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State of Missouri

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Tom Reichard
Executive Director

Meeting Notice

September 6, 2011

10:00 a.m.

**State Committee for Social Workers
Division of Professional Registration
3605 Missouri Boulevard
Jefferson City, MO**

Notification of special needs as addressed by the Americans with Disabilities Act should be forwarded to the State Committee for Social Workers, 3605 Missouri Blvd, Jefferson City, MO 65102 or by calling (573) 751-0885 to ensure available accommodations. The text telephone for the hearing impaired is (800) 735-2966.

Except to the extent disclosure is otherwise required by law, the State Committee for Social Workers is authorized to close meetings, records and votes, to the extent they relate to the following: Chapter 610.021 subsections (1), (3), (5), (7), (13), (14), and Chapter 324.001.8 and 324.001.9 RSMo.

The State Committee for Social Workers may go into closed session at any time during the meeting. If the meeting is closed, the appropriate section will be announced to the public with the motion and vote recorded in open session minutes.

TENTATIVE AGENDA
OPEN SESSION
September 6, 2011
10:00 a.m.

State Committee for Social Workers

Division of Professional Registration
3605 Missouri Boulevard
Jefferson City, MO 65109

- I. Call to Order
- II. Roll Call
- III. Approval of Agenda
- IV. Introduction of Guests
- V. Approval of Minutes
 - June 23-24, 2011
 - July 18, 2011
- VI. Executive Director Report
 - Board Totals
 - Other
- VII. CMS Requirements
- VIII. Scope of Practice Task Force Meeting
- VIII. Other
- IX. **CLOSED SESSION-** Closed session as per Section 610.021 Subsection (1) for the purpose of discussion of confidential or privileged communication between this agency and its attorney; Section 610.021 Subsection (14) and Section 324.001.8 for the purpose of discussing applicants for licensure. Closed under Sections 610.021 for the purpose of reviewing and approving the closed minutes of one or more previous meetings. Closed under Sections 610.021(14) and 324.001.8, RSMo, for the purpose of discussing investigative reports and/or complaints.
- X. Adjournment

**Open Minutes
June 23-24, 2011**

**State Committee for Social Workers
Hampton Inn
4800 Country Club Drive
Jefferson City, MO 65109-4542**

Members Present

Terri Marty, Chairperson
Kathie Miller, Secretary
M. Jenise Comer
Hal Agler
Laura Neal
Jane Overton, Public Member

Staff Present

Tom Reichard, Executive Director
Katie Johnson, Administrative Office Assistant
Elizabeth Willard, Licensing Technician II
Sarah Ledgerwood, Legal Counsel
Audrey Danner, Legal Intern

Guests Present

Tamitha Price, Executive Director, National Association of Social Workers-Missouri Chapter (NASW-MO)

Call to Order – Terri Marty, Chairperson

The State Committee for Social Worker's Open Session meeting was called to order by Terri Marty, Chairperson, at 10:21 a.m. on June 23, 2011 at the Hampton Inn, Jefferson City, Missouri.

Approval of Agenda

A motion was made by Hal Agler and seconded by Jenise Comer to approve the open session agenda. Ms. Comer, Ms. Marty, Mr. Agler, Ms. Neal, Ms. Overton and Ms. Miller voted in favor of the motion.

Approval of Minutes

A motion was made by Hal Agler and seconded by Jenise Comer to approve the March 29, 2011 open session minutes as amended. Ms. Comer, Ms. Marty, Mr. Agler, Ms. Neal, Ms. Overton and Ms. Miller voted in favor of the motion.

Election of Officers

A motion was made by Kathie Miller and seconded by Jane Overton to nominate Terri Marty as committee chair. Ms. Comer, Ms. Marty, Mr. Agler, Ms. Neal, Ms. Overton and Ms. Miller voted in favor of the motion.

A motion was made by Terri Marty and seconded by Laura Neal to nominate Kathie Miller as committee secretary. Ms. Comer, Ms. Marty, Mr. Agler, Ms. Neal, Ms. Overton and Ms. Miller voted in favor of the motion.

Executive Director Report

Tom Reichard, Executive Director, informed the committee of the current board totals. There are currently 5,387 active licensees; 5 LBSW-IP, 14 LBSW, 4,958 LCSW, 46 CSW Under Supervision (under the new law), 364 LMSW, 593 LCSW pending checklist, and 164 LMSW pending checklist.

Mr. Reichard stated that the 2010 ASWB examination pass/fail rates are provided in the open agenda. He stated that the breakdown per school will be discussed in closed session. He noted that the pass/fail rates are very consistent from what we've had in the past.

Mr. Reichard informed the committee that the ASWB Delegate Assembly meeting will be held November 3-5, 2011 in Oklahoma City. He will provide further information on that meeting once received in the committee office.

The committee will conduct another 100% of continuing education this year. Renewal forms will be mailed the first part of July. Each renewal form will also include a bright green insert with audit information. Mr. Reichard asked the committee to begin thinking about what they would like to do for the next renewal period. Some of the options would include requiring all licensees to submit proof of CE with their renewal form and have staff pull a percentage or offer online renewal to all except for a percent.

Mr. Reichard stated that beginning with the 2012 renewal cycle, all supervisors will be required to obtain 3 clock hours in a supervision training update course. A reminder will be posted on the committee's website, under the supervision requirements section.

Laura Neal asked Mr. Reichard for an update on new board appointments. Mr. Reichard stated that he sent another request to the Division Director, Jane Rackers, last week pleading for one more committee member. In this request, he provided information on those currently serving on expired terms and included the dates of meetings that had to be rescheduled due to loss of quorum. At this time, he has not received a response back. Mr. Reichard thinks they are working on it and hopes that the Governor's office will make some appointments this summer.

In addition to the vacant LCSW spot, there are also vacancies to be filled by a LMSW and LBSW. Tamitha Price stated that the NASW-MO Chapter has submitted a number of recommendations to the Governor's office. She stated that she plans to follow-up with the Governor's office on the submissions made.

NASW-MO Chapter Update

Tamitha Price, Executive Director, NASW-MO Chapter, stated that she will be unable to attend the open session meeting tomorrow (June 24, 2011) and may send her assistant.

Ms. Price stated that the NASW-MO Chapter recently published information on HB1311 in their June 2011 newsletter. This addressed the new law requiring licensure as Behavior Analysts. According to statute, social workers are not required to carry a dual license. The committee may want to add this information to the website.

Ms. Price has been receiving feedback on the new Supervision Progress Reporting Form. Supervisors have stated that the form is more rigorous than it should be and some are unsure on how to complete the last page, in blank spaces provided.

The NASW-MO Chapter will be offering 6 hours of continuing education free to disaster victims. The chapter will also forward information to members for 15 hours of free online continuing education offered by the national chapter. Ms. Price stated that any licensee who has lost proof of

continuing education obtained from the NASW may contact the office for certificates to be reprinted. Ms. Price stated that she has around 20 members in Joplin and a few in St. Louis and Cape Girardeau.

Ms. Price noted that in the recent NASW-MO Chapter newsletter, front page, they provided information on a MO Social Work Disaster Relief Fund. She stated that they have started to receive donations. This money will go towards rebuilding offices and homes. The national chapter legal counsel is working with them on records and billing; how to bill offsite and/or how to bill with no medical records. Ms. Price stated that they are trying to maintain contact with individuals in that area.

Ms. Price stated that the NASW-MO Chapter board is still interested in forming a safety task force. She said she hopes that the board will begin to pursue this within the next month.

Ms. Price stated the the NASW-MO Chapter board has been looking at the scope of practice and defined terms used in Massachusetts and New Jersey. Ms. Price believes that supervisors are using the terms clinical and case management interchangeably and that they seem to be mixing things up.

Mr. Reichard stated that some states require a specific number of hours of actual clinical work. That is something the committee office staff often question. He asked Ms. Price if the board has considered adding specific hours for supervision. Ms. Price stated that the NASW-MO Chapter board has talked about a percentage in the past. Mr. Reichard stated that a change like this may help with reciprocity down the road.

Ms. Price stated that the supervisors she has heard from so far really like the supervision progress report form. They feel like they now have some guidance.

Ms. Price thinks that defining the scope will be more helpful. She doesn't think they would mind it.

Ms. Price stated that she has been given feedback from some licensees regarding safety training. So far, she hasn't had any push back. She stated that Wisconsin allows social workers to conceal and carry.

The NASW-MO Chapter board is meeting Saturday by conference call and will look further into safety training and definitions. Ms. Price stated that she is currently down one staff member and will begin to train Jennifer on the continuing education process.

Ms. Price stated that the supervisor training course is going well.

Ms. Price will add the committee free online jurisprudence exam to her list of free CE provided to disaster victims.

Closed Meeting

A motion was made by Jane Overton and seconded by Jenise Comer to move to closed session as per Section 610.021 Subsection (1) for the purpose of discussion of confidential or privileged communication between this agency and its attorney; Section 610.021 Subsection (14) and Section 324.001.8 for the purpose of discussing applicants for licensure. Closed under Sections 610.021 for the purpose of reviewing and approving the closed minutes of one or more previous meetings. Closed under Sections 610.021(14) and 324.001.8, RSMo, for the purpose of discussing investigative reports and/or complaints. Ms. Comer, Ms. Marty, Mr. Agler, Ms. Neal, Ms. Overton and Ms. Miller voted in favor of the motion.

Open Session

The board reconvened in open session at 8:13 a.m. on July 24, 2011.

NASW Supervisor Training

The e-mail advertisement for the NASW-MO Chapter supervisor training states that the refresher course is due by the 2011 renewal; however, this requirement is not effective until 2012. A motion was made by Jenise Comer and seconded by Jane Overton to send a letter to the NASW-MO Chapter to ask that they indicate that the refresher course is not needed until 2012. Those who take this training for their 2011 will not be able to count it in 2013. Ms. Comer, Ms. Overton, Ms. Marty, Mr. Agler, Ms. Neal and Ms. Miller voted in favor of the motion.

Updating Online Jurisprudence Exam

The committee would like the updated exam posted online October 1, 2011.

Questions to be added include information from new language; supervisor requirements, new licensure tiers, supervision progress reports, current licensure process; how to locate forms; appropriate supervision.

Annual Supervision Progress Report

When a supervisee changes status, they will maintain the same annual date. The new supervisor would just pick up. The committee likes the form as is.

Limit No. of Exam Attempts

Mrs. Comer stated that she is not in favor of this change at this point. She is looking forward to seeing what the new testing vendor addresses. Ms. Comer stated that the impression on the minority community is that the test is biased.

The ASWB is looking into limiting the number of attempts, but has not made a decision yet. The ASWB wants to protect the integrity of the exam.

The committee reviewed a handout listing the exam limits currently in place for various states.

The committee would like to table this discussion until vendor changes, if ASWB makes the recommendation or after we see how results have changed with the new requirement to obtain the LMSW first and take the clinical exam after supervision.

Mr. Reichard asked what the staff should do with those under supervision, under the old rules, who have been in the process for well over 4 years and have taken the exam multiple times. The committee would like to invite these individuals to appear at a board meeting. This will be a way for the committee to find out what they are doing and provide recommendations. At this point, the committee would like to invite the supervisees only, beginning with 10 individuals.

Safety Training/Social Media

Ms. Price is working on setting up a task force.

Safety training is now required in Kansas, possibly only on first time renewals.

If NASW would like to create training on social media, the committee would support that. However, the committee does not wish to make this a requirement at this time.

Practine Beyond State Lines

If a client is a resident of Missouri, the social worker must be licensed in Missouri.

If the committee wishes to further clarify, they may do so by rule.

Denial Due to Bad Attestations

Ms. Ledgerwood stated that the committee has the authority to write rules regarding bad attestations. However, it would be cleaner in statute.

The committee would like to begin discussing clean-up language to submission of acceptable attestation forms.

Reciprocity Language/Exam

Current statutory language for LCSW reciprocity does not require completion of the exam if the individual has held a clinical license in another state for at least 5 years. The committee does not wish to pursue changing this language at this time.

Specific Areas of Supervised Experience

The committee would like to table this discussion until further discussion is made regarding the scope of practice.

Scope of Practice

The committee would like to create a task force to further define the clinical scope.

Volunteers include: Laura Neal, Terri Marty and Tamitha Price.

The committee would like to invite Steve Franklin, Diane Orton, Suzanne Cary and something in the elderly/nursing home field.

Mr. Reichard will contact the individuals listed and scheduling a meeting.

Ms. Marty stated that the task force could meet at her office in Columbia, MO.

Submission of Contract for Supervision

A motion was made by Kathie Miller and seconded by Laura Neal to clean-up rule regarding submission of contact for supervision by removing "30 days" and adding "submitted prior to approval", in 20 CSR 2263-2.031(5)(H). Ms. Comer, Ms. Marty, Mr. Agler, Ms. Neal, Ms. Overton and Ms. Miller voted in favor of the motion.

2012 Meeting Dates

March 6, 2012

June 7-8, 2012

September 11, 2012

December 4, 2012

Joplin CE/Renewals

The committee will not require submission of proof of CE for those individuals affected by a natural disaster.

The committee would like a statement added to the website for those individuals.

Adjournment

A motion was made by Jenise Comer and seconded by Laura Neal to adjourn the meeting. Ms. Comer, Ms. Marty, Mr. Agler, Ms. Neal, Ms. Overton and Ms. Miller voted in favor of the motion.

The meeting was adjourned at 12:14 p.m. on June 24, 2011.

Open Minutes
July 18, 2011
Conference Call

State Committee for Social Workers
Professional Registration
3605 Missouri Boulevard
Jefferson City, Missouri 65109

Members Present

Terri Marty, Chairperson
Kathie Miller, Secretary
M. Jenise Comer
Hal Agler
Laura Neal
Jane Overton, Public Member

Staff Present

Tom Reichard, Executive Director
Elizabeth Willard, Licensing Technician II

Guests Present

Ron Smith, Attorney General's Office
Mike Cherba, Attorney General's Office

Call to Order – Terri Marty, Chairperson

The State Committee for Social Worker's Open Session meeting was called to order by Terri Marty, Chairperson, at 1:07 p.m. on July 18, 2011 at the Division Professional Registration, Jefferson City, Missouri via conference call.

Approval of Agenda

A motion was made by Jane Overton and seconded by Kathie Miller to approve the open session agenda. Ms. Comer, Ms. Marty, Mr. Agler, Ms. Neal, Ms. Overton and Ms. Miller voted in favor of the motion.

Closed Meeting

A motion was made by Jane Overton and seconded by Kathie Miller to move to closed session as per Section 610.021 Subsection (1) for the purpose of discussion of confidential or privileged communication between this agency and its attorney; Section 610.021 Subsection (14) and Section 324.001.8 for the purpose of discussing applicants for licensure. Closed under Sections 610.021 for the purpose of reviewing and approving the closed minutes of one or more previous meetings. Closed under Sections 610.021(14) and 324.001.8, RSMo, for the purpose of discussing investigative reports and/or complaints. Ms. Comer, Ms. Marty, Mr. Agler, Ms. Neal, Ms. Overton and Ms. Miller voted in favor of the motion.

Open Session

The board reconvened in open session at 1:36 p.m.

Adjournment

A motion was made by Jane Overton and seconded by Laura Neal to adjourn the meeting. Ms. Comer, Ms. Marty, Mr. Agler, Ms. Neal, Ms. Overton and Ms. Miller voted in favor of the motion.

The meeting was adjourned at 1:36 p.m. on July 18, 2011.

From: Kathryn Aebel-Groesch [REDACTED]
Sent: Wednesday, June 22, 2011 10:44 AM
To: State Committee for Social Workers
Subject: LCSW or LMSW?

Dear Mr. Reichard:

I am contacting you for guidance regarding the Missouri requirements for social workers who work in dialysis clinics. When the licensure options changed a few years ago there was much discussion and controversy surrounding which license was appropriate for those of us who work in dialysis clinics. At that time, most agreed that we practice clinical social work, so the LCSW should be required. In the fall of 2008 CMS revised its Conditions for Coverage for dialysis clinics. Emphasis was placed on the social worker's "specialization in clinical practice" because "this level of knowledge and skill is needed to deal with an increasingly older, sicker, and more complex dialysis patient population." "...nephrology social workers must be skilled in assessing for psychosocial influences and their interrelatedness in predicting treatment outcomes, and must 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..... Most nephrology social workers provide psychosocial services autonomously as primary providers without social work supervision or consultation..."

Rather than specifically requiring LCSW, the Conditions for Coverage state, "All dialysis staff must meet the applicable scope of practice board and licensure requirements in effect in the State in which they are employed."

From the Committee's web site:

"Clinical social work", the application of social work theory, knowledge, values, methods, principles, and techniques of case work, group work, client-centered advocacy, community organization, administration, planning, evaluation, consultation, research, psychotherapy and counseling methods and techniques to persons, families and groups in assessment, diagnosis, treatment, prevention and amelioration of mental and emotional conditions;

(11) "Licensed master social worker", any person who offers to render services to individuals, groups, families, couples, organizations, institutions, communities, government agencies, corporations, or the general public for a fee, monetary or otherwise, implying that the person is trained, experienced, and licensed as a master social worker, and who holds a current valid license to practice as a master social worker. A licensed master social worker may not treat mental or emotional disorders, provide psychotherapy without the direct supervision of a licensed clinical social worker, or diagnose a mental disorder;

After reviewing the CMS Conditions for Coverage and the MO Professional Registration Board's definitions of LCSW and LMSW, it appears that the LCSW is appropriate for the dialysis setting. I would like to ask for your opinion and have attached the CMS Conditions for Coverage that pertain to social work for your review. I appreciate your time and consideration!

Sincerely,

Kathy Aebel-Groesch, MSW, LCSW

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7/13/2011

These are pages
23, 38, 51-56 & 114
from a 116 page document
sent from Beth Witten
7/12/11

appointments when other patients are agreeable. Dialysis patients who work or attend school should be encouraged to continue doing so and dialysis facilities should recommend the most appropriate modality and setting for dialysis. While we are not requiring a facility to provide every modality or schedule to accommodate patients' unique schedules, we are now requiring that facilities inform the patient where such accommodations may be obtained. We have added new language at § 494.70(a)(7), giving the patient the right to receive resource information about dialysis modalities not offered by that facility, including alternative scheduling options for working patients. Accommodations for working patients may include, for example, home hemodialysis, peritoneal dialysis, or extended facility hours.

Comment: One commenter objected to the proposal that facilities be required to fully inform all patients about isolation, stating that the regulation should ensure that patients have access to policies but not require all policies be provided to all patients.

Response: This requirement is not a new mandate, but has been retained from part 405, subpart U, the ESRD Conditions for Coverage. Open communication between the facility staff and the patient, as well as patient access to information, are both important for enhancing the patient's participation in his or her care; this requirement will remain in the final rule.

Comment: Two commenters recommended that the facility inform the patient about the health and safety risks involved in reusing dialyzers, provide accurate reuse data, provide the patient with treatment options other than reuse, and notify the patient that reuse is a patient choice. Another commenter stated that patients should have the right to decline reuse and receive single use dialyzers in a facility. One commenter questioned whether there should be a reuse consent form, while another asked how patient choice would be protected.

Response: Reuse is a safe practice when performed correctly. Reuse language at proposed § 494.50 was retained from existing regulation and now requires ESRD facilities reusing hemodialyzers to meet the new guidelines and standards adopted by AAMI. Additionally, section 1881(f)(7) of the Act directly addresses dialyzer reuse. Reuse is a care decision that is to be made between the patient and his or her physician. Patients also have the option to seek treatment in a facility that exclusively uses new dialyzers.

Comment: One commenter suggested deletion of the requirement that facilities inform patients of their own medical status. Another suggested that we add broader language in the regulation text, which would allow physicians, nephrologists, nurse practitioners or physician assistants to provide patients with their own medical information.

Response: Providing the patient with his or her medical information is an existing requirement and is found at § 405.2138(a)(3). The commenter provided no rationale for the deletion of this standard language and thus, the language has been retained. We have added the nurse practitioner, clinical nurse specialist and/or physician's assistant treating the patient for ESRD to the list of authorized personnel at § 494.70(a)(10), which now states that patients have the right to be informed by the physician, nurse practitioner, clinical nurse specialist, or physician's assistant treating the patient for ESRD of his or her own medical status as documented in his or her medical record, unless the medical record contains a documented contraindication. Individual facilities may determine policies and procedures, in accordance with the State Boards of Practice, regarding the practice of advance practice nurses and PAs in the facility.

Comment: A commenter objected to the requirement that facilities fully inform patients about charges not covered by Medicare. Another commenter suggested that trained and informed staff should explain non-covered charges.

Response: The intent of the existing subpart U language at § 405.2138(a)(2) was carried over into the proposed language at § 494.70(a)(10), now redesignated as § 494.70(a)(11) in this final rule, which requires facilities to tell patients what services are available in the facility, and inform them of charges for services not covered under Medicare. Additionally, if a facility plans to bill a patient for items and/or services which are usually covered by Medicare, but which may not be considered reasonable and necessary for a particular situation (according to section 1862 of the Act), an advanced beneficiary notice must be given pursuant to section 1879 of the Act.

Comment: A few commenters suggested that regulatory language require that patients be given access to social work and psychological services, psychosocial counseling, and nutritional counseling. Some commenters suggested that language be added to the "Patients' rights" condition

that specifies that patients would have access to, and receive counseling from, a qualified social worker and a dietitian. Some commenters recommended that patients have the right to receive a referral for mental health services, physical or occupational therapy and/or vocational rehabilitation, as needed. Another commenter suggested the addition of language that would stipulate that patients would have the right to receive necessary services, as authorized by their insurance plan.

Response: The "Patient assessment" and the "Patient plan of care" conditions for coverage (§ 494.80 and § 494.90, respectively), require input by an interdisciplinary team. This team of professionals includes, at minimum, a registered nurse, physician, social worker and dietitian. The team is responsible for properly assessing and treating the patient, which would include identifying additional treatment needs, such as psychosocial counseling, etc. Therefore, we believe that expanding the language at § 494.70(a)(12) to include social work and psychological services, psychosocial counseling and nutritional counseling, as suggested by these public comments, would be redundant under the final rule. Under the final rule, following the comprehensive assessment required at § 494.80, a plan of care for each patient must be implemented, which must include care and services deemed necessary by the interdisciplinary team. The requirements for the provision of services under the "Plan of care" condition at § 494.90, do include nutritional and social services, such as psychosocial and nutritional counseling. Furthermore, the "Patients' rights" condition at § 494.70(a)(11) requires facilities to inform patients of their right to be informed of services available in the facility and the charges for services not covered under Medicare. At § 494.70(a)(12), patients have the right to receive the necessary services outlined in the patient plan of care. Therefore, we believe the concerns of commenters are adequately addressed at § 494.70, § 494.80 and § 494.90.

Comment: Some commenters suggested adding language to specify that facilities must inform patients of their responsibilities, including punctuality, following dietary/fluid restrictions, following treatment regimens, exhibiting appropriate personal behavior, informing the team of scheduling problems, and issues in filling prescriptions. Other commenters stated that facilities should inform patients that the patients have a responsibility to listen and ask

Guidelines for Cardiovascular Disease in Chronic Kidney Disease (American Journal of Kidney Disease 45:S1–S154, 2005 (supplement 3)). The commenter stated that the NKF recommends that electrocardiograms be performed in all patients at the initiation of dialysis, once patients have achieved dry weight, and at 3 yearly intervals thereafter. In addition, appropriate blood pressure management is an important part of dialysis care and contributes directly to cardiovascular health.

Response: Cardiovascular disease is a concern for dialysis patients and is affected by renal bone disease, blood pressure, and fluid management as well as any other risk factors the patient may have. Dialysis patients often have a number of co-morbidities. The patient's medical history and co-morbidities are to be assessed as required at § 494.80(a)(1). Any problems identified by the comprehensive assessment are to be addressed in the patient plan of care as required at § 494.90. Since very little support came from commenters specifically to add a cardiovascular disease component to the plan of care, we have not added this requirement. However, dialysis-related cardiovascular health problems must be addressed in the plan of care whenever it is appropriate for an individual patient, as determined by the interdisciplinary team. Although core components of the plan of care are listed in this final rule, the interdisciplinary team has flexibility to add areas to the plan of care as identified in the comprehensive assessment.

Comment: We received many comments regarding whether a social services component should be required in the "Patient plan of care" condition. Most of the comments recommended that social services be part of the plan of care and referred to current research regarding social work services. Commenters stated that studies have shown that social work intervention improves patients' quality of life, their adherence to the ESRD treatment regimes and fluid restrictions, and improves medication compliance. Another example of improved outcomes provided by a commenter is that social work interventions can reduce patients' blood pressure and anxiety levels.

Commenters suggested including emotional and social well-being criteria in the final rule. Some commenters recommended including functional status measures that they believe correlate with better survival and hospitalization rates. Other commenters recommended requirements that would specify psychosocial criteria along with MSW tasks and responsibilities, and

which would require that MSWs provide information and training to patients. Some commenters suggested adding specific language that would address measurable improvement in physical, mental, and clinical health outcomes * * *, "psychosocial status and appropriate referral for services * * *," and would "provide the necessary care and services to achieve and sustain effective psychosocial status * * *." Many commenters suggested that we require use of a tool to assist in measuring psychosocial status. Tools suggested include the Zung Self-Assessment Depression Scale or Hamilton Anxiety Scale, and a quality-of-life tool such as the SF-36, or SF-12 (version 2.0 tool), that commenters state are used to measure depression, functional status, and predict mortality and morbidity. Commenters cited research supporting social work interventions that they believe would contribute to meeting patient care team goals.

Response: In response to the large number of comments, and in light of current academic research supporting social service interventions to improve patient care, we are adding a social services component, called "psychosocial status" to the plan of care requirements at § 494.90(a)(6). We are requiring that a standardized tool, chosen by the social worker, be used to monitor patient status, and that counseling be provided and referrals be made as appropriate. This new requirement reads, "The interdisciplinary team must provide the necessary monitoring and social work interventions, including counseling and referrals for social services, to assist the patient in achieving and sustaining an appropriate psychosocial status as measured by a standardized mental and physical assessment tool chosen by the social worker, at regular intervals, or more frequently on an as-needed basis."

The standardized tool should be a professionally accepted, valid, reliable tool, such as the SF-36, and should relate to the patient's functional health and well-being. The tool must be used as a monitoring aid that assists in determining the patient's psychosocial status. The SF-36 model uses metrics that measure physical health as related to functional level and presence of pain, and mental health as related to social functioning, emotional and mental health. Reliability and validity studies have been performed for this instrument. More information about the SF-36 may be found in numerous articles or on the Web at <http://www.sf-36.org/tools/sf36.shtml>. The SF-12 survey form was derived from the

SF-36 form and scales the 36 question survey down to a 1-page, 2-minute version. However, we are not specifying which tool must be used in order to allow flexibility and to limit the amount of burden. The choice of which standardized tool to use is best left to the facility social worker.

Comment: Although most comments recommended that social services be part of the plan of care, two commenters disagreed, stating that social workers have too big a caseload and are not capable of providing professional counseling services. One commenter stated that until there is consensus on outcomes, CMS should not include an outcomes-based social service requirement in the plan of care. Commenters supporting social services in the plan of care submitted a lengthy list of references that highlight the importance of social services as related to improved patient outcomes.

Response: In the previous conditions (§ 405.2162) as well as in this final rule (§ 494.180(b)), dialysis facilities are required to have adequate staff available to meet the care needs of their dialysis patients. This requirement applies to the provision of social services as well. Facilities may want to assess the caseloads of social workers to ensure there are adequate staff to provide the appropriate level of social services, including counseling. Social workers who meet the qualifications at § 494.140(d) are capable of providing counseling services to dialysis patients. Furthermore, Medicare payment for social worker counseling services is included in the dialysis facility composite rate.

We are setting forth some process requirements within the "Patient plan of care" condition because measurable outcomes in all areas are not yet available. When evidence-based or consensus outcome measures and standards become available, we may consider whether some process requirements may be removed from the conditions for coverage in the future.

Comment: We received a comment recommending that consistent language be used for all plan of care elements so that for all care plan areas the dialysis facility "must provide the necessary care and services to achieve and sustain an effective (treatment program)."

Response: Requiring the facility to provide all necessary care and services for all elements of the patient plan of care may overstep the facility's scope of practice in some areas, as pointed out by several commenters.

Comment: One commenter questioned the need to list components of the plan of care, since a qualified care team

§ 405.2163(b), with minor revisions. The dialysis facility must provide or make available laboratory services to meet the needs of their patients, and these services must be furnished by or obtained from a facility that meets the requirements for laboratory services in accordance with 42 CFR part 493.

Comment: One commenter recommended that we add language in the final rule to specify that facilities must have an agreement with a primary or secondary laboratory that meets the Certified Laboratory Improvement Amendments of 1988 (CLIA) requirement.

Response: CLIA certification is addressed at § 494.130 by reference to part 493. It states that all Medicare-certified laboratories performing laboratory tests be certified under CLIA. Therefore, we have adopted the language as proposed.

Comment: One commenter suggested the addition of language to the final rule saying that to "ensure that composite rate lab tests for each ESRD beneficiary are accounted for in a single, centralized database for proper application of ESRD laboratory billing rules, composite rate lab tests performed by any other laboratory must be billed through the primary laboratory." Another commenter suggested adding language to specify that in the event a facility uses a secondary laboratory, it must enter into an agreement with the facility or the facility's primary laboratory to bill the facility or the primary laboratory for laboratory tests that are subject to ESRD laboratory billing rules. One commenter suggested we require a facility's primary laboratory to be the single laboratory permitted to bill Medicare for tests listed as composite rate laboratory tests. Another commenter suggested that local laboratories (in close proximity to an ESRD facility) should be able to bill for tests through a "primary laboratory." One commenter remarked that the final regulation should address problems with Health Maintenance Organizations (HMOs) and mandate that required testing be conducted in laboratories equipped to do such testing. The commenter stated that HMOs often refuse referrals to properly equipped laboratories affiliated with the patient's ESRD unit.

Response: The commenters' concerns are related to Medicare payment for services and are therefore outside the scope of this rule. The commenters' concerns have been forwarded to the appropriate officials within CMS for consideration.

Comment: One commenter suggested the regulation require that primary

laboratories agree to furnish the dialysis facility with laboratory test data electronically upon request so that the data can be submitted to ESRD Networks.

Response: The ESRD Conditions for Coverage cover dialysis facilities and do not extend to testing laboratories. Facilities must provide for or make available laboratory services to meet the needs of the ESRD patient. Laboratory services must be furnished by or obtained from, a facility that meets the requirements for laboratory services specified in part 493 of this chapter (§ 494.130). However, dialysis facilities may enter into business agreements with laboratories willing to provide requested data electronically.

Comment: One commenter stated "convenience" lab draws need to be addressed in the final rule.

Response: We believe the commenter is referring to those laboratory tests, such as histocompatibility tests, ordered by a patient's outside physician, which could be drawn in the ESRD facility while a patient is undergoing dialysis treatment. Drawing additional laboratory tests while the patient is undergoing treatment is convenient for the patient; individual facilities have the flexibility to determine if this is a service they wish to offer.

4. Subpart D (Administration)

a. Personnel Qualifications (Proposed § 494.140)

To avoid placing substantive requirements within the definitions section as written in part 405, subpart U (at § 405.2102), we proposed a separate condition to set forth requirements for dialysis facility staff qualifications. We proposed that the dialysis facility medical director be a physician who has completed a board approved training program in nephrology and has at least 12 months experience providing care to patients receiving dialysis. We did not retain transplantation experience as a qualification, which was previously set out at § 405.2102(d), because this rule applies to dialysis centers and not to transplantation centers. We proposed to carry forward the part 405, subpart U waiver provision for instances when a physician meeting the medical director qualifications is not available. We proposed that the facility nurse manager be an RN and a full time employee, as required under part 405, subpart U, and have at least 12 months of clinical nursing experience and an additional 6 months of dialysis experience. We proposed that the self-care home dialysis training nurse be an RN with at

least 12 months of nursing experience and an additional 3 months of dialysis experience in the modality for which he or she would provide training. We proposed new qualifications for the charge nurse, who would be required to be an RN or licensed practical nurse (LPN) with 12 months of nursing experience, including 3 months of dialysis experience. We also proposed new qualifications for the staff nurse, who would have to be an RN or LPN and meet the State practice requirements. The proposed qualifications for the facility dietitian included the registered dietitian (RD) credential and at least one year of professional work experience as a RD. We proposed social worker qualifications that would require the social worker to have a master's degree in social work from a school of social work accredited by the Council on Social Work Education. Our proposed social worker qualifications did not include the grandfather clause (see § 405.2102, "Qualified personnel" paragraph (f)(2)), which allowed non-master's prepared social workers who were employed for at least two-years as of September 1976 to hold dialysis facility social worker positions when there was a consultative relationship with a master's prepared social worker. We proposed to recognize patient care dialysis technicians for the first time in the proposed conditions for coverage, and set forth proposed qualifications. We proposed that patient care dialysis technicians have a high school diploma or equivalency and at least 3 months experience under the direct supervision of an RN, and that they complete a training program that would include specified topics and be approved by the medical director and governing body. We proposed that the clinical staff meet State practice requirements (§ 494.140) and be licensed according to State provisions (§ 494.20 and § 494.140(e)(1)). We proposed new qualifications for the water treatment system technicians, who would complete a training program approved by the medical director and governing body. Personnel qualifications that were not carried forward from part 405, subpart U, included those for the chief executive officer, medical record practitioner, and the transplantation surgeon.

We received more comments (more than 150) on the proposed "Personnel qualifications" condition for coverage at § 494.140 than on any other condition.

Comment: A large number of commenters suggested that the title of this condition be changed to "Personnel qualifications and responsibilities" and

that the specific responsibilities of all members of the interdisciplinary team be included. Commenters suggested that the medical director and patient be excluded from assignment of responsibilities under the "Personnel qualifications" condition. Some commenters said that since medical director responsibilities were included at § 494.150, other team member responsibilities should be listed in the regulation as well. Some commenters stated that it would be helpful if clinical social worker responsibilities were listed in regulation; they state that social workers are unable to provide clinical social services to patients because they are often tasked with clerical work that fills the majority of their time.

Response: We have sought to be less prescriptive in this rule in order to allow dialysis facilities flexibility in meeting Medicare requirements. We expect that as professional caregivers, members of the interdisciplinary team are aware of their discipline's professional standards of practice and provide quality care to their patients in keeping with those standards. Under the "Patient assessment" and "Patient plan of care" conditions (§ 494.80 and § 494.90), we require that members of the interdisciplinary team complete a comprehensive assessment followed by a plan of care that identifies goals for patient care and the services that will be provided in order to meet those goals. This includes psychosocial and nutrition services to be provided by the social worker and the registered dietitian. The assessment and plan of care requirements necessitate that the RN, social worker, and dietitian provide appropriate professional care to each patient. Specifically, the dialysis facility must ensure that the social worker provides timely psychosocial assessments and social work interventions in accordance with the plan of care in order to meet these conditions for coverage. We are also requiring at § 494.140 that the interdisciplinary team, which includes the RN, social worker, and dietitian, play an active role in the QAPI program. This final rule requires that the interdisciplinary team provide appropriate care to dialysis patients and improve patient care on an ongoing basis. We do not agree that all the responsibilities of the entire interdisciplinary team need to be enumerated in regulation.

Comment: Many commenters objected to the change in medical director qualifications, as proposed in standard § 494.140(a), and recommended that the medical director be board-eligible or board-certified, as previously required

at § 405.2102(e). These commenters included patient organizations, dialysis organizations, as well as physicians. One commenter stated that nephrology is a recognized sub-specialty, which requires specialized knowledge and training and that removing the "board eligible or board-certified" requirement could affect the continued existence of this sub-specialty. Another commenter said this "board-certified" requirement is the accepted industry standard for evidence of proficiency in a specialty. A commenter stated that to lower standards could jeopardize patient care across the nation and that board eligibility and certification needs to be recognized. Other commenters object to lowering of standards for this important position, except on a case-by-case basis. One commenter recommended that the medical director be required to be a nephrologist. Two commenters supported our proposed medical director qualifications.

Response: Many commenters communicated quality-of-care concerns regarding our proposed deletion of the requirement under former § 405.2102 that the facility medical director be "board-eligible" or "board-certified" in internal medicine or pediatrics. Our goal is to improve quality of care via this final rule and to ensure that the medical director has the appropriate qualifications. Therefore, in response to comments, we have revised the proposed requirement in the final rule, so that the medical director must be "board-certified" in internal medicine or pediatrics by a nationally recognized professional board at § 494.140(a). We are not including the term board-eligible, as it is no longer used, defined, or recognized by the American Board of Internal Medicine (http://www.abim.org/cert/policies_ssneph.shtml). We have retained the proposed requirement that the medical director complete a board-approved training program in nephrology.

Comment: A commenter recommended that the time period during which a physician is in a training program and providing care to dialysis patients should satisfy the 12-month experience requirement for medical directors. Another commenter requested clarification of whether or not experience gained during a training program could count towards the 12 months of experience for medical director qualifications. The commenter noted that if this time were not counted, then nephrologists completing their training programs could not become a medical director for at least 12 months.

Response: The required 12 months of experience caring for dialysis patients may include experience gained while a physician is enrolled in a nephrology-training program. This will be reflected in the interpretive guidelines for this regulation.

Comment: A commenter requested further clarification of the process that would allow a physician who does not meet the medical director requirements at § 494.140(a)(1) to serve as the medical director as permitted at § 494.140(a)(2).

Response: A physician who does not meet § 494.140(a)(1) requirements may only serve as the medical director when a qualified physician is not available, and when approved by the Secretary as required at § 494.140(a)(2). This provision was retained from part 405, subpart U. A dialysis facility seeking to place an alternate physician in the role of the medical director must contact their CMS Regional Office to make a request for the Secretary's approval.

Comment: While most commenters supported the proposed RN qualifications at § 494.140(b), one commenter suggested an increase in RN experience requirement, to 2 years of clinical and 1 year of dialysis experience. Another suggested that the RN experience qualification be reduced to 6 months. One commenter asked whether one RN could fulfill all four roles listed under nursing services (§ 494.140(b)) if he or she met all the qualifications.

Response: Very few commenters disagreed with the proposed experience qualifications for RNs; therefore, we will adopt the requirement for 12 months of nursing experience and 3 to 6 months of dialysis experience (depending on the role of the RN) in this final rule. A single RN may fulfill multiple nursing roles in the dialysis facility if he or she possesses the appropriate qualifications for each role and if this does not jeopardize the facility's ability to meet the staff requirement at § 494.180(b)(1).

Comment: A few commenters suggested a revision of the qualifications for the charge nurse. A commenter suggested that 12 months of experience for charge nurses be changed to 6 months because the nursing shortage necessitates not eliminating new nursing graduates from the hiring pool. Another commenter stated that 3 months of dialysis experience should not include "orientation time," as 3 months of experience is barely adequate. Two commenters stated that they believe the 3 months of dialysis experience to be inadequate and recommended that the requirement be changed to at least 6 months, since some States, such as California, have no

minimum training requirements; the commenters believe that this endangered patients.

Response: There was disagreement among commenters regarding the proposed qualifications for charge nurses, with some commenters advocating longer experience requirements and others suggesting shorter experience requirements. Our goal for this provision is to ensure that a qualified nurse who can adequately protect patient safety acts as the charge nurse. We believe that the level of experience for charge nurses as stated in the proposed rule (12 months experience in providing nursing care, including 3 months of dialysis nursing care) is reasonable. Given that there is disagreement among commenters and no evidence was presented supporting a modification, we have adopted the charge nurse experience requirements as proposed at § 494.140(b)(3)(ii).

Comment: Many commenters objected to the proposed charge nurse qualifications, which commenters state would allow a licensed practical nurse to serve as a charge nurse, because state practice boards generally do not allow an LPN to supervise an RN. Some commenters stated that the level of responsibility for the charge nurse requires an RN, and LPNs are not qualified for this position. Other commenters stated that experienced dialysis LPNs are very capable individuals. Two commenters stated that due to the nursing shortage, an LPN should be allowed to act as the charge nurse only when an RN is not available. Another commenter stated that the nursing shortage should not be used to justify use of unqualified personnel. One commenter stated that LPNs could function as charge nurses without any RN supervision on-site, and another stated that the LPNs at her facility have more experience than the RNs. One commenter noted that LPNs are used more frequently by LDOs.

Response: We have revised the requirement formerly found at subpart U (§ 405.2162), so that an RN must be present in the facility, and an LPN could still act as a charge nurse if he or she met the proposed qualifications. We did not intend for a LPN to supervise an RN, as suggested by the commenters.

The RN must be present in the facility when patients are being treated, as required at § 494.180(b)(2). An LPN might act as the charge nurse but would not necessarily be supervising an RN. All dialysis nurses must adhere to their state practice requirements. We have modified § 494.140(b)(3)(iii) to clarify this by adding language to indicate that, if the charge nurse is a licensed

practical nurse or licensed vocational nurse, that he/she must work under the supervision of a registered nurse when required by the State nursing practice act provisions.

Comment: A few commenters objected to proposed § 494.140(b)(1)(i), which requires the nurse manager RN to be a full-time employee of the facility, and recommended deletion of this requirement. Two commenters said it was unrealistic to require the nurse manager to be employed full-time because small rural units are only open part-time. Some units share the same nurse manager. A commenter stated that requiring a full-time employee as nurse manager would not be a good use of a scarce resource.

Response: The full-time requirement is not a new provision (refer to former § 405.2162(a)). Dialysis facilities should already be fully compliant with this provision. In the case of small dialysis facilities that are not open for at least 40 hours per week the "full-time nurse" would be employed at all times the facility is open. For example, a dialysis facility that is only open for 24 hours per week would only need to employ the nurse manager for 24 hours per week to satisfy this requirement. We have retained this requirement as proposed.

Comment: We received a few comments regarding the qualifications of the self-care training nurse.

Response: Please refer to the earlier discussion of self-care training nurse qualifications found under the discussion of § 494.100 in this preamble.

Comment: A commenter suggested that we change the position title "self-care training nurse" to "self-care or home training nurse" in order to specify that self-care nurses can train patients for in-home or in-facility dialysis.

Response: We agree, and have modified the position title at § 494.140(b)(2) to clarify that "self-care" includes home dialysis. The new position title is "self-care and home dialysis training nurse."

Comment: A commenter suggested that staff nurse requirements be the same as those proposed for PCTs, which are at least 3 months experience, following a training program that is approved by the governing body.

Response: We agree that the requirements should be similar. We have eliminated the experience requirements for both staff nurses (§ 494.140(b)(4)) and PCTs (§ 494.140(e)). Each professional, however, will be required to meet the training requirements appropriate to their specialty.

Comment: One commenter suggested that a statement be added to the final rule that would mandate that there could be no contract nurse(s) filling the roles of the nurse manager, self-care training nurse, or the charge nurse.

Response: We agree, and are adopting the proposed requirement at § 494.140(b)(1)(i) that the nurse manager be a full-time employee of the facility, which means this position cannot be filled by a contracted nurse. The self-care and home dialysis training nurse and the charge nurse positions do not have this restriction and may be either employees or contractors. Employees are subject to the following directions of an employer relative to what needs to be done and how it should be done. Contractors, on the other hand, are generally not held to how a job is done and the methods that are used. A nurse manager fills a critical role and it is important that his or her actions meet the needs of the facility's governing body. If a nurse under contract fills these roles, he or she must have the proper qualifications and complete the orientation for the position as required in this final rule at § 494.180(b)(3).

Comment: A commenter suggested we specify that RNs have training in the care of patients with chronic disease and physical, emotional, and psychosocial issues.

Response: We would expect that RNs have received training in each of these areas as part of their nursing curriculum. We do not agree there is a need to specify this training in regulation.

Comment: One commenter suggested that advance practice nurses should serve as "case managers" and be reimbursed for this role.

Response: This rule does not preclude the use of advance practice nurses in dialysis facilities, but we do not feel we should be this prescriptive because of the degree of regulatory burden imposed upon facilities. In addition, this final rule does not address reimbursement issues.

Comment: We received more than 15 comments on dietitian qualifications at § 494.140(c). The majority of commenters agreed and supported our proposal to require a "minimum of one year's professional work experience in clinical nutrition as a registered dietitian". One commenter suggested that the American Dietetic Association (ADA) registration is not enough and minimum experience criteria are needed.

The ADA agreed with the proposed qualifications for dietitians. The ADA noted that registered dietitians (RDs) also possess clinical knowledge and

skills to manage anemia and bone disease and to conduct urea kinetic analysis. The ADA stated that according to the Commission on Dietetic Registration, there are more than 72,000 RDs nationwide, and the supply of RDs is well established.

One commenter stated that 1 year of registered dietitian professional work experience in clinical nutrition is acceptable, but 2 years would be ideal. Newly hired RDs without renal experience should have a training period of at least 2 weeks with an experienced renal dietitian. This commenter also noted that the role of the dietitian has expanded and recommended that the responsibilities of dietitians include monitoring adherence and response to diet, and recommending interventions for improving nutritional status. The commenter provided examples of the expanded role of the dietitian, which included anemia manager, and bone and urea kinetic modeling manager, to improve clinical outcomes.

One commenter agreed with the proposed 1-year experience requirement since quality care depends on renal training and specialization, but said facility managers point to the difficulty of finding sufficient numbers of experienced dietitians. This commenter suggested that the one year of experience be preferred but not required.

Three commenters disagreed with the proposed 1-year professional experience requirement. One commenter stated the 1 year of professional work experience is unnecessary; only registration with the Commission on Dietetic Registration is needed. This commenter stated that instead, mentoring and direction from an experienced renal dietitian is needed. The commenter stated that the experience requirement would diminish the pool of qualified dietitians. Another commenter also stated that adding a year of experience as a requirement for RDs would create even more of a RD shortage and is not necessary given their extensive education.

Another commenter suggested that we delete "as a registered dietitian" from regulations text, so that experience obtained prior to becoming a registered dietitian could be counted, and professional work experience gained during an internship would apply. This commenter further suggested that all dialysis dietitians be required to participate in training from experienced dietitians.

Three commenters recommended that the dietitian qualifications match the medical nutrition therapy (MNT) regulation requirements, which call for

a bachelor of arts degree or higher, an academic program in nutrition or dietetics, 900 hours of supervised dietetics practice, and being licensed or certified as a dietitian or nutritional professional by the State in which the professional is practicing. One of these commenters agreed with requiring a minimum of 1 year's professional work experience as a registered dietitian.

Response: The dietitian qualifications in subpart U at § 405.2102(b) specify at least 1-year experience in clinical nutrition. In this final rule, we redesignated proposed § 494.140(c)(3) as § 494.140(c)(2), which requires 1 year of professional work experience in clinical nutrition as a registered dietitian. Renal nutrition is a specialized area within the practice of dietetics. The dialysis facility dietitian must be able to perform independently complex nutritional assessments, evaluate laboratory results, and assist the interdisciplinary team in managing anemia, renal bone disease, and performing kinetic modeling. A typical therapeutic diet for a hemodialysis patient has multiple restrictions and is limited in sodium, phosphorus, potassium, fluid, and includes specified amounts of protein. Many patients must follow additional dietary restrictions such as low cholesterol or diabetic limitations. We believe that a registered dietitian would need at least one year of experience to perform this specialized work. The majority of commenters recognized the specialized work of a RD in the dialysis setting.

The MNT dietitian qualifications at 42 CFR 410.134 require the MNT provider to be a registered dietitian with the Commission on Dietetic Registration or to have a bachelor's degree or higher in nutrition or dietetics, 900 hours of supervised experience and state licensure, if applicable. The MNT dietitian qualifications allow a nutritionist who is not a registered dietitian to provide medical nutrition therapy. By contrast, dialysis dietitians must be registered dietitians under both the previous ESRD regulations and the proposed rule. We have not removed the registered dietitian qualification requirement, as we find no reason to do so.

We do not have evidence that there is a shortage of registered dietitians that necessitates deletion of the clinical experience requirement. While mentoring programs are desirable, we did not propose them and have not added this requirement to the final rule. Registered dietitians must be oriented to the facility and their work responsibilities (§ 494.180(b)(3)) and have an opportunity for continuing

education and related development activities (§ 494.180(b)(4)).

Comment: Two commenters suggested including the word "clinical" in the "professional work experience" phrase so that foodservice experience does not apply.

Response: The proposed rule at § 494.140(c)(3), (now § 494.140(c)(2)), requires dietitians "have a minimum of one year's professional work experience in clinical nutrition as a registered dietitian." This wording would preclude a dietitian who only has foodservice professional experience from qualifying for a position as a dialysis dietitian. We do not agree that a change in wording is needed here because clearly, the experience must be in "clinical nutrition."

Comment: One commenter recommended that dietitian-to-patient caseloads be limited to 90–100 patients per dietitian.

Response: We address adequate staffing under the "Governance" condition for coverage at § 494.180(b). Some States have implemented staff-to-dialysis patient ratios, and we defer to State provisions on this issue. Dialysis dietitian caseloads must not prevent RDs from providing care consistent with national standards of practice for dietitians. National standards have been published by the ADA entitled "Standards of Practice in Nutrition Care and Updated Standards of Professional Performance" in April 2005 (Kieselhorst, K.J., Journal of the American Dietetic Association, Vol. 105, No. 4, April 2005).

Comment: One commenter suggested that dietetic technicians be included in the final rule. The commenter stated that she strongly supported the use of dietetic technicians, registered (DTRs) under RD supervision and that DTRs are nationally certified and have education requirements similar to the RDs.

Response: We do not agree that RDs and DTRs have similar education requirements. According to the ADA, DTRs must complete at least a 2-year associate's degree while an RD must complete a minimum of a bachelor's degree at a U.S. regionally accredited college or university. A DTR must complete a dietetic technician program accredited and approved by the Commission on Accreditation for Dietetics Education (CADE), including 450 hours of supervised practice experience. An RD must complete a CADE accredited supervised practice program that typically runs 6 to 12 months in length. RDs and DTRs also have different continuing education requirements.

This final rule requires an RD to be a member of the dialysis facility interdisciplinary team, perform patient assessments, and participate in patient care planning and the QAPI program. The RD may use a DTR to provide assistance under RD supervision, but it is the RD who must meet these conditions for coverage. Therefore, we have not added DTRs to the "Personnel qualifications" condition.

Comment: We received more than 70 comments regarding social worker qualifications. The vast majority of commenters supported the proposed social worker qualifications, which require a master's degree in social work from a school of social work accredited by the Council on Social Work Education.

Commenters stated that dialysis patients have highly complex needs and require care from an MSW who has a "specialization in clinical practice" education. Commenters made the following statements in support of an MSW with a specialization in clinical practice. They stated that the nephrology social workers must be skilled in assessing for psychosocial influences and their interrelatedness in predicting treatment outcomes, and must 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 MSWs enables 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 use validated tools, such as the SF36 (the Medical Outcomes Study 36-item short-form health survey) and the KDQOL (Kidney Disease Quality of Life), to improve care and to monitor the outcomes of directed interventions. Most nephrology social workers provide psychosocial services autonomously as primary providers without social work supervision or consultation, using highly developed social work intervention skills obtained in a master's level curriculum. The masters in social work degree provides an additional 900 hours of specialized training beyond a baccalaureate degree in social work. An MSW curriculum is the only curriculum that offers additional specialization in the Bio-Psycho-Social-Cultural, Person-in-Environment model of understanding human behavior. Undergraduate degrees or other mental health credentials do not offer this specialized and comprehensive training. The National Association of Social Workers Standards of Classification considers the

baccalaureate degree as a basic level of practice, while the masters degree is considered a specialized level of professional practice and requires a demonstration of skill or competency in performance. These commenters provided references and citations along with these comments.

A few commenters suggested that the master's degree qualification be eliminated because it is difficult to recruit MSWs in some rural areas. A commenter stated that in California a licensed clinical social worker requires 2 years of supervision and two examinations, which makes it difficult to get a licensed clinical social worker license. Another commenter suggested that we keep the MSW requirement but include an "exceptions process" for units that cannot hire an MSW. Some commenters stated that bachelor's prepared social workers are competent as long as they are supervised by an MSW.

Response: We appreciate the large degree of support for the MSW qualification for social workers. We have revised the MSW requirement in § 494.140(d)(1) by adding "specialization in clinical practice," as specified in part 405, subpart U, as the majority of comments supported this. The consensus among the commenters is that this level of knowledge and skill is needed to deal with an increasingly older, sicker, more complex dialysis patient population.

Comment: One commenter recommended that we delete § 494.140(d) in its entirety or delete any preamble references to MSWs performing counseling, long-term behavioral and adaptation therapy, and grieving therapy. The commenter stated that such counseling exceeds the expertise of MSWs, and that patients should be referred outside the units for this service. The commenter also claimed that an "expansion" of counseling requirements represents a potential \$18 million burden to his large dialysis organization.

Response: The "Personnel qualifications" condition for coverage at § 494.140 does not specify tasks or responsibilities for dialysis facility social workers, but only their education and qualifications. The proposed rule preamble discussion provided examples of social worker services that facilities might offer, including counseling services, long-term behavioral and adaptation therapy, and grieving therapy (70 FR 6222) that would require the education and training of an MSW. The proposed rule's preamble discussion is consistent with part 405, subpart U social worker requirements at

§ 405.2163(c), which state that "Social services are provided to patients and their families and are directed at supporting and maximizing the social functioning and adjustment of the patient." Social services needed for each patient should be determined during the assessment and identified in the plan of care.

Only one commenter suggested § 494.140(d) be deleted in its entirety, while a very large number of comments supported this requirement, and the consensus was to retain MSWs in dialysis units. MSWs are trained and competent to counsel patients. The social worker professional standards of practice (<http://www.socialworkers.org/practice/standards/NASWHealthCareStandards.pdf>) do include patient and family counseling within the scope of services provided by a social worker. MSW services, which include counseling, is incorporated into the Medicare composite payment rate and should not be outsourced or separately billed.

Comment: We received a large number of comments regarding our proposed deletion of the master's degree "grandfather clause" for social workers. Many commenters agreed with eliminating the "grandfather clause" because "30 years was more than enough time for dialysis social workers to obtain masters degree." Commenters stated that MSW and BSW tasks could be broken out into separate job descriptions so that BSWs may assist MSWs. Commenters said that there was no MSW shortage.

A larger number of commenters suggested that we retain the "grandfather clause" for non-MSWs so that currently employed non-MSWs working as dialysis social workers do not lose their jobs. Some commenters suggested that experienced non-MSW social workers were competent and had much to offer dialysis patients. A few commenters recommended that we continue the grandfather clause until the year 2015 to allow current non-MSWs who met the subpart U requirements to finish out their careers.

Response: According to the definition of "Qualified personnel" at § 405.2102, a non-masters degree social worker may serve as an ESRD social worker (under § 405.2102(f)(2), qualified personnel) when he or she "has served for at least 2 years as a social worker, 1 year of which was in a dialysis unit or transplantation program prior to September 1, 1976, and has established a consultative relationship with a social worker who qualifies under paragraph (f)(1) of this definition" (that is, has completed a course of study with

specialization in clinical practice at, and holds a masters degree from a graduate school of social work). This subpart U grandfather clause only applies to non-MSWs who have been practicing social work since 1974, and any ESRD social workers who do not have 2 years of experience prior 1976 must have a masters degree.

While we believe the number of non-masters-degree social workers still practicing over the past 32 years is small, we do not intend that these long-time employees should become unqualified for their jobs because of deletion of the "grandfather clause." In response to comments we will adopt the proposed "grandfather clause" and add the existing provision from subpart U to the final rule at § 494.140(d)(2) to read as follows: "Has served at least 2 years as a social worker, 1 year of which was in a dialysis unit or transplantation program prior to September 1, 1976, and has established a consultative relationship with a social worker who qualifies under § 494.140(d)(1) of this part." The grandfather clause may not be applied to social workers who do not meet the 1976 experience criterion. Bachelors-prepared social workers may function as assistants to the MSW. The MSW is the staff member who must satisfy these conditions for coverage.

Comment: A few commenters suggested that we eliminate the proposed § 494.140(d)(2) requirement, "Meets the practice requirements for social services in the State in which he or she is employed."

Response: Adherence to State scope-of-practice requirements is an appropriate minimum requirement for a federal health and safety regulation. This final rule supports compliance with State regulations. The final rule provision for meeting applicable scope-of-practice board and licensure requirements for dialysis facility personnel has been moved to the beginning of § 494.140 to avoid redundancy within the standards for each of the dialysis facility staff members.

Comment: Several commenters suggested that we add a social worker licensure requirement to § 494.140(d)(2).

Response: The proposed rule at § 494.20 required licensure for all staff. To prevent confusion regarding whether licensure is required under personnel qualifications, we have moved the requirement to the beginning of § 494.140, to read: "All dialysis facility staff must meet the applicable scope of practice board and licensure requirements in effect in the State in which they are employed."

Comment: Many social workers as well as some commenters who are not social workers suggested that a new social worker aide personnel standard be added to the final rule. The rationale given was that this new staff member could perform many of the clerical tasks (admissions, billing, transportation, transient patient paperwork, determining insurance coverage) often assigned to social workers, so that the social worker would be freed up to perform clinical social services, such as counseling, that would result in improved patient care and better outcomes. Many commenters stated this position should be required for dialysis facilities with more than 75 patients.

Response: This final rule requires each facility to have adequate staff to meet patient needs. Paragraph § 494.180(b)(1) applies to all dialysis staff, including social workers. The use of ancillary staff is not precluded by this regulation. Some dialysis facilities do employ staff to assist the social worker with clerical tasks, while other facilities may employ more than one social worker. Each facility should assess their staffing needs and determine appropriate staffing levels. While we agree that using an MSW to perform clerical tasks and manage patient financial information may not be the most effective or efficient use of trained and licensed professional clinical staff, we are not requiring that dialysis facilities employ social worker aides. We encourage dialysis facilities to use staff resources in the most effective and efficient manner to provide quality care to dialysis patients.

Comment: Many commenters suggested that the final rule state that MSWs could not be assigned non-MSW tasks. These commenters object to the number of clerical tasks that are assigned to social workers.

Response: Dialysis facilities have the flexibility to assess facility-staffing needs and use staff as necessary. This final rule requires social workers to provide appropriate clinical services to dialysis patients under the "Patient assessment" and "Patient plan of care" conditions for coverage (§ 494.80 and § 494.90 respectively). The social worker must also participate in the facility QAPI program (§ 494.110). The facility must have a sufficient social services staff to meet dialysis patient needs as required at § 494.180(b)(1), which applies to all dialysis staff, including social workers. We would expect that any tasks assigned to the social worker would not compromise the social worker's ability to meet his or her obligations to patients and these conditions for coverage. We have not

added restrictions regarding staff assignments to this final rule.

Comment: Many commenters recommended that we specify a maximum MSW caseload or an MSW-to-patient ratio.

Response: As discussed above, adequate staffing is addressed under the "Governance" condition for coverage at § 494.180(b). Some states have implemented staff-to-dialysis patient ratios, and we defer to State provisions on this issue.

Nephrology social workers should adhere to the professional standards of practice for social workers. The National Association of Social Workers published "NASW Standards for Social Work Practice in Health Care Settings" in 2005. These professional practice standards may be found at <http://www.socialworkers.org/practice/standards/NASWHealthCareStandards.pdf>. The National Association of Social Workers and Council of Nephrology Social Workers jointly published "NASW/NKF Clinical Indicators for Social Work and Psychosocial Service in Nephrology Settings" in October 1994, which may be found at <http://www.socialworkers.org/practice/standards/nephrologysettings.asp>. In addition, the NKF has published the 2003 Council of Nephrology Social Workers "Standards of Practice for Nephrology Social Work." These standards of practice include guidelines for clinical practice, a description of the nephrology social work role, as well as staffing information.

Comment: A commenter suggested that the final rule state that different facilities can share the same renal dietitian or social worker.

Response: Neither part 405, subpart U nor the proposed rule precludes facility sharing of renal dietitians and social workers, as long as each facility has adequate staff and staff hours to meet patient needs and provide care consistent with professional practice standards. Please refer to § 494.180(b)(1), which applies to all dialysis staff.

Comment: We received a very large number of comments on § 494.140(e), addressing patient care dialysis technician qualifications. Commenters generally supported the addition of technician qualifications and training requirements to the conditions for coverage.

More than 20 commenters, including the National Kidney Foundation, American Association of Kidney Patients, American Kidney Fund, CNSW, some of the ESRD Networks, the National Association of Nephrology

renal dialysis facility may not exceed 8 months in any 12-month period.

(b) *Standard: Service limitation.*

Special purpose renal dialysis facilities are limited to areas in which there are limited dialysis resources or access-to-care problems due to an emergency circumstance. A special purpose renal dialysis facility may provide services only to those patients who would otherwise be unable to obtain treatments in the geographic locality served by the facility.

(c) *Standard: Scope of requirements.*

(1) *Scope of requirements for a vacation camp.* A vacation camp that provides dialysis services must be operated under the direction of a certified renal dialysis facility that assumes full responsibility for the care provided to patients. A special purpose renal dialysis facility established as a vacation camp must comply with the following conditions for coverage—

- (i) Infection control at § 494.30;
- (ii) Water and dialysate quality at § 494.40 (except as provided in paragraph (c)(1)(viii) of this section);
- (iii) Reuse of hemodialyzers at § 494.50 (if reuse is performed);
- (iv) Patients' rights and posting of patients' rights at § 494.70(a) and § 494.70(c);
- (v) Laboratory services at § 494.130;
- (vi) Medical director responsibilities for staff education and patient care policies and procedures at § 494.150(c) and § 494.150(d);
- (vii) Medical records at § 494.170; and
- (viii) When portable home water treatment systems are used in place of a central water treatment system, the facility may adhere to § 494.100(c)(1)(v) (home monitoring of water quality), in place of § 494.40 (water quality).

(2) *Scope of requirements for an emergency circumstance facility.* A special purpose renal dialysis facility set up due to emergency circumstances may provide services only to those patients who would otherwise be unable to obtain treatments in the geographic areas served by the facility. These types of special purpose dialysis facilities must comply with paragraph (c)(1) of this section and addition to complying with the following conditions:

- (i) Section 494.20 (compliance with Federal, State, and local laws and regulations).
- (ii) Section 494.60 (physical environment).
- (iii) Section 494.70(a) through section 494.70(c) (patient rights).
- (iv) Section 494.140 (personnel qualifications).
- (v) Section 494.150 (medical director).
- (vi) Section 494.180 (governance).
- (d) *Standard: Physician contact.* The facility must contact the patient's

physician, if possible, prior to initiating dialysis in the special purpose renal dialysis facility, to discuss the patient's current condition to assure care provided in the special purpose renal dialysis facility is consistent with the patient plan of care (described in § 494.90).

(e) *Standard: Documentation.* All patient care provided in the special purpose facility is documented and forwarded to the patient's usual dialysis facility, if possible, within 30 days of the last scheduled treatment in the special purpose renal dialysis facility.

§ 494.130 Condition: Laboratory services.

The dialysis facility must provide, or make available, laboratory services (other than tissue pathology and histocompatibility) to meet the needs of the ESRD patient. Any laboratory services, including tissue pathology and histocompatibility must be furnished by or obtained from, a facility that meets the requirements for laboratory services specified in part 493 of this chapter.

Subpart D—Administration

§ 494.140 Condition: Personnel qualifications.

All dialysis facility staff must meet the applicable scope of practice board and licensure requirements in effect in the State in which they are employed. The dialysis facility's staff (employee or contractor) must meet the personnel qualifications and demonstrated competencies necessary to serve collectively the comprehensive needs of the patients. The dialysis facility's staff must have the ability to demonstrate and sustain the skills needed to perform the specific duties of their positions.

(a) *Standard: Medical director.*

(1) The medical director must be a board-certified physician in internal medicine or pediatrics by a professional board who has completed a board-approved training program in nephrology and has at least 12-months of experience providing care to patients receiving dialysis.

(2) If a physician, as specified in paragraph (a)(1) of this section, is not available to direct a certified dialysis facility another physician may direct the facility, subject to the approval of the Secretary.

(b) *Standard: Nursing services.*

(1) *Nurse manager.* The facility must have a nurse manager responsible for nursing services in the facility who must—

- (i) Be a full time employee of the facility;
- (ii) Be a registered nurse; and
- (iii) Have at least 12 months of experience in clinical nursing, and an

additional 6 months of experience in providing nursing care to patients on maintenance dialysis.

(2) *Self-care and home dialysis training nurse.* The nurse responsible for self-care and/or home care training must—

- (i) Be a registered nurse; and
- (ii) Have at least 12 months experience in providing nursing care and an additional 3 months of experience in the specific modality for which the nurse will provide self-care training.

(3) *Charge nurse.* The charge nurse responsible for each shift must—

(i) Be a registered nurse, a licensed practical nurse, or vocational nurse who meets the practice requirements in the State in which he or she is employed;

(ii) Have at least 12 months experience in providing nursing care, including 3 months of experience in providing nursing care to patients on maintenance dialysis; and

(iii) If such nurse is a licensed practical nurse or licensed vocational nurse, work under the supervision of a registered nurse in accordance with state nursing practice act provisions.

(4) *Staff nurse.* Each nurse who provides care and treatment to patients must be either a registered nurse or a practical nurse who meets the practice requirements in the State in which he or she is employed.

(c) *Standard: Dietitian.* The facility must have a dietitian who must—

(1) Be a registered dietitian with the Commission on Dietetic Registration; and

(2) Have a minimum of 1 year professional work experience in clinical nutrition as a registered dietitian.

(d) *Standard: Social worker.* The facility must have a social worker who—

(1) Holds a master's degree in social work with a specialization in clinical practice from a school of social work accredited by the Council on Social Work Education; or

(2) Has served at least 2 years as a social worker, 1 year of which was in a dialysis unit or transplantation program prior to September 1, 1976, and has established a consultative relationship with a social worker who qualifies under § 494.140(d)(1).

(e) *Standard: Patient care dialysis technicians.* Patient care dialysis technicians must—

(1) Meet all applicable State requirements for education, training, credentialing, competency, standards of practice, certification, and licensure in the State in which he or she is employed as a dialysis technician; and

(2) Have a high school diploma or equivalency;

Johnson, Katie

From: Reichard, Tom
Sent: Tuesday, July 12, 2011 1:22 PM
To: Johnson, Katie
Subject: FW: ESRD Regulations
Attachments: conditions of participation 2008.pdf

Tom Reichard, Executive Director
State Committee for Social Workers
State Committee of Dietitians
Office of Endowed Care Cemeteries
Interior Design Council

From: Nugent, William
Sent: Tuesday, July 12, 2011 8:36 AM
To: Reichard, Tom
Subject: ESRD Regulations

Hello Tom, here is the regulations that we use when doing the CMS surveys in the ESRD facilities. Look at V691 on page 270 it addresses the Standard for the Social Worker and qualifications. The rule is on the left side and the interpretive guidance is on the right. I hope this helps the committee understand the regulations a little better instead of the comment period on the regulations. I am fine no matter which way the committee goes, I am not sure it this may create a hardship on the MSW if they have to be LCSW or a LMSW. Let me know what the committee thinks.
Thanks,
Bill

8/23/2011

TAG NUMBER	REGULATION	INTERPRETIVE GUIDANCE
V688	(4) <i>Staff nurse.</i> Each nurse who provides care and treatment to patients must be either a registered nurse or a practical nurse who meets the practice requirements in the State in which he or she is employed.	An LPN/LVN cannot be the only licensed person in a dialysis facility while patients are on dialysis. Refer to V759 which requires a registered nurse to be present whenever in-center patients are being treated.
V689	(c) <i>Standard: Dietitian.</i> The facility must have a dietitian who must— (1) Be a registered dietitian with the Commission on Dietetic Registration; and	The Commission on Dietetic Registration is the credentialing agency for the American Dietetic Association. Dietitians working in dialysis must have evidence of registration with that organization.
V690	(2) Have a minimum of 1 year professional work experience in clinical nutrition as a registered dietitian;	The registered dietitian must have one year of professional work experience in clinical nutrition after registration as a dietitian. Experience in clinical nutrition as an intern (prior to registration) would not count toward this requirement, nor would foodservice experience after registration as a dietitian meet this requirement.
V691	(d) <i>Standard: Social worker.</i> The facility must have a social worker who— (1) Holds a master's degree in social work with a specialization in clinical practice from a school of social work accredited by the Council on Social Work Education; or (2) Has served at least 2 years as a social worker, 1 year of which was in a dialysis unit or transplantation program prior to September 1, 1976, and has established a consultative relationship with a social worker who qualifies under § 494.140 (d)(1).	The social worker must have a master's degree in social work from a college or university that is accredited by the Council on Social Work Education (CSWE). The CSWE website database lists accredited masters level social work degree programs. The Association of State Boards of Social Work website has links to State regulations and rules for social work practice in each State. The curriculum of masters-level programs in schools accredited by the CSWE includes courses in human behavior, family dynamics, diagnosis, mental health treatment, conflict management, and ethics. Therefore, any one whose degree is from a school accredited by the CSWE is presumed to have a "specialization in clinical practice." Licensure requirements for master-prepared social workers in clinical practice vary from state to state. The masters prepared social worker

TAG NUMBER	REGULATION	INTERPRETIVE GUIDANCE
V692	<p>(e) <i>Standard: Patient care dialysis technicians.</i> Patient care dialysis technicians must—</p> <p>(1) Meet all applicable State requirements for education,</p>	<p>must meet the licensure requirements in the state of practice. Refer to V681.</p> <p>Staff without master's degrees in social work, including bachelor's prepared social workers, may function as assistants under the supervision of the qualified social worker and provide services such as assisting with transportation arrangements; providing information and helping patients apply for Medicare, Medicaid and other insurance benefits to assure payment for care; and locating resources to assist in payment for adequate nutrition, housing, and medications. Only masters-prepared social workers may do assessments, develop psychosocial plans of care, provide counseling to patients and families, and participate as the social worker in the facility's QAPI program.</p> <p>The grandfather clause at (2) applies to very few social workers, as it only applies to those social workers who have worked in dialysis or transplant facilities since September 1, 1975 and who had at least two years of social work experience on September 1, 1976 when the original ESRD Conditions for Coverage became effective. The social worker who "qualifies" as a social worker through this grandfather clause must have a "consultative relationship" with a qualified social worker. A "consultative relationship" requires a written agreement outlining the supervision that will be provided by the masters-prepared social worker. Since the professional responsibility for services lies with the masters-prepared social worker, this agreement needs to be consented to and signed by both parties. Having the masters-prepared social worker co-sign social service medical record entries made by the other social worker is not sufficient to meet the consultative relationship requirement.</p> <p>A "patient care (dialysis) technician" (PCT) means any person who provides direct care to patients and who is not classified as another professional, e.g., nurse, dietitian, or social worker. A biomedical</p>