

Delivery of Dialysis Treatment
Within the
Long Term Care Facility

ESRD Special Project

ESRD Special Study

Delivery of Dialysis Treatment Within the Long-Term Care Facility

Project Report

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Special Project on the Delivery of Dialysis Treatment
Within the Long-Term Care Facility

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1.0 Executive Summary

The Centers for Medicare & Medicaid Services (CMS) contracted with The Renal Network, Inc. (End Stage Renal Disease (ESRD) Network 9/10) in collaboration with The ESRD Network of New England, Inc (Network 1) for a special project to convene a Technical Expert Panel (TEP) to develop recommendations for providing dialysis in the long-term care facility. The need for more information focusing on quality of care, financial responsibilities and structural issues was identified following a meeting of renal stakeholders in June 2004. Convening a nationally focused Technical Expert Panel to develop recommendations for providing dialysis in a nursing home that ensures quality of care for these patients represents an important first step in benefiting ESRD patients residing in LTC facilities. The model defined in this project will begin to provide the benchmark for quality dialysis services within the LTC facility.

The contract period was from July 1, 2005 to June 30, 2006. The contract specified nine key tasks to be completed within the 12-month timeframe.

Task	Task Requirement
1	Submit a detailed work plan to CMS
2	Conduct a focused literature review
3	Identify a Technical Expert Panel
4	Arrange TEP meeting
5	Facilitate and Document TEP discussions
6	Document proposed recommendations
7	Obtain input from renal community
8	Prepare Final Report
9	Obtain TEP evaluations

2.0 Literature Review

2.1 Methods

A MEDLINE search was conducted to review the literature to gain an understanding of the current knowledge of the care and dialysis of ESRD patients in the nursing home. The MESH term “dialysis” was combined with nursing

home, skilled nursing facility, long term care facility, and hospice. The table below lists total number of citations for each combination, number of unique citations, and number of possibly relevant citations based on abstract review. There was substantial overlap between search results.

Search Terms	Total Citations	Cited in Other Search	Possibly Relevant
Nursing home and dialysis	54	0	39
Extended care facility and dialysis	13	11	1
Skilled nursing facility and dialysis	11	11	0
Long term care facility and dialysis	12	4	4
Hospice and dialysis	24	1	9

Each possibly relevant article was retrieved and references were reviewed to yield additional relevant articles. All relevant articles were abstracted and categorized into a customized database. Current ESRD program requirements were obtained from documents available on the CMS website and from the Code of Federal Regulations (CFR).

Note: For convenience, the term long-term care (LTC) facility will be used throughout this document to represent the terms skilled nursing facility, long-term care facility, extended care facility, and nursing home.

2.2 Project Background

There are increasing numbers of dialysis patients throughout the United States being dialyzed within LTC facilities, however there are no officially recognized models of treatment. A conference hosted by Network 9/10 in June 2004 resulted in the successful collaboration of dialysis providers, state agencies, Networks and CMS and identified the need for a structure of quality management for patients receiving dialysis in a LTC facility. This conference only touched on describing the parameters for a model delivery system for dialysis in residential settings.¹

Knowledge of dialysis in the LTC facility would benefit the ESRD program and its patients. The goal of this project was to develop recommendations for providing dialysis in a LTC facility environment that ensures quality of care for these patients.

2.3 The Need for Dialysis for LTC Facility Residents

There were approximately 1.6 million individuals residing in nursing homes in 1999.² The 2004 USRDS Annual data report estimated that in 1999, 16,408 point prevalent ESRD patients resided in LTC facilities. This represents 4.8% of ESRD patients.³ This appears to be a growing trend. Data from a study of ESRD patients dialyzed in Network 5 between April 1990 and December 1991 suggested that a minimum of 1000 to 1500 ESRD patients reside in nursing homes at any given time. The authors estimated that 2000 to 3000 ESRD patients enter a nursing home in the United States each year.⁴ Elderly individuals without ESRD recruited from hospital geriatric wards and nursing homes were surveyed to determine their desire for dialysis treatment should they need it. Eighty-three percent of nursing home residents indicated they would want dialysis if it became necessary and 75% said they would prefer home dialysis.⁵ The need for dialysis services to LTC facility

residents is likely to grow as both the general and ESRD populations continue to age.⁶⁻¹⁰

2.4 The Need for Staff-Assisted Dialysis Within a LTC Facility Setting

LTC facility patients may be transported to hospital-based or freestanding dialysis facilities for treatment or obtain self-dialysis treatment through a home program. Transporting LTC facility patients to off-site dialysis facilities is burdensome to both patients and LTC facilities. LTC patients are often frail, sensitive to temperature variations, and uncomfortable while being transported to dialysis facilities.^{1, 11} Patients routinely miss meals, medications, rehabilitation services, resident activities, and other services provided by the LTC facility due to the length of dialysis treatment, time associated with preparing for transfer to and from the dialysis facility, and actual transportation time.¹ Some patients are unable to be transported due to their complex medical needs such as ventilator dependency.

Transporting LTC facility patients to off-site dialysis facilities is costly. CMS recognizes the difficulty in transporting LTC facility patients and therefore allows a LTC facility to be considered a patient's home for the purpose of payment of self-dialysis.^{11, 15} However, given that 57.5% of the incident nursing home ESRD patients in 1999-2000 had moderately to severely impaired decision-making ability, more than 44 percent were unable to walk independently and 25% were unable to transfer from bed to chair³, it seems likely that the majority of LTC facility patients are unable to perform self-dialysis.

2.5 Current ESRD Program

2.5.1 Approved Facility Types

The current ESRD program is defined in the Code of Federal Regulations, Title 42, Part 405, Subpart U Conditions for Coverage of Suppliers of End-Stage Renal Disease (ESRD) Services. The ESRD program is comprised of five CMS approved facility types according to §405.2102 of the Conditions for Coverage including the renal transplantation center, renal dialysis center, renal dialysis facility, self-dialysis unit, and special purpose renal dialysis facility.¹⁶

A *renal dialysis center* is defined as a hospital-based unit that furnishes the full spectrum of diagnostic, therapeutic, and rehabilitative services including inpatient dialysis to ESRD patients. A renal dialysis center may provide inpatient or outpatient dialysis either directly using its own staff and employees or under arrangement. A *renal dialysis facility* is approved to furnish dialysis services directly to ESRD patients using its own staff and employees, or through individuals under direct contract to furnish such services for the facility (not through “agreements” or “arrangements”). A *self-dialysis unit* is part of an approved renal dialysis program that furnishes self-dialysis services. Self-dialysis is defined as dialysis provided by an ESRD patient who has completed an appropriate course of self-dialysis training. Lastly, a *special purpose renal dialysis facility* furnishes dialysis at special locations on a short-term basis to a group of patients who are unable to obtain treatment in the geographical area. The locations must be special rehabilitative (including vacation) locations serving ESRD patients temporarily

residing there, or locations in need of ESRD facilities under emergency conditions.¹⁶

Inpatient dialysis is defined as dialysis furnished to an ESRD patient on a temporary basis in a hospital due to medical necessity. *Outpatient dialysis* is defined as dialysis provided on an outpatient basis at either a renal dialysis center or facility and includes *staff-assisted dialysis* or *self-dialysis*. *Self-dialysis* and *home dialysis training* is defined as a program that trains patients and/or their family member or caregiver to perform self-dialysis or home dialysis with little or no professional assistance. Services to home dialysis patients are expected to be at least equivalent to those provided to in-center patients.¹⁶ A skilled nursing facility may be considered a patient’s home for self-dialysis.¹⁵

2.5.2 Billing Considerations

The composite rate payment system is used to pay for outpatient maintenance dialysis services in hospital-based centers and freestanding facilities. The composite rate system is also used for Method I payment for home dialysis services. Under the composite rate system, the dialysis facility must furnish all necessary dialysis services, equipment, and supplies for one set payment. Physician patient care services, certain laboratory services, and drugs are billed separately.¹⁵

Home patients must complete form CMS 382 upon initiating home dialysis. The form requires patients to indicate the location where home dialysis will be provided (private residence, skilled nursing facility, or nursing home) and to choose a billing method (Method I or II). Method I payment utilizes the composite rate system discussed above. Method II payment pays suppliers directly for supplies and

equipment. A patient may use only one Method II supplier for all equipment and supplies. The supplier must have a written agreement with a Medicare approved dialysis facility to serve as a provider for backup, support, and emergency dialysis services. The dialysis facility bills separately for any backup, support, or emergency dialysis services provided. There are payment limits for support services. Support services include, but are not limited to: monitoring of the patient's home adaptation, including home visits; consultation for the patient by qualified social worker and dietitian; maintaining a medical record-keeping system; maintaining and submitting all required documentation to the ESRD network; assuring appropriate water quality; assuring supplies are ordered on an on-going basis; arranging for all ESRD laboratory testing; testing and appropriate water treatment for dialysis; monitoring the functioning of dialysis equipment; documentation of Method II supplier provided items and services in the medical record; written plans of care; and all other dialysis services required under the ESRD Conditions for Coverage. If the patient receives home CAPD, the facility must also provide observation of the patient performing CAPD and ongoing training necessary to assure proper administration of treatment; documenting presence or absence of peritonitis and related treatment; monitoring of catheter exit site; changing the connection tubing. When a patient receives dialysis in a LTC facility, the dialysis services are excluded from the LTC facility's consolidated billing and home dialysis services are billed by either the ESRD provider facility or supplier, depending on the payment method selected.¹⁵

Home dialysis is based on the assumption that the patient and/or a family member or caregiver has received thorough training by a qualified home training nurse and the patient, family member or caregiver will administer the treatment.^{16, 17} There is no

payment provision to reimburse a paid assistant.^{11, 13} Also, reimbursement for home dialysis is based on one machine being used for only one patient.¹⁸

2.5.3 Back-up Facility Considerations

As stated above, a Method II supplier must have a written agreement with a back-up dialysis facility to provide backup, support, and emergency dialysis services (see section 2.5.2 for details regarding required dialysis support services). The back-up provider is required to be within reasonable driving distance from the patient's home. If the Method II supplier is unable to enter into an agreement with a backup provider located within a reasonable distance from the patient's home, then the supplier may use a provider outside the geographical area if the backup provider enters into a written agreement with a local dialysis facility to provide in-facility dialysis should it become necessary. In this case, the out-of-area back-up provider will provide dialysis support services, coordinate care, and conduct frequent home visits. The signed agreement must detail how these support services will be provided.¹⁵

2.5.4 Staffing Considerations

Conditions for Coverage specify that one currently licensed health professional (physician, RN, or LPN) experienced in providing ESRD care is on duty (present and available) during dialysis. Qualified home training nurses are required to have 12 months of clinical nursing experience and 6 months of ESRD experience. Three months of that experience must be in ESRD self-care training.¹⁶

Conditions for Coverage specify requirements for "qualified" social workers and dietitians.¹⁶ The LTC facility's social worker and dietitian may not meet the definition of "qualified".

2.5.5 Facility Oversight Considerations

Home patients are considered as receiving care through an approved dialysis facility; therefore ESRD Networks are required to monitor the patients through data collection and quality improvement activities and to process grievances. LTC surveyors do not survey dialysis services provided on site at LTC facilities; this currently falls under the purview of ESRD surveyors, who may not know that dialysis is occurring within a LTC facility. LTC surveyors may generate a complaint for the ESRD surveyors to investigate if potential problems are noted during their LTC survey process.¹⁸

2.5.6 Dialysis and Hospice

Hospice care is underutilized by ESRD patients.^{19, 20} If ESRD is the reason for the terminal illness, the hospice provider must absorb the cost of dialysis treatments within their per diem payment.^{19, 21} Because the hospice per diem rate is insufficient to cover the cost of dialysis treatments, most hospice programs will not accept actively dialyzing patients if their terminal illness is due to ESRD.²⁰ If a patient withdraws from dialysis, he/she is a candidate for hospice because death is imminent. Hospice is also an option for ESRD patients receiving dialysis if they have a terminal illness other than ESRD and a life expectancy less than 6 months. If the terminal illness is not related to ESRD, a patient may receive covered services from both the ESRD and hospice Medicare benefits.^{19, 21}

2.6 Proposed Conditions for Coverage

On February 4, 2005, CMS published the proposed rule to update the Conditions for Coverage for End-Stage Renal Disease Facilities in the Federal Register. Comments regarding the proposed conditions were accepted until May 5, 2005. The proposed Conditions for Coverage contain a few changes related to home dialysis and dialysis provided in the LTC facility. §494.100(a) specifies that

home training can only be provided by a dialysis facility certified to provide home dialysis services. Therefore durable medical equipment (DME) companies will continue to be prohibited from providing home dialysis training. The training program content is more fully defined in the Proposed Conditions compared to the current Conditions.¹¹

A summary of additional proposed changes related to home treatment follows.

§494.100(b)(2) requires collection and review of patient data at least every two months. In §494.100(c)(1)(iii) CMS would require the use of the same clinical performance measures for home dialysis patients as used for in-center patients.

§494.100(c)(1)(v) requires onsite evaluation of the water system for home hemodialysis patient. §494.100(c)(1)(vii) requires facilities to plan and arrange for backup dialysis services.

§414.330(a)(2)(ii)(C) requires DME companies to report all services and items supplied to the patient to the dialysis facility every 30 days.^{1, 11}

CMS requested input on whether current home dialysis regulations should be modified to protect hemodialysis patients receiving dialysis within a LTC facility, and ways to do so. Additionally, CMS clarified the requirement that dialysis facilities are to be responsible for coordinating and providing patient care, rather than DME companies. CMS proposed requiring a written agreement between the LTC facility, the dialysis facility, and DME company (if applicable). CMS also requested input to determine if home dialysis services provided in a LTC facility must meet all of the proposed Conditions for Coverage. CMS solicited input regarding the requirement that a registered nurse (RN) is on the premises and available whenever in-center patients receive treatment, and if the RN can be a LTC facility RN trained by the ESRD facility or a RN provided by the dialysis facility. If a LTC facility RN is allowed,

then limits on his/her other duties while patients are being dialyzed may be necessary. The competency and training requirements for the LTC facility RN must also be determined. CMS also requested comments on whether they should require specific patient to staff ratios for dialysis of patients in this setting.¹¹

Public comments to the proposed Conditions for Coverage are posted on the CMS website. Many comments stated that home dialysis is inappropriate for most residents in the LTC setting and urged CMS to consider the development of a separate definition for the provision of dialysis within LTC facilities.²²⁻²⁹ Commenters reported that staff-assisted dialysis in the LTC facility is needed, but it must be economically feasible and provide reimbursement for all staff who provide the treatment.²⁵⁻²⁹ American Association of Kidney Patients (AAKP) stated that staff-assisted dialysis services in the LTC setting may be more costly due to the need for more intense services,²² but other commenters suggested that transportation savings would be realized.^{26, 27, 29}

Both AAKP and the National Kidney Foundation (NKF) acknowledged barriers to access to LTC facility care.^{22, 23} NKF commented that the increased requirements for LTC facilities will cause LTC facilities to either refuse admission of dialysis patients or “fall short in meeting their responsibilities”.²³ AAKP stated that increased payment for LTC facility-based dialysis may reduce barriers to access to care.²²

The need for coordination of care was discussed by the commenters. The American Health Care Association (AHCA) stated that CMS must delineate the responsibilities between the ESRD provider and the LTC facility and clarify how the regulations for each party will interface. The areas of infection control, staff responsibility, physician communication, coordination of care and

responsibilities in the event of emergency evacuation were specific examples cited.²⁵ The Advocate of Not-For-Profit Services for Older Ohioans (AOPHA) requested clarification regarding who should be responsible for arranging and paying for the dialysis caregiver services for patients in LTC facilities since friends or relatives may not be available to provide services. AOPHA reported that ESRD or DME providers claim to be prohibited from providing the caregiver service for free due to fraud and abuse laws. As a result, LTC facilities may arrange for the services. AOPHA expressed concern that LTC facilities may be subject to the federal anti-kickback statute (42 USC 1320a-7a(a)(5); 42 CFR 1003.102(1)(13) if they provide the services for free. However, Medicaid patients would be unable to personally pay for the cost of caregiver services.³⁰ The California Dialysis Council stated that the current recommendation for a written document describing the relationship between the LTC facility and ESRD provider is sufficient to define the coordination of care arrangements between parties.³¹ One commenter recommended monthly joint provider meetings to review patients.³²

Several commenters from hospitals and hospital associations asserted that CMS is authorized under Sections 1881(b)(1) and 1888(e)(2)(A)(i)(II) to pay LTC facilities the composite rate for dialysis services under Part B.²⁶⁻²⁹ These organizations propose three payment options: 1) ESRD provider provides dialysis services at LTC facility and is directly paid the composite rate; 2) LTC facility provides dialysis services and receives separate payment for services outside PPS for Part A; and 3) LTC facility provides dialysis services, without separate ESRD licensure, for beneficiaries who have exhausted Part A benefits.^{28, 29} The California Hospital Association requested clarification to the questions of can a LTC facility prevent a patient from choosing Method II and can

they limit patients to specific dialysis providers or DME providers?²⁸

Concerns regarding the clinical and legal liability to LTC facilities for providing home dialysis in the LTC facility were discussed by AHCA and AOPHA.^{25, 30}

Commenters generally agreed that it is appropriate to require a RN be on the premises when dialysis is performed^{25, 28, 29}, although AOPHA stated that administration of hemodialysis, not peritoneal dialysis, requires direct supervision by a RN.³⁰ A current LTC facility dialysis provider stated that an experienced licensed practical nurse (LPN) is acceptable, and that a designated RN be on call at all times when dialysis is being provided.³² AHCA recommended that the RN present and providing supervision during the dialysis treatments not be responsible for other LTC residents during dialysis treatments. AHCA noted that nurse recruitment is problematic for both LTC and ESRD providers due to the nursing shortage, so adequate reimbursement will be required.²⁵

Additional staff-related comments included the need to specify training requirements, use of a dedicated dialysis facility nurse, infection control nurse, and LTC facility-based Advanced Practice Nurse (APN).²⁵ It was recommended that LTC facility staff be required to be trained in the care of ESRD patients and that dialysis facility staff should monitor its own staff and not be responsible for monitoring LTC facility staff. It was suggested that a minimum of one year of hemodialysis experience be required for the licensed nurse.³² Commenters stated that CMS should not mandate specific patient-to-caregiver ratios.^{28, 29}

Lastly, commenters requested CMS provide guidance regarding what patients are appropriate for a LTC facility dialysis program.^{25, 32} It was suggested that the program be reserved for LTC residents who should not be transported to an outside ESRD facility²⁵, yet another commenter

advised that patients dialyzing in the LTC facility be capable of being transported to and safely dialyzed in an outpatient dialysis facility in the event back-up dialysis services are required.³²

2.7 LTC Facility ESRD Patient Outcomes

As noted in section 2.3, 4.8% of ESRD patients resided in nursing homes in 1999.³ No information was provided to describe where their dialysis was provided (off-premise dialysis in approved dialysis facility vs. home dialysis with treatment provided in the LTC facility directly). Networks (and therefore USRDS) cannot currently distinguish patients dialyzing in LTC facilities from home patients.³³ Therefore, quality oversight by Networks for these patients cannot occur. In a letter to The Renal Network, Inc. from CMS, it was noted that dialysis organizations are requesting data be suppressed on the Dialysis Facility Compare website for patients receiving dialysis in the LTC facility setting, billed through the home program methods. The Renal Network, Inc. responded,

“ESRD providers must take responsibility for the outcomes of all of their patients. If an ESRD provider enters into an agreement with a DME or nursing home to provide dialysis treatment on-site at the nursing home and allows the provider number to be used for billing for these patients, the provider needs to realize that oversight of care for those patients remains with the ESRD provider. Patients receiving treatment within the nursing home setting are entitled to the same treatment as those being

treated within the dialysis facilities...”

One published article contained data regarding outcomes of patients residing in LTC facilities who received hemodialysis treatments (86%) at in-center dialysis facilities (not in the LTC facility setting) or peritoneal dialysis (13%). Three, six, and twelve-month survival rates from date of LTC facility admission were 74%, 56%, and 42% respectively. Increasing age, poorer activity of daily living score, and peritoneal dialysis were independent survival risks.⁴ Yearly survival rates from date of first dialysis between years one and five were 83%, 63%, 45%, 35%, and 24% per year. These percentages are similar to that of the general dialysis population⁴ The appropriate benchmark for dialysis patient survival rates from date of LTC facility admission is unknown.

It may be useful to differentiate patients as being admitted for short- term rehabilitation vs. permanent placement in the LTC facility. Length of stay may be an appropriate measure for patients admitted for short term rehabilitation.³⁴

There have been seven published articles regarding outcomes of patients receiving peritoneal dialysis (PD) in LTC facilities (see Appendix A).^{6, 7, 10, 35-38} Two of the articles referred to the same dataset.^{10, 38} The PD home programs analyzed varied with one dialysis facility referring patients to either one LTC facility or to many. Peritonitis rates published in 5 papers varied from 0.61 to 2.43 episodes/patient-year.^{6, 7, 10, 35, 37, 38} Exit site infection rate, published in only two studies, ranged from 0.2 episodes/patient-year to 0.5 episodes/patient-year.^{6, 35} Hospitalization rates reported in 3 studies ranged from 18.5 to 44.6 days/patient-year.^{6, 7, 35} In one study, patients who switched modality to hemodialysis had better survival rates.⁶

2.8 Other Considerations

The rate of LTC facility placement is lower for ESRD patients than the general population, suggesting barriers to LTC facility placement such as transportation, financial difficulties, and a general reluctance of LTC facilities to admit ESRD patients.⁴ The inability to provide LTC facility-based dialysis treatment may delay hospital discharge and reduce effectiveness of rehabilitation programs.³⁹

There are practical advantages to allowing LTC facility dialysis areas to be treated as an extension of an existing dialysis facility. If a dialysis facility is built within a LTC facility, it must conform to all LTC facility regulations. Additionally, adding a dialysis facility to an older LTC facility may require it to upgrade its systems throughout the facility to meet current code, making it cost prohibitive. It may be possible to build a freestanding facility adjacent to the LTC facility for less money,⁴⁰ but a sufficient number of patients would be needed to make building a full unit cost effective.

The Renal Network, Inc. received comments from the California Dialysis Council (CDC) in preparation for the TEP meeting. The CDC recommended that the TEP discuss coverage for dialysis in a wide range of institutional settings including SNFs, intermediate care facilities, LTC facilities, long term acute care centers, comprehensive outpatient rehabilitation facilities, and hospices. They also recommended inclusion of non-ESRD patients who require dialysis on a temporary basis (such as in acute renal failure). CDC stated that patients requiring such care in a lower-cost setting such as a SNF are unable to obtain this care, and thus the healthcare system pays excessively for their care within the acute hospital setting. CDC advised creating a program separate from the home dialysis program. The organization suggested that most patients receiving dialysis in institutional settings will have already been dialysis patients, and therefore already have long-term programs,

patient care plans, etc. They requested avoiding duplicative requirements for patients who are in the alternate dialysis setting on a temporary basis. The CDC advised that special coding be created to allow identification of the method of dialysis being performed in the alternate site facility, and to use coding to distinguish between ESRD and non-ESRD patients. They also advised creating a coding solution to reflect patient acuity (such as a code for dialyzing ventilator-dependent patients).⁴¹

2.9 National Renal Administrators Association Recommendations

In February 2003, the National Renal Administrators Association (NRAA) published a position paper on home dialysis for nursing home residents. The NRAA supported the use of home hemodialysis for LTC facility patients on LTC facility premises and encouraged CMS to ensure that the services not become cost prohibitive, and therefore limit availability. The position paper provided specific staffing, support service, facility, and hospital coverage recommendations. Benefits to patients for LTC facility-based hemodialysis included avoidance of the physical and emotional strain of transportation to a dialysis facility, missed meals, and missed resident activities. Medicaid savings were estimated at \$156 million per year in saved transportation costs.¹

The NRAA explicitly opposed defined staffing ratios due to the potential economic burden. They recommended all staff have a minimum of two years prior dialysis experience. NRAA suggested a registered nurse (RN) with at least two years dialysis experience supervise all on-site staff (licensed practical nurses or dialysis technicians) and that the RN be accessible at all times while dialysis treatments are being administered. The RN would be responsible for all initial patient assessments, staff training, and be present

on-site at least once each month. The RN should also participate in care planning meetings as specified in the Conditions for Coverage.¹

The NRAA recommended social workers and dietitians with ESRD patient experience provide services to the dialysis patients. These clinicians could work directly for the nursing home (if they had adequate ESRD experience) or be affiliated with the backup dialysis facility.¹

The LTC facility should have an arrangement with a medical director of an approved dialysis facility or home program. The medical director would be responsible for ensuring appropriate care to patients and other requirements according to the Conditions for Coverage. The position paper recommended that each LTC facility have a backup agreement with a nearby Medicare-approved in-center dialysis facility in case the approved home dialysis provider is unable to provide treatments. They also recommended each LTC facility have an agreement with a nearby hospital to allow admission of hemodialysis patients when needed.¹

The NRAA opposed any requirement that the area within the LTC facility set up to provide dialysis be certified as a dialysis facility. Each individual LTC facility is likely to dialyze only a few patients, making certification cost prohibitive. Instead, they advocated the LTC facility-based dialysis services be established as an extension of a Medicare-certified ESRD home program. The NRAA supported the use of a central area within the LTC facility to provide dialysis services to multiple patients, but did not go so far as to recommend multiple patients share dialysis machines.¹

2.10 TRN Dialysis in Nursing Homes Conference

In June 2004, The Renal Network, Inc. (TRN) convened a meeting of 27

representatives from CMS, The Renal Network Inc., the Illinois Department of Public Health, Fresenius Medical Care, Gambro Healthcare, and Circle Medical Management to discuss dialysis in the LTC facility setting. Discussion focused on the provision of hemodialysis. Attendees expressed that there is a need for hemodialysis within LTC facilities and that the number of patients requiring this service is likely to expand. Attendees recommended that a new model for service, dubbed “Method 3”, be developed with its own set of regulations. Discussion at the meeting explored staffing, equipment, water treatment, quality oversight, infection control, medication administration, and billing issues related to hemodialysis on LTC facility premises.³³

Most corporations provide their own dialysis staff instead of using LTC facility staff. However, coordination of care between dialysis staff and LTC facility staff is essential. An experienced RN typically oversees the program, training of staff and patients, and provides staff supervision. Current ESRD dietary and social services regulations are appropriate for the LTC facility setting. It was recommended that nephrologists and geriatricians should round on the patients at least once a month and multidisciplinary care plan meetings should be held.³³

Dialysis of stable patients in a common room would allow a technician to dialyze more than one patient at a time. Attendees unanimously agreed that the “one patient one machine” rule be abolished. One attendee mentioned that a facility could more easily maintain fewer machines. It was felt that water treatment should follow AAMI standards applicable to in-center dialysis facilities. The providers attending the conference did not perform dialyzer reuse.³³

Quality oversight would begin at the facility level. It was noted that Networks cannot currently distinguish patients

dialyzing in LTC facilities from home patients. It was recommended that LTC facility patient data be identified to allow separate data analysis for quality oversight purposes. Conference attendees noted that state surveyors would need to be trained to survey both LTC facilities and ESRD facilities.³³

Billing and reimbursement issues were discussed. Various medication administration scenarios were suggested such as LTC facility staff give oral medications instead of IV medications when possible and LTC facility staff administer Erythropoietin when the patient is not on dialysis. Regulations regarding reimbursement for medication and supplies would need to be adjusted to accommodate “Method 3”. It was suggested that reimbursement policies also consider longer or more frequent dialysis sessions and increased staff-to-patient ratios to care for high acuity patients. Financial incentives to promote expertise and excellence were recommended. Lastly, cost savings could be realized by eliminating the need to transport patients to dialysis facilities.³³

3.0 Technical Expert Panel (TEP)

A Technical Expert Panel was convened in Baltimore on January 20 and 21, 2006 to assist the contractor (ESRD Network 9/10) in developing recommendations for providing staff-assisted dialysis in the LTC facility. TEP members, including patients and professionals, were sought to represent various ESRD stakeholders involved in or impacted by dialysis in the LTC facility. Members were chosen by the contractor and CMS based on their area of expertise and knowledge of the subject area. Individual TEP members were approved by CMS. The final TEP membership included a patient and spouse, physicians, and representatives from state departments of health; CMS; quality improvement organization; nursing home administration; Large Dialysis Organizations (LDOs); DME representative, and members of

American Nephrology Nurses' Association (ANNA) and NRAA. Observers included additional CMS staffers and representatives from nursing home programs.

The TEP was tasked with making recommendations on the following: recommended program structure; minimum staffing, staff qualifications and training requirements; patient assessment; patient plan of care; access to nephrologist; vascular access care; infection control; medications; end of life issues; back-up treatment facility; physical environment; water quality; coordination of care; internal and external oversight; system for data collection; certification process; and financial model development.

4.0 Recommendations for Staff-Assisted Dialysis in the Long-Term Care Facility Setting

The following recommendations propose a new model of dialysis care: Staff-Assisted Dialysis (hemodialysis and peritoneal) in the Long-Term Care Facility. These recommendations do not eliminate current models of providing dialysis such as home dialysis or Medicare-certified in-center dialysis facilities adjacent to LTC facilities. Additionally, all recommendations were made considering the adult population, however the recommendations do not preclude provision of care to pediatric patients under this proposed model.

4.1 Rationale

There are increasing numbers of dialysis patients throughout the United States being dialyzed within long-term care (LTC) facilities, but there are currently no officially recognized models of staff-assisted treatment in the LTC setting. Providing dialysis care on the premises of LTC facilities would provide cost savings by avoiding the need to transport patients to freestanding dialysis facilities. The frequency and duration of dialysis treatments could be more flexible and patients would be available for services such as rehabilitation, possibly decreasing the length of stay if nursing home

admission was of a rehabilitative nature. Dialysis care at the nursing home would offer convenience to patients because they would be less likely to miss meals and medication doses. TEP members believed patients may experience increased quality of life by avoiding the discomforts and inconvenience associated with long waits for transportation to and from an outside dialysis facility. Coordination and continuity of care between dialysis facilities and LTC facilities would likely increase and overall access to nursing home care may improve for dialysis patients. Additionally, hospitalized patients may be discharged earlier if dialysis is available in the LTC facility setting.

4.2 Recommended Program Structure

The TEP discussed how to structure the staff-assisted dialysis program within LTC facilities. The decision was made to use the term *long-term care (LTC) facility* (hereafter referred to as LTC facility), consistent with guidance in the CMS Survey and Certification Group Addendum I to S&C Letter 04-24 on the Care for Residents of Long-Term Care (LTC) Facilities Who Receive End Stage Renal Disease (ESRD) Services, dated July 8, 2004.¹⁸ The term LTC facility refers to nursing homes including skilled nursing facilities and nursing facilities. Institutions for persons with mental retardation or rehabilitation facilities are not included.

The TEP recognized that a large spectrum of ESRD patients require dialysis care within the LTC facility: 1) stable dialysis patients who require LTC facility care; 2) individuals with progressive renal failure that develop an acute illness, start dialysis in the hospital, and are discharged to a LTC facility; 3) individuals who develop new acute renal failure and are discharged to a LTC facility; and 4) patients with multiple organ failure who are discharged to a LTC facility. The decision was made to define a program inclusive of all ESRD patients.

Dialysis providers may ultimately decide the level of medical acuity they are willing to accept into their program.

The TEP recommended that the staff-assisted dialysis LTC facility program be organized as a *subunit* of a Medicare-certified ESRD provider (hereafter referred to as Dialysis Subunit). The Dialysis Subunit may only provide hemodialysis treatments if the Dialysis Provider main facility offers hemodialysis. Likewise, an ESRD provider that only offers peritoneal dialysis may only provide peritoneal dialysis in the LTC facility. A program organized or affiliated with an ESRD provider that is certified for home dialysis training only should not be permitted to open a subunit.

It was recommended that the Dialysis Subunit only dialyze residents of the LTC facility. It is expected that several patients may be dialyzed together in a common area or dialysis room or patients may be dialyzed in their rooms (e.g. ventilator or traction dependent patients).

Additionally, it was recommended that proposed Conditions for Coverage be scrutinized to ensure dialysis patients residing in nursing facilities are provided the same level of protection and ancillary services as are provided to patients receiving care under the staff-assisted in-center model.

4.3 Minimum Staffing, Staff Qualifications and Training Requirements

It was acknowledged that no data addresses specific staff ratios for staff-assisted dialysis in nursing facilities and that staff quality is more important than staff quantity if a minimum is met. It was recognized that centers providing more treatments will have a higher level of staff experience and skill. As a result, it may be possible to eventually establish “Centers of Excellence” based on treatment volume and staff skill level.

The TEP felt strongly that in the case of hemodialysis, the entire treatment must be visibly monitored by a qualified caregiver. It was recommended that properly trained personnel be present and available in adequate numbers to meet the needs of the patients, including those arising from medical and non-medical emergencies, consistent with language in the Proposed Conditions for Coverage of Suppliers of End-Stage Renal Disease (ESRD) Services §494.180(b), with the exception that §494.180(b)(2) incorporate the term LTC facility. The revised Proposed language is as follows: *The governing body or designated person responsible must ensure that -- (1) An adequate number of qualified personnel are present whenever patients are undergoing dialysis so that the patient/staff ratio is appropriate to the level of dialysis care given and meets the needs of the patients. (2) A licensed nurse, educated in ESRD is present onsite at the LTC facility at all times that patients are being treated. (3) All employees have appropriate orientation to the facility and their work responsibilities upon employment; (4) All employees have an opportunity for continuing education and related development activities; and (5) There is an approved written training program specific to dialysis technicians that includes...; (6) When State requirements meet or exceed §494.180(b)(5) the State requirements must be met.*

4.3.1 Nursing

There was lengthy discussion regarding nurse staffing and coordination of care with the LTC facility. TEP members discussed whether the licensed nurse must be a Registered Nurse (RN) and if the nurse must be in the building during dialysis treatment. The recommendations that follow assume that LTC facility staff will take care of all patient needs outside the dialysis needs of the patient.

4.3.1a Nurse Responsible for Dialysis Subunit Program

The TEP agreed with the proposed Conditions for Coverage requirements for the responsible nurse and recommended these apply to the nurse assigned responsibility for the subunit(s) as well. It was recommended that a qualified RN be responsible for the hemodialysis and/or peritoneal Dialysis Subunit program. It was recommended that the Responsible Nurse must (i) Be a fulltime employee of the dialysis facility; (ii) Be a registered nurse who meets the practice requirements of the State in which he or she is employed; (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.

4.3.1b On-Site Nurse

In the case of hemodialysis, a licensed nurse educated in ESRD must be present on-site and readily available during the dialysis treatment to assist in the event of an emergency. In the case of peritoneal dialysis, a licensed nurse educated in ESRD must be available to support staff-assisted peritoneal dialysis. The on-site nurse may or may not be the same person as the nurse responsible for the Dialysis Subunit program. The on-site nurse must meet the practice requirements of the State in which she is employed, and for hemodialysis programs, complete a training curriculum that includes: principles of dialysis; care of patient with kidney failure; an understanding of dialysis procedures and documentation, including the initiation, monitoring, and termination of dialysis; possible complications of dialysis; water treatment; infection control; safety; access care; medications; and emergency take-off procedures.

Completion of a training program in manual and automated peritoneal dialysis is required if peritoneal dialysis is provided by the Dialysis Subunit. The training program should be focused on the types of peritoneal dialysis; understanding the

administration of manual and automated peritoneal dialysis; access care including signs, symptoms, and treatment of catheter exit site infections; signs, symptoms, and treatment of peritonitis; measurement of adequacy of dialysis; and infection control.

4.3.2 Patient Care Technicians

The TEP recommended adoption of the language proposed in §494.140(e) and §494.180(b)(5)(i)-(viii), with an increased hemodialysis experience requirement of two years and a training curriculum specific to either hemodialysis or peritoneal dialysis modalities, as applicable.

Current proposed language is as follows §494.140(e): *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.*

The TEP recommended increasing the experience requirement of patient care technicians administering staff-assisted hemodialysis in a Dialysis Subunit to two years because the patient care technician would need to function more independently and with less back-up personnel on the premises in the Dialysis Subunit setting compared to patient care technicians working at in-center dialysis facilities. The TEP recommended the following language: *(3)(i) Have completed at least two years hemodialysis patient care experience, following a training program that is approved by the medical director and governing body. This training experience must be under the direct supervision of a registered nurse, and be focused on the operation of kidney dialysis equipment and machines, providing direct patient care, and communication and interpersonal skills including patient sensitivity training and care of difficult patients.*

The TEP recommended adding an experience and training requirement for patient care technicians administering peritoneal dialysis in LTC facilities. The TEP recommended the following language:

(ii) If administration of peritoneal dialysis (manual or automated) is applicable, then the patient care technician must have three months peritoneal dialysis patient care experience, following a training program that is approved by the medical director and governing body. This training experience must be under the direct supervision of a registered nurse trained in administration of peritoneal dialysis, and be focused on the administration of manual and automated peritoneal dialysis, access care, signs and symptoms of peritonitis and catheter exit site infections, measurement of adequacy of dialysis, infection control, providing direct patient care, and communication and interpersonal skills including patient sensitivity training and care of difficult patients.

The TEP recommended modifying language in the proposed condition that specifies training program requirements §494.180(b)(5)(i)-(viii) as follows: (4) *successful completion of a training program that includes: (i) Principles of dialysis; (ii) Care of patients with kidney failure, including interpersonal skills; (iii) Dialysis procedures and documentation, including the initiation, monitoring, and termination of dialysis; (iv) Possible complications of dialysis; (v) Water treatment; (vi) Infection control; (vii) Safety; (viii) Access care; (ix) Applicable medications; (x) Emergency take-off procedures; (xi) Dialyzer reprocessing, if applicable; and (5) have completed a training program in manual and automated peritoneal dialysis, if applicable. (6) When state requirements meet or exceed (3) above, then the State requirements must be met.*

Ongoing high quality performance of patient care technicians is essential. The

TEP recommended that the ESRD provider be required to periodically monitor performance including at least an annual evaluation of patient care technician skills and knowledge, including observation of competency.

4.3.3 Other Staff

The TEP recommended that the Medicare-certified ESRD provider assign a Medical Director that meets the proposed conditions language in §494.140(a). The Medical Director may serve as the Medical Director for other Dialysis Subunits or ESRD facilities. §494.140(a): (1) *The medical director must be a physician 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.*

The TEP recommended adopting language from the proposed Conditions for both Dietitians (§494.140(c)) and Social Workers (§494.140(d)). §494.140(c) *specifies: The facility must have a dietitian who must – (1) Be a registered dietitian with the Commission on Dietetic Registration; (2) Meet the practice requirements in the State in which he or she is employed; and (3) Have a minimum of one year's professional work experience in clinical nutrition as a registered dietitian. §494.140(d) specifies: The facility must have a social worker who – (1) Holds a master's degree in social work from a school of social work accredited by the Council on Social Work Education; and (2) Meets the practice requirements for social work practice in the State in which he or she is employed.*

The TEP recommended adoption of proposed Conditions language for Biomedical Technicians. *Proposed Condition §494.140(f) Water treatment*

system technicians states: Technicians who perform monitoring and testing of the water treatment system must complete a training program that has been approved by the medical director and the governing body.

4.4 Patient ESRD Care Assessment

The TEP recommended patient ESRD care assessment (which includes assessment of appropriateness of modality selection) be consistent with proposed Condition §494.80, with modifications of interdisciplinary team members and frequency of assessment.

The Condition defines the facility interdisciplinary team as including at a minimum, the patient or the patient's designee, a registered nurse, a nephrologist or the physician treating the patient for ESRD, a social worker, and a dietitian. The TEP recommended the interdisciplinary team also include member(s) of the LTC facility staff.

The TEP recommended the initial comprehensive assessment be completed within two weeks of admission to the Dialysis subunit and reassessment every month thereafter due to the short length of stay of many patients and their high level of acuity.

4.5 Patient ESRD Plan of Care

The TEP recommended the patient ESRD plan of care be consistent with proposed Condition §494.90, with modifications of interdisciplinary team members, communication and frequency of assessment.

The TEP recommended the interdisciplinary team developing the plan of care also include member(s) of the LTC facility staff. In addition to the proposed Condition, it was recommended that the ESRD plan of care demonstrate communication between the staff of the

Dialysis Subunit and the LTC facility and integrate the LTC facility plan of care.

The TEP recommended modification of Proposed Condition §494.90(b)(4) as follows: The dialysis facility must ensure that all dialysis patients are seen by a physician providing the ESRD care at least monthly, and at least every other month during the patient's treatment in the Dialysis Subunit, as evidenced by a monthly progress note placed in the patient's medical record.

4.6 Access to Nephrologist

LTC facility patients receive 24-hour care and are more closely monitored than other dialysis patients. The TEP felt it would be overly burdensome to expect a nephrologist to travel to Dialysis Subunits to see patients on a weekly basis, particularly because patients may be located within several Dialysis Subunits across a wide geographical area. As a result, the TEP recommended that patients be assessed by the nephrologist in the Dialysis Subunit within the first two weeks of admission or readmission to a Dialysis Subunit. The TEP advised that stable patients be seen by the nephrologist monthly thereafter, with these visits being in the dialysis subunit at least every other month. Unstable patients should be seen more frequently. The TEP felt it would be acceptable for Nephrology Nurse Practitioners or Physicians Assistants to see the patients in addition to the monthly visit by the nephrologist. It was suggested that CMS consider reimbursing nephrologists at the home dialysis rate, since the frequency of nephrologist visits is likely to be similar to the frequency of visits of home dialysis patients.

4.7 Vascular Access Care

The assessment and care of patient vascular access is covered by the Patient ESRD Care Assessment and Patient ESRD Plan of Care (see sections 4.4 and 4.5 above). It will be important for communication to occur

between the Dialysis Subunit and the LTC facility regarding the care and monitoring of vascular access. The TEP advised that LTC residents who receive long-term dialysis services should have the goal of a functioning fistula as their dialysis access, however the TEP recognized this may often not be possible. It was recommended that all ESRD data related to patients receiving care in LTC facilities, including vascular access data, be reported and reviewed separately from in-center data.

4.8 Infection Control

The TEP recommended adoption of language consistent with proposed Condition §494.30 Infection Control. Communication and coordination of care between the LTC facility and Dialysis Subunit will be critical. It was recommended that dialysis providers be required to educate LTC facility staff about Center for Disease Control and Prevention requirements specific to dialysis.

4.9 Medications

Administration of medications may be handled in various ways. For example, Erythropoietin could be administered subcutaneously or intravenously during dialysis or subcutaneously by the LTC facility when the patient is off dialysis. Coordination of care will require that medication administration be well defined in terms of who administers the medications, what form of medication is to be given (e.g. IV or oral), and when the medication will be administered. Medications given by the dialysis provider must be reported to the LTC facility so that the pharmacy can monitor care as is required by LTC facility regulations. The quality of care should equal that provided to in-center dialysis patients.

4.10 End of Life Issues

The LTC facility and Dialysis Subunit care providers should work together to facilitate advance care planning discussions and decision-making by patients and their

families. The TEP recommended that patient advance directives be communicated from the LTC facility staff to the Dialysis Subunit staff. Decisions to terminate dialysis treatments should be discussed with the nephrologist.

The TEP discussed barriers to providing hospice care for dialysis patients. If ESRD is the cause of the terminal illness, then dialysis services cannot be billed under the Medicare Part B payment system, but would need to be covered under the hospice benefit. Dialysis patients with terminal illnesses unrelated to their kidney failure may continue dialysis under Part B and receive the hospice benefits.

4.11 Physical Environment

The TEP recommended that the Dialysis Subunit comply with all applicable federal, state, and local regulations related to physical environment for LTC facilities (including the requirement for a functional emergency call system in the room(s) used for dialysis) and for dialysis facilities (see proposed Condition §494.60).

4.12 Water Quality

The TEP recommended that facilities meet standards for water and the practice guidelines for dialysate as published by the Association for the Advancement of Medical Instrumentation (AAMI).

4.13 Coordination of Care

The TEP believes that coordination of care is critical to the success of staff-assisted dialysis within the Dialysis Subunit setting. Responsibilities must be clearly delineated and useful or necessary information in the care of the patient must flow bidirectionally between the LTC facility staff and Dialysis Subunit staff on a routine basis.

The TEP recommended that the Conditions require a Letter of Agreement between the ESRD provider and the LTC facility specific to this service. This letter of agreement should clearly define areas of

responsibility and how care will be coordinated between parties to safeguard the health and safety of ESRD patients. The Letter of Agreement should be reviewed and signed by both parties annually. The TEP recommended specific items be required within the Letter of Agreement as follows.

4.13.1 LTC Facility Expectations

The LTC facility will be responsible for the overall care delivered to the patient, monitoring of the patient prior to and after the completion of each dialysis treatment, and providing for all non-dialysis needs of the patient including during the time period when the patient is receiving dialysis.

The LTC facility Medical Director should be responsible for each patients' comprehensive plan of care, which should address dialysis. The LTC facility Medical Director is expected to be involved in the coordination of ESRD patient care.

The Letter of Agreement should specify that ESRD staff be educated on applicable LTC facility protocols and that LTC facility staff be educated regarding ESRD. LTC facility staff should be prepared to assist in the event of an emergency during dialysis. The LTC Facility record of care should include dialysis treatment records.

4.13.2 ESRD Provider Expectations

The Letter of Agreement should specify that the ESRD provider will be responsible for providing dialysis staff; dialysis treatments; monitoring the patient during treatment; oversight of dialysis care and dialysis staff; dialysis staff training; LTC facility staff training regarding ESRD; patient and family ESRD education and modality selection; dialysis orders; patient ESRD assessment and plan of care; provision of qualified social worker and registered dietitian services; installation, testing, and maintenance of the water and dialysate systems and all dialysis equipment; appropriate reporting; and

maintenance of patient dialysis records at both the LTC facility and ESRD provider offices.

4.13.3 Emergencies During Dialysis Treatment

The parties should define their responsibilities for emergencies during dialysis. Both the ESRD provider and LTC facility must have specific policies and procedures in place to handle medical and non-medical emergencies that may be anticipated during dialysis. The ESRD provider must have a protocol that identifies the arrangements for physician and hospital services in the event of an emergency during dialysis.

4.13.4 Back-up Treatment Facility

ESRD providers should be required to have a written plan for back-up dialysis treatment. If a Dialysis Subunit cannot provide treatment on site, there must be capacity to provide dialysis elsewhere either directly by the ESRD provider or under arrangement. These back-up facilities must be within a reasonable geographic distance of the LTC facility.

4.13.5 Utilities

The Letter of Agreement should specify who is responsible for the provision of utilities.

4.13.6 Communication

The Letter of Agreement should specify that the LTC facility and the ESRD subunit share state survey statements of deficiencies. Other areas of coordination that should be carefully defined in the letter of agreement include interdisciplinary patient assessment and plan of care (sections 4.4 and 4.5), vascular access care (section 4.7), infection control (section 4.8), provision of medications (section 4.9), and end of life issues (section 4.10).

There was significant TEP discussion regarding the coordination of care between

parties to meet the nutritional needs of the patient. In theory, the provision of dialysis at the LTC facility should automatically improve communication and planning between the LTC facility dietitian and renal dietitian. However, given scheduling restraints and the fact that many LTC facility dietitians are consultants who are at the LTC facility on a limited basis, and that the ESRD RD may seldom visit the LTC facility, particular effort should be made to ensure real dialogue and joint care-planning occur. Dialysis patients are at high risk of malnutrition. LTC facility dietary services should be expected to provide a variety of palatable meals that provide sufficient protein and calories, are nutritionally complete, and renal-compatible while taking into account patient preferences. Creative menu writing has the potential to overcome the common problem of lack of variety and insufficient food choice.

4.14 Internal Oversight

The TEP recommended that Dialysis Subunits meet proposed Condition §494.110 Quality assessment and performance improvement. *§494.110(a)(2) specifies the program must include, but not be limited to, the following: (i) Adequacy of dialysis; (ii) Nutritional status; (iii) Anemia management; (iv) Vascular access; (v) Medical injuries and medical errors identification; (vi) Hemodialyzer reuse program, if the facility reuses hemodialyzers; (viii) Patient satisfaction and grievances.* The TEP recommended that data from Dialysis Subunits be reported and reviewed separately from in-center data. Dialysis Subunits should report their quality assurance results to both the LTC facility and the ESRD facility.

4.15 External Oversight

The TEP recommended that Dialysis Subunit data be included in quality reporting by the provider, but a Dialysis Subunit identifier should be added to the dataset to facilitate separate data analysis. The Dialysis Subunit data should be

reported to ESRD Networks on a unit by unit basis, but not be posted on the Dialysis Facility Compare (DFC) website, because patient numbers could be very small. DFC reports could aggregate provider Dialysis Subunit data as a report separate from the provider in-center data, if applicable. Additionally, DFC should report that staff-assisted dialysis in LTC facilities is a service offered by the ESRD provider. The TEP recommended that Dialysis Subunit-specific quality standards should be defined, however it was recognized that data identifiable as Dialysis Subunit data must first be collected and analyzed to develop specific standards.

4.16 System for Data Collection

The TEP recommended that current data collection methods be changed so that analysis can distinguish treatment type, treatment setting, patient residency, frequency of treatment, and modality type.

4.17 Certification Process

The TEP recommended the following process to certify ESRD providers for the provision of staff-assisted dialysis within long-term care facilities. Providers would submit an application to the state agency for service. The application should require an estimate of patient capacity. The new certification of a provider or the addition of a Dialysis Subunit to existing providers would require an onsite survey prior to initiating Dialysis Subunit dialysis treatments. After the initial Dialysis Subunit is approved, if an ESRD provider chooses to open additional Dialysis Subunits, they would need to notify the state agency of this intent. After the state agency acknowledges the intent to open, the certified ESRD facility could open the additional Dialysis Subunits, understanding that a survey would occur as soon as possible. Waiting for a survey would not hold up opening of additional Dialysis Subunits. It is expected that a transition period will be required to certify existing

LTC facility Dialysis subunits under the new regulations. A request for expansion by an existing Dialysis Subunit to add dialysis stations when dialysis is provided in a common area would need to be sent to the state agency.

If a Dialysis Subunit is out of compliance at a Condition level, the Dialysis Facility and all Subunits under that dialysis provider would be considered out of compliance. If the facility failed to correct the deficient practice(s), the provider would lose certification for their entire ESRD program. The CMS Regional Office must be notified when a provider with a Dialysis Subunit is determined to have Conditional level non-compliance. It was recommended that the ESRD Network be informed if an ESRD provider with a Dialysis Subunit is out of compliance.

4.18 Financial Model Development

The TEP recommended that a separate section be created on the Medicare Cost Reports to identify LTC facility dialysis services. The TEP suggested that CMS simultaneously develop a case-mix adjustment methodology and conduct a pilot project. The composite rate for these higher acuity patients is expected to incorporate the cost of labor.

5.0 Conclusions

In summary, a TEP was convened to formulate recommendations for the development of a definition and method to

provide staff-assisted dialysis within the LTC facility setting. A WebEx call was held on January 9, 2006 to familiarize all participants to the issues and tasks for the project. Strategies to structure the dialysis program, staffing issues, patient coordination of care issues, physical environment and technical considerations, oversight, facility certification process, and a financial model were further discussed during a two day face- to- face meeting on January 20 and 21, 2006 in Baltimore. A draft report containing TEP recommendations was then prepared and made available for public comment through May 15, 2006. The recommendations were sent to representatives of major renal organizations as well as state departments of health, quality improvement organizations, and leadership of the large dialysis organizations. Public feedback was collated and sent to the TEP members to review. The TEP reconvened by WebEx in June to discuss the public comments and to decide how to revise the final report.

The TEP urged CMS to consider creation of this new model because the need for staff-assisted dialysis in the LTC setting is anticipated to grow as the population continues to age and the current use of the home dialysis method in the LTC setting does not appropriately meet this need.

6.0 Technical Expert Panel, Consultants, Observers & Staff

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