North Carolina Department of Health and Human Services
Division of Health Service Regulation
Certificate of Need Section
2704 Mail Service Center • Raleigh, North Carolina 27699-2704
http://www.ncdhhs.gov/dhsr/

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July 6, 2012

S. Todd Hemphill
Bode, Call & Stroupe, L.L.P.
P. O. Box 6338
Raleigh, NC 27628-6338

RE: No Review / Piedmont Dialysis Center of Wake Forest University / Provision of Home Dialysis to Residents of Nursing Facilities / Forsyth County
FID #: 944661

Dear Mr. Hemphill:

The Certificate of Need (CON) Section received your letters of June 6, 2012 and June 21, 2012 regarding the above referenced proposal. Based on the CON law **in effect on the date of this response to your request,** the proposal described in your correspondence is not governed by, and therefore, does not currently require a certificate of need, subject to the following conditions:

1. Piedmont Dialysis Center of Wake Forest University will provide dialysis training in all home modalities, including home peritoneal dialysis and home hemodialysis.
2. Piedmont Dialysis Center of Wake Forest University will continue to provide home dialysis training for its patients and to the patients of Salem Kidney Center of Wake Forest University (FID# 944758), Northside Dialysis Center of Wake Forest University (FID# 000193), and Miller Street Dialysis Center of Wake Forest University (FID# 070671).
3. Piedmont Dialysis Center of Wake Forest University will enter into written coordination agreements with each nursing home as required by the Centers for Medicare & Medicaid Services (CMS) in CMS S&C: 04-24 and 04-37.
4. Piedmont Dialysis Center of Wake Forest University will comply with the survey standards imposed by the Acute and Home Care Licensure and Certification Section.
5. Piedmont Dialysis Center of Wake Forest University will coordinate with each nursing facility to ensure conformity with any requirements imposed by the Nursing Home Licensure and Certification Section.
6. Piedmont Dialysis Center of Wake Forest University will provide home dialysis to the following nursing facilities:

Facility	FID #
Brian Center Health and Retirement	952994
Clemmons Nursing and Rehab Center	923335
Lutheran Home – Winston-Salem	923392
Oak Forest Health and Rehabilitation	933496
Piney Grove Nursing and Rehabilitation Center	923023

Salemtowne	923440
Springwood Care Center	923294
The Oaks	923497
Winston-Salem Nursing and Rehabilitation Center	923570

However, please note that if the CON law is subsequently amended such that the above referenced proposal would require a certificate of need, this determination does not authorize you to proceed to develop the above referenced proposal when the new law becomes effective.

It should be noted that this determination is binding only for the facts represented by you. Consequently, if changes are made in the project or in the facts provided in your correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by the Certificate of Need Section. Changes in a project include, but are not limited to: (1) increases in the capital cost; (2) acquisition of medical equipment not included in the original cost estimate; (3) modifications in the design of the project; (4) change in location; and (5) any increase in the number of square feet to be constructed.

In addition, you should contact the Acute and Home Care Licensure and Certification Section, DHSR & Nursing Home Licensure and Certification Section, DHSR to determine if they have any requirements for development of the proposed project. Please contact the CON Section if you have any questions. Also, in all future correspondence you should reference the Facility I.D.# (FID) if the facility is licensed.

Sincerely,

Lisa Pittman
Team Leader

Craig R. Smith, Chief
Certificate of Need Section

cc: Acute and Home Care Licensure and Certification Section, DHSR
Nursing Home Licensure and Certification Section, DHSR

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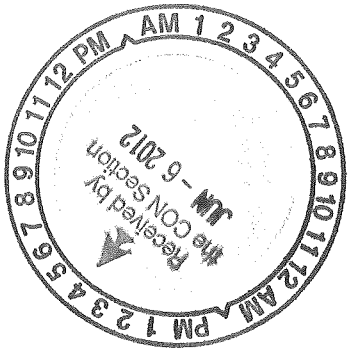
June 6, 2012



HAND DELIVERY
Craig R. Smith, Chief
Certificate of Need Section
NC Department of Health and Human Services
Division of Health Service Regulation
809 Ruggles Drive
Raleigh, NC 27603

Re: Piedmont Dialysis Center of Wake Forest University – Home Dialysis in Nursing Homes

Dear Mr. Smith:

This firm represents Piedmont Dialysis Center of Wake Forest University ("PDC"), which has been providing dialysis services in Forsyth County for nearly 30 years. PDC provides in-center hemodialysis services as well as home dialysis training and support for home hemodialysis and peritoneal dialysis modalities. Since its inception PDC has strived to provide exceptional quality care to the patients it serves, adapting new technologies and methods of care and through research activities, contributing to the development of those programs for the betterment of the renal community. PDC is a Medicare participating provider as well as a preferred provider of care for the patients of Medicaid, VA, and commercial insurance.

PDC is currently certified for 62 in-center stations with a utilization capacity of 55.6%. The facility is certified to offer all ESRD modalities, and serves 138 in-center patients and 123 home therapy patients who have chosen peritoneal dialysis or home-hemodialysis (NxStage).

In recent years the Centers for Medicare and Medicaid Services (CMS) has championed efforts to increase the number of dialysis patients participating in home dialysis, including home dialysis in nursing homes. Attached as *Exhibits 1 and 2* are CMS S&C: 04-24 and 04-37, which outline CMS's position on this issue.[1] Due to the large number of nursing home patients the dialysis centers of Wake Forest University serve in Forsyth County - 43 patients representing

[1] Our clients were made aware of the CMS materials by Karen Senger, Surveyor of Dialysis Services for the Illinois Department of Public Health. She was able to describe to them how such a proposal is successfully functioning within Illinois, a CON state. Her guidance in pursuing this proposal has been very helpful.

nine nursing homes[2] – PDC would like to offer home dialysis to patients at their homes, the nursing homes where they live.

Research into ESRD home dialysis in nursing homes demonstrates that CMS is allowing dialysis providers in other CON states, to provide all home ESRD therapies, including peritoneal dialysis and home hemodialysis (NxStage), to nursing home patients in their home. PDC proposes to offer these services within Forsyth County to the nursing home patients it and its sister facilities[3] serve. No dialysis provider currently offers home training or home dialysis therapies within the nursing home environment in North Carolina.

William McDonald, Director of Development for Health Systems Management, Inc. which manages Wake Forest University Health Sciences' dialysis facility, has spoken with Azzie Conley, Chief of the North Carolina Division of Health Service Regulation's Acute and Home Care Licensure and Certification Section and Beverly Speroff, Chief of the Nursing Home Licensure and Certification Section, regarding the provision of home dialysis services in nursing homes. Ms. Conley and Ms. Speroff also have been provided with copies of CMS S&C: 04-24 and 04-37. Both have advised that they do not have a problem with approving such a proposal based on the information provided in the CMS S&Cs, so long as the CON Section determines that the proposed service conforms with the CON law and does not require a certificate of need.

We understand that Mr. McDonald has also spoken with you and with Martha Frisone, Assistant Section Chief of the CON Section, and discussed the issue concerning home therapies provided within a patient's home and related these same scenarios to an ESRD patient that is within a nursing home, and that it was suggested that we convey the above information in a letter to you and formally request a determination that the proposal does not require a CON.

PDC believes that offering home dialysis services to nursing home patients will be beneficial to the patients, the care providers and the community. Patients who undergo home peritoneal dialysis and home hemodialysis receive a much higher level of benefit than those who receive in-center hemodialysis. Performing home dialysis within the nursing home can alleviate patient stress during transportation, granting the nursing home dialysis patient a better, more comfortable quality of life while at the same time potentially providing improved medical outcomes such as lower mortality risk. The result of decreasing in-center hemodialysis populations by performing peritoneal dialysis or home hemodialysis in nursing homes will be a lesser utilization of existing in-center hemodialysis facilities and a greater flexibility for shift scheduling of the remaining and new patients. This is truly a proposal that represents a win-win for everyone involved.

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[2] Those nine nursing homes are Brian Center Health and Retirement, Clemmons Nursing and Rehab Center, Lutheran Home – Winston-Salem, Oak Forest Health and Rehabilitation, Piney Grove Nursing and Rehabilitation Center, Salemtowne, Springwood Care Center, The Oaks, and Winston-Salem Nursing and Rehabilitation Center. There also are four other nursing homes in Forsyth County. See Department of Health and Human Services Nursing Facility by County, *Exhibit 3* hereto.

[3] PDC provides home dialysis training for the patients of Salem Kidney Center of Wake Forest University, Northside Dialysis Center of Wake Forest University, and Miller Street Dialysis Center of Wake Forest University, all of which are located in Forsyth County.

Under G.S. §131E-176(16), PDC's proposal to offer home dialysis within a patient's home (in this case, a nursing home) does not create a "new institutional health service." PDC does not propose to transfer dialysis stations or change bed capacity. PDC does not propose to offer a service (home dialysis) that it is not already certified to provide, and has been providing for greater than 12 months. PDC does not propose to expend capital in an amount greater than $2,000,000 to develop or expand a health service.

In essence, PDC is simply proposing to offer home dialysis services to more of its patients within their residence, that being a nursing home. Dialysis training will be provided in all home modalities, including home peritoneal dialysis and home hemodialysis. PDC will enter into written coordination agreements with each nursing home as required in CMS S&C: 04-24 and 04-37, which requires definition and distinction of care services.[4] PDC will comply with the survey standards imposed by the Acute and Home Care Licensure and Certification Section, and as needed, will coordinate with each nursing facility to ensure conformity with any requirements imposed by the Nursing Home Licensure and Certification Section.

Based on all of the foregoing, PDC respectfully requests confirmation that the services proposed do not constitute a new institutional health service and are not subject to certificate of need review.

Please let us know if you need further information or it there are questions we can answer.

Very truly yours,

BODE, CALL & STROUPE, L.L.P.

S. Todd Hemphill

STH:sh
Enclosures

cc w/enc.: William F. McDonald

[4] See, e.g., *Exhibit 1*, p. 4 and Attachment A, p. 2 of 16.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-12-25
Baltimore, Maryland 21244-1850

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C: 04-24

DATE: **March 19, 2004**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Clarification of Certification Requirements and Coordination of Care for Residents of Long-Term Care (LTC) Facilities Who Receive End Stage Renal Disease (ESRD) Services.

Letter Summary

- Regardless of the type of ESRD services provided, all Medicare-approved ESRD facilities must meet the Conditions for Coverage (CfCs) at 42 CFR §405.2130 through §405.2163 unless otherwise specified by the regulations.
- With respect to the provision of home dialysis training and support in LTC facilities, the Centers for Medicare & Medicaid Services (CMS) will approve only those ESRD applications that meet the specifications put forth in this memorandum and attachments. Applicants seeking approval must file the Form CMS-3427 or CMS-3427A as specified in this memorandum and may be subject to an on-site survey prior to approval.
- Attachments: Survey protocols for ESRD facilities and LTC facilities where residents qualify for and receive home dialysis. These protocols reflect currently existing requirements found in either the ESRD or LTC regulations.

This memorandum describes the steps CMS is taking to ensure that necessary safeguards are in place for residents of LTC facilities who receive dialysis. To that end, we are providing clarifications regarding the approval process for facilities that intend to provide dialysis to LTC residents.

EXHIBIT 1

We recognize that many residents of LTC facilities (skilled nursing facilities (SNFs), and nursing facilities (NFs)) who require dialysis would prefer the convenience of receiving dialysis in the LTC facility. And there has been a great deal of interest in the provision of home dialysis training and support in the LTC setting. While CMS regulations do not preclude this type of arrangement under certain circumstances, CMS has been holding all initial applications to provide home dialysis and training within LTC facilities pending assessment of their ability to provide home dialysis in a way that ensures the provision of adequate safeguards, clear lines of responsibility and accountability between the ESRD facility and the LTC facility, and quality care.

The purpose of this memorandum is to ensure that there are necessary safeguards and coordination of care for Medicare-approved facilities that provide home dialysis services for residents of LTC facilities. Specifically, this memorandum intends to: 1) clarify the applicable certification requirements and approval processes for Medicare-certified ESRD facilities; 2) specify the conditions under which home dialysis and training may be provided; and 3) augment CMS surveyor guidance to ensure that there is coordination of care, with defined lines of accountability and responsibility for quality safeguards for ESRD facilities providing home dialysis and training for LTC patients.

Certification Requirements

Part 42 of the Code of Federal Regulations (CFR), §405.2102, defines an ESRD facility as a Renal Transplantation Center, a Renal Dialysis Center, a Renal Dialysis Facility, a Self-Dialysis Unit, or a Special Purpose Facility. This section further defines an ESRD facility as "a facility which is approved to furnish at least one specific ESRD service." These services are: transplantation service; dialysis service; and self-dialysis and home dialysis training. While an ESRD facility may opt to provide all, or only one of the above services, Medicare-certified ESRD facilities must meet all of the ESRD Conditions for Coverage (CfC) unless otherwise provided by the regulations. For example, all ESRD facilities must meet the CfCs at Sections 405.2130 through 405.2163. However, sections 405.2161, 405.2162, and 405.2163 apply only to Renal Dialysis Centers and Renal Dialysis Facilities. Similarly, section 404.2164 exempts special purpose facilities from certain CfCs, but also applies additional standards. Therefore, while an ESRD "facility" may opt to offer home dialysis training as its only service, it must comply with all applicable CfCs, which include all ESRD CfCs except those specifically applicable to renal transplant centers (405.2170 and 405.2171) and special purpose dialysis facilities (405.2164).

The State Operations Manual (SOM) at §2274 states that an ESRD facility must file an application with its State Survey Agency (SA) to establish eligibility for a change, expansion, or initial provision of an ESRD service. Therefore, prior to providing home dialysis training and support for LTC residents, a facility must seek Medicare approval. This memorandum is intended to provide guidance for facilities, states, and regions regarding determinations of approval for this service. Where this ESRD service already exists, states and regions will use this memorandum to determine compliance with the current regulations through the ongoing recertification process.

The SA will work with the relevant Regional Office (RO) to determine whether an on-site survey will be required before approval of an ESRD home dialysis training and support program. According to section 2278 of the State Operations Manual (SOM), a SA survey is required if the facility has not been surveyed in more than six months, or if substantial changes have been made. If a survey is not required, the RO includes the rationale for not surveying the ESRD facility.

If the SA determines a survey is needed to add the "training and support" services or if an initial certification survey is required, the SA visits the ESRD facility that is requesting approval for the service and the LTC facilities with which the ESRD facility has an agreement to provide "training and support" services.

Upon receipt of the survey report from the SA, the RO reviews all material and approves or disapproves the ESRD facility's request for "Patient Dialysis Training." The RO, in accordance with SOM 2278, forwards a copy of the notice to the SA and other required information to the fiscal intermediary.

ESRD facilities approved for training and support services for LTC residents are required to meet applicable regulations at 42 CFR 405.2130-405.2163. During a recertification visit, the SA surveys the facility using the guidance presented in this Memorandum. If the SA determines the ESRD facility's "training and support program" for LTC residents does not meet applicable requirements, the SA issues a CMS-2567, Statement of Deficiencies. The ESRD facility may have an opportunity to submit an acceptable plan of correction and regain compliance with required regulations.

Home Dialysis and Self/Home Dialysis Training in LTC Facilities

Part 42 CFR §405.2102 defines home dialysis as dialysis performed by an appropriately trained patient at home. CMS has considered LTC facilities as the patient's home for purposes of this benefit. This section further defines self-dialysis and home dialysis training as programs that train ESRD patients to perform self-dialysis or home dialysis with little or no professional assistance, and trains other individuals to assist patients in performing self-dialysis or home dialysis. In order for Medicare payment of home dialysis to be made, the patient must have actively elected to become a home dialysis patient and have completed a training program provided by an approved ESRD facility. Home dialysis is intended to be self-dialysis performed by the patient and/or with the assistance of other individuals, (i.e., a designated family member or caregiver). However, there is the recognition that some Medicare beneficiaries may have physical, developmental, or cognitive limitations that would preclude the patient from completing the required home dialysis training without significant involvement and assistance from other individuals. As a result, for purposes of payment CMS permits the patient to play a secondary or limited role in the dialysis training and service provision in instances where a designated family member or caregiver is present to actively participate.

Coordination of Services and Clarification of Responsibility and Accountability

While this model of care provides greater flexibility for dialysis patients, it also creates additional programmatic vulnerabilities that we believe can be minimized by adherence to the CfCs and active and ongoing care coordination between LTC and ESRD facilities. CMS will only approve applications of ESRD facilities to provide home training and support for LTC residents if the ESRD facility can assure CMS that the applicable facilities have a documented coordination agreement that outlines clear lines of responsibility and accountability.

Both the ESRD facility and the LTC facility will be held accountable for the coordination and quality of dialysis services delivered to LTC facility residents. The ESRD facility is responsible for providing the dialysis treatments, including training the patient and caregiver, monitoring the patient and patient's home, dietary and nutritional consultations, assuring continuity of care, installing and maintaining equipment, testing and treating the water, and ordering supplies. The LTC facility remains responsible for the overall care delivered to the resident including monitoring after completion of the dialysis treatment.

Under the ESRD regulations at 42 CFR §405.2136(b), 405.2136(c), 405.2136(d), and 405.2136(e) written documentation is required which specifies the terms and responsibilities of various providers of services. Therefore, to ensure that there is adequate coordination of care to effectively provide home dialysis training and support services to residents of LTC facilities, the ESRD facility will enter into a written coordination agreement with each LTC facility in which home dialysis patients reside. The purpose of this agreement is to coordinate the provision of such specific services to maximize patient safety and program efficiency. However, in no case may the ESRD facility or the LTC facility transfer responsibility for matters that each are otherwise required by law or regulation to provide.

Identify the Provision of Home Dialysis in LTC Facilities

Consistent with section 2274 of the SOM, in order to establish eligibility to provide ESRD services under Medicare, an applicant must complete Part I of the ESRD Application and Survey and Certification Report, Form CMS-3427/CMS-3427A. The Form CMS 3427/CMS-3427A is required when requesting initial approval, expansion or addition of stations, and a change in location, ownership, and/or in services provided. Any ESRD facility that plans to perform home dialysis and/or training as part of its initial application or as a part of an expansion of its services must request CMS approval. Part I of Form CMS-3427 must be submitted for an Initial Application. Part I of Form CMS-3427A must be submitted to request the "Addition of Services." Item 27 of CMS-3427 must identify those ESRD facilities that plan to provide or are providing training and support services to residents in a SNF and/or NF in lieu of transporting those patients to an ESRD facility to be dialyzed. Item 27 should include a list of the LTC facilities that are participants in the ESRD facilities' home training and support program. Item 27 does not need to reference those situations in which the dialysis is being furnished by a Medicare-approved ESRD outpatient facility.

ESRD surveyors should ensure that Item 27 of CMS-3427/CMS-3427A is appropriately completed to identify the provision of home dialysis in LTC facilities. LTC surveyors should report to the SA which LTC facilities provide home dialysis to residents and any concerns that they have about the provision of dialysis services in a specific facility. The appropriate CMS RO will then ensure this information is entered into QIES/OSCAR in a timely manner so that these arrangements may be appropriately monitored.

Protocols

To assist with consistent application of the guidance in this memorandum, we are attaching two survey protocols that provide guidance in regard to the application of specific regulatory requirements. Attachment A provides guidance to qualified ESRD surveyors who survey ESRD facilities that provide home dialysis to residents of LTC facilities. Attachment B includes guidance to qualified LTC surveyors who survey facilities having residents who receive dialysis. These protocols reflect already existing requirements found in either the ESRD or the LTC regulations. These protocols are not all inclusive, but rather they are intended to assist facilities and surveyors in determining compliance with current requirements.

Contact: Judith Kari (jkari@cms.hhs.gov), 410-786-6829

Effective Date: This guidance is effective immediately for all recertifications, complaint surveys or initial application reviews. Nothing in this Memorandum should be construed to require the rescheduling of a recertification review.

Training: The information contained in this announcement should be shared with all survey and certification staff, their managers and ESRD Networks.

/s/
Thomas E. Hamilton

Attachments:
A – Survey Protocol for the Medicare-approved ESRD Facilities
B – Survey Protocol for Long-Term Care Facilities

Survey Protocol for Medicare-Approved ESRD Facilities

The Medicare-approved ESRD facility must monitor the dialysis care of Long-Term Care (LTC) facility residents for whom they are providing care, whether the care is provided in an ESRD facility or in a LTC facility. The survey process must include a review for compliance with ESRD requirements at both the residents' LTC facility and the Medicare-approved ESRD training and support facility.

This survey protocol includes references to potential regulatory citations for ESRD facilities by V-Tag numbers to assist the survey team in determining the facility's compliance or non-compliance with Conditions for Coverage. These references are provided after each highlighted protocol.

Pre-Survey Preparation or Entrance Conference Information

All home dialysis in a LTC facility requires that a Medicare-approved ESRD facility be responsible for all aspects of the dialysis care, whether the care is provided by Method I (i.e., supplies, equipment, training, and support care delivered by a Medicare-approved ESRD facility) or by Method II (i.e., supplies and equipment provided by a Durable Medical Equipment [DME] supplier with support care and training delivered by a Medicare-approved ESRD facility). Determine either prior to the survey or during the entrance conference the type and extent of ESRD services provided to LTC residents who participate in home dialysis. When the ESRD facility provides home dialysis services onsite in a LTC facility, the survey team must make a visit to the LTC facility to conduct additional investigations.

Interview staff and conduct record review to determine:

- The contractual arrangements related to both financial aspects and patient care responsibilities between the ESRD training and support facility, the LTC facility, and the DME supplier.
- The number of LTC facility residents who are dialyzing in the LTC facility. Are they dialyzing as a skilled nursing facility's (SNF) or nursing facility's (NF) residents? How long have they been residents of the LTC facility? Are they on hemodialysis or peritoneal dialysis? Identify the number of LTC facility patients on Method I or Method II. If on Method II, what DME supplier is used? Review of the ESRD beneficiary selection form, CMS 382, will indicate which patients selected each method. For patients on Method II, determine if there is a backup agreement between the ESRD facility and the DME supplier.
- Whether residents in the LTC facility are dialyzed in a common room or in their bedrooms. During which days/hours is dialysis performed? Ideally, the surveyor will visit during a dialysis treatment.

NOTE: This protocol is to be used with existing survey procedures and interpretive guidelines found in the State Operations Manual, Appendix H. The following investigative components are added to address the home dialysis component of the survey. The Medicare-approved ESRD facility must meet the Conditions for Coverage at 42 CFR §405.2130-405.2163.

Coordination Agreement and Governance

The ESRD facility shall have a written coordination agreement, signed by the ESRD facility and each LTC facility in which home dialysis patients reside. The agreement needs to ensure that there is adequate coordination of care to provide home dialysis training and services to residents of LTC facilities. The ESRD facility assumes responsibility for appropriately delivering ESRD care, even if the care is delivered outside of the venue of the ESRD facility, i.e. the LTC facility.

If the ESRD facility provides home dialysis on the premises of the LTC facility, conduct an onsite visit to determine if:

- There is a written coordination agreement, signed by the ESRD facility and the applicable LTC facilities, which delineates respective responsibilities and accountability for routine and emergency care, care planning, and communication. The coordination agreement must include information on financial aspects and patient care responsibilities among the ESRD training and support facility, the LTC facility, and the DME supplier (if applicable).
- The coordination agreement is reviewed at least annually.
- The written coordination agreement clearly delineates where patients will be sent in the event of an emergency situation.
- There are clear lines of responsibility and accountability between the ESRD facility and the LTC facility that safeguard the health and safety of LTC patients who receive dialysis treatments.
- The ESRD facility staff communicates patient care issues with LTC facility staff.

§405.2136 Governing Body and Management

V110 Condition: Governing Body and Management. The ESRD facility is under the control of an identifiable governing body, or designated person(s) so functioning, with full legal authority and responsibility for the governance and operation of the facility.

V121 Operational Objectives Established. The operational objectives of the ESRD facility, including the services that it provides, are established by the governing body and delineated in writing. The governing body adopts effective administrative rules and regulations that are designed to safeguard the health and safety of patients and to govern the general operations of the facility, in accordance with legal requirements.

V122 Operational Objectives in Writing. Such rules and regulations are in writing and dated.

V123 Revised Operational Objectives. The governing body ensures that they are operational, and that they are reviewed at least annually and revised as necessary.

V135 CEO: Administrative Function and Accountability. Organizing and coordinating the administrative functions of the facility, re-delegating duties as authorized, and establishing formal means of accountability for those involved in patient care.

V156 Use of Outside Resources. If the ESRD facility makes arrangements for the provision of a specific service as authorized in this subpart, the responsibilities, functions, objectives, and the terms of each arrangement, including financial provisions and charges, are delineated in a document signed by an authorized representative of the facility and the person or agency providing the service. The chief executive officer when utilizing outside resources, as a consultant, assures that he is apprised of recommendations, plans for implementation, and continuing assessment through dated, signed reports, which are retained by the chief executive officer for follow-up action and evaluation of performance.

V157 Patient Care Policies. The ESRD facility has written policies, approved by the governing body, concerning the provision of dialysis and other ESRD services to patients.

V165 Patient Care Policies: Emergencies. Care of patients in medical and other emergencies.

V175 Medical Supervision and Emergency Coverage. The governing body of the ESRD dialysis and/or transplant facility ensures that the health care of every patient is under the continuing supervision of a physician.

V176 Medical Emergency Coverage. That a physician is available in emergency situations.

V177 Medical Supervision: Orders. The physician responsible for the patient's medical supervision evaluates the patient's immediate and long-term needs and on this basis prescribes a planned regimen of care which covers indicated dialysis and other ESRD treatments, services, medication, diet, special procedures recommended for the health and safety of the patient, and plans for continuing care and discharge.

V179 Medical Supervision: Emergency Roster. The governing body ensures that there is always available medical care for emergencies, 24 hours a day, 7 days a week. There is posted at the nursing/monitoring station a roster with the names of the physicians to be called, when they are available for emergencies, and how they can be reached.

§405.2140 Physical Environment

V276 Emergency preparedness. Written policies and procedures specifically define the handling of emergencies that may threaten the health or safety of patients. Such emergencies would exist during a fire or natural disaster or during functional failures in equipment. Specific emergency preparedness procedures exist for different kinds of emergencies.

§405.2160 Affiliation Agreement/Arrangement

V411 Affiliation Agreement: Pts Accepted in Emergencies. The affiliation agreement or arrangement provides the basis for effective working relationships under which inpatient hospital care or other hospital services are available promptly to the dialysis facility's patients when needed. The dialysis facility has in its file documentation from the renal dialysis center to the effect that patients from the dialysis facility will be accepted and treated in emergencies.

Infection Control

Because of the extracorporeal blood exchanges in dialysis treatments, there is a risk of transmission of blood-borne infections/diseases.

Determine through observations, interviews, and record reviews if:

- There is evidence of collaboration between the ESRD facility and the LTC facility to investigate, control and prevent infections. Infection control policies of the LTC facility and ESRD facility are to be reviewed by the Medical Director of the Medicare-approved ESRD facility.
- The staff providing dialysis follows appropriate hand washing and gloving procedures.
- Items used for dialysis are either dedicated to single use or appropriately cleaned and disinfected.
- The multiple-use of single-use vials of Epoetin Alfa (EPO) is performed according to the Centers for Disease Control and Prevention (CDC) guidance.
- Clean and contaminated areas for dialysis are clearly separated and used appropriately.
- External transducer protectors are changed between patients and not reused.
- Dialysis stations and machines are disinfected between uses.
- Waste is managed and disposed of appropriately.

§405.2140 Physical Environment

V265 Functional, Sanitary, & Comfortable. The facility is maintained and equipped to provide a functional, sanitary, and comfortable environment with an adequate amount of well-lighted space for the service provided.

V266 Infection Control. There are written policies and procedures in effect for preventing and controlling hepatitis and other infections. These policies include, but are not limited to, appropriate procedures for surveillance and reporting of infections, housekeeping, handling and disposal of waste and contaminants, and sterilization and disinfection, including the sterilization and maintenance of equipment. Where dialysis supplies are reused, there are written policies and procedures covering the rinsing, cleaning, disinfection, preparation, and storage of reused items that conform to requirements for reuse.

V274 Contamination Prevention: Policies/Functions. The written patient care policies specify the functions that are carried out by facility personnel and by the self-dialysis patients with respect to contamination prevention.

§405.2150 Reuse

V388 Transducer filters. To control the spread of hepatitis, transducer filters are cleaned after each dialysis treatment and are not reused.

Water Treatment

For health and safety reasons, it is critical that the water used to reprocess dialyzers and to mix with concentrates to make dialysate is appropriately treated and monitored.

Determine through observations, interview and record review if the ESRD facility assures the following standards are met:

- The LTC location has equipment that ensures water used in dialysis treatments will meet the AAMI minimum standards for chemical contaminants and bacteriology.
- The LTC location ensures on a daily basis the water in the facility used for dialysis meets the AAMI minimum standards for the following: total chlorine less than 0.5 ppm and chloramines less than 0.1 ppm. Does the long-term care location test chlorines/chloramines daily prior to patient treatments?
- The water is cultured at least monthly. Are the results either less than 200 cfu/ml by culture for bacteria or less than 5 eu/ml by LAL for endotoxins?
- The dialysate is cultured monthly. Are the results less than 2000 cfu/ml for bacteria?
- The chemical analysis of the water done at least annually. Do the results meet AAMI standards?
- The person responsible for water treatment has an appropriate understanding of the water treatment equipment, testing, and procedures.

§405.2140 Physical Environment

V261 Water Treatment. The ESRD facility must employ the water quality requirements listed in paragraph (a)(5)(ii) of this section developed by the Association for the Advancement of Medical Instrumentation (AAMI) and published in "Hemodialysis Systems," second edition, which is incorporated by reference. **(ii)** Required water quality requirements are those listed in sections 3.2.1, Water Bacteriology; 3.2.2 Maximum Level of chemical contaminants; and in Appendix B: Guideline for Monitoring Purity of Water Used for Hemodialysis as B1 through B5.

V262 AAMI: Water Bacteriology. Total viable microbial count should not exceed 200/ml. A method of cleaning the equipment so that the equipment is capable of meeting this requirement shall be recommended by the manufacturer or supplier.

V263 AAMI: Dialysate Bacteriology. Total viable microbial count for the dialysate should not exceed 2000/ml.

V264 AAMI: Maximum Chemical Contaminants. The water used to prepare dialysate shall not contain chemical contaminants at concentrations in excess of those in Table 2, AAMI.

§405.2161 Physician Director

V423 Responsibility for Training Staff. Assuring adequate training of nurses and technicians in dialysis techniques.

Reuse

If a home dialysis program in a LTC facility reuses dialyzers, the reuse process must conform to Federal standards for reuse per **42 CFR §405.2150 (V300-V392).**

Equipment Installation and Maintenance

If a DME supplier provides equipment for home dialysis in a LTC facility under Method II, the Medicare-approved ESRD support facility remains responsible for overall management and oversight of equipment maintenance and installation.

Determine through observations, interview and record review if:

- There is an emergency tray, including emergency drugs, medical supplies, and emergency equipment available and accessible at all times at the ESRD facility's LTC location. Emergency equipment and supplies should be comparable to those located in an outpatient ESRD facility.
- Staff/caregivers are appropriately monitoring machine safety alarms as needed and continuously monitoring machine-derived blood pressure and fluid status.
- Equipment records show that preventive maintenance and repairs were done in a timely manner.
- A system is in place to monitor equipment function, identify equipment problems, and to ensure updates on preventive maintenance.

§405.2140 Physical Environment

V258 Equipment Preventive Maintenance. All electrical and other equipment used in the facility is maintained free of defects, which could be a potential hazard to patients and personnel. There is established a planned program of preventive maintenance of equipment used in dialysis and related procedures in the facility.

V281 Emergencies: Drugs and Supplies. There is available at all times on the premises a fully equipped emergency tray, including emergency drugs, medical supplies, and equipment.

V283 Emergencies: Staff Trained in Procedures. The staff is familiar with the use of all dialysis equipment and procedures to handle medical emergencies.

§405.2150 Reuse

V305 Equipment Maintenance Record. A log must be maintained of the date of preventive maintenance procedures and the date of results of scheduled testing in order to ensure the proper functioning of reprocessing equipment, environmental-control equipment, safety equipment, or other equipment.

§405.2161 Physician Director

V423 Responsibilities: Training Staff. Assuring adequate training of nurses and technicians in dialysis techniques.

V424 Responsibilities: Monitoring Process. Assuring adequate monitoring of the patient and the dialysis process, including, for self-dialysis patients, assuring periodic assessment of patient performance of dialysis tasks.

§405.2162 Staff

V434 Staff Numbers Meet Patient Needs. An adequate number of personnel are readily available to meet medical needs.

Staffing, Staff Training and Patient Monitoring During Treatment

In reviewing staffing and staff training, the survey process needs to determine that either the LTC facility resident or the resident's assistant (i.e., "caregiver") has the required knowledge and skills to perform required dialysis tasks. The surveyors also must determine if the staff in the LTC facility is trained to handle medical emergencies while residents are dialyzing and whether ongoing care is appropriate for dialysis patients. The LTC facility resident needs to be observed during dialysis treatment to ensure that treatments are delivered appropriately.

Determine through observation, interview and record review if:

- A "qualified" nurse, who has at least 3 months of his/her ESRD experience in training patients in self-care, is in charge of all training for "home" dialysis in a LTC facility, including caregivers and LTC facility staff.
- The training curriculum is appropriate for the type of dialysis provided and covers medical emergencies. Medical emergencies can include the administration of CPR and intravenous medication, and the treatment of air emboli, blood loss, and severe hypotension.
- There is an appropriately trained caregiver providing adequate monitoring while patients are dialyzing in the ESRD facility's LTC locations.

- For purposes of home dialysis in a LTC facility, the ESRD facility must ensure either through direct employment or other contractual arrangement with the LTC facility that one or more currently licensed health professionals experienced in rendering ESRD care is on duty to oversee ESRD patient care whenever patients are undergoing dialysis. The licensed health professional must have practical experience in or be trained by the ESRD facility to perform assessments, observe the patients pre and post dialysis, respond to emergency situations relative to dialysis treatments, and administer any necessary intravenous, intradialytic and intramuscular medications in accordance with all Federal and State requirements.
- A "qualified" renal dietitian monitors the dialysis patient's nutritional and dietary needs.
- A "qualified" renal social worker monitors the social service needs and services provided to the dialysis patient.
- The Physician Director of the ESRD facility assumes responsibility for ensuring adequate training of the staff and the availability of patient teaching materials.
- Trained personnel (staff/caregiver) are responsible for treatments.
- There are patient care policies, which are specific to care provided in the LTC setting, that cover the care of patients in medical and other emergencies.
- The treatment being received match the orders for treatment, and blood pressure and fluid status are continuously being monitored.
- Staff/caregiver is appropriately trained in preparing the dialysate bath, dialysis machine, dialyzer, and priming the machine with initial settings.
- Staff/caregiver is appropriately trained to handle equipment emergencies.

§405.2136 Governing Body

V144 Personnel Policies/Procedures: Staff Qualified. These policies and procedures ensure that: **(1)** All members of the facility's staff are qualified to perform the duties and responsibilities assigned to them and meet such Federal, State, and local professional requirements as may apply.

V170 Patient Care Policies: Consultants. Consultant qualifications, functions, and responsibilities.

§405.2140 Physical Environment

V282 Emergencies: Staff Trained in Equipment. There is available at all times on the premises a fully equipped emergency tray, including emergency drugs, medical supplies, and equipment, and staff are trained in its use.

V283 Emergencies: Staff Trained in Procedures. The staff is familiar with the use of all dialysis equipment and procedures to handle medical emergencies.

§405.2161 Physician Director

V421 Qualifications. The director of a dialysis facility is a qualified physician director.

V423 Responsibilities: Training Staff. Assuring adequate training of nurses and technicians in dialysis techniques.

V424 Responsibilities: Monitoring Process. Assuring adequate monitoring of the patient and the dialysis process, including, for self-dialysis patients, assuring periodic assessment of patient performance of dialysis tasks.

V426 Responsibilities: Self Care. When self-dialysis training is offered, assuring that patient teaching materials are available for the use of all trainees during training and at times other than during the dialysis procedure.

§405.2162 Staff

V430 Condition: Staff of a Renal Dialysis Facility or Renal Dialysis Center. Properly trained personnel are present in adequate numbers to meet the needs of the patients, including those arising from medical and nonmedical emergencies.

V431 Registered Nurse. The dialysis facility employs at least one full time qualified nurse responsible for nursing service.

V432 On-duty personnel: Licensend Person. Whenever patients are undergoing dialysis: (1) one currently licensed health professional (e.g. physician, registered nurse, or licensed practical nurse) experienced in rendering ESRD care is on duty to oversee ESRD patient care.

V433 Staff Ratios Meet Patient Needs. An adequate number of personnel are present so that the patient/staff ratio is appropriate to the level of dialysis care being given and meets the needs of patients.

V434 Staff Numbers Meet Patient Needs. An adequate number of personnel are readily available to meet medical needs.

V436 Self-care dialysis training personnel. If the facility offers self-care dialysis training, a qualified nurse is in charge of such training.

§405.2163 Minimal Service Requirements

V446 Social Worker Qualified. Social services are furnished by a qualified social worker who has an employment or contractual relationship with the facility.

V448 (d) Dietetian Qualified. Each patient is evaluated as to his nutritional needs by the attending physician and by a qualified dietician who has an employment or contractual relationship with the facility.

Patient Care Plans and Long-Term Program

Coordination of care and communication between the ESRD facility staff and the LTC facility staff should be clearly documented in the patients' medical records at the ESRD facility and at the LTC location.

Determine through observation, record review and interview if:

- There is a multidisciplinary, written, individualized patient care plan that is updated as required.
- The LTC staff and ESRD facility staff communicates and coordinates the development and implementation of the individualized patient care plan.
- There is a long-term program that is updated annually.
- The ESRD renal dietitian and social worker participate in long-term care plans and patient care planning, and communicate and coordinate with the long-term care facility staff to address individual patient needs.
- The Physician Director of the ESRD facility assumes responsibility for participating in the long-term program.
- The physician responsible for the patient's dialysis treatments work with a professional ESRD team to develop and review the individualized patient care plans.

§405.2136 Governing Body

V174 Patient Care Policies. The governing body adopts policies to ensure there is evaluation of the progress each patient is making towards the goals stated in the patient's long-term program and patient's care plan. Such evaluations are carried out through regularly scheduled conferences, with participation by the staff involved in the patient's care.

§405.2137 Long Term Program and Patient Care Plan

V187 Patient Long-Term Program: Written There is a written long-term program representing the selection of a suitable treatment modality (i.e., dialysis or transplantation) and dialysis setting (e.g., home, self-care) for each patient.

V188 LTP: Team Members. The program is developed by a professional team which includes but is not limited to the physician director of the dialysis facility or center where the patient is currently being treated, a physician director of a center or facility which offers self-care dialysis training (if not available at the location where the patient is being treated), a transplant surgeon, a qualified nurse responsible for nursing services, a qualified dietitian and a qualified social worker.

V189 LTP: Reviewed by Team. The program is formally reviewed and revised in writing as necessary by a team which includes but is not limited to the physician director of the dialysis facility or center where the patient is presently being treated, in addition to the other personnel listed in paragraph (a)(1) of this section at least every 12 months or more often as indicated by the patient's response to treatment.

V192 Patient Care Plan: Written, Assessed. There is a written patient care plan for each patient of an ESRD facility (including home dialysis patients under the supervision of the ESRD facility), based upon the nature of the patient's illness, the treatment prescribed, and an assessment of the patient's needs.

V193 PCP: Individualized. The patient care plan is personalized for the individual, reflects the psychological, social, and functional needs of the patient, and indicates the ESRD and other care required as well as the individualized modifications in approach necessary to achieve the long-term and short term goals.

V194 PCP: Team. The plan is developed by a professional team consisting of at least the physician responsible for the patient's ESRD care, a qualified nurse responsible for nursing services, a qualified social worker, and a qualified dietitian.

V195 PCP: Patient Involved. The patient, parent, or legal guardian, as appropriate, is involved in the development of the care plan, and due consideration is given to his preferences.

V196 PCP: Frequency. The care plan for patients whose medical condition has not become stabilized is reviewed at least monthly by the professional patient care team described in paragraph (b)(2) of this section. For patients whose condition has become stabilized, the care plan is reviewed every 6 months. The care plan is revised as necessary to insure that it provides for the patients' ongoing needs.

V197 PCP: Copy with Transfer. If the patient is transferred to another facility, the care plan is sent with the patient or within 1 working day.

V198 PCP: Home Patients. For a home-dialysis patient whose care is under the supervision of the ESRD facility, the care plan provides for periodic monitoring of the patient's home adaptation, including provisions for visits to the home by qualified facility personnel to the extent appropriate.

V199 PCP: EPO at Home. Beginning July 1, 1991, for a home dialysis patient, and beginning January 1, 1994, for any dialysis patient who uses EPO in the home, the plan must provide for monitoring home use of EPO that includes the following: (i) Review of diet and fluid intake for indiscretions as indicated by hyperkalemia and elevated blood pressure secondary to volume overload.

§405.2138 Patient Rights

V222 Participation in Planning. All patients treated in the facility are afforded the opportunity to participate in the planning of their medical treatment and to refuse to participate in experimental research.

Patient Rights and Responsibilities

Determine through interview with patients and families if:

- The patient/family was fully informed of options, including options for different modalities and settings. Form CMS-382, ESRD Beneficiary Selection, may be reviewed to verify patient election of Method I or Method II.
- Patients' rights are being observed, including the rights to privacy and respect.

- The patient/family is fully informed of services available in the facility and of related charges for services not covered under Medicare.
- If the patient/family is aware that there are grievance/complaint procedures.

§405.2138 Patients Rights and Responsibilities

V215 Condition: Patients' Rights and Responsibilities. The governing body of the ESRD facility adopts written policies regarding the rights and responsibilities of patients and, through the chief executive officer, is responsible for development of, and adherence to, procedures implementing such policies. These policies and procedures are made available to patients and any guardians, next of kin, sponsoring agency (ies), representative payees, and to the public.

V217 Informed of Rights/Responsibilities. All Patients in the Facility: (1) Are fully informed of these rights and responsibilities, and of all the rules and regulations governing patient conduct and responsibilities.

V218 Informed of Services/Charges. Are fully informed of services available in the facility and of related charges including any charges for services not covered under title XVIII of the Social Security Act;

V219 Informed of Medical Condition. Are fully informed by a physician of their medical condition unless medically contraindicated (as documented in their medical records).

V220 Informed of Reuse. Are fully informed regarding the facility's reuse of dialysis supplies, including hemodialyzers. If printed materials such as brochures are utilized to describe a facility and its services, they must contain a statement with respect to reuse; and

V221 Informed of Modalities. Are fully informed regarding their suitability for transplantation and home dialysis.

V224 Respect, Dignity, and Privacy. All patients are treated with consideration, respect, and full recognition of their individuality and personal needs, including the need for privacy in treatment.

V225 Translators. Provision is made for translators where a significant number of patients exhibit language barriers.

V226 Confidentiality. All patients are ensured confidential treatment of their personal and medical records, and may approve or refuse release of such records to any individual outside the facility, except in case of their transfer to another health care institution or as required by Federal, State, or local law and the Secretary for proper administration of the program.

Medical Records

Patient records (electronic or paper) must be accessible at both the ESRD facility and the ESRD facility's LTC location.

Determine if:

- The medical records are complete and maintained both at the LTC facility and at the Medicare-approved ESRD facility.
- The records document the operation, disinfection and preventive maintenance and repair of dialysis, water treatment, and reuse equipment.
- The results of testing and cultures are consistently documented and reviewed.
- Affiliation agreements are appropriate and complete.

§405.2139 Medical Records

V230 Condition: Medical Records. The ESRD facility maintains complete medical records on all patients (including self-dialysis patients within the self-dialysis unit and home dialysis patients whose care is under the supervision of the facility) in accordance with accepted professional standards and practices. A member of the facility's staff is designated to serve as supervisor of medical records services, and ensures that all records are properly documented, completed, and preserved. The medical records are completely and accurately documented, readily available, and systematically organized to facilitate the compilation and retrieval of information.

V231 Medical Records: Identify, Justify, Document. Each patient's medical record contains sufficient information to identify the patient clearly, to justify the diagnosis and treatment, and to document the results accurately.

V232 Patient Assessments. All medical records contain the following general categories of information. Documented evidence of assessment of the needs of the patient,

V233 Reuse Information. Whether the patient is treated with a reprocessed hemodialyzer,

V234 LTP and PCP. Establishment of an appropriate plan of treatment, and of the care and services provided.

V235 Patient Involvement in LTP/PCP. Evidence that the patient was informed of the results of the assessment.

V236 ID and Social Data. Identification and social data.

V237 Consents. Signed consent forms, referral information with authentication of diagnosis.

V238 Medical & Nursing History. Medical and nursing history of patient.

V239 Physician Exams. Report(s) of physician examination(s).

V240 Orders. Diagnostic and therapeutic orders.

V241 Progress Notes. Observations and progress notes.

V242 Treatments and Findings. Reports of treatments and clinical findings.

V243 Lab Reports. Reports of laboratory and other diagnostic tests and procedures.

V244 Discharge Summary. Discharge summary including final diagnosis and prognosis.

V245 Protection of Medical Record Information. The ESRD facility safeguards medical record information against loss, destruction, or unauthorized use. The ESRD facility has written policies and procedures which govern the use and release of information contained in medical records. Written consent of the patient, or of an authorized person acting in behalf of the patient, is required for release of information not provided by law. Medical records are made available under stipulation of confidentiality for inspection by authorized agents of the Secretary, as required for administration of the ESRD program under Medicare.

V246 Medical Records Supervisor. A member of the ESRD facility's staff is designated to serve as supervisor of the facility's medical records service. The functions of the medical records supervisor include, but are not limited to, the following: Ensuring that the records are documented, completed, and maintained in accordance with accepted professional standards and practices; safeguarding the confidentiality of the records in accordance with established policy and legal requirements; ensuring that the records contain pertinent medical information and are filed for easy retrieval. When necessary, consultation is secured from a qualified medical record practitioner.

V247 Completion of Medical Records and Centralization of Clinical Information. Current medical records and those of discharged patients are completed promptly. All clinical information pertaining to a patient is centralized in the patient's medical record.

V248 Self Care/Home Patients. Provision is made for collecting and including in the medical record medical information generated by self-dialysis patients. Entries concerning the daily dialysis process may either be completed by staff, or be completed by trained self-dialysis patients, trained home dialysis patients or trained assistants and countersigned by staff.

V249 Retention and Preservation of Records. Medical records are retained for a period of time not less than that determined by the State statute governing records retention or statute of limitations; or in the absence of a State statute, 5 years from the date of discharge; or, in the case of a minor, 3 years after the patient becomes of age under State law, whichever is longest.

V250 Location and Facilities. The facility maintains adequate facilities, equipment, and space conveniently located, to provide efficient processing of medical records (e.g., reviewing, filing, and prompt retrieval) and statistical medical information (e.g., required abstracts, reports, etc.).

V251 Transfer of Medical Information. The facility provides for the interchange of medical and other information necessary or useful in the care and treatment of patients transferred between treating facilities, or in determining whether such patients can be adequately cared for otherwise than in either of such facilities.

Quality Assurance/Quality Improvement

The Medicare-approved ESRD facility must monitor the care of LTC facility residents who are receiving dialysis treatments, whether in an ESRD facility or in a LTC facility.

Determine through record review and interview if:

- The dialysis care, including patient outcomes, is monitored, reviewed, and identified problems are corrected.
- The ESRD staff report and review incidents and accidents regarding dialysis care in LTC facilities to both the LTC facility and the ESRD support facility.

§405.2136 Governing Body

V112 Governing Body: Health and Safety. And to the health care and safety of patients,

V146 Incidents Reviewed. Reports of incidents and accidents to patients and personnel are reviewed to identify health and safety hazards.

§405.2150 Reuse

V387 Surveillance of Patient Reactions. In order to detect bacteremia and to maintain patient safety when unexplained events occur, the facility- (i) Takes appropriate blood cultures at the time of a febrile response in a patient; and

§405.2161 Physician Director

V424 Responsibilities: Monitoring Process. Assuring adequate monitoring of the patient and the dialysis process, including, for self-dialysis patients, assuring periodic assessment of patient performance of dialysis tasks;

Laboratory Services

The laboratory services may either be performed by the ESRD facility that is Clinical Laboratory Improvement Amendments (CLIA) certified or by arrangements with a CLIA-certified laboratory. Determine through record review and interview if the facility has systems in place to ensure laboratory services are provided to the patients.

§405.2163 Minimal Service Requirements

V443 Laboratory Services: In-house. The dialysis facility makes available laboratory services (other than the specialty of tissue pathology and histocompatibility testing), to meet the needs of the ESRD patient. All laboratory services must be performed by an appropriately certified laboratory in accordance with part 493 of this chapter. If the renal dialysis facility furnishes its own laboratory services, it must meet the applicable requirements established for certification of laboratories found in part 493 of this chapter.

V444 Laboratory Services: Outside. If the facility does not provide laboratory services, it must make arrangements to obtain these services from a laboratory certified in the appropriate specialties and subspecialties of service in accordance with the requirements of part 493 of this chapter.

Attachment B

Survey Protocol for Long Term Care Facilities

The provision of home dialysis treatments in a Long Term Care (LTC) facility place an increased burden on the LTC facility staff and may place the resident population at increased risk for negative outcomes. To protect the residents and ensure adherence to and compliance with Federal regulatory requirements and current standards of quality, it is critical for survey teams to recognize situations where home dialysis is occurring in the LTC setting and to understand the roles and responsibilities of both the LTC and the End-Stage Renal Disease (ESRD) facilities.

This survey protocol includes references to potential regulatory citations for LTC Facilities by F-Tag numbers, though not all-inclusive, to assist the survey team in determining the facility's compliance or non-compliance with regulatory requirements. These references are provided after each highlighted protocol.

Survey Preparation and Procedures for Long Term Care Facilities (SNF/NF)

The provision of home dialysis in the LTC facility is the responsibility of the Medicare-approved ESRD facility. The LTC survey teams are to survey the LTC facility with the existing regulations for all residents who receive dialysis whether in an outpatient treatment setting or onsite in the LTC facility. For all residents who receive dialysis, the LTC facility is responsible for the delivery of care and services to residents before transferring the resident to the ESRD facility or onsite team and after the resident has received dialysis and is assessed as stable for transfer back to the LTC facility team. When the ESRD facility is providing the home dialysis procedure on the premises of the LTC facility and the facility allows their staff to contract with the ESRD facility to provide aspects of the dialysis care, the LTC surveyors must be more astute to issues surrounding this hybrid model of care. To evaluate the LTC facility's compliance with current regulations and standards of quality, the LTC survey team uses current survey procedures. The survey team must use the skills of observation, record review, and interview to validate or invalidate the facility's compliance.

Entrance Conference:

During the entrance conference, interview staff to determine if:

- The Skilled Nursing Facility (SNF) or Nursing Facility (NF) is Medicare-approved as an ESRD provider, has a designated area in the facility that is Medicare-approved as an ESRD provider, and/or has home dialysis services onsite. If home dialysis occurs onsite in the facility, identify this as an area of concern for the survey.
- There are residents in the facility who are receiving home dialysis. If so, have the facility provide a list of the residents' names, room numbers, the name of the ESRD assigned caregiver/technician (and identify if this caregiver is provided by the ESRD facility, the DME supplier, or the LTC facility), and the days and times when each resident will receive his/her dialysis treatment.

- The care is coordinated for residents who receive dialysis. Ask the Administrator to explain how the coordination of care is developed, implemented, and monitored. Obtain a copy of the written contract, agreement, arrangement, polices/procedures and/or plan of care, specifying how care is coordinated, to assist with the evaluation of care. Review the documents as described in the LTC survey protocol (Appendix P, page P-54). Alert the State Survey Agency's (SA) ESRD survey team that dialysis is being provided within this LTC facility and to any concerns identified during the survey of the LTC facility.

Initial Tour:

During the tour and observation of the facility, observe and interview residents, staff, and/or family to determine if home dialysis is being provided in the facility and document any facility practices that appear questionable. Observe locations for the storage of dialysis equipment (in resident's room or on the unit). For identified concerns, share information with team members and add selected residents to the sample.

During the LTC survey, if residents, family, or staff voice concerns about the provision of care to residents during the home dialysis procedure, or if you identify concerns through your investigations related to the care of the resident during dialysis, identify the involved resident(s), specific issues, and copy pertinent documents in the resident(s) record pertaining to the concerns. **Notify the SA and file a complaint against the ESRD facility for review by the ESRD survey team.**

NOTE: This protocol is to be used with existing survey procedures and guidance to surveyors found in the State Operations Manual, Appendix P and PP. The following investigative components are added to address the home dialysis component of the survey.

Resident Rights

Many residents in the LTC facility will not be able to independently participate in the dialysis process and will require the ESRD facility/DME supplier to assign a caregiver/technician. Determine through interview with residents, families/responsible party, LTC facility staff and medical record review if:

- The LTC and ESRD/DME provider coordinated the home dialysis care to ensure that the resident and/or family was informed of the resident's suitability for home dialysis and the role of the ESRD facility staff including the assigned caregiver/technician; and
- The ESRD facility staff documented that the resident or family/responsible party was given explanations of the benefits, reasonable risks of the home dialysis treatment, and any related charges for services not covered by Medicare.

483.10 Resident Rights (b) Notice of rights and services and (d) Free Choice

F154 (3) The resident has the right to be fully informed in language that he or she can understand of his or her total health status, including but not limited to, his or her medical condition; **(d) (2)** Be fully informed in advance about care and treatment and of any changes in that care for treatment that may affect the resident's well being.

F155 (4) The resident has the right to refuse treatment, to refuse to participate in experimental research, and to formulate an advance directive as specified in paragraph (8) of this section

F156 (5) The facility must—**(i)(b)** inform each resident of those other items and services that the facility offers and for which the resident may be charged, and the amount of charges for those services; **(6)** The facility must inform each resident before, or at the time of admission, and periodically during the resident's stay, of services available in the facility and or charges for those services, including any charges for services not covered under Medicare or by the facility's per diem rate. **(9)** The facility must inform each resident of the name, specialty, and way of contacting the physician responsible for his or her care.

483.75 Administration

514 (l) Clinical Records **(1)** The facility must maintain clinical records on each resident in accordance with accepted professional standards and practices that are **(i)** Complete; **(ii)** Accurately documented; **(iii)** Readily accessible; and **(iv)** Systematically organized.

Coordination of Care

The LTC and ESRD facilities' staff are to coordinate the assessment and care planning to ensure that the ESRD and LTC interdisciplinary teams appropriately assessed the resident's suitability for home dialysis and meet to develop and revise the plan of care, in accordance with the LTC facility regulatory requirements and the individual resident's needs and preferences.

Determine through observation, record review, and interview with residents, family/responsible party, and LTC facility staff if:

- The comprehensive care plan was developed by the interdisciplinary teams from both the ESRD and LTC facilities including the physicians, registered nurses, dieticians, social workers, ESRD social worker, ESRD dietician, the resident, ESRD home dialysis assigned caregiver/technician (if applicable), and family member, or responsible party.
- The care plan is implemented by qualified staff and the services implemented meet professional standards of quality.
- The care plan was reviewed and revised based on the resident's response to home dialysis and outpatient dialysis in accordance with regulatory requirements.
- The LTC facility staff communicates identified concerns with the resident's nutritional status or psychosocial needs to the ESRD social worker and/or dietitian.

483.20 Resident Assessment

F272 (b) Comprehensive Assessments. **(1)** Resident Assessment Instrument (RAI). A facility must make a comprehensive assessment of a resident's needs, using the RAI specified by the State.

F274 (ii) Within 14 days after the facility determines, or should have determined, that there has been a significant change in the resident's physical or mental condition.

F279 (k) Comprehensive Care Plans. **(1)** The facility must develop a comprehensive care plan for each resident that includes measurable objectives and timetables to meet a resident's medical, nursing, and mental and psychosocial needs that are identified in the comprehensive assessment. The care plan must describe the following: **(i)** The services that are to be furnished to attain or maintain the resident's highest practicable physical, mental, and psychosocial well being as required under 483.25.

F280 (k)(2)(ii) A comprehensive care plan must be prepared by an interdisciplinary team, that includes the attending physician, a registered nurse with responsibility for the resident, and other appropriate staff in disciplines as determined by the resident's needs, and, to the extent practicable, the participation of the resident, the resident's family or the resident's legal representative; and **(iii)** Periodically reviewed and revised by a team of qualified persons after each assessment.

F281 (k)(3) The services provided or arranged by the facility must **(i)** Meet professional standards of quality.

F282(ii) Be provided by qualified persons in accordance with each resident's written plan of care.

483.75 Administration

514 (l) Clinical Records **(1)** The facility must maintain clinical records on each resident in accordance with accepted professional standards and practices that are **(i)** Complete; **(ii)** Accurately documented; **(iii)** Readily accessible; and **(iv)** Systematically organized.

Provision of Care

The ESRD/ DME assigned caregiver/technician and licensed health professional designated by the ESRD facility is responsible for the surveillance of the resident(s) during the dialysis treatment and documentation of the resident's response to dialysis. During the LTC survey process, determine if:

- The LTC facility ensures the availability of sufficient staffing for other residents in the facility when home dialysis is provided onsite.
- The LTC facility ensures physician supervision of the care for the resident who receives dialysis treatments, physician availability during emergencies and how this is accomplished.

- The Medical Director has reviewed the policies and procedures for care of the residents receiving dialysis.
- The resident is receiving EPO. Investigate to determine if:
    a) the ESRD and LTC facility staff coordinated how hemoglobin and hematocrit lab values are ordered, monitored, and results reported to the physician;
    b) the LTC facility pharmacist or consultant pharmacist reports irregularities of EPO administration and potential drug interaction concerns; and
    c) the ESRD and LTC facility staff have established policies and procedures for the dispensing and storage of EPO.
- The LTC facility staff ensures that the resident's room or area used for dialysis has a functioning resident call system or other device to summon help in the event of an emergency.
- The resident's room or designated area in the LTC facility is set up and equipped to afford personal privacy and respect during the home dialysis treatment.
- Through observation and interview with LTC facility staff and review of training records if the LTC facility staff demonstrates competency in the:
    a) Clinical monitoring and care of the resident's vascular access (fistula, graft or central venous catheter) and post dialysis complications;
    b) Clinical monitoring for residents who receive EPO;
    c) Clinical monitoring and reporting of medication side effects and adverse drug reactions; and
    d) Identification, monitoring and reporting of nutritional and hydration complications.

483.10 Resident Rights

F157 (b) (11) Notification of changes. **(i)** A facility must immediately inform the resident; consult with the resident's physician; and if known, notify the resident's legal representative or an interested family member when there is **(B)** A significant change in the resident's physical, mental, or psychosocial status (i.e., a deterioration in health, mental, or psychosocial status in either life-threatening conditions or clinical complications) **(C)** A need to alter treatments significantly (i.e., a need to discontinue an existing form of treatment due to adverse consequences, or to commence a new form of treatment); or **(D)** A decision to transfer or discharge the resident from the facility as specified in 483.12(a).

F164 (e) Privacy and confidentiality. The resident has the right to personal privacy and confidentiality of his or her personal and clinical records. **(1)** Personal privacy includes accommodations, medical treatment, written and telephone communications, personal care, visits, and meetings of family and resident groups, but this does not require the facility to provide a private room for each resident.

483.15 Quality of Life

F241 (a) Dignity. The facility must promote care for residents in a manner and in an environment that maintains or enhances each resident's dignity and respect in full recognition of his or her individuality.

483.20 Resident Assessment

F282 (ii) Be provided by qualified persons in accordance with each resident's written plan of care.

483.25 Quality of Care

F309 Quality of Care. Each resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well being, in accordance with the comprehensive assessment and plan of care.

F312 (3) A resident who is unable to carry out activities of daily living receives the necessary services to maintain good nutrition, grooming, and personal and oral hygiene.

F316 (2) A resident who is incontinent of bladder receives appropriate treatment and services to prevent urinary tract infections and to restore as much normal bladder function as possible.

F326 The resident **(i) (2)** Receives a therapeutic diet when there is a nutritional problem.

F327 (j) Hydration. The facility must provide each resident with sufficient fluid intake to maintain proper hydration and health.

F329 (l) (1) Unnecessary drugs. General. Each resident's drug regimen must be free from unnecessary drugs. An unnecessary drug is any drug when used:
(iii) without adequate monitoring; or
(v) in the presence of adverse consequences, which indicate, the dose should be reduced or discontinued.

483.30 Nursing Services

F353 The facility must have sufficient nursing staff to provide nursing and related services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident, as determined by resident assessments and individual plans of care.

483.40 Physician Services

F385 (a) Physician supervision. The facility must ensure that (1) The medical care of each resident is supervised by a physician; and (2) Another physician supervises the medical care of residents when their attending physician in unavailable.

F389 (d) Availability of physicians for emergency care. The facility must provide or arrange for the provision of physician services 24 hours a day, in case of emergency.

483.60 Pharmacy services.

F425 The facility must provide routine and emergency drugs and biologicals to its residents, or obtain them under an agreement described in section 483.75 (h) of this part. The facility may permit unlicensed personnel to administer drugs if State law permits, but only under the general supervision of a licensed nurse.

F428 (c) Drug regimen review. **(1)** The drug regimen of each resident must be reviewed at least once a month by a licensed pharmacist.

F429 (c) (2) The pharmacist must report any irregularities to the attending physician, and the director of nursing.

F432 (e) Storage of drugs and biologicals. (1) In accordance with State and Federal laws, the facility must store all drugs and biologicals in locked compartments under proper temperature controls, and permit only authorized personnel to have access to the keys.

483.70 Physical Environment

F457 (i) Accommodate no more than four residents.

F463 (f) Resident call system. The nurse's station must be equipped to receive resident calls through a communication system from – **(1)** Resident rooms; and **(2)** Toilet and bathing facilities.

483.75 Administration

F501 (i) Medical Director. **(2)** The medical director is responsible for –
(i) implementation of resident care policies; and
(ii) the coordination of medical care in the facility.

F502 (3) Laboratory services. **(1)** The facility must provide or obtain laboratory services to meet the needs of its residents. The facility is responsible for the quality and timeliness of the services.

F505 (ii) Promptly notify the attending physician of the findings.

F507 (iv) File in the resident's clinical record laboratory reports that are dated and contain the name and address of the testing laboratory.

F514 (l) Clinical Records. **(1)** The facility must maintain clinical records on each resident in accordance with accepted professional standards and practices that are **(i)** Complete; **(ii)** Accurately documented; **(iii)** Readily accessible; and **(iv)** Systematically organized.

Infection Control:

The LTC facility staff ensures that disposal of biohazardous waste is done in accordance with LTC facility infection control regulatory requirements and practices. Determine if:

- The LTC and ESRD facilities staff have coordinated policies related to infection control practices for the resident receiving home dialysis treatment.
- These policies and procedures have been reviewed and approved by the LTC Medical Director.
- The LTC facility staff ensures that the ESRD facility staff disposes of biohazardous waste in accordance with the LTC infection control practices and regulatory requirements.

483.65 Infection Control

F441 Infection control. The facility must establish and maintain an infection control program designed to provide a safe, sanitary, and comfortable environment and to help prevent the development and transmission of disease and infection.
(a) Infection control program. The facility must establish an infection control program under which it --
(1) Investigates, controls, and prevents infections in the facility;
(3) Maintains a record of incidents and corrective actions related to infections.

Equipment Maintenance

The ESRD facility is responsible for the maintenance of all dialysis equipment for the resident. Determine if the LTC facility ensures that there is an emergency electrical system available in the rooms used for dialysis; and that the plan for an emergency water supply addresses provision of additional water for dialysis treatments.

483.70 Physical Environment

F455 (b) Emergency Power. **(1)** An emergency electrical power system must supply power adequate at least for lighting all entrances and exits; equipment to maintain the fire detection, alarm, and extinguishing systems; and life support systems in the event the normal electrical supply is interrupted. **(2)** When life support systems are used, the facility must provide emergency electrical power with an emergency generator.

F466 (h)(1) Establish procedures to ensure that water is available to essential areas when there is a loss of normal water supply.

Medical Records

Determine if the LTC facility ensures that the resident's medical record is complete, accurate, and reflects the resident's care during dialysis treatment as well as his/her response to the dialysis process. This includes documentation of complications and notifications to physicians, families/responsible party, and ESRD personnel.

483.75 Administration

F514 (1) Clinical Records. **(1)** The facility must maintain clinical records on each resident in accordance with accepted professional standards and practices that are **(i)** Complete; **(ii)** Accurately documented; **(iii)** Readily accessible; and **(iv)** Systematically organized. **(5)** The clinical record must contain— **(i)** Sufficient information to identify the resident; **(ii)** A record of the resident's assessments; **(iii)** The plan of care and services provided; **(iv)** The results of any preadmission screening conducted by the State; and **(v)** Progress notes.

F515 (2) clinical records must be retained for – **(i)** The period of time required by State law; or **(ii)** Five years from the date of discharge when there is not a requirement in State law; or **(iii)** For a minor, three years after a resident reaches legal age under State law.

F516 (3) The facility must safeguard clinical record information against loss, destruction, or unauthorized use.

Quality Assurance

Determine if the LTC facility has identified problems with dialysis treatment and care through the Quality Assessment and Assurance Program. If so, interview LTC facility staff to determine if corrective actions have been implemented to ensure the quality and continuity of care, minimization of infections and injuries, and coordination of the plan of care.

483.75 Administration

(o) Quality assessment and assurance. F521 (ii) Develops and implements appropriate plans of action to correct identified quality deficiencies.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-12-25
Baltimore, Maryland 21244-1850

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-04-37

DATE: **July 8, 2004**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: 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

Letter Summary

- S&C Letter 04-24, issued March 19, 2004, clarified certification requirements and coordination of care expectations for residents of LTC facilities who receive ESRD services.
- This addendum to that letter includes as an attachment follow-up Questions and Answers (Qs &As) regarding the scope of the guidance and the responsibilities of the providers.

On March 19, 2004, we issued S&C Letter 04-24. This letter was developed to provide clarification regarding the expectations and approval process for facilities that intend to offer care for residents in a LTC facility. The issuance of S&C Letter 04-24 stimulated questions about the scope of the guidance, responsibilities for service and care, and survey procedures related to this service. In this addendum, we provide answers to the questions that have emerged. The Qs and As follow as an attachment.

Effective Date: Immediately

Training: The information contained in this announcement should be shared with all survey and certification staff, their managers, and the state/RO training coordinator.

/s/
Thomas E. Hamilton

cc: Survey and Certification Regional Office Management (G-5)

Attachment

EXHIBIT
2

Follow-up Questions and Answers 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

Basis for Guidance:

Q1. What is the basis for the guidance for ESRD facilities and LTC facilities detailed in S&C Letter #04-24?

A1. The guidance specified in S&C Letter #04-24 reflects current requirements specified ESRD regulations at 42 CFR §405.2100 and LTC facility regulations at 42 CFR §483. ESRD facilities are required to meet the Conditions at §405.2130 through §405.2163 unless otherwise specified by the regulations. LTC facilities are required to meet the regulations at §483.

Relationship to Rules:

Q2. What is the relationship between the policy memo guidance and current rules?

A2. S&C Letter # 04-24 provides guidance to state and federal surveyors in applying existing regulations. There are no new regulations in the letter. S&C Letter #04-24 organizes existing regulations in a single document for added convenience. The letter then provides guidance to surveyors in the application of those regulations.

Locating Form CMS-3427A:

Q3. Where do we locate Form CMS-3427A that is to be used for applicants seeking approval to provide ESRD services in a LTC facility?

A3. Applicants should use Form CMS-3427 found on the CMS website at www.cms.hhs.gov/forms. Form 3427A is no longer in print.

Application to Hospital-based Nursing Homes:

Q4. Do the ESRD and LTC survey protocols in this letter apply to hospital-based nursing homes that offer outpatient dialysis services to residents with ESRD?

A4. Yes. The survey protocols apply to all nursing home facilities that offer home dialysis to residents whose dialysis services are paid under the Medicare ESRD Part B benefit. If the dialysis care is not covered under the Medicare ESRD program, then care may be reviewed in a different manner.

Agreement between Durable Medical Equipment (DME) Supplier and a Nursing Facility:

Q5. For patients using Method II, is a written coordination agreement required to specify respective responsibilities between the DME supplier and the nursing facility?

A5. No, an agreement is required between an ESRD facility and a LTC facility, and between the DME supplier and the ESRD facility. The DME supplier is responsible to and reports to the ESRD facility regarding the provision of supplies and equipment in the LTC facility. The DME supplier does not need to have a formal relationship with the LTC facility.

Types of Facilities Covered by Guidance:

Q6. What facilities are covered by S&C Letter #04-24? Are intermediate care facilities for persons with mental retardation or related conditions (ICF/MR) facilities covered?

A6. This guidance is directed to dialysis in nursing homes only. In the future, we will describe requirements and expectations regarding dialysis in other types of care facilities. In this guidance we used the terminology "long-term care facility" because the regulations at 42 CFR §483, Subpart B, Requirements for Long Term Care Facilities use this terminology in referring to nursing homes. In §483.5 a facility is defined as "a skilled nursing facility (SNF) that meets the requirements of sections 1819 (a), (b), (c), and (d) of the ACT, or a nursing facility (NF) that meets the requirements of sections 1919 (a), (b), (c), and (d) of the ACT...." but does not include an institution for persons with mental retardation or with related conditions described in §440.150 [Intermediate Care Facility (ICF/MR) services] of this chapter.

States Allowing Dialysis in LTC Facilities:

Q7. Are states required to allow home dialysis in LTC facilities?

A7. No, states may have requirements that prohibit the introduction of home dialysis into LTC facilities in their states. According to §405.2135, the ESRD facility must be in compliance with applicable Federal, State, and local laws, and regulations.

One Patient per Machine:

Q8. What actions should be taken if more than one home dialysis patient is using a single machine in a LTC facility?

A8. Reimbursement for home dialysis therapies is based upon one machine per patient. If more than one home dialysis patient is using a single machine, the respective CMS Regional Office should report this to the appropriate Fiscal Intermediary.

Monitoring of and by Licensed Health Professionals:

Q9. What are the responsibilities for monitoring the capabilities of the licensed health professionals? What is the expectation of the ESRD-experienced licensed health care professional?

A9. Facilities, including their governing bodies and physician directors, are responsible for ensuring that appropriate and adequate staff are hired, trained, and supervised. ESRD regulations at §405.2136 and §405.2161 define the staff monitoring relationships of the governing body and the physician-director. ESRD regulations require that whenever patients are undergoing dialysis, one currently licensed health professional (e.g. physician, registered nurse, or licensed practical nurse) experienced in rendering ESRD care is on duty to oversee ESRD patient care. The preamble language for this section recognizes that "this regulation is a minimum requirement." Therefore, CMS expects that at least one of the above-mentioned professionals is on duty during dialysis.

Licensed health professionals also have responsibilities that are defined by state licensure requirements, state practice acts, state pharmaceutical acts, and other state laws that impact on professional practice, such as education laws.

Responsibilities of the Physician Director of the ESRD facility:

Q10. Does the Physician Director of the ESRD facility have any responsibility for patients being dialyzed in the nursing home?

A10. The ESRD Physician Director is responsible for oversight of care including responsibility for patients dialyzed in center and for all home patients. These specific responsibilities are found at §405.2136(f)(2), §405.2161(b)(3), and §405.2161(b)(5).

Home Training Nurses Responsibilities:

Q11. Who is responsible for training the staff performing the dialysis treatments?

A11. The qualified home training nurse of the approved ESRD facility must be in charge of all home training both for home patients and for individuals who assist patients in home dialysis. The expectation of CMS is that the qualified home training nurse is directly responsible for all home training.

Nursing Home Social Worker and Dietitian:

Q12. Can the nursing home's staff social worker (MSW) and dietitian (RD) substitute for staff from the DME or the ESRD provider?

A12. No, the ESRD benefit includes support services from a "qualified" social worker (MSW) and a "qualified" dietitian (RD) provided by the ESRD facility.

Responsibilities for Medications:

Q13. Who is responsible for providing medications for the dialysis patient/resident?

A13. The ESRD and LTC facilities should delineate the responsibilities for the patients' medications in the written agreement. The LTC facility provides routine and emergency drugs for its residents. If dialysis drugs are maintained in the LTC facility pharmacy, applicable regulatory requirements for LTC apply. Erythropoietin (EPO) is provided to the patient by the ESRD facility. The safe and effective use of EPO by patients at home requires that the patient's dialysis facility or physician responsible for all dialysis-related services make a comprehensive assessment of the patient and the patient's needs at the time of selection for EPO therapy according to ESRD regulations at §405.2163(g).

Care in an Emergency:

Q14. In the event of an emergency, who is responsible for the patient while the patient is undergoing dialysis?

A14. The ESRD facility and LTC facility are expected to define responsibilities for emergencies in the written agreement. The ESRD facility is required to have specific policies and procedures for handling medical and nonmedical emergencies that threaten patient health or safety related to the patient's dialysis treatments. ESRD facilities are governed by regulations at §405.2136(f)(1)(v), 405.2136(g), and 405.2160(b) that require the facilities to have policies governing the care of patients in emergencies and to arrange for physician services and hospital services for emergency care.

Patient's Right to Select Treatment:

Q15. Do patients/residents continue to have the right to select a treatment method for dialysis?

A15. S&C Letter #04-24 reaffirms the patient's right to choose a modality and setting. These rights are regulated in both the care planning and patients' rights sections of the respective ESRD and LTC regulations.

Adequacy of Caregiver/Technician Training:

Q16. How will the adequacy of caregiver/technician training be assessed?

A16. Responsibility for oversight of caregiver/technician training for home dialysis in LTC settings rests primarily with the governing body and the physician director of the ESRD facility. The governing body of the ESRD facility [§405.2136(f)] must approve patient care policies concerning the provision of home dialysis support services. The physician director [§405.2161(b)(3)] is responsible for assuring adequate monitoring of the patient and the home dialysis process with periodic assessment of the performance of dialysis tasks.

ESRD Networks and Home Dialysis in LTC Facilities:

Q17. What responsibilities will ESRD Networks have for home dialysis in LTC facilities?

A17. Since these patients receive care through an ESRD facility that is under the purview of an ESRD Network whose role is defined by statute, these beneficiaries will be treated like other ESRD beneficiaries. ESRD Networks will undertake their statutory role with respect to quality improvement activities, data management, and grievance/appeals processing just as they do for other ESRD beneficiaries.

Role of LTC Surveyor regarding Appropriate Dialysis:

Q18. What are the expectations for LTC surveyors, many of whom do not have ESRD survey experience?

A18. The LTC surveyors are not expected to survey for appropriate dialysis treatments. ESRD surveyors will conduct the dialysis survey. The LTC surveyors are surveying the nursing home under current regulatory requirements as stated in the protocols. The LTC surveyors will observe care. If a LTC surveyor feels that there may be a potential problem, the surveyor will generate a complaint and referral to an ESRD surveyor.

Responsibilities of the LTC Medical Director:

Q19. Does the LTC medical director have to know anything about dialysis?

A19. Currently, residents with diagnoses of ESRD reside in LTC facilities. The LTC Medical Director is required to be in compliance with current regulations at 483.40 Physician Services and 483.75 (i) Medical Director. The regulatory requirement at 483.20(k)(2)(ii)- F280 states "A comprehensive care plan must be prepared by an interdisciplinary team, that includes the attending physician, a registered nurse with responsibility for the resident, and *other appropriate staff* in disciplines as determined by the resident's needs, and, to the extent practicable, the participation of the resident, the resident's family or the resident's legal representative."

Since the resident has a diagnosis of ESRD and is receiving dialysis treatments, CMS expects that "other appropriate staff" includes the ESRD physician, ESRD nurse, ESRD social worker, and ESRD dietitian. It is expected that this coordination is outlined in the agreement between the ESRD facility and the nursing home.

Citation for LTC Medical Director:

Q20. Which LTC regulation is cited if there is a lack of compliance in areas of medical responsibility for the LTC Medical Director?

A20. The LTC survey team will cite F501 if the team has evidence that the facility is not in compliance with the regulatory requirement for the Medical Director. F501 Medical Director. (2) The medical director is responsible for –(i) Implementation of resident care policies; and (ii) the coordination of medical care in the facility.

Coordination of ESRD and LTC citations:

Q21. How do States with multiple survey agencies (separate agencies for LTC and ESRD) coordinate citations?

A21. Citations are not coordinated. Non-compliance with LTC requirements is cited at 42 CFR 483, Requirements for LTC Facilities. Non-compliance with ESRD Conditions of Coverage is cited at 42 CFR 405.2100. Since there are no alternative sanctions for ESRD regulations, LTC must be processed separately, using LTC guidelines and timelines.

Nursing Facility by County

Department of Health and Human Services - Division of Health Service Regulation

As of: June 4, 2012

(Numbers in parenthesis indicate the maximum number of nursing or adult care home beds for which the facility is licensed)

FORSYTH

Arbor Acres United Methodist Retirement Community Inc
Lurana Day, Administrator (336)724-7921
1250 Arbor Road Fax: (336)721-1042
Winston Salem, NC 27104-1197
Lic No: NH0378 Provider: None (SNF # 67)(ACH # 102)

Brian Center Health & Retirement/Winston Salem
Timothy D Jenkins, Administrator (336)744-5674
4911 Brian Center Lane Fax: (336)744-7569
Winston-Salem, NC 27106-6423
Lic No: NH0266 Provider: 345149 (SNF # 40)(ACH # 40)

Brookridge Retirement Community
William E Wood, Administrator (336)759-1044
1199 Hayes Forest Drive Fax: (336)759-9276
Winston Salem, NC 27106-
Lic No: NH0067 Provider: 345209 (SNF # 85)(ACH # 36)

Clemmons Nursing & Rehab Center
Jonathan D Richard, Administrator (336)766-9158
P.O. Box 249, 3905 Clemmons Road Fax: (336)766-8666
Clemmons, NC 27012-0249
Lic No: NH0404 Provider: 345131 (SNF # 120)(ACH # 0)

Kindred Transitional Care and Rehab-Silas Creek
Penny McCoy, Administrator (336)765-0550
3350 Silas Creek Parkway Fax: (336)765-9508
Winston Salem, NC 27103-3071
Lic No: NH0203 Provider: 345003 (SNF # 90)(ACH # 0)

Lutheran Home-Winston-Salem
Cynthia McCoy, Administrator (336)595-2166
5350 Old Walkertown Road Fax: (336)595-2169
Winston Salem, NC 27105-2060
Lic No: NH0058 Provider: 345088 (SNF # 217)(ACH # 0)

Oak Forest Health and Rehabilitation
Steven Kerley, Administrator (336)776-5000
5680 Windy Hill Drive Fax: (336)776-9401
Winston Salem, NC 27105
Lic No: NH0548 Provider: 345443 (SNF # 170)(ACH # 0)

Piney Grove Nursing and Rehabilitation Center
Kevin Tuttle, Administrator (336)996-4038
728 Piney Grove Road Fax: (336)996-0644
Kernersville, NC 27284-0335
Lic No: NH0256 Provider: 345354 (SNF # 92)(ACH # 0)

Salemtowne
James T Matthews II, Administrator (336)767-8130
1000 Salemtowne Drive Fax: (336)767-4090
Winston Salem, NC 27106-
Lic No: NH0154 Provider: 345479 (SNF # 84)(ACH # 46)

FORSYTH

Springwood Care Center
Felton B Wooten, Administrator (336)767-2750
5755 Shattalon Drive Fax: (336)767-3862
Winston Salem, NC 27105-1332
Lic No: NH0423 Provider: 345039 (SNF # 200)(ACH # 0)

The Oaks
Susan Hollett, Administrator (336)768-2211
901 Bethesda Road Fax: (336)774-6545
Winston Salem, NC 27103-3023
Lic No: NH0439 Provider: 345284 (SNF # 151)(ACH # 0)

UniHealth Post-Acute Care-High Point
Raymond E Cooper, Administrator (336)869-3524
3830 North Main Street Fax: (336)869-7498
High Point, NC 27265-1126
Lic No: NH0021 Provider: 345105 (SNF # 100)(ACH # 0)

Winston Salem Nursing & Rehabilitation Center
Raymond Cooper, Administrator (336)724-2821
1900 West First Street Fax: (336)725-8314
Winston Salem, NC 27104-4240
Lic No: NH0125 Provider: 345092 (SNF # 230)(ACH # 0)

FRANKLIN

Franklin Oaks Nursing and Rehabilitation Center
Lynn Bullock, Administrator (919)496-7222
1704 Highway 39 North Fax: (919)496-1418
Louisburg, NC 27549
Lic No: NH0486 Provider: 345335 (SNF # 166)(ACH # 10)

Louisburg Nursing Center
Cheryl Vermilyea, Administrator (919)496-2188
202 Smoketree Way; P O Box 629 Fax: (919)496-3364
Louisburg, NC 27549-0629
Lic No: NH0264 Provider: 345358 (SNF # 92)(ACH # 0)

GASTON

Alexandria Place
Kimberly L Fowler, Administrator (704)853-8175
1770 Oak Hollow Road Fax: (704)852-4045
Gastonia, NC 28054-1749
Lic No: NH0547 Provider: 345441 (SNF # 60)(ACH # 40)

Belaire Health Care Center
Dennis Carver, Administrator (704)867-7300
2065 Lyon Street Fax: (704)867-3939
Gastonia, NC 28052-
Lic No: NH0561 Provider: 345457 (SNF # 80)(ACH # 0)