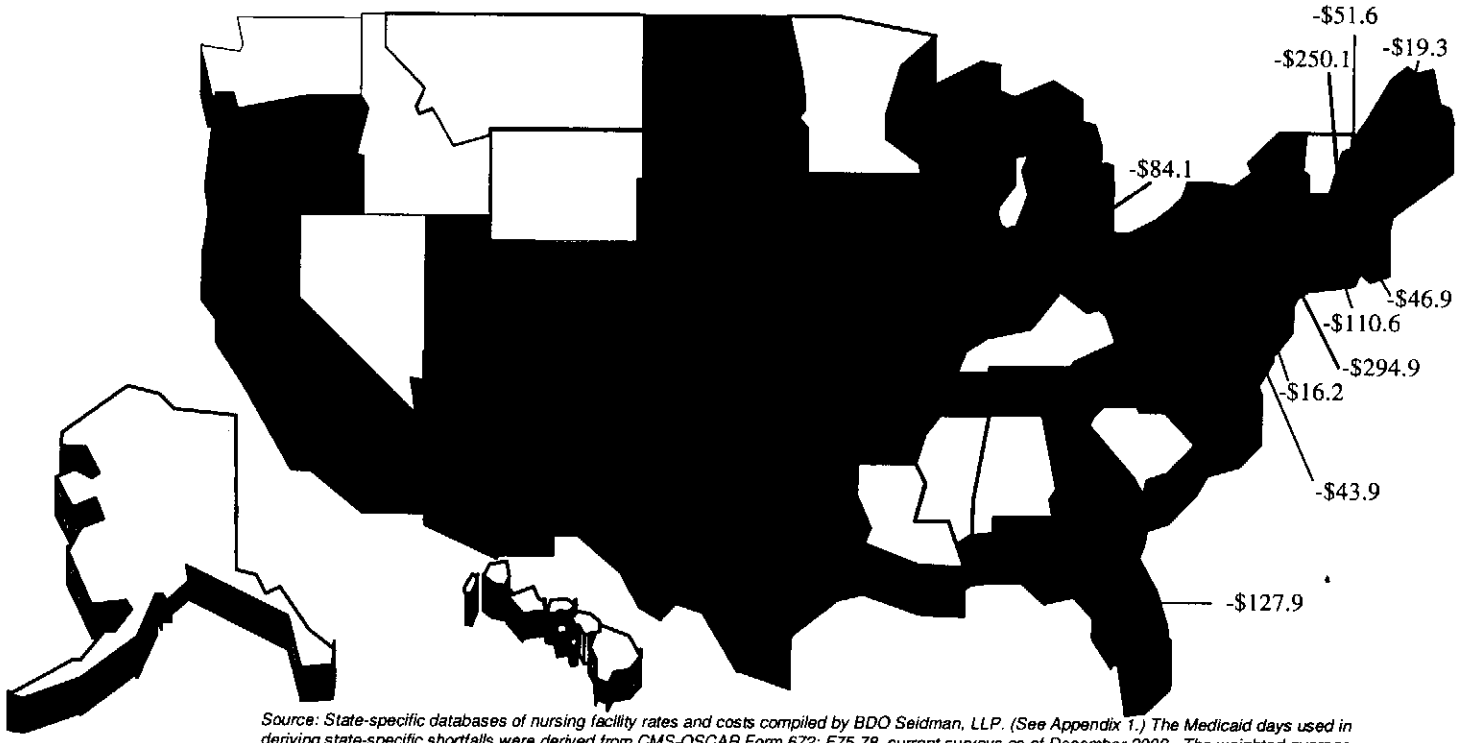
Source: State-specific databases of nursing facility rates and costs compiled by BDO Seidman, LLP. (See Appendix 1.) The amounts represent the difference between Medicaid rates and allowable Medicaid costs for each facility weighted by the facility's annual Medicaid days. It is not the average disparity between Medicaid rates and costs for only those facilities experiencing shortfalls in Medicaid reimbursement. If this were the case, the shortfalls would be much higher.

BDO

CHART 2

Disparity By State Between Total Medicaid Revenue and Total Allowable Medicaid Costs (In Millions)

$4.5 Billion Medicaid Funding Shortfall Nationwide



Source: State-specific databases of nursing facility rates and costs compiled by BDO Seidman, LLP. (See Appendix 1.) The Medicaid days used in deriving state-specific shortfalls were derived from CMS-OSCAR Form 672: F75-78, current surveys as of December 2002. The weighted average shortfall for the 36 states reporting exceeded $3.8 billion dollars, based upon 306 million Medicaid days. Extrapolating this shortfall to 355 million Medicaid days nationwide (per CMS-OSCAR Data) results in a $4.5 billion national shortfall.

BDO

PROJECT APPROACH AND METHODOLOGY

The American Health Care Association initially surveyed its state affiliates as to the availability of a database of state-specific Medicaid rate and allowable cost information. Those that responded in the affirmative were asked to complete "data collection spreadsheets" reflecting the Medicaid rates and allowable costs for each provider based upon the provider's fiscal or calendar year ending in 2002. Sample data collection spreadsheets are included as Appendix III.

BDO Seidman, LLP (BDO) was engaged to assist in this process by:

1. Developing the data collection spreadsheets;
2. Instructing and guiding state affiliates through the process;
3. Reviewing the results for reasonableness and compliance with document instructions;
4. Contacting other sources such as state agencies, their consultants and independent accounting firms to obtain the data in those states where the data was readily available, but the state affiliate did not have it; and
5. Compiling the results into a report.

In almost all cases, the state affiliates indicated that the data was derived from a database of Medicaid rates and allowable costs obtained from their state agencies. Allowable costs include only those costs recognized by the state agency as directly or indirectly related to patient care and typically exclude necessary operating costs including, but not limited to, marketing and public relations, bad debts, income taxes, stockholder servicing costs, contributions, certain legal and professional fees, property costs related to purchases of facilities, and out-of-state travel. In over 60% of the states, the cost database reflected costs that have been audited or desk-reviewed by the Medicaid state agency. BDO did not replicate the calculations nor trace individual facility cost or rate data to Medicaid cost reports, rate worksheets, or state agency databases.

Comparisons of Medicaid rates and allowable costs for 2002 were derived for 36[8] states representing over 86% of the Medicaid patient days in the country. The remaining states not reflected in the comparisons indicated that the data was not readily available. However, as can be seen by the chart on page 11, these 36 states reflect all regions of the country and are a fair representation of Medicaid shortfalls nationwide. The comparisons include most of the states representing the largest Medicaid populations including California, Florida, Illinois, Massachusetts, New York, Ohio, Pennsylvania and Texas. Based upon the high percentage of nationwide Medicaid patient days represented by the 36 states, it is likely that the overall results would not materially change had all states been represented.

[8] The Minnesota and Kentucky state affiliates were excluded from the computations. In Minnesota, only a minority of providers still file cost reports. The majority of providers are paid a percentage increase on their prior year rate and are not required to file cost reports. In Kentucky, cost reports exclude non-labor costs and property expenses, thereby making it impossible to provide a meaningful comparison of costs and rates.

Appendix I

Calculation of 2002 Weighted Average Medicaid Shortfall

State-by-State Comparison

Calculation of 2002 Weighted Average Medicaid Shortfall

State	Rate	Cost	Difference	Annual Medicaid Days	Gross Revenue	Gross Cost	Difference x Medicaid Days
Arizona	$ 112.43	$ 135.62	$ (23.19)	3,101,040	$ 348,649,927	$ 420,563,045	$ (71,913,118)
Arkansas	$ 94.48	$ 94.74	$ (0.26)	4,861,070	$ 459,273,894	$ 460,537,772	$ (1,263,878)
California	$ 113.20	$ 123.17	$ (9.97)	25,082,435	$ 2,839,331,642	$ 3,089,403,519	$ (250,071,877)
Colorado	$ 125.51	$ 141.66	$ (16.15)	3,558,020	$ 446,567,090	$ 504,029,113	$ (57,462,023)
Connecticut	$ 162.81	$ 178.48	$ (15.67)	7,055,450	$ 1,148,697,815	$ 1,259,256,716	$ (110,558,902)
Delaware	$ 165.33	$ 185.00	$ (19.67)	825,995	$ 136,561,753	$ 152,809,075	$ (16,247,322)
Florida	$ 135.40	$ 143.47	$ (8.07)	15,843,190	$ 2,145,167,926	$ 2,273,022,469	$ (127,854,543)
Georgia	$ 99.73	$ 102.69	$ (2.96)	10,341,910	$ 1,031,398,684	$ 1,062,010,738	$ (30,612,054)
Illinois	$ 93.45	$ 109.77	$ (16.32)	18,656,245	$ 1,743,426,095	$ 2,047,896,014	$ (304,469,918)
Indiana	$ 103.65	$ 112.14	$ (8.49)	9,905,005	$ 1,026,653,768	$ 1,110,747,261	$ (84,093,492)
Iowa	$ 93.09	$ 99.08	$ (5.99)	5,237,020	$ 487,514,192	$ 518,883,942	$ (31,369,750)
Kansas	$ 97.20	$ 108.53	$ (11.33)	4,154,065	$ 403,775,118	$ 450,840,674	$ (47,065,556)
Maine	$ 133.37	$ 144.16	$ (10.79)	1,790,690	$ 238,824,325	$ 258,145,870	$ (19,321,545)
Maryland	$ 154.14	$ 161.83	$ (7.69)	5,712,980	$ 880,598,737	$ 924,531,553	$ (43,932,816)
Massachusetts	$ 139.31	$ 159.89	$ (20.58)	12,151,945	$ 1,692,887,458	$ 1,942,974,486	$ (250,087,028)
Michigan	$ 124.73	$ 135.71	$ (10.98)	10,192,260	$ 1,271,280,590	$ 1,383,191,605	$ (111,911,015)
Missouri	$ 97.17	$ 119.98	$ (22.81)	8,971,335	$ 871,744,622	$ 1,076,380,773	$ (204,636,151)
Nebraska	$ 121.15	$ 127.48	$ (6.33)	2,712,680	$ 328,641,182	$ 345,812,446	$ (17,171,264)
New Hampshire	$ 125.63	$ 154.61	$ (28.98)	1,779,010	$ 223,497,026	$ 275,052,736	$ (51,555,710)
New Jersey	$ 142.41	$ 170.26	$ (27.85)	10,590,110	$ 1,508,137,565	$ 1,803,072,129	$ (294,934,564)
New Mexico	$ 108.57	$ 122.02	$ (13.45)	1,662,210	$ 180,466,140	$ 202,822,864	$ (22,356,725)
New York	$ 173.55	$ 194.78	$ (21.23)	30,985,215	$ 5,377,484,063	$ 6,035,300,178	$ (657,816,114)
North Carolina	$ 106.20	$ 116.20	$ (10.00)	9,756,450	$ 1,036,134,990	$ 1,133,699,490	$ (97,564,500)
North Dakota	$ 125.27	$ 127.33	$ (2.06)	1,274,215	$ 159,620,913	$ 162,245,796	$ (2,624,883)
Ohio	$ 146.52	$ 153.13	$ (6.61)	19,208,125	$ 2,814,374,475	$ 2,941,340,181	$ (126,965,706)
Oklahoma	$ 93.51	$ 97.90	$ (4.39)	5,148,325	$ 481,419,871	$ 504,021,018	$ (22,601,147)
Oregon	$ 112.26	$ 127.10	$ (14.84)	2,094,005	$ 235,073,001	$ 266,148,036	$ (31,075,034)
Pennsylvania	$ 145.04	$ 159.72	$ (14.68)	19,020,150	$ 2,758,682,556	$ 3,037,898,358	$ (279,215,802)
Rhode Island	$ 132.92	$ 154.01	$ (21.09)	2,223,215	$ 295,509,738	$ 342,397,342	$ (46,887,604)
South Dakota	$ 90.69	$ 107.02	$ (16.33)	1,476,060	$ 133,863,881	$ 157,967,941	$ (24,104,060)
Tennessee	$ 101.71	$ 112.07	$ (10.36)	8,873,880	$ 902,562,335	$ 994,495,732	$ (91,933,397)
Texas	$ 95.68	$ 98.38	$ (2.70)	21,987,600	$ 2,103,773,568	$ 2,163,140,088	$ (59,366,520)
Utah	$ 102.87	$ 119.75	$ (16.88)	1,158,510	$ 119,175,924	$ 138,731,573	$ (19,555,649)
Virginia	$ 103.58	$ 115.22	$ (11.64)	6,570,730	$ 680,596,213	$ 757,079,511	$ (76,483,297)
West Virginia	$ 131.06	$ 139.74	$ (8.68)	2,667,055	$ 349,544,228	$ 372,694,266	$ (23,150,037)
Wisconsin	$ 118.27	$ 133.45	$ (15.18)	8,901,985	$ 1,052,837,766	$ 1,187,969,898	$ (135,132,132)
TOTALS				305,530,185	$ 37,913,749,072	$ 41,757,114,206	$ (3,843,365,134)
Weighted Averages					$ 124.09	$ 136.67	$ (12.58)
Shortfall extrapolated to all 50 states							$ (4,465,662,280)
Total States				36			

Appendix II

Impact of High Cost Providers on the Medicaid Average Shortfall

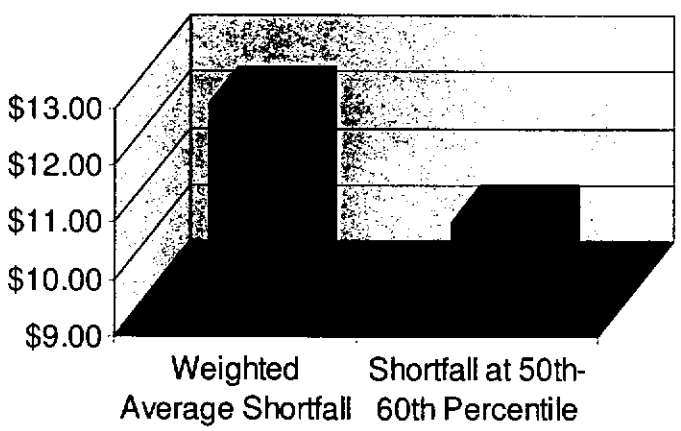
IMPACT OF HIGH COST PROVIDERS ON THE MEDICAID AVERAGE SHORTFALL

Some researchers and analysts reviewing this report have expressed concern that the use of averages, even weighted averages, can skew the Medicaid shortfall results. The issue raised is that the inclusion of all providers, especially outliers with shortfalls significantly above or below the norm, will distort the findings.

We did find that extremely high cost providers, such as hospital-based units, tended to skew the average shortfall upward to a greater degree than the tendency of the lowest cost providers to skew the average downward. Therefore, we also examined the Medicaid shortfall of those providers whose per diem costs rank at or around the mid-range of all providers in each state. In each state, we determined the weighted average Medicaid shortfall of providers with per diem costs that rank between the 50th and 60th percentile of per diem costs of all providers. Providers at these cost levels would be considered efficient and economical under any reasonable cost standard. A graphic comparison between the weighted average shortfall for all providers and the weighted average shortfall for providers with costs between the 50th and 60th percentile is reflected in Figure IV.

FIGURE IV

Medicaid Shortfall Comparison – All States Weighted Average Shortfall for All Providers vs. All States Weighted Average Shortfall of Providers with Per Diem Costs at 50th - 60th Percentile



Our findings reflect that even providers whose costs are very reasonable are incurring substantial Medicaid shortfalls. When examining all the states in the study, the average Medicaid shortfall for providers whose per diem costs rank in the 50th to 60th percentile of all providers in each state was $10.50. While this is just over $2 per patient day less than the average shortfall for all providers, it demonstrates that Medicaid reimbursement is substantially inadequate in reimbursing even reasonable cost providers. In fact, in not one of the states were providers in the 50th to 60th percentile cost group reimbursed, on average, more than their allowable costs.

Appendix III

Data Collection Document

AHCA DATA COLLECTION INSTRUCTIONS FOR 2002 DATA

General Instructions:

Please provide Excel spreadsheets similar to those attached, identifying the difference between Medicaid allowable costs and Medicaid rates for each facility based upon 2002 cost report data. The rates must match the cost report period; not vice versa. We've attached sample spreadsheets that reflect the format and documentation that is required for this project. In essence, we need the average Medicaid rate and Medicaid allowable cost for each facility for its fiscal year that ends in 2002 and the supporting documentation reflecting the computation for each facility.

On the spreadsheets, please indicate whether the data is "as reported" or "audited/desk-reviewed" and the data source. (State agency database, etc.) We ask, if at all possible, that the data be "audited/desk-reviewed."

If your state utilizes a provider tax program, the tax should be included as an allowable cost, unless the Medicaid rates are net of the reimbursement for provider taxes.

Summary Tab:

This tab summarizes the weighted average Medicaid rate and allowable cost for each facility. The rate allowable cost for each facility is brought forward from the "Rates" and "Costs" tabs.

Rate Tab:

The rate tab provides an example of the supporting documentation that is needed for each facility. The Medicaid rate(s) for each facility are weighted by the days or months that they were in effect during the cost report period. The rates must include any supplemental Medicaid payments facilities receive such as add-ons for specialty services or populations if the associated cost of that service is included as an allowable cost.

Cost Tab:

The cost tab provides an example of supporting documentation that is needed for each facility. Your worksheet will reflect the cost categories utilized in your state in determining Medicaid allowable costs.

Note:

We have included a sample calculation for one facility so you can better understand the information needed and the required format.

AHCA DATA COLLECTION

Is the data "as reported" or "audited/desk-reviewed"	
Data Source (please write in)	

FACILITY	PROVIDER NUMBER	FACILITY YEAR END	AVERAGE MEDICAID RATE	AVERAGE MEDICAID COST	DIFFERENCE	TOTAL MEDICAID DAYS	TOTAL MEDICAID PROFIT / SHORTFALL
Facility #1			*100.96*	*110.49*	*(9.54)*	*32,676*	*(311,570)*

MEDICAID RATE FOR COST REPORTING PERIOD*

* In most cases, the rate period will not correspond with the cost report period. This will require a computation averaging two or more Medicaid rates for the applicable time frame that each was in effect for the cost report period.

** In determining weighted average Medicaid rates, rates can be weighted by Medicaid days for the applicable time period or calendar days or months, depending upon the information available.

FACILITY	MEDICAID RATE (1)	DAYS APPLICABLE**	SUBTOTAL	MEDICAID RATE (2)	DAYS APPLICABLE**	SUBTOTAL
Facility #1	*100.45*	*10,849*	*1,089,782*	*101.19*	*10,939*	*1,106,917*

MEDICAID RATE (3)	DAYS APPLICABLE**	SUBTOTAL	TOTAL MEDICAID REVENUE	TOTAL DAYS	WEIGHTED AVERAGE MEDICAID RATE PER DAY
101.23	*10,888*	*1,102,192*	*3,298,892*	*32,676*	*100.96*

MEDICAID ALLOWABLE COST FOR COST REPORTING PERIOD

FACILITY	PROVIDER YEAR END	RN SALARIES	LPN SALARIES	AIDE SALARIES	TOTAL NURSING SALARIES	NURSING OTHER	DIETARY SALARIES	DIETARY OTHER
Facility #1	*12/31/2002*	*486,391*	*552,251*	*886,396*	*1,925,038*	*524,424*	*202,997*	*284,484*

LAUNDRY SALARIES	LAUNDRY OTHER	HOUSE-KEEPING SALARIES	HOUSE-KEEPING OTHER	SOCIAL SERVICES SALARIES	SOCIAL SERVICES OTHER	ACTIVITIES SALARIES	ACTIVITIES OTHER
43,742	*21,869*	*124,122*	*47,699*	*52,609*	*11,384*	*63,970*	*25,879*

A&G SALARIES	A&G OTHER	MAIN-TENANCE SALARIES	MAIN-TENANCE OTHER	UTILITIES	FRINGE BENEFITS	PROPERTY	PROPERTY TAXES
129,899	*288,154*	*25,255*	*64,931*	*73,964*	*528,437*	*346,453*	*28,639*

TOTAL EXPENSE ($)	TOTAL DAYS	TOTAL EXPENSES PPD	TOTAL MEDICAID DAYS
4,813,949	*43,568*	*110.49*	*32,676*

April 29, 2005

Centers for Medicare an Medicaid Services
Department of Health and Human Services
Attention: CMS - 3818-P
PO Box 8012
Baltimore, MD 21244-8012

To the Centers for Medicare and Medicaid:

I have attached my response to the purposed changes for the Conditions for Coverage for End Stage Renal Disease facilities reference code CMS 3818-P.

Thank you for your consideration in this matter.

Sincerely,

Kathy Merritt, MSW

Kathy Merritt, MSW
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CMS-3818-P

494.70 Condition Patients' Rights (a) Standard: Patients' rights	**Comment:** I support the language of a5. **Rationale:** Advance directives establish in writing an individual's preference with respect to the degree of medical care and treatment desired or who should make treatment decisions if the individual should become incapacitated and lose the ability to make or communicate medical decisions. ***Add***: (new 17) "Attend care planning meetings with or without representation." ***Rationale***: Promoting patient participation in care requires that patients have the right to attend their own care planning meetings. ***Add***: (new 18) "Receive counseling from a qualified social worker to address concerns related to the patient's adjustment to illness, including changes to life-style and relationships because of his illness, developmental issues affected by his illness, and any behavior that negatively affects his health or standing in the facility." ***Rationale***: Patients are faced with numerous adjustment issues due to ESRD and its treatment regimes. Master's level social workers are trained to intervene within areas of need that are essential for optimal patient functioning and adjustment ***References:*** McKinley & Callahan, 1998; Vourlekis & Rivera-Mizzoni, 1997
494.70 Condition Patients' Rights (b) Standard: Right to be informed regarding the facility's discharge and transfer policies.	***Add to b1***: "Receive counseling and support from the team to resolve behavioral issues and be informed of behaviors that will lead staff to notify police or refer for evaluation of risk to self or others" ***Rationale***: Facilities should be encouraged first to try counseling to resolve difficult situations ***References:*** Forum of ESRD Networks, 2003; Johnstone S, et al, 1997; King & Moss, 2004; Rau-Foster, 2001; Renal Physicians Association and American Society of Nephrology, 2000 ***Add***: (new 2) "Not be involuntarily discharged from the facility for non-adherence with the treatment plan, including missing or shortening in-center hemodialysis treatments, excessive fluid weight gain, or lab tests that would suggest dietary indiscretions unless it can be shown that the patient's behavior is putting other patients or the facility operations at risk." ***Rationale***: The ESRD Networks and the preamble of these proposed Conditions for Coverage have both stated that non-compliance should not be a basis for involuntary discharge from lifesaving dialysis treatment. Patients often are not educated as to the reasons why these behaviors may be harmful to them; it is therefore inappropriate to refuse them care due to their lack of knowledge. If consistent difficulties are

	noted with a patients' ability to follow the treatment plan, a team evaluation should be initiated to investigate and address all potential factors. For example, a patient who is trying to maintain a full-time job to support a family may choose to leave treatment early rather than risk losing employment; or a patient who is taking a medication that causes dry mouth may be unable to follow the fluid limits for in-center hemodialysis. ***References:*** Forum of ESRD Networks, 2003; Johnstone S, et al., 1997; King & Moss, 2004; Rau-Foster, 2001; Renal Physicians Association and American Society of Nephrology, 2000
494.80 Condition Patient assessment (a) Standard: Assessment criteria.	***Change***: The language of "social worker" in the first sentence to "qualified social worker" ***Rationale***: This will clarify any ambiguity of the social work role. ***Comment:*** I support the language of a2, a3, a4, a5, a6 ***Change***: (a7) to "Evaluation of psychosocial needs (such as but not limited to: coping with chronic illness, anxiety, mood changes, depression, social isolation, bereavement, concern about mortality & morbidity, psycho-organic disorders, cognitive losses, somatic symptoms, pain, anxiety about pain, decreased physical strength, body image issues, drastic lifestyle changes and numerous losses of [income, financial security, health, libido, independence, mobility, schedule flexibility, sleep, appetite, freedom with diet and fluid], social role disturbance [familial, social, vocational], dependency issues, diminished quality of life, relationship changes; psychosocial barriers to optimal nutritional status, mineral metabolism status, dialysis access, transplantation referral, participation in self care, activity level, rehabilitation status, economic pressures, insurance and prescription issues, employment and rehabilitation barriers)." ***Rationale***: Much like the elaboration of a1, a4, a8, a9, elaborating what "psychosocial issues" entails will ensure national coherence of the exact psychosocial issues that must be assessed for each patient. There is clear literature that identifies these psychosocial issues throughout this response. ***Comment:*** CNSW supports the language of a8

	Add: (9)(new i) "If the patient is not referred for home dialysis, the basis for non-referral must be documented in the medical record. Lack of availability of home dialysis in the facility is not a legitimate basis for non-referral." ***Rationale***: Requiring that the basis for non-referral for home dialysis be documented will help to ensure that patients have access to these therapies and will provide needed data for QAPI purposes. ***Comment:*** I support the language of a10, a11, a12, a13
494.80 Condition Patient assessment (b) Standard Frequency of assessment for new patients	***Change***: (b1) to "An initial comprehensive assessment and patient care plan must be conducted within 30 calendar days after the first dialysis treatment." ***Rationale***: Permitting 30 days for assessment and development of a care plan allows for full team participation and adequate assessment of patient needs. Patients are often traumatized with diagnosis and often experience signs/symptoms of uremia on admission. Allowing for 30 days for assessment the team will be able to complete a more comprehensive assessment and care plan. ***Comment:*** I support the language of b2
494.80 Condition Patient Assessment (d) Standard patient reassessment	**Comment:** I agree with the purposed change to reassess patients at three months
494.90 Condition Patient plan of care. (a) Standard: Development of patient plan of care.	***Add***: (a) the *patient* to those developing the plan and include: "If the patient or his or her representative does not participate in care planning, the basis for nonparticipation must be noted in the patient's medical record, the patient/representative must sign the care plan." ***Rationale***: The patient must be explicitly listed as part of the care planning process ***Add***: (new 3) "*Psychosocial status*. The interdisciplinary team must provide the necessary care and services to achieve and sustain an effective psychosocial status." ***Rationale & References***: Eighty-nine percent of ESRD patients report experiencing significant lifestyle changes from the disease (Kaitelidou, et al., 2005). The chronicity of end stage renal disease and the intrusiveness of its required treatment provide renal patients with multiple disease-related and treatment-related psychosocial stressors that affect their everyday lives (Devins et al., 1990). Researchers including

	Auslander, Dobrof & Epstein (2001), Burrows-Hudson (1995), and Kimmel et al. (1998) have found that psychosocial issues negatively impact health outcomes of patients and diminish patient quality of life. Therefore, "psychosocial status" must be considered as equally important as other aspects of the care plan. ***Add***: (new 6) Home dialysis status. All patients must be informed of *all* home dialysis options, including CAPD, CCPD, conventional home hemodialysis, daily home hemodialysis, and nocturnal home hemodialysis, and be evaluated as a home dialysis candidate. When the patient is a home dialysis candidate, the interdisciplinary team must develop plans for pursuing home dialysis. The patient's plan of care must include documentation of the (i) Plan for home dialysis, if the patient accepts referral for home dialysis; (ii) Patient's decision, if the patient is a home dialysis candidate but declines home dialysis; or (iii) Reason(s) for the patient's non-referral as a home dialysis candidate as documented in accordance with § 494.80(a)(9)(ii) of this part. ***Rationale***: Home therapies allow greater flexibility, patient control, fewer dietary and fluid restrictions, need for fewer medications, potential for improved dialysis adequacy, and improved likelihood of employment. CMS has stated encouragement of home dialysis as a goal. Every patient must be informed of home dialysis options, evaluated for candidacy for home dialysis, and, if not a candidate, the reason(s) why not should be reported. This allows quality assessment and improvement activities to be undertaken in the area of home dialysis. ***Add***: (renumbered 8) "Rehabilitation status. The interdisciplinary team must provide the necessary care and services to: (i) help patients maintain or improve their vocational status (including paid or volunteer work) as measured by annually tracking the same employment categories on the CMS 2728 form (ii) help pediatric patients (under the age of 18 years) to obtain at least a high school diploma or equivalency as measured by annually tracking student status. (iii) Reasons for decline in rehabilitation status must be documented in the patient's medical record and interventions designed to reverse the decline." ***Rationale***: The goals of the current proposed section are vague, not measurable, and not actionable. To improve rehabilitation outcomes, facilities must meet certain standards. From the perspective of the

	Medical Education Institute, which administers the Life Options Rehabilitation Program, "rehabilitation" can be measured by a functioning and well-being vocational assessment. Annually tracking employment status through Networks using the same categories on the CMS 2728 and including this as a QAPI would improve the likelihood that rehabilitation efforts would be successful. **Comment:** I am also in agreement with a single care plan that is comprehensive and updated annually. I also agree with deleting of the transplant surgeon as a member of the interdisciplinary team responsible for the completion of the care plan. Having referral criteria, as part of the plan of care is appropriate and will facilitate the completion of the care plan in a timely fashion.
494.90 Condition Patient plan of care. (b) Standard: Implementation of the patient care plan.	***Add to 3b***: "If the expected outcome is not achieved, the interdisciplinary team must describe barriers encountered, adjust the patient's plan of care to either achieve the specified goals or establish new goals, and explain why new goals are needed." ***Rationale***: When goals are not met, barriers must be identified and goals re-examined for feasibility of success. Sometimes barriers can be eliminated so original goals can be met; other times, new goals must be set that are more reasonable.
494.90 Condition Patient plan of care. (d) Standard: Patient education and training.	***Add to d***: "The patient care plan must include, as applicable, education and training for patients and family members or caregivers or both, and must document training the following areas in the patient's medical record: (i) The nature and management of ESRD (ii) The full range of techniques associated with treatment modality selected, including effective use of dialysis supplies and equipment in achieving and delivering the physician's prescription of Kt/V or URR, and effective erythropoietin administration (if prescribed) to achieve and maintain a hemoglobin level of at least 11 gm/dL (iii) How to follow the renal diet, fluid restrictions, and medication regimen (iv) How to read, understand, and use lab tests to track clinical status (v) How to be an active partner in care (vi) How to achieve and maintain physical, vocational, emotional and social well-being (vii) How to detect, report, and manage symptoms and potential dialysis complications (viii) What resources are available in the facility and community and how to find and use them (ix) How to self-monitor health status and record and report health status information (x) How to handle medical and non-medical emergencies

	(xi) How to reduce the likelihood of infections (x) How to properly dispose of medical waste in the dialysis facility and at home **Rationale**: Life Options Research has demonstrated among 372 randomly-selected in-center hemodialysis patients that higher levels of dialysis knowledge are correlated with higher mental component summary (MCS) scores on the SF-12, which are, in turn, predictive of longer survival and lower hospitalization. The specific aspects of education delineated above are what Life Options believes to be core skills that ESRD patients must gain in order to become active partners in care, producing their own best health outcomes and monitoring the safety and quality of the care that is delivered to them. ***References:*** Curtin, et al. 2002; Curtin, Klag, Bultman & Schatell, 2002; Curtin, Sitter, Schatell & Chewning, 2004; Johnstone, et al., 2004
494.140 Condition Personnel qualifications (d) Standard: Social worker.	***Change the language of d to***: Qualified *Social worker*. The facility must have a qualified social worker who—(1) Has completed a course of study with specialization in clinical practice, and holds a masters degree from a graduate school of social work accredited by the Council on Social Work Education; (2) Meets the requirements for social work practice in the State in which he or she is practicing; and (3) Is responsible for the following tasks: initial and continuous patient assessment and care planning including the social, psychological, cultural and environmental barriers to coping to ESRD and prescribed treatment; provide emotional support, encouragement and supportive counseling to patients and their families or support system; provide individual and group counseling to facilitate adjustment to and coping with ESRD, co morbidities and treatment regimes, including diagnosing and treating mood disorders such as anxiety, depression, and hostility; providing patient and family education; helping to overcome psychosocial barriers to transplantation and home dialysis; crisis intervention; providing education and help completing advance directives; promoting self-determination; assisting patients with achieving their rehabilitation goals (including: overcoming barriers ; providing patients with education and encouragement regarding rehabilitation; providing case management with local or state vocational rehabilitation agencies); providing staff in-service education regarding ESRD psychosocial issues; recommending topics and otherwise participating in the facility's quality assurance program; mediating conflicts between patients, families and staff; participating in interdisciplinary care planning and collaboration, and advocating on behalf of patients in the clinic and community-at-large. The qualified social worker will not be responsible for clerical tasks related to transportation, transient arrangements, insurance or billing, but will supervise the case aide who is responsible for these tasks.

Rationale & References: Clinical social work training is essential to offer counseling to patients for complex psychosocial issues related to ESRD and its treatment regimes. I support the elimination of the "grandfather" clause of the previous conditions of coverage, which exempted individuals hired prior to the effective date of the existing regulations (September 1, 1976) from the social work master's degree requirement. As discussed in the preamble for these conditions, we recognize the importance of the professional social worker, and we believe there is a need for the requirement that the social worker have a master's degree. We agree that since the extension of Medicare coverage to individuals with ESRD, the ESRD patient population has become increasingly more complex from both medical and psychosocial perspectives. In order to meet the many and varied psychosocial needs of this patient population, we agree that qualified master's degree social workers (MSW) trained to function autonomously are essential. We agree that these social workers must have knowledge of individual behavior, family dynamics, and the psychosocial impact of chronic illness and treatment on the patient and family. This is why we argue that a specialization in clinical practice must be maintained in the definition.

Master's level social workers are trained to think critically, analyze problems, and intervene within areas of need that are essential for optimal patient functioning, and to help facilitate congruity between individuals and resources in the environment, demands and opportunities (Coulton, 1979; McKinley & Callahan, 1998; Morrow-Howell, 1992; Wallace, Goldberg, & Slaby, 1984). Social workers have an expertise of combining social context and utilizing community resource information along with knowledge of personality dynamics. The master of social work degree (MSW) requires two years of coursework and an additional 900 hours of supervised agency experience beyond what a baccalaureate of social work degree requires. An MSW curriculum is the only curriculum, which offers additional specialization in the biopsychosocialcultural, person-in-environment model of understanding human behavior. An undergraduate degree in social work or other mental health credentials (masters in counseling, sociology, psychology or doctorate in psychology, etc.) do not offer this specialized and comprehensive training in bio-psycho-social assessment and interaction between individual and the social system that is essential in dialysis programs. The National Association of Social Workers Standards of Classification considers the baccalaureate degree as a basic level of practice (Bonner & Greenspan, 1989; National Association of Social Workers, 1981). Under these same standards, the Masters of Social Work degree is considered a specialized level of professional practice and requires a demonstration of skill or competency in performance (Anderson, 1986). Masters-prepared social workers are trained in conducting empirical evaluations of their own practice interventions (Council on Social Work Education). Empirically, the

training of a masters-prepared social worker appears to be the best predictor of overall performance, particularly in the areas of psychological counseling, casework and case management (Booz & Hamilton, Inc., 1987; Dhooper, Royse & Wolfe, 1990). The additional 900 hours of supervised and specialized clinical training in an agency prepares the MSW to work autonomously in the dialysis setting, where supervision and peer support is not readily available. This additional training in the biopsychosocial model of understanding human behavior also enables the masters-prepared social worker to provide cost-effective interventions such as assessment, education, individual, family and group therapy and to independently monitor the outcomes of these interventions to ensure their effectiveness.

The chronicity of end stage renal disease and the intrusiveness of required treatment provide renal patients with multiple psychosocial stressors including: cognitive losses, social isolation, bereavement, coping with chronic illness, concern about worsening health and death, depression, anxiety, hostility, psycho-organic disorders, somatic symptoms, lifestyle, economic pressures, insurance and prescription issues, employment and rehabilitation barriers, mood changes, body image issues, concerns about pain, numerous losses (income, financial security, health, libido, strength, independence, mobility, schedule flexibility, sleep, appetite, freedom with diet and fluid), social role disturbance (familial, social, vocational), dependency issues, and diminished quality of life (DeOreo, 1997; Gudes, 1995; Katon & Schulberg, 1997; Kimmel et al., 2000; Levenson, 1991; Rabin, 1983; Rosen, 1999; Vourlekis & Rivera-Mizzoni, 1997). The gravity of these psychosocial factors necessitates an assessment and interventions conducted by a qualified social worker as outlined above.

It is clear that social work intervention can maximize patient outcomes:

- Through patient education and other interventions, nephrology social workers are successful in improving patient's adherence to the ESRD treatment regime. Auslander and Buchs (2002), and Root (2005) have shown that social work counseling and education led to reduced fluid weight gains in patients. Johnstone and Halshaw (2003) found in their experimental study that social work education and encouragement were associated with a 47% improvement in fluid restriction adherence.
- Beder and colleagues (2003) conducted an experimental research study to determine the effect of cognitive behavioral social work services. They found that patient education and counseling by nephrology social workers was significantly associated with increased medication compliance. This study also determined that such interventions improved patients' blood pressure. Sikon (2000) discovered that social work counseling can reduce patients' anxiety level. Several researchers have

	determined that nephrology social work counseling significantly improves ESRD patient quality of life (Chang, Winsett, Gaber & Hathaway, 2004; Frank, Auslander & Weissgarten, 2003; Johnstone, 2003). Nephrology social work interventions also tend to be valued by patients. Siegal, Witten, and Lundin's 1994 survey of ESRD patients found that 90% of respondents "believed that access to a nephrology social worker was important" (p.33) and that patients relied on nephrology social workers to assist them with coping, adjustment, and rehabilitation. Dialysis patients have ranked a "helpful social worker" as being more important to them than nephrologists or nurses (Rubin, et al., 1997). In a study by Holley, Barrington, Kohn and Hayes (1991), 70% of patients said that social workers gave the most useful information about treatment modalities compared to nurses and physicians. These researchers also found that patients thought that social workers were twice as helpful as nephrologists in helping them to choose between hemodialysis and peritoneal dialysis for treatment.
§494.180 Condition Governance. (b1) Standard. Adequate number of qualified and trained staff.	***Add***: (1i) No dialysis clinic should have more than 75 patients per one full time social worker. ***Rationale & References***: A specific social worker-patient ratio must be included in the conditions of coverage. Currently, there are no such national ratios and as a result social workers have caseloads as high as more than 300 patients per social worker in multiple, geographically separated, clinics. This is highly variable among different dialysis units-letting dialysis clinics establish their own ratios will leave ESRD care in the same situation as we have now with very high social work caseloads. For many years, CNSW has had an acuity-based social work-patient ratio (contact the National Kidney Foundation for the formula) which has been widely distributed to all dialysis units. This has largely been ignored by dialysis providers, who routinely have patient-to-social work ratios of 125-300. The new conditions of coverage must either identify an acuity-based social work staffing ratio model to be used in all units (we would recommend CNSW's staffing ratio), or set a national patient-social worker ratio. Leaving units to their own devices regarding ratios will not affect any change, as is evidenced by today's large caseloads and variability in such. CNSW has determined that 75:1 is the ideal ratio. If CMS refuses to include language about social work ratios, we strongly urge that the final conditions include language for "an acuity-based social work staffing plan developed by the dialysis clinic social worker" (rather than having nursing personnel who have limited understanding of social work training or role to determine social work staffing). Large nephrology social work caseloads have been linked to decreased patient satisfaction and poor patient rehabilitation outcomes (Callahan, Moncrief, Wittman & Maceda, 1998). It is also the case

that social workers report that high caseloads prevent them from providing adequate clinical services in dialysis, most notably counseling (Merighi, & Ehlebracht, 2002, 2005). In Merighi and Ehlebracht's (2004a) survey of 809 randomly sampled dialysis social workers in the United States, they found that only 13% of full time dialysis social workers had caseloads of 75 or fewer, 40% had caseloads of 76-100 patients, and 47% had caseloads of more than 100 patients.

In a recent study by Bogatz, Colasanto, and Sweeney (2005), nephrology social workers reported that large caseloads hindered their ability to provide clinical interventions. Social work respondents in this study reported caseloads as high as 170 patients and 72% of had a median caseload of 125 patients. The researchers found that 68% of social workers did not have enough time to do casework or counseling, tasks mandated by the current conditions of coverage, 62% did not have enough time to do patient education, and 36% said that they spent excessive time doing clerical, insurance, and billing tasks. One participant in their study stated: 'the combination of a more complex caseload and greater number of patients to cover make it impossible to adhere to the federal guidelines as written. I believe our patients are being denied access to quality social work services' (p.59).

Patient-social work ratios are critical so that social workers can effectively intervene with patients and enhance their outcomes. It is clear that social work intervention can maximize patient outcomes (doing these requires reasonable ratios):

- Through patient education and other interventions, nephrology social workers are successful in improving patient's adherence to the ESRD treatment regime. Auslander and Buchs (2002), and Root (2005) have shown that social work counseling and education led to reduced fluid weight gains in patients. Johnstone and Halshaw (2003) found in their experimental study that social work education and encouragement were associated with a 47% improvement in fluid restriction adherence.
- Beder and colleagues (2003) conducted an experimental research study to determine the effect of cognitive behavioral social work services. They found that patient education and counseling by nephrology social workers was significantly associated with increased medication compliance. This study also determined that such interventions improved patients' blood pressure. Sikon (2000) discovered that social work counseling can reduce patients' anxiety level. Several researchers have determined that nephrology social work counseling significantly improves ESRD patient quality of life (Chang, Winsett, Gaber & Hathaway, 2004; Frank, Auslander & Weissgarten, 2003; Johnstone, 2003). A study currently being conducted by Cabness shows that social work intervention is related

	to lower depression. Nephrology social work interventions also tend to be valued by patients. Siegal, Witten, and Lundin's 1994 survey of ESRD patients found that 90% of respondents "believed that access to a nephrology social worker was important" (p.33) and that patients relied on nephrology social workers to assist them with coping, adjustment, and rehabilitation. Dialysis patients have ranked a "helpful social worker" as being more important to them than nephrologists or nurses by Rubin, et al. (1997). In a study by Holley, Barrington, Kohn and Hayes (1991), 70% of patients said that social workers gave the most useful information about treatment modalities compared to nurses and physicians. These researchers also found that patients thought that social workers were twice as helpful as nephrologists in helping them to choose between hemodialysis and peritoneal dialysis for treatment.
§**494.180 Condition** Governance. (b4) Standard. Adequate number of qualified and trained staff.	***Comment:*** CNSW agrees that all employees must have an opportunity for continuing education and related development activities.

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