EXECUTIVE SUMMARY

Loretto Health and Rehabilitation Center (Loretto or Facility) is an existing and operating 583-bed Residential Health Care Facility (RHCF), located at 700 East Brighton Avenue, Syracuse (Onondaga County), NY 13205. The Facility is submitting this Mother Cabrini Health Foundation, Inc. Grant-Funded Limited Review Application (LRA) that seeks approval to certify the service of "Nursing Home Hemodialysis" and complete renovations to construct one (1), four-(4)-station dialysis den at the Facility. This LRA is seeking permanent approval to provide home hemodialysis to the facility's nursing home residents. This LRA also includes the formal closure and decertification of Loretto's 50-slot Adult Day Health Care Program (ADHCP). Loretto's ADHCP closed in March 2020 as required by the New York State Department of Health (NYSDOH) due to the COVID-19 pandemic. Loretto subsequently decided not to re-open the ADHCP when it was permitted to do so and is now seeking to officially close the ADHCP and re-utilize the space to develop an on-site hemodialysis program for its skilled nursing and short-term rehabilitation residents. This Application includes the required Closure Plan and Health Equity Impact Assessment.

Loretto has partnered with Dialyze Direct NY, LLC (Dialyze Direct), which upon approval of this LRA, will provide home hemodialysis services at this site exclusively to the residents of Loretto in a dialysis den and at the resident's bedside when necessary. Dialyze Direct is an existing Article 28 Diagnostic and Treatment Center that is certified to provide "Home Hemodialysis Training and Support". Dialyze Direct will add Loretto as an approved Nursing Home Hemodialysis site upon approval of this LRA.

When RHCF residents must routinely travel off-site to receive hemodialysis, their risk of exposure to COVID-19, among other communicable diseases, and death significantly increases, and both the quality of their lives and their rights as patients within the health care system are negatively affected. This also increases the chance that they could transmit viruses to other residents and staff at Loretto when they return from their off-site treatment. Many of the residents of the Facility are elderly, have multiple medical conditions and co-morbidities, and need dialysis services. Unnecessary transport or disruption of their normal day-to-day schedule increases their risk for additional complications. This project responds to and reflects the long-term needs of the residents of Loretto by providing them with a dialysis service that will eliminate the need for them to go outside the Facility for dialysis services. Locating this service in the Facility provides residents with accessible and lower-risk options for dialysis services.

There are currently 17 residents at Loretto who are required to go off-site to receive dialysis services. Residents will receive dialysis services in a designated dialysis treatment area, known as a "Dialysis Den". The Dialysis Den will be located on the first floor of the Facility; will include space for four (4) dialysis machines; and will include the required associated support space. It is proposed to convert an existing and vacant 2,517-square-foot former ADHCP on the first floor of Loretto to a four-(4)-chair dialysis den with expansion space for additional chairs should the Department's policy on the number of chairs per dialysis den change in the future. The Dialysis Den will be safe and sanitary for the provision of dialysis services, including infection control practices, isolation, monitoring and mitigation hazards, and prohibiting unauthorized intrusions in the dialysis environment during treatment. Bedside dialysis will also be an option.

Of note, according to Northwell Health System (Northwell), New York State's largest healthcare provider, and as published in Kidney International, the journal of the International Society of Nephrology, doctors and researchers from the Northwell system saw an alarming number of hospitalized COVID-19 patients develop acute kidney injury during the pandemic. This further supports the need to expand dialysis services.

Residents of Loretto who require dialysis services will be accepted into the dialysis program based on pre-determined admission criteria. Residents will receive dialysis services in compliance with applicable local, State and Federal codes including 10 New York Codes, Rules and Regulations (10 NYCRR), including staffing requirements. All equipment and supplies, as well as staffing for the dialysis services, will be provided by Dialyze Direct.

Loretto will adhere to its current Construction Safety Policies & Procedures to ensure that any contractors entering the building will have no contact with any resident.

Limited Review Application

State of New York Department of Health
Office of Primary Care and Health Systems Management

LRA Cover Sheet

Project to be Proposed/Applicant Information

This application is for those projects subject to a limited review pursuant to 10 NYCRR 710.1(c)(5)-(7). Please check the appropriate box(es) reflective of the project being proposed by your facility (**NOTE** – Some projects may involve requisite "Construction". If so, and ***total*** project costs are below designated thresholds, then **both boxes** must be checked and necessary LRA Schedules submitted). ***Please read the LRA Instructions to ensure submission of an appropriate and complete application:***

☒ **Minor Construction** – Minor construction project with total project costs of up to $15,000,000 for general hospitals and up to $6,000,000 for all other facilities, if not relating to clinical space – check "Non-Clinical" box below).

Necessary LRA Schedules: Cover Sheet, 2, 3, 4, 5, and 6.

☐ **Equipment** – Project related to the acquisition, relocation, installation or modification of certain medical equipment, with total project costs of up to $15,000,000 for general hospitals and up to $6,000,000 for all other facilities. (**NOT** necessary for "1-for-1" replacement of existing equipment without construction, pursuant to Chapter 174 of the Laws of 2011 amending Article 28 of the Public Health law to eliminate limited review and CON review for one for one equipment replacement)
Necessary LRA Schedules: Cover Sheet, 2, 3, 4, and 5.

☒ **Service Delivery** – Project to decertify a facility's beds/services; add services which involve a total project cost up to $15,000,000 for general hospitals and up to $6,000,000 for all other facilities; or convert beds within approved categories. (*If construction associated, also check "Construction" above.*)
Necessary LRA Schedules: Cover Sheet, 2, 6, 7, 8, 10, and 12. **If proposing to decertify beds within a nursing home, provide a description of the proposed alternative use of the space including a detailed sketch (unless the decertification is being accomplished by eliminating beds in multiple-bedded rooms). If proposing to convert beds within approved categories, an LRA Schedule 6 and all supporting documentation are required to confirm appropriate space for the new use.*

☐ **Cardiac Services** – Project by an appropriately certified facility to add electrophysiology (EP) services; or add, upgrade or replace a cardiac catheterization laboratory or equipment. (*If construction associated, also check "Construction" above.*)

Necessary LRA Schedules: Cover Sheet, 2, 7, 8, 10, and 12.

☐ **Relocation of Extension Clinic** – Project to relocate an extension clinic within the same service area which involve a total project cost up to $15,000,000 for general hospitals and up to $6,000,000 for all other facilities. (*If construction associated, also check "Construction" above.*)

Necessary LRA Schedules: Cover Sheet, 2, 3, 4, 5, 6 and 7. Also include a Closure Plan for vacating extension clinic.

☐ **Part-Time Clinic** – Project to operate, change services offered, change hours of operation or relocate a part-time clinic site – for applicants already certified for "part-time clinic". (*If construction associated, also check "Construction" above.*)

Necessary LRA Schedules: Cover Sheet, 2, 8, 10, 11, and 12.

OPERATING CERTIFICATE NO.	CERTIFIED OPERATOR	TYPE OF FACILITY
3301327N	Loretto Health and Rehabilitation Center	RHCF-SNF

OPERATOR ADDRESS – STREET & NUMBER		PFI	NAME AND TITLE OF CONTACT PERSON		
700 East Brighton Avenue		0648	Frank M. Cicero, Cicero Consulting Associates		
CITY	COUNTY	ZIP	STREET AND NUMBER		
Syracuse	Onondaga	13205	925 Westchester Avenue, Suite 201		
PROJECT SITE ADDRESS – STREET & NUMBER		PFI	CITY	STATE	ZIP
700 East Brighton Avenue		0648	White Plains	NY	10604
CITY	COUNTY	ZIP	TELEPHONE NUMBER	FAX NUMBER	
Syracuse	Onondaga	13205	(914) 682-8657	(914) 682-8895	
TOTAL PROJECT COST: $317,205			CONTACT E-MAIL: conadmin@ciceroassociates.com		

SCHEDULE LRA COVER SHEET ATTACHMENT

Nursing Home Checklist

Supplemental Information

Closure Plan

SUPPLEMENTAL DOCUMENTS

Back-Up Dialysis Agreement
Dialyze Direct Agreement
RN Education and Experience Requirements
Dialyze Direct Operating Certificate
Policies & Procedures

Loretto Health and Rehabilitation Center

Limited Review Application: Certify the Service of "Nursing Home Hemodialysis" at an Existing Residential Health Care Facility in Onondaga County

Contract Requirements	ESRD Provider	Nursing Home
Compliance with ESRD CfC 42 CFR 494.1 – 494.180	☒	
Coordination between the ESRD IDT and the NH IDT regarding the provision of dialysis treatments and ongoing communication regarding the resident's condition and treatments. Provide consult with NH IDT regarding resident's condition and provide face to face meeting if necessary.	☒	
Coordination with the NH to ensure that the RN trained in HD provides onsite supervision of the dialysis treatment.	☒	
Coordination with the NH to ensure qualified administering dialysis personnel remain in visual contact with the resident throughout the dialysis treatment.	☒	
Initial/on-going verification of competencies of the dialysis administering personnel including documented evidence of ESRD staff training in fire safety and medical emergencies prior to the start of initiation of patient care	☒	
Ordering/providing dialysis supplies/medications.	☒	
Communication regarding the safety/cleanliness of the nursing home dialysis environment and resolution	☒	☒
Provision of emergency care during dialysis in accordance with resident wishes and advanced directives.	☒	☒
Immediate reporting of any unexpected/adverse events during dialysis to the resident, their nephrologist, nursing home medical and nursing staff, and their responsible party.	☒	
Following the dialysis prescription, the dialysis related medications, communicating all changes in the orders to the dialysis administering personnel and nursing home IDT.	☒	
Review of treatment records to ensure accurate documentation of delivered dialysis treatments and effects on the resident during dialysis, including adverse events.	☒	
Monitoring lab values related to dialysis and acting upon them, if indicated. Ensuring all dialysis equipment is maintained in good working order.	☒	
Test and monitor the water and dialysate quality for HD equipment.	☒	
Monthly visits with nephrologist or the practitioner treating the residents.	☒	
Providing periodic training to the nursing home staff regarding basic care of the dialysis patient.	☒	
Incorporation of services provided to residents into ESRD facility QAPI program.	☒	
Providing a safe and sanitary environment for dialysis including infection control practices, room type specifics (isolation/roommate	☒	☒

selection), monitoring/mitigating hazards, prohibiting intrusions into dialysis environment during treatment, and cleaning/disinfecting all dialysis equipment and usable supplies.		
Protecting the personal dialysis equipment/supplies of the resident from unauthorized access.		☒
All supportive care of the resident (monitoring weight, dietary/fluid intake, conditions related to fluid overload/depletion/infection/electrolyte imbalance post dialysis)		☒
Written communication between the NH and ESRD on dialysis treatment orders, medication orders, patient assessment, and any changes in the patient condition.	☒	☒
Reviewing NH and ESRD plans of care and making collaborative revisions to ensure that the resident's needs are met, and their goal are attained.	☒	☒
Documentation that assessments, care provided, interventions by both facilities is complete, timely, and accurate.	☒	☒
Training and competency credential files for dialysis administering personnel are maintained by ESRD facility and NH. Guidance and Instructions for Submitting a Limited Review Application for Nursing Home Hemodialysis Services Page 7 of 7 August 2019 Contract Requirements ESRD Provider Nursing Home	☒	☒
Attestation that only an RN employed by the ESRD provider can initiate and discontinue dialysis and must be present throughout the entire dialysis treatment	☒	☒

Supplemental Information

I. Clinical

1. Primarily, supply lines will be used in the Dialysis Den at the Facility, and pre-packaged dialysate may be used on occasion, which will be stocked in the Dialysis Den. Pre-packaged dialysate will be stored in the dry storage room in the Dialysis Den.
2. The dialysis machines will remain locked in the dialysis den while they are producing dialysate fluid in batches.
3. The model and make of the dialysis machine to be used is the NxStage System 1 by NxStage Medical Inc. and is meant for home dialysis use only. These machines are self-contained and produce dialysate; therefore, an RO machine is not necessary.
4. Locked drawers in the Dialysis Den and/or within the nearby dialysis storage room at the Facility will contain the required five (5) days of emergency supplies and other medical supplies. Dialysis supplies will be disposable, and the Dialysis Den will contain one (1) large trash bin and two (2) bio-hazard materials receptacles in the Storage Room for disposal of those supplies. Emergency supplies will be stored securely inside the storage room within the Dialysis Den.
5. The patient's nephrologist will follow the patient, write orders and see the patient for their monthly visit.
6. Residents will have the choice of continuing with their current provider, or converting to using the Dialysis Den provider.
7. The ESRD provider has incorporated the COVID 19 emergency guidelines in to their protocols for patient treatment.

II. Operations

1. Resident equipment will be stored near the Dialysis Den until patient pick up after treatment. This practice is similar to what is done in the Facility, and will not impede foot traffic in the area of the Dialysis Den. The equipment will remain readily available to the residents as needed. The Facility has never had a security issue related to equipment theft or tampering, and is confident this will remain as is going forward.
2. Similar protocols will be in place for TV usage in the Dialysis Den as they are in the Nursing Home, whereby TV's will be available on a first-come, first-served basis and where multiple patients may use one (1) television.
3. The proposed Dialysis Den will be added to the existing Nurse Call system. As is the protocol in the Facility, an overhead paging system will be utilized to call in an emergency and request for the appropriate staff members to respond to the location of the emergency. The in-house nursing supervisor will be summoned to the location as well and will coordinate the response.
4. In the event a resident is on quarantine, dialysis services will be provided at bedside in the private resident room.
5. Staff will utilize a rolling work desk positioned near the patients so that they can work and monitor the patients within close proximity.
6. The Dialysis Den will be locked and secured when not in use to limit access only to the dialysis staff. The mobile dialysis unit that will be used, only when needed for bedside treatment in the facility's isolation room, will be securely stored in the storage room.
7. The Dialysis Den will contain one (1) large trash bin, two (2) bio-hazardous materials receptacles and one (1) sharps container for the disposal of waste and bio-hazardous materials.

These receptacles will be emptied daily, and the ESRD provider will have a contract with a company to remove and dispose of these materials.

8. The Dialysis provider performs dialysis den treatments in group sessions. Specifically, all patients are transferred to the den and placed in their dialysis chairs together. While the transfer is occurring, all the curtains are drawn open, allowing for wheel chair accessibility and transfer to the each dialysis chair. Per CMS and NYS DOH state regulations, all dialysis patients must be within the caregiver's sight while dialysis care is being rendered. Given this requirement and considering that the Dialysis provider provides den dialysis care at a 1 to 2 staff to patient ratio, all curtains remain open while dialysis care is being rendered. After the treatments end, all dialysis station curtains remain open, as all patients are transferred back to their units collectively. The only time a curtain is closed is when the Dialysis provider needs to cannulate a patient, and the patient requests privacy. This only occurs after all patients have been transferred to their dialysis chairs and any wheelchairs used for transfer have been removed from the den.
9. The weighing of residents will be performed in their rooms prior to den treatments using a mobile scale. As an alternative, if there is room for a wall mounted drop down scale, it will be accomplished in the den.

III. Architectural

1. All electric outlets in the room serve the equipment (active use or stored) and will be connected to emergency power so the equipment will remain operational in a power outage.
2. The water at the Facility will be provided through a public municipality.
3. Wheel chair accessibility is provided and discussed in #II.8 above.
4. Each individual treatment station is provided an area of no less than 80 SF and each is provided a cubicle curtain defining that area.

IV. Assurances

1. The Facility assures that the space and plan have been reviewed and approved by Facility infection control leadership, and the project will comply with the most current State and Federal guidance related to treatment of patients with known or suspected COVID-19;
2. Environmental services are in place including provisions for regular and regulated medical waste disposal;
3. Necessary air exchange and HVAC system requirements, depending on the type of clinical services provided, are in place and adequate;
4. An infection control plan including cleaning and disinfection protocols and access to handwashing is in place and appropriate personal protective equipment (PPE) is available;
5. Staffing and training plans are adequate and in place;
6. Fire protection plan for the identified additional or alternate site proposal, including any required fire and carbon monoxide alarm systems, is in place;
7. Provisions for patient privacy and confidentiality are in place;
8. The Facility has and will continue to secure any required local permits or approvals;
9. Nursing Facility has contracted with Dialyze Direct NY, LLC (Dialysis Facility) to provide home hemodialysis services within its nursing facility. Dialysis Facility is HHD-certified for Nursing Home Dialysis. The executed contract is enclosed;

10. All healthcare personnel (Dialysis Staff) providing or involved in providing home hemodialysis care at the nursing facility will comply with the most current State and Federal guidance related to the treatment of patients with known or suspect COVID-19, including the Interim Infection and Prevention and Control Recommendations for Patients with Confirmed Coronavirus Disease 2019 (COVID-19) or Persons Under Investigation for COVID-19 in Healthcare Settings;
11. All Dialysis Staff will wear necessary personal protective equipment when providing dialysis care, specifically isolation gowns, gloves, facemask, and eye protection. All dialysis residents with suspected or confirmed COVID-19 (COVID-19 Dialysis Residents) will wear facemasks when receiving dialysis care;
12. Nursing Facility anticipates accommodating COVID-19 Dialysis Residents. All COVID-19 Dialysis Residents will receive home hemodialysis care at stations that allow for at least a six-(6)-foot separation radius between the nearest stations. Please refer to the enclosed plan;
13. All COVID-19 Dialysis Residents will receive dialysis (a) in isolation at bedside in COVID-19 Dialysis Resident's unit or (b) in the home dialysis den. All dialysis care provided to COVID-19 Dialysis Residents will be performed with at least six (6) feet of separation between masked COVID-19 Dialysis Residents and other residents during dialysis treatment, in accordance with *CMS Guidance for Infection Control and Prevention of Coronavirus Disease 2019 (COVID-19) in Dialysis Facilities, QSO-20-19-ESRD, issued March 10, 2020, and any subsequent updates that may be issued by CMS*;
14. Any surface, supplies, or equipment (e.g., dialysis machine) located within six (6) feet of COVID-19 Dialysis Residents will be discarded or disinfected with disinfectants that meet EPA's criteria for use against SARS-CoV-2;
15. All COVID-19 Dialysis Residents will receive home hemodialysis care at stations that allow for at least a six-(6)-foot separation radius between the nearest stations. The distance between chairs, when chairs are reclined, will still maintain this distance requirement;
16. The distance between the (dirty) trash bin, (dirty) bio-hazard receptacles, and (dirty) sharps container and the (clean) dialysis equipment will be sufficient and does not present an infection control hazard;
17. There will be no loss of recreation, dining or other services as a result of this project; and
18. The dialysis service is going to be utilized only by residents of the facility.

Pursuant to communication from the Department, the applicant understands that the Department's expectation is that facilities that are approved for den dialysis should also be certified and capable of providing bedside dialysis. All of the equipment and supplies for bedside dialysis will be kept within the dialysis den and will be brought to the patient's room during bedside dialysis and then returned to the dialysis den and secured and maintained within the same compliance areas as within the den location. All staff providing beside dialysis will be employees of the ESRD provider. The nurse will maintain direct contact with the resident and will always be in the room while the resident is connected to the dialysis machine.

Loretto Health and Rehabilitation Center
700 East Brighton Avenue, Syracuse (Onondaga County), New York 13205
(315) 413-3708
Operating Certificate No. 3301327N; PFI No. 0648
June 1, 2025

Closure Plan for Adult Day Health Care Program

Loretto Health and Rehabilitation Center (Loretto), is a 583-bed residential health care facility (RHCF) located at 700 East Brighton Avenue, Syracuse (Onondaga County), New York 13205. Loretto also has an Adult Day Health Care Program (ADHCP, the "Program") which was located on-site at the RHCF. Please refer to **Appendix A** for a copy of Loretto's operating certificate.

The ADHCP closed in March 2020 as required by the New York State Department of Health (NYSDOH) due to the COVID-19 pandemic. Loretto subsequently decided not to re-open the Program when it was permitted to do so and is now seeking to officially close the ADHCP and re-utilize the space to develop an on-site hemodialysis program for its skilled nursing and short-term rehabilitation residents. Under separate cover, Loretto is submitting a Limited Review Application for a four-(4)-chair dialysis den and to formerly close the ADHCP.

1. **Evidence of verbal and written notification.**

   Verbal notification will be provided to the Central New York Regional Office (CNYRO) upon submission of the Limited Review Application to formerly close the ADHCP by of Loretto. Submission of this Closure Plan serves as the written notification to CNYRO.

2. **Fiscal Intermediary Contact and request for Form 855A.**

   Not Applicable.

3. **Target closure date, facility capacity, current census.**

   The ADHCP closed in March 2020 as required by the New York State Department of Health (NYSDOH) due to the COVID-19 pandemic. The ADHCP is certified for 50 registrants. Current census is therefore zero (0).

4. **Closure Plan Contact Person.**
   Ms. Margaret Lally
   Vice President, Finance Operations & Revenue
   Loretto Health and Rehabilitation Center
   (315) 413-3895
   mlally@lorettosystem.org

5. **Coordinator Closure Contact Information.**
   Ms. Margaret Lally
   Vice President, Finance Operations & Revenue
   Loretto Health and Rehabilitation Center
   (315) 413-3895
   mlally@lorettosystem.org

6. Plan to Notify Residents, Staff, Family, Physicians.

As noted above, the ADHCP closed in March 2020 as required by NYSDOH due to the COVID-19 pandemic and has not reopened since. There are no current registrants in the Program. Therefore, there will be no notification to ADHCP registrants, family, staff or physicians.

7. Ancillary Service Provision.

This Closure Plan is for the closure of an Adult Day Health Care Program.

8. Media Contact and Press Release.

Media contacts will be managed by Ms. Margaret Lally, Vice President, Finance Operations & Revenue at Loretto. Any media releases will be coordinated with NYSDOH and the Department's Press Office prior to release. Ms. Lally's contact information is as follows:

Ms. Margaret Lally
Vice President, Finance Operations & Revenue
Loretto Health and Rehabilitation Center
(315) 413-3895
mlally@lorettosystem.org

9. Ombudsperson Involvement.

Written notification will be provided to Loretto's Ombudsperson regarding the closure of the ADHCP. Loretto will also provide regular updates on the status of the Closure Plan and progress in closing the ADHCP.

10. Discontinuance of Admissions.

As noted above, the ADHCP closed in March 2020 as required by NYSDOH due to the COVID-19 pandemic and has not reopened since.

11. Resident Placement Opportunities.

As noted above, the ADHCP closed in March 2020 as required by NYSDOH due to the COVID-19 pandemic and has not reopened since.

There are two (2) other RHCFs in Onondaga County certified to operate an ADHCP:

- Central Park Rehabilitation and Nursing Center, located 2.3 miles from Loretto at 116 Martin Luther King East in Syracuse; and
- Jewish Home of Central New York d/b/a Menorah Park of Central New York, located 7.0 miles from Loretto at 4101 E Genesee Street, Syracuse.

12. Transfer of Health Information.

As noted above, the ADHCP closed in March 2020 as required by NYSDOH due to the COVID-19 pandemic and has not reopened since. Medical records including assessments, care plans, medications and treatment records, histories, identifying information, etc. will be maintained by Loretto for the statutorily required amount of time. Upon request, records for any previous registrants of the ADHCP will be securely transferred to the registrant's new ADHCP provider. Where possible, the records will be transmitted electronically to the new provider. If the record cannot be electronically transferred to the new provider, the registrant's medical record documentation will be placed in a sealed envelope with the registrant's name on the outside. This first sealed envelope will then be placed into another sealed envelope, with the name and address of the new provider, as well as the name of the authorized person accepting the documents noted on the outside of this second envelope. Both envelopes will be marked "CONFIDENTIAL." Loretto will deliver the documents either via messenger and/or designated agency personnel to the accepting provider. There will be a form used to identify the courier from Loretto, which will indicate the date, time of delivery, and the signature of the authorized person from the accepting provider.

13. Transfer of Resident Belongings.

ADHCP registrants are not inpatients. Loretto does not hold or maintain any registrant belongings.

14. Allocation of Resident Funds and Resident Council Funds.

There are no resident council funds.

15. Evaluation of Modes of Transportation for Resident Transfer.

There are no current registrants of the ADHCP. As noted above, the ADHCP closed in March 2020 as required by NYSDOH due to the COVID-19 pandemic and has not reopened since.

16. Plan for Resident Follow-up.

As noted above, the ADHCP closed in March 2020 as required by NYSDOH due to the COVID-19 pandemic and has not reopened since.

17. Plan for Building (content) Disposition.

The ADHCP was located on-site at Loretto. Under separate cover, Loretto is submitting a Limited Review Application to convert the ADHCP area for use as an on-site hemodialysis program for its skilled nursing and short-term rehabilitation residents. As appropriate, any

building contents (equipment, furniture, etc.) utilized by the ADHCP will be maintained for future use by Loretto.

18. Plan for Disposal of Biological, Chemical and Radioactive Material.

Any drugs, biologicals, chemicals and/or radioactive materials will be maintained by Loretto for future use by the RHCF in its ongoing operations.

19. Plan for Record Retention.

Loretto will maintain all clinical records for prior ADHCP registrants for the statutorily required amount of time in 10 NYCRR Section 415.22, which will include maintaining clinical records for ten (10) years from the date of disenrollment from the ADHCP. Clinical records will be stored in compliance with New York State law and will be made available to registrants upon written request.

Loretto, the operator of the ADHCP, will maintain all fiscal and statistical reports filed by the facility with the Department pertaining to the ADHCP, including underlying books, records and documentation for the statutorily required amount of time in 10 NYCRR Section 86-2.7, which includes maintaining such records for at least six (6) years from the date of filing, or the date upon which they were to be filed, whichever is later. Financial and statistical reports, including underlying books, records and documentation are maintained in compliance with the RHCF's record retention policy, which includes the scanning of records into electronic format allow for retrieval of records, as needed, and copies are made available to authorized parties and agencies upon written request.

20. Staff Information – R/T Payroll, Benefits, Recertification and Employment Opportunities.

As noted above, the ADHCP closed in March 2020 as required by NYSDOH due to the COVID-19 pandemic and has not reopened since. Therefore, there are no staff affected by the closure of the ADHCP. Any staff of the ADHCP at the time of the initial closure in March 2020 were, at that time, reassigned to other areas of the RHCF.

21. Plan for Ongoing Communication with DOH.

Ms. Margaret Lally, Vice President, Finance Operations & Revenue at Loretto, will contact CNYRO on a weekly basis, or more often, when necessary, to provide a summary of the week's events related to the closure of the ADHCP. This communication process will continue until approval of this Closure Plan and for a mutually agreed upon timeframe following the official closure of the ADHCP.

22. Plan for Ensuring Adequate Staffing During Closure Process.

As noted above, the ADHCP closed in March 2020 as required by NYSDOH due to the COVID-19 pandemic and has not reopened since. There are no current staff assigned to the ADHCP.

23. Transfer, Sale, Signed Agreement.

Not Applicable.

24. Medicaid Liabilities.

Ms. Margaret Lally, Vice President, Finance Operations & Revenue at Loretto, has conferred with the facility's financial office and determined that there are no outstanding liabilities to the Medicaid program.

25. Surrender of Facility Operating Certificate.

Upon approval of this Closure Plan, Ms. Margaret Lally, Vice President, Finance Operations & Revenue at Loretto, will meet with the appropriate CNYRO staff to demonstrate that all aspects of the Closure Plan have been successfully completed.

The original copy of the Loretto's operating certificate will be returned to the CNYRO upon receipt of a revised operating certificate from the Department. A copy of the current operating certificate is included under **Appendix A** of this Closure Plan

LORETTO HEALTH AND REHABILITATION CENTER

APPENDIX A

OPERATING CERTIFICATE

Facility Id. 648
Certificate No. 3301327N

State of New York
Department of Health
Office of Primary Care and Health Systems Management

Certified Beds - Total **583**
RHCF 583

OPERATING CERTIFICATE

Residential Health Care Facility - SNF

Effective Date: 08/07/2018
Expiration Date: NONE

Loretto Health and Rehabilitation Center
700 East Brighton Avenue
Syracuse, New York 13205

Operator: Loretto Health and Rehabilitation Center
Operator Class: Voluntary Not for Profit Corporation

Has been granted this Operating Certificate pursuant to Article 28 of the Public Health Law for the service(s) specified.

Baseline | Adult Day Health Care (50) | Clinical Laboratory Service

Keith W. Lewis

20180824 Deputy Director Office of Primary Care and Health Systems Management

This certificate must be conspicuously displayed on the premises.

Howard Zucker M.D.

Commissioner

LORETTO HEALTH AND REHABILITATION CENTER

APPENDIX B

LETTER TO OMBUDSPERSON

LETTER TO OMBUDSPERSON

(Loretto Letterhead)

(Date)

Dear _____:

Throughout our history, Loretto Health and Rehabilitation Center (Loretto) has continuously evolved to meet the needs of older New Yorkers and our community. As you all well know, the healthcare landscape is challenging and rapidly changing, causing us to constantly reevaluate the services we provide in order to meet the needs of our community.

We have made the decision to officially close our Adult Day Health Care Program (ADHCP). The ADHCP closed in March 2020 as required by NYSDOH due to the COVID-19 pandemic and has not reopened since. Loretto is submitting a Closure Plan to the New York State Department of Health to permanently close the ADHCP and to instead re-utilize that space to develop an on-site hemodialysis program for our skilled nursing and short-term rehabilitation residents. Loretto is preparing to submit a Limited Review Application for a 4-chair dialysis unit, enabling 24 residents per week to receive treatment on-site.

As the ADHCP has been closed since March 2020, there are currently no program registrants. There will be therefore be no impact on any ADHCP registrants. Please feel free to contact me if you have any questions or concerns.

Sincerely,

Ms. Margaret Lally
Vice President, Finance Operations & Revenue
Loretto Health and Rehabilitation Center

BACK-UP DIALYSIS AGREEMENT

THIS BACK-UP DIALYSIS AGREEMENT ("Agreement") is made and entered into as of this 25th day of May 2021 by and between Eric County Medical Center Corporation (hereinafter referred to as "ECMCC") and Dialyze Direct NY, LLC, a New York limited liability company (hereinafter referred to as "Dialyze").

This Agreement shall be for a term of one (1) year beginning on the date first above written and ending the day before the first anniversary of that date, and shall renew automatically annually. Either party may terminate this Agreement without cause by providing thirty (30) days' prior written notice to the other party.

Both parties agree that in the interest of quality care for patients and the assurance of the continuity of such care, this Agreement provides that ECMCC will provide back-up dialysis services for Dialyze's patients in the event of an emergency that would leave Dialyze unable to render dialysis services so long as the following conditions are met:

(a) **Acceptance of Patients**. Upon recommendation of any attending physician who treats patients for Dialyze, and pursuant to the provisions of this Agreement, ECMCC agrees to accept the transfer of Dialyze patients requiring hospitalization and other services provided by ECMCC from Dialyze provided that customary admission requirements, applicable State and Federal laws and regulations are met, the transfer has been approved by an attending physician at or on behalf of ECMCC, and ECMCC has the capacity and ability to treat the patient, as determined in its sole discretion. A request for a patient transfer shall be made by Dialyze as soon as possible once the need for a transfer has been identified. After receiving a transfer request, ECMCC shall exercise its reasonable best efforts to promptly communicate whether it has the capacity to accept the transfer. ECMCC further agrees to exercise its reasonable best efforts to provide for the prompt admission of transferred patients.

(b) **Appropriate Transfer**. It shall be Dialyze's responsibility, at no cost to ECMCC, to arrange for appropriate and safe transportation and care of the patient during such transport. Dialyze shall ensure that the entity providing transportation has automobile liability coverage of no less than one million dollars ($1,000,000) per accident. To the extent that Dialyze has responsibilities under the Emergency Medical Treatment and Labor Act ("EMTALA"), Dialyze shall assure that the transfer is an "appropriate transfer" as defined in EMTALA and related regulations, and is carried out in accordance with any other applicable laws and regulations. Dialyze shall provide all available information regarding the patient when requesting a transfer, and shall comply with Section 2 below regarding the transmission of the patient's medical record to ECMCC. Direct communication between the patient's attending physician from Dialyze and an attending physician and/or an Emergency Department Physician at ECMCC is required before ECMCC will agree to accept the requested transfer.

ECMCC will be responsible for billing the patients for services provided by ECMCC.

The parties agree and understand the Transfer Agreement entered into by Dialyze and ECMCC on December 23, 2019, is still in effect. To the extent that this Agreement conflicts with the terms of the Transfer Agreement, the Transfer Agreement shall control. Should the Transfer Agreement expire or be terminated, this Agreement shall concurrently terminate.

[SIGNATURE PAGE FOLLOWS]

Long-Term Care Facility
Renal Dialysis Coordination Agreement

THIS LONG-TERM CARE FACILITY RENAL DIALYSIS COORDINATION AGREEMENT (this "Agreement") is entered into as of the 8 day of April 2025 (the "Effective Date") by and between Dialyze Direct NY, LLC, a New York limited liability company ("Dialyze"), and Loretto Health & Rehabilitation Center, a New York not-for-profit corporation (the "LTC ENTITY").

RECITALS

WHEREAS, LTC ENTITY operates a long-term care facility, licensed by the state of New York (the "LTC Facility"), which provides long-term care services to its residents, some of whom have been diagnosed with chronic renal failure and require renal dialysis services;

WHEREAS, Dialyze operates a Medicare-certified end-stage renal disease facility, licensed by the state of New York (the "Dialysis Facility");

WHEREAS, the parties desire to enter into an agreement whereby the Dialysis Facility will provide a shorter, more frequent home hemodialysis that on average lasts three (3) hours per treatment, and is administered up to five (5) treatments per week, pursuant to a physician's order, ("Renal Dialysis") to residents of the LTC Facility (each, a "Resident") on the premises of the LTC Facility through the Dialysis Facility's home program, including the provision of training services in the delivery of Renal Dialysis to Residents; and

WHEREAS, the parties desire to promote continuity of care and treatment appropriate to the needs of their patients, to use the skills and resources of their respective facilities in a coordinated and cooperative fashion to facilitate the provision of care to Residents requiring Renal Dialysis, and to assure communication for information between the Dialysis Facility and the LTC Facility.

NOW, THEREFORE, in consideration of the premises above, the parties hereto, intending to be legally bound, hereby agree to the following:

1. Initiation of Services.
    A. The LTC Facility shall notify the Dialysis Facility when a Resident requires Renal Dialysis and submit information to the Dialysis Facility regarding the Resident as requested by the Dialysis Facility.

    B. The Dialysis Facility shall accept medically stable Residents into its home Renal Dialysis program, within the limits of its programs and facilities. Each such Resident accepted into the Dialysis Facility's home hemodialysis program is referred to herein individually as a "Dialysis Resident" and collectively as, the "Dialysis Residents." The Dialysis Facility reserves the right to refuse treatment to any Resident of the LTC Facility that does not meet its admission criteria. At a minimum, in order for a Resident of the LTC Facility to be accepted into the Dialysis Facility's home hemodialysis program, such Resident must have a prescription for home hemodialysis written by a physician who has either temporary or permanent clinical privileges at the Dialysis Facility.

C. The Dialysis Facility shall provide a registered nurse who has completed a training course approved by the Dialysis Facility to be on site to supervise all dialysis treatments in the LTC Facility.

D. Dialysis Facility shall not be required to treat Residents that weigh above 400 pounds. Additionally, the Dialysis Facility shall be permitted to allow only one (1) bariatric patient to be provided Renal Dialysis per dialysis shift.

2. Control of Care. The medical management of the Dialysis Residents will be under the direction of each Dialysis Resident's attending physician. The LTC Facility retains primary responsibility for the development and implementation of each Dialysis Resident's overall plan of care. The Dialysis Facility will cooperate with the LTC Facility in developing and coordinating this plan of care when Renal Dialysis is involved, and shall follow the Dialysis Resident's nephrologist-ordered dialysis prescription and dialysis-related medication prescriptions. The Dialysis Facility shall monitor Dialysis Residents to confirm they are receiving monthly visits by their nephrologist or other medical practitioner treating the Dialysis Resident's end-stage renal disease.

   Coordination of care may include coordination of the following:

   A. Day(s), date(s) and time(s) of appointments with the Dialysis Facility.
   B. Transportation arrangements, if necessary.
   C. Information transmitted to the Dialysis Facility by the LTC Facility.
   D. Information transmitted to the LTC Facility by the Dialysis Facility.
   E. Dialysis access orders.
   F. The LTC Facility will provide consulting privileges for a Dialysis Resident's nephrologist that has been credentialed by Dialysis Facility.

3. Provision of Renal Dialysis Services at the LTC Facility.

   A. The Dialysis Facility shall provide training services regarding the administration of Renal Dialysis treatments to each Dialysis Resident admitted into its home hemodialysis program and to the LTC Facility staff members responsible for the care of such Dialysis Resident, including Trained Caregivers (as defined below).

   B. The Dialysis Facility shall provide Renal Dialysis support services to such Dialysis Resident, including dietary services, social work services, periodic evaluation of the Dialysis Resident's progress on Renal Dialysis, and arranging for the provision of laboratory tests related to the Dialysis Resident's renal condition. The Dialysis Facility shall receive, monitor, and act upon (if indicated) laboratory results for Dialysis Residents as related to Renal Dialysis. The Dialysis Facility shall incorporate all Renal Dialysis services provided to Dialysis Residents into the Dialysis Facility's Quality Assurance and Performance Improvement ("QAPI") Program.

   C. The Dialysis Facility shall provide in service training as needed to staff of the LTC Facility with respect to the nursing, social service, dietary and other needs ("Interdisciplinary Services") of the Dialysis Residents who are receiving Renal

Dialysis from the Dialysis Facility. As needed, the Dialysis Facility shall provide Interdisciplinary Services consultation to the LTC Facility regarding the condition of a Dialysis Resident, including face-to-face meetings with the Dialysis Resident.

D. The Dialysis Facility shall provide Renal Dialysis treatment, equipment (not including Renal Dialysis chairs) and supplies (including drugs and biologicals and diagnostic laboratory tests related to the Dialysis Resident's Renal Dialysis treatment) that are designated for a single Dialysis Resident. The Dialysis Facility shall ensure that all dialysis equipment is maintained in good working order. LTC Facility shall accept delivery and facilitate storage of all Renal Dialysis equipment and supplies that arrive at the LTC Facility, including but not limited to concentrates, bloodlines, dialyzers, ancillary supplies, medication, saline, dialysis machines, and dialysis chairs.

E. Each Renal Dialysis treatment provided to a Dialysis Resident at the LTC Facility will be provided by a person who is a registered nurse trained in hemodialysis ("RN"), licensed practical nurse ("LPN") or certified dialysis technician ("Technician") who is qualified as a "Trained Caregiver." The RN shall initiate and discontinue the Renal Dialysis treatments. Trained Caregivers are not, and will not be deemed, employees or agents of LTC Facility. Dialysis Facility shall ensure that all Trained Caregivers are appropriately credentialed and qualified as required by state and federal rules and regulations. The parties acknowledge that because the Renal Dialysis is provided under a home hemodialysis program, the LTC Facility is required to reimburse Dialysis Facility for its cost of each Trained Caregiver for each Renal Dialysis treatment in accordance with Section 3(G). Dialysis Facility shall provide one (1) Trained Caregiver for up to three (3) Dialysis Residents receiving Renal Dialysis treatments in the general dialysis room within the LTC Facility.

F. Dialysis Facility shall operate two (2) Renal Dialysis shifts per day: a four (4) hour morning shift and a four (4) hour afternoon shift (individually, a "Dialysis Shift" or collectively, the "Dialysis Shifts"). "Full Shift Capacity" for two (2) Trained Caregivers is defined as six (6) Dialysis Residents per Dialysis Shift. "Combined Daily Capacity" for Dialysis Shifts is defined as twelve (12) Dialysis Residents. The LTC Facility must first reach Full Shift Capacity in one (1) Dialysis Shift before scheduling Dialysis Residents for Treatments in the second Dialysis Shift.

G. For each Dialysis Shift during which the Trained Caregivers provide Renal Dialysis treatments to Dialysis Residents, LTC Facility will compensate Dialysis Facility for the Trained Caregiver services in accordance with this Section 3(G):

    i. Dialysis Facility shall charge a flat rate of $40.00 per Renal Dialysis treatment in the general hemodialysis room for the Trained Caregivers services (the "Caregiver Service Fee").

ii. Notwithstanding anything herein to the contrary, in the event Dialysis Facility determines that a Dialysis Resident is insured by a third-party payor that reimburses Dialysis Facility for the Trained Caregiver's provision of Renal Dialysis treatments to a Dialysis Resident (each a "Managed Care Dialysis Resident"), Dialysis Facility shall not seek reimbursement from the LTC Facility for the Renal Dialysis treatments provided to the Managed Care Dialysis Resident.

iii. The Caregiver Service Fee shall increase by 3% on an annual basis.

iv. In the event the LTC Facility fails to adhere to the agreed upon schedule for the drop off or pickup Dialysis Residents at the designated general hemodialysis room and such failure results in the Dialysis Facility incurring overtime costs for the Trained Caregivers, the Dialysis Facility shall charge the LTC Facility for such overtime costs (the "Off-Schedule Overtime Costs").

H. In addition to the Caregiver Service Fees pursuant to Section 3(G) and in light of the significant carrying costs incurred by Dialysis Facility in providing the Trained Caregivers, in the event that during any month there are Dialysis Shifts for which there are no Dialysis residents to receive Renal Dialysis treatments by a Trained Caregiver, such Trained Caregiver shall be deemed to be on "Standby" for such Dialysis Shift and the LTC Facility shall reimburse the Dialysis Facility for such Trained Caregiver at an hourly rate for each Dialysis Shift he or she was deemed to be on "Standby" during such month as further described in, and calculated pursuant to, Exhibit A of this Agreement (the "Caregiver Standby Reimbursement"); provided, however, that no Caregiver Standby Reimbursement shall be payable for the first two (2) months following the Service Commencement Date.

I. Notwithstanding Sections 3(G) and 3(H), in the event that after nine (9) months from the Service Commencement Date, the average daily patient census during the prior three (3) months is less than 25% of the Combined Daily Capacity, then future Caregiver Service Fees, Caregiver Standby Reimbursement, and Off-Schedule Overtime Costs shall be replaced with a flat hourly rate for the Trained Caregivers. Specifically, the Dialysis Facility will charge the LTC Facility flat hourly rates of $67.00 per hour for the RN, and $37.00 per hour for the licensed practical nurse or dialysis technician (the "Flat Hourly Rates") for all hours worked by the Trained Caregivers. The Flat Hourly Rates shall increase by 3% on an annual basis.

J. Dialysis Facility shall, on or before the tenth (10th) day of the month following the month in which a Trained Caregiver's services are provided, provide LTC Facility with an itemized invoice for the Trained Caregiver's services for the previous month, including the Caregiver Service Fees, together with any Off-Schedule Overtime Costs and any Caregiver Standby Reimbursement, or if applicable, the Flat Hourly Rates. LTC Facility will pay all invoices received from Dialysis Facility in full within forty-five (45) days of receipt.

K. Dialysis Facility shall provide initial and ongoing verification of Trained Caregiver competency to administer Renal Dialysis treatments.

L. Dialysis Residents undergoing Renal Dialysis, including their vascular access, must be visible to the Trained Caregiver at all times throughout the dialysis treatment.

M. Trained Caregivers will complete treatment sheets in full at the time of each service, as directed by the Dialysis Facility.

N. Dialysis Facility will (i) immediately report any adverse events orally to the Dialysis Resident's Nephrologist, and the Dialysis Resident and/or Dialysis Resident's responsible party; and (ii) submit an incident report as provided by the Dialysis Facility within one business day of the occurrence. Adverse events include, but are not limited to, the following: (1) blood loss; (2) access problems or access-related infections; (3) signs and symptoms of infection; (4) treatment errors; (5) medication errors; and (6) hospitalization immediately following treatment.

O. The LTC Facility shall operate in compliance with the applicable federal and state regulations for nursing facilities, including, but not limited to, those requirements set forth in the Center for Medicare & Medicaid Services' Guidance and Survey Process for Reviewing Home Dialysis Services in a Nursing Home, QSO-18-24-ESRD (issued August 17, 2018 and later revised on March 22, 2023). The LTC Facility shall operate in compliance with all long-term care requirements for participation under 42 CFR Part 483 applicable to the care of residents receiving dialysis treatments at the nursing home and cooperate with the Dialysis Facility's efforts to demonstrate the Dialysis Facility's compliance with those federal and state regulations that are applicable to the Dialysis Facility's operations.

P. LTC Facility will provide the following:

   i. a designated dialysis treatment room and bedside environment (as applicable) that is safe and sanitary for the provision of Renal Dialysis treatments to Dialysis Residents, including infection control practices, isolation and roommate selection, monitoring and mitigating hazards, and prohibiting unauthorized intrusions in the dialysis environment during treatment. If beside care is provided, the LTC Facility shall consult with the Dialysis Facility regarding the sufficiency of space and resources required for such care;

   ii. adequate space to store hemodialysis machines, water systems and medical supplies required by Dialysis Resident volume and complexity of Renal Dialysis treatments provided;

   iii. all Renal Dialysis chairs;

   iv. adequate and sufficient utilities, including water, electricity, gas and HVAC needed to perform Renal Dialysis in accordance with Dialysis Facility standards;

v. access to sufficient and dedicated GFI electrical outlets necessary for the proper functioning of dialysis equipment, water purification devices and any other electrical device that may be required for patient care;

vi. general maintenance and upkeep of the general dialysis room, including but not limited to structural, electrical, plumbing, heating, cooling maintenance services, Renal Dialysis chair maintenance, battery changing, lock maintenance, cabinetry maintenance, and dialysis machine replacement packing/unpacking/lifting;

vii. janitorial, in-house messenger, laundry, medical records, transcription, and environmental services, all as related to the Renal Dialysis;

viii. medical and hazardous waste removal; and

ix. access to the LTC Facility's cable modem, a separate static Internet Protocol address at a minimum speed of 20 megabits per second, access to a wired network connection that is located in a secure location within reasonable proximity to patients receiving Renal Dialysis bedside treatments, and access to the LTC Facility's primary WiFi network for areas that Dialysis Facility's router is unreachable for Dialysis Facility's personnel.

4. Exclusivity. LTC ENTITY acknowledges that the Dialysis Facility will provide training to the staff of the LTC Facility and will expend significant resources in establishing the Renal Dialysis home services program at the LTC Facility and accordingly, LTC ENTITY, hereby covenants and agrees that during the Term (defined herein) of this Agreement, (i) the Dialysis Facility shall be its exclusive provider of on-premises Renal Dialysis treatments and services to Residents in the LTC Facility and (ii) neither LTC ENTITY nor the LTC Facility shall contract with any other company or facility to provide any Renal Dialysis services or treatments to Residents on the premises of the LTC Facility. The parties acknowledge and agree that this Section 4 shall not prohibit the LTC Facility Dialysis Residents from receiving their Renal Dialysis treatments at an outpatient dialysis facility.

5. Right of First Offer. LTC ENTITY acknowledges and agrees that, in order to provide the Renal Dialysis services outlined in this Agreement, the Dialysis Facility must invest significant time and expense, including time and expense to hire and train its employees, purchase equipment and invest in software. As a material inducement to Dialyze to enter into this Agreement, and in consideration of the value provided to LTC ENTITY under this Agreement, LTC ENTITY agrees, in an effort to protect Dialyze's legitimate business interests, to grant Dialyze the right(s) of first offer and the restraint against competing with Dialyze, each as described below.

A. Home Hemodialysis at Related Facilities. LTC ENTITY further grants to Dialyze the right of first offer (pursuant to the procedures set forth in Section 5.B below) to provide any home hemodialysis services in any other long-term care facility directly or indirectly owned, managed, or operated by LTC ENTITY or any of its affiliates within the Territory (as defined below) (a "Related Facility") which LTC

ENTITY or its affiliates decide to make available, through a third party, to residents in any Related Facility during the Term. "Territory" means: (i) the geographic territory within the state of New York, unless a court of competent jurisdiction determines that the geographic territory is unenforceable under applicable law because it is too large, in which case the geographic territory will be (ii) the geographic territory (a) within 10 miles of the LTC Facility or (b) within 50 miles of any dialysis service site owned or operated by Dialyze or any of its affiliates, unless a court of competent jurisdiction determines that the geographic territory is unenforceable under applicable law because it is too large, in which case the geographic territory will be (iii) the geographic territory within 5 miles of the LTC Facility.

B. Notice and Exercise of Rights of First Offer. If LTC ENTITY desires or intends to permit a third party to provide any home hemodialysis services in a Related Facility as set forth in Sections 5.A above (together, "ROFO Services"), LTC ENTITY shall first provide written notice to Dialyze of its intention prior to negotiating with a third party to provide the ROFO Services. LTC ENTITY shall then negotiate in good faith with Dialyze on an exclusive basis for a period of 30 days with respect to terms and conditions upon which Dialyze would be willing to provide the applicable ROFO Services. If, at the end of such 30-day period, Dialyze and LTC ENTITY have not agreed to terms and conditions upon which Dialyze will provide such ROFO Services, then LTC ENTITY may negotiate with third parties with respect to the ROFO Services; provided, however, that before entering into a binding agreement with a third party with respect to the ROFO Services, LTC ENTITY shall provide written notice to Dialyze of the material terms that have been agreed to in principle with the third party and afford Dialyze with a 10-day period to match or exceed such terms. If Dialyze does not match or exceed the terms agreed to in principle with the third party within such 10-day period, then LTC ENTITY may enter in an agreement with the third party for the ROFO Services. The procedures set forth in this Section 5.B shall apply to each distinct instance of ROFO Services that LTC ENTITY desires or intends to permit a third party to provide.

C. Availability of Rights of First Offer. The rights of first offer provided in Sections 5.A and 5.B shall be exercisable and shall remain in effect for the Term of this Agreement, unless otherwise terminated as provided herein.

D. Injunctive Relief. Upon the occurrence of any breach of LTC ENTITY's obligations as set forth in Sections 5.A, 5.B, 5.C and 5.D above, the parties expressly agree and acknowledge that Dialyze shall be entitled to seek immediate injunctive relief from any court of competent jurisdiction as provided without providing notice or otherwise complying with Section 28 below. The parties further expressly agree and acknowledge that the damages caused to Dialyze as a result of any breach of these obligations may be difficult or impossible to calculate, and that as a matter of law Dialyze lacks an adequate legal remedy. LTC ENTITY expressly waives any right to contest any injunctive relief sought by Dialyze based on the

availability or calculation of damages and/or that Dialyze has an adequate legal remedy.

6. Provision of Renal Dialysis Services at an Outpatient Dialysis Facility. From time to time, it may be necessary for a Dialysis Resident to receive a Renal Dialysis treatment on the premises of an outpatient dialysis facility. The Dialysis Facility will coordinate such care with the LTC Facility.

7. Communication.

   A. Emergency and non-emergency changes in a Dialysis Resident's medical condition will be promptly communicated, in writing, by the party having primary knowledge of the change to the other party, regardless of the location of the patient at the time of the change. The LTC Facility shall immediately report, in writing, any change in a Dialysis Resident's condition which may possibly be related to Renal Dialysis to the Dialysis Facility and the Dialysis Resident's attending physician in the LTC Facility.

   B. The party on whose premises medical or non-medical emergencies occur with respect to a Dialysis Resident will be responsible for providing emergency services of a medical or non-medical nature. Any Dialysis Resident who requires emergency treatment in association with Renal Dialysis treatments when on the premises of the LTC Facility shall be transported to a hospital with which the LTC Facility has a transfer agreement. The LTC Facility shall provide the Dialysis Facility with the name(s) of such hospital(s) and, upon request, a copy of such transfer agreements. In the event a Dialysis Resident requires emergency care during dialysis, the Dialysis Facility shall provide emergency care in accordance with the Dialysis Resident's preferred intensity of care and/or advance directives. If necessary, the LTC Facility shall assist the Dialysis Facility with providing the emergency care.

   C. Dialysis Facility shall notify LTC Facility, in writing, of all changes in a Dialysis Resident's dialysis prescription and dialysis-related medication prescription.

   D. The LTC Facility will notify the Dialysis Facility, in writing, when a Dialysis Resident refuses scheduled medical management or demonstrates non-compliance with medical management relating to renal replacement therapy, i.e., diet, fluid restriction, and medications.

   E. The LTC Facility will provide a monthly listing of all Dialysis Residents showing their current medications.

   F. The LTC Facility will notify the Dialysis Facility of any pertinent information regarding the Dialysis Resident's next of kin, insurance coverage (including any changes thereto), or any other information which may affect the dialysis therapy or reimbursement thereof.

   G. The LTC Facility will notify the Dialysis Facility as soon as possible if a Dialysis Resident will be unable to keep a scheduled appointment with the Dialysis Facility

for any reason, and specifically will notify the Dialysis Facility if a Dialysis Resident has been hospitalized.

8. Education. The LTC Facility shall make staff available to receive education from Dialysis Facility involved in caring for Dialysis Residents in the following areas to assure the LTC Facility staff's ability to perform supportive care interventions for Dialysis Residents when necessary:

    A. Monitoring of fluid gain and loss (including conditions as related to systems of fluid overload/depletion/infections/electrolyte imbalance), including assessment of weight, blood pressure, pulse, respirations and intake and output.

    B. Assessment of laboratory values such as: BUN, serum creatinine, sodium, potassium, calcium, magnesium, phosphate levels, WBC, hemoglobin and hematocrit.

    C. Monitoring of nutritional needs, i.e., specialized diet. Evaluation(s) by a registered dietitian.

    D. Provision of support services for emotional and social well-being of the Dialysis Resident upon identification of problems which may include complaints of feeling hopeless, helpless, denial of reality or acceptance of need for dialysis, decreased social activity, withdrawal, depression, self-neglect, non-compliance with regimen.

    E. Monitoring and controlling infection: redness, warmth, swelling at dialysis access site.

    F. Monitoring for altered thought process, nausea, vomiting, agitation, changes in behavior.

    G. Management of emergencies and complications which include equipment failure and alarm systems, bleeding/hemorrhaging and infection/bacteremia/ septic shock with immediate notification of the physician.

    The Dialysis Facility agrees to provide the LTC Facility staff with written information and verbal review of such information necessary for the LTC Facility staff to provide care to the Dialysis Residents as described in this Agreement.

9. Care of Access Site. LTC Facility will cooperate in monitoring and caring for Dialysis Resident's access sites including:

    A. Avoidance of blood pressure readings, venipuncture, and trauma in the extremity with dialysis access.

    B. Evaluation of patency of the dialysis access including, but not limited to, grafts and fistulas.

    C. Monitoring of the dialysis access for signs of bleeding.

10. Equipment. The Dialysis Facility will assume responsibility for disinfection of equipment and items used during services rendered in the Dialysis Facility's location and shall coordinate with the LTC Facility regarding the maintenance and disinfection of such equipment and items on the premises of the LTC Facility. The Dialysis Facility shall provide the testing and monitoring of water and dialysate quality, as applicable, for the dialysis equipment. The LTC Facility shall protect dialysis equipment and supplies of each Dialysis Resident from unauthorized access.

11. Drugs. The Dialysis Facility and the LTC Facility will coordinate regarding the storage of drugs and biologicals and diagnostic laboratory tests related to the Dialysis Resident's Renal Dialysis treatment in the LTC Facility's pharmacy.

12. Waste Disposal. The Dialysis Facility will assume responsibility for any items used for access site cleaning and disposal of all medical waste according to waste management procedures for Dialysis treatments provided at LTC Facility, provided that LTC Facility will be ultimately responsible for medical and hazardous waste removal from the LTC Facility. The Dialysis Facility shall ensure the dialysis environment within the LTC Facility remains safe and clean to provide Renal Dialysis treatments.

13. Patient Transfer. The LTC Facility will be responsible for arranging transportation to and from the Dialysis Facility for clinic visits, if applicable, and will be responsible for the Dialysis Resident during transfer to and from the Dialysis Facility's location. Dialysis Facility will be responsible for the Dialysis Resident from the time the Dialysis Resident is accepted at the Dialysis Facility's location until the Dialysis Resident is released to return to the LTC Facility.

14. Patient Disclosure. To the extent required by state and federal law, LTC Facility shall inform patients of the existence of this Agreement. Any such disclosure shall include a statement that the patient may choose a different provider of dialysis services.

15. Medical Records. The Dialysis Facility and the LTC Facility shall each maintain complete medical records (electronic or paper) on each Dialysis Resident in accordance with accepted professional standards and practices, state and federal laws. Without limiting the generality of the foregoing, the LTC Facility shall ensure that the medical records it maintains for each Dialysis Resident contain a copy of such Dialysis Resident's treatment flow sheets. Dialysis Facility shall review Dialysis Resident medical records to ensure accurate documentation of the delivered dialysis treatments and intra-dialytic effects on the resident at each treatment. Each party shall cooperate fully with the other party by making copies of or providing access to, upon reasonable request, all relevant portions of each Dialysis Resident's medical records in order to assure each party is able to meet all requirements for participation in the federal Medicare program. Each party shall ensure they are maintaining complete, timely, and accurate documentation for all assessments, care provided, and interventions for Dialysis Residents.

16. Billing and Collections. The Dialysis Facility shall be responsible for billing and collection for all Renal Dialysis services and supplies.

17. Insurance. The Parties agree that each shall maintain in continuous force and effect throughout this Agreement comprehensive general liability, professional liability, and worker's compensation insurance covering those services within the scope of this Agreement. The policy limits of the general liability and professional liability insurance shall be in the minimum amount of one million dollars ($1,000,000) per occurrence and three million dollars ($3,000,000) in the aggregate.

18. Autonomy; Independent Contractors. This Agreement shall not be construed in any way to affect the autonomy of the LTC Facility or the Dialysis Facility nor the exclusive control of the governing authority of either; including the management, assets, and affairs of each respective organization. The execution and delivery of this Agreement shall not be construed as an assumption of any liability for any debt or obligation of either party, including each and every present or future financial or legal obligation of either party. It is understood and agreed that the parties to this Agreement are independent contractors, and nothing herein shall be construed to establish a partnership, joint venture, agency or employer-employee relationship between the parties.

19. Amendment. This Agreement may be altered or amended at any time only by mutual written agreement of both parties.

20. Term and Termination.

    A. The initial term of this Agreement shall be for a period of one (1) year (the "Initial Term"), commencing on the day the Dialysis Facility provides the first Renal Dialysis treatment at the LTC Facility ("Service Commencement Date"). This Agreement shall automatically renew for consecutive one-year terms (a "Renewal Term") unless either party provides written notice of non-renewal to the other party at least ninety (90) days prior to the expiration of the then-current term (the Initial Term and the Renewal Term are sometimes referred to herein together as the "Term"). After the Initial Term, either party may terminate this Agreement upon ninety (90) days written notice to the other party at any time after the Initial Term.

    B. The LTC Facility agrees to complete all renovations and provide all furnishings to the general dialysis room as the parties shall mutually agree (the "Dialysis Den") within sixty (60) days of the Effective Date.

    C. Either party shall have the right to terminate this Agreement in the event that (i) the other party fails to comply with any material term, condition, or obligation of this Agreement; (ii) the non-breaching party provides notice to the breaching party specifying the breach; and (iii) the breaching party fails to cure such breach within thirty (30) days after receipt of such notice.

21. Indemnification.

    A. LTC Facility shall indemnify and hold harmless the Dialysis Facility, Dialyze and each of their directors, officers, agents, employees and affiliates ((collectively, the "Dialysis Facility Parties"), individually and collectively, from and against any and all third party claims, demands, costs, expenses, liabilities and losses (including reasonable attorneys' fees) (collectively, "Losses") arising out of (i) the negligent

acts, omissions or willful misconduct of one or more of the LTC ENTITY, the LTC Facility, or any of their respective directors, officers, agents and employees (the "LTC Facility Parties"), or (ii) any breach by LTC Facility of its representations, warranties and covenants hereunder; provided in each case that such indemnity shall not apply to the extent any Losses arise out of the negligence or willful misconduct of any of the Dialysis Facility Parties.

B. The Dialysis Facility shall indemnify and hold harmless the LTC Facility Parties, individually and collectively, from and against any and all Losses arising out of (i) the negligent acts, omissions or willful misconduct of the Dialysis Facility Parties, or (ii) any breach by Dialysis Facility of its representations, warranties and covenants hereunder; provided in each case that such indemnity shall not apply to the extent any Losses arise out of the negligence or willful misconduct of any of the LTC Facility Parties.

22. Confidentiality.

A. Each party shall use its best efforts to preserve the confidentiality of all of the other's nonpublic and/or proprietary information, including but not limited to nonpublic financial information, manuals, protocols, marketing and strategic information, client lists, patient health information, patient care and outcomes data, and methods of doing business including, but not limited to, operational methods, scheduling, amounts charged and manner of determining and/or billing charges, with all such information collectively referred to as "Confidential Information". Neither party shall use for its own benefit or disclose to third parties the other party's Confidential Information without prior written consent. Upon termination of this Agreement, all Confidential Information and copies thereof shall be returned to the disclosing party. Each party shall comply with applicable state and federal laws and regulations with respect to Confidential Information.

B. Neither party shall, during the term of this Agreement, copy or divulge to any third party any of the Confidential Information, except to its accountants and attorneys, without the prior written consent of the other party. This Section 22(B) shall not apply to Confidential Information which (i) is publicly known or (ii) is or becomes available to a party on a non-confidential basis from a third-party source. Each party agrees to exercise at least the same standard of care to protect Confidential Information as is used to protect its own such data from unauthorized disclosures, but no less than commercially reasonable standards. This restrictive covenant shall survive the expiration or termination of this Agreement.

C. Both parties shall comply with all federal and state laws governing the privacy and confidentiality of patient health information, including, without limitation, the Health Insurance Portability and Accountability Act of 1996 and implementing regulations (as such may change from time to time).

23. Entire Agreement. This Agreement represents the final agreement and understanding between the parties hereto with respect to the subject matter hereof and supersedes any prior

understanding or agreements between the parties hereto with respect to the subject matter hereof.

24. SNF and Dialyze Direct Partnership Operational Guidelines. The LTC Facility and the Dialysis Facility agree to follow the SNF and Dialyze Direct Partnership Operational Guidelines available at the following weblink: DD722 Operational Guideline-final.pdf

25. Waiver of Breach. The waiver by a party of a breach or default under any term or provision of this Agreement by the other party shall not operate or be construed as a waiver of subsequent breach or default under the same or any other term or provision of this Agreement by that party. Any waiver must be provided in writing signed by the party providing the waiver.

26. Non-Discrimination. To ensure continuity of care in the treatment of stable, chronic Renal Dialysis patients, the parties agree that any patient who may appropriately be treated at any clinic operated by the Dialysis Facility shall be accepted without discrimination as to race, creed, color, age, religion, sex, national origin, disability, sexual orientation, sponsor or marital status.

27. Patient Census. The LTC Facility's Renal Dialysis program patient census shall not fall below, on average, 50% of the Renal Dialysis program's capacity at the LTC Facility during any ninety (90) day period of the Term. For purposes of this section, capacity shall be defined as twelve (12) Renal Dialysis patients per day. This section shall be considered a material condition of this Agreement.

28. Compliance. Notwithstanding any other provision of this Agreement, each party remains responsible for ensuring that any service that it provides pursuant to this Agreement complies with all pertinent provisions of federal, state, and local statutes, rules and regulations.

29. Notice. Any and all communications required under this Agreement required to be in writing shall be sent by registered or certified mail, return receipt requested, postage prepaid, or by nationally recognized overnight courier service and shall be addressed as follows:

If to LTC Facility:

Loretto Health & Rehabilitation
700 E. Brighton Ave.
Syracuse, NY 13205
Attention: Chief Nursing Officer
CC: General Counsel

If to Dialysis Facility:

Dialyze Direct NY, LLC
c/o Dialyze Direct, LLC
3297 State Route 66

Neptune, NJ 07753
Attention: General Counsel and Chief Compliance Officer

30. Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of New York.

31. Counterparts. This Agreement may be executed in two (2) counterparts, each of which will be deemed an original and together will constitute one and the same agreement, with one counterpart being delivered to each party hereto. Signatures provided by facsimile transmission or in Adobe Portable Document Format (PDF) sent by electronic mail shall be deemed to be original signatures.

[Space left blank intentionally, signature page follows]

EXHIBIT A

Caregiver Standby Reimbursement

Pursuant to Section 3(H), in the event that during any month (other than the initial two (2) months of service), there are Dialysis Shifts for which there are no Dialysis residents to receive Renal Dialysis treatments by a Trained Caregiver, such Trained Caregiver shall be deemed to be on "Standby" for such Dialysis Shift, and the LTC Facility shall reimburse the Dialysis Facility for such Trained Caregiver for each Dialysis Shift he or she was deemed to be on "Standby" during such month, as illustrated by the following chart:

	Shift 1		Shift 2	
# Patients	RN	LPN/PCT	RN	LPN/PCT
0 Patients	Standby	Standby	Standby	Standby
1-2 Patients	Dialysis	Standby	Standby	Standby
3-6 Patients	Dialysis	Dialysis	Standby	Standby
7 + Patients	Dialysis	Dialysis	Dialysis	Dialysis

Each Dialysis Shift consists of four (4) hours and the Caregiver Standby Reimbursement for each Dialysis Shift shall be $37.00 per hour for each licensed practical nurse or dialysis technician deemed to be on "Standby" for such Dialysis Shift and $67.00 per hour for each RN deemed to be on "Standby" for such Dialysis Shift.

The Caregiver Standby Reimbursement shall not exceed $536.00 per day for the RN's time (based on two Dialysis Shifts per day) and shall not exceed $296.00 per day for the licensed practical nurse or dialysis technician's time.

The hourly rates for the Caregiver Standby Reimbursement shall increase by 3% on an annual basis.

BUSINESS ASSOCIATE AGREEMENT

THIS BUSINESS ASSOCIATE AGREEMENT (this "***Agreement***") is made and entered into as of this 8 day of April, 2025 (the "***Effective Date***") by and between Dialyze Direct NY, LLC ("***Covered Entity***") and LHR LLC ("***Business Associate***").

WHEREAS, Business Associate will provide certain services (the "***Services***") as set forth more fully in the Long-Term Care Facility Renal Dialysis Affiliation Agreement with Covered Entity and Business Associate of even date herewith (the "***Services Agreement***");

WHEREAS, Covered Entity and Business Associate are required to meet the requirements of the Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191 (the "***Act***"), the privacy standards adopted by the U.S. Department of Health and Human Services ("***HHS***") as they may be amended from time to time, 45 C.F.R. parts 160 and 164, subparts A and E (the "***Privacy Rule***"), the security standards adopted by HHS as they may be amended from time to time, 45 C.F.R. parts 160 and 164, subparts A and C (the "***Security Rule***"), and the privacy provisions (Subtitle D) of the Health Information Technology for Economic and Clinical Health Act, Division A, Title XIII of Pub. L. 111-5, and its implementing regulations (the "***HITECH Act***"), due to their status as a "Covered Entity" or a "Business Associate" under the Act. (The Act, the Privacy Rule, the Security Rule, and the HITECH Act are collectively referred to herein as "***HIPAA***" for the purposes of this Agreement.);

WHEREAS, in order to provide the Services under the Services Agreement, Covered Entity may disclose to Business Associate certain Protected Health Information ("***PHI***"); and

WHEREAS, the parties desire to enter into this Agreement to (i) protect the privacy, and provide for the security of PHI disclosed by Covered Entity to Business Associate, and (ii) to satisfy certain requirements imposed upon the parties by HIPAA.

NOW, THEREFORE, in consideration of the mutual benefits of complying with laws and regulations stated above, Covered Entity and Business Associate agree as follows:

ARTICLE I

DEFINITIONS

1.1 **"Business Associate"** shall generally have the same meaning as the term "business associate" at 45 C.F.R. § 160.103, and in reference to this Agreement, shall mean the entity defined above as the Business Associate.

1.2 **"Covered Entity"** shall generally have the same meaning as the term "covered entity" at 45 C.F.R. § 160.103, and in reference to this Agreement, shall mean the entity indicated as the Covered Entity above.

1.3 Other Terms. Capitalized terms not specifically defined in this Agreement shall have the meanings attributed to them under HIPAA.

ARTICLE II

PRIVACY AND SECURITY OF PROTECTED HEALTH INFORMATION

2.1 Permitted Uses & Disclosures.

(a) Business Associate may use and disclose PHI on behalf of Covered Entity pursuant to the Services Agreement between Business Associate and Covered Entity or as Required By Law. Except for the specific uses or disclosures set forth in this Section 2.1, Business Associate may not use or disclose PHI in a manner that would violate the Privacy Rule if done by Covered Entity. Business Associate shall limit its use, disclosure, or request of PHI to the Minimum Necessary.

(b) Unless otherwise limited herein and except where prohibited by law, Business Associate may (i) use or disclose PHI for the proper management and administration of Business Associate; and (ii) disclose PHI to fulfill any present or future legal responsibilities of Business Associate; provided that any disclosure described by Subsection (i) or (ii) of this Section is Required by Law, or Business Associate obtains reasonable assurances from the person to whom the PHI is disclosed that it will be kept confidential and used or further disclosed only as Required by Law or for the purpose for which it was disclosed to the person, and the person agrees to notify Business Associate of any instances of which it is aware in which the confidentiality of the information has been breached.

2.2 Prohibited Uses and Disclosures.

(a) Requests for Non-Disclosure. As applicable, Business Associate shall abide by a request from an Individual pursuant to 45 C.F.R. § 164.522(a) to refrain from making certain uses or disclosures of the Individual's PHI (i) to which Covered Entity has agreed; or (ii) to a health plan in connection with an item or service for which the Individual has paid out-of-pocket, in full, to which the Covered Entity is required to agree.

(b) Prohibition on Sale of PHI. Business Associate shall not sell PHI or receive any direct or indirect remuneration in exchange for PHI.

(c) Prohibition on Marketing. Business Associate shall not transmit, to any Individual for whom Business Associate has PHI, any communication about a product or service that encourages the recipient of the communication to purchase or use that product or service unless permitted to do so.

2.3 Safeguards for the Protection of PHI. Business Associate shall use appropriate safeguards and shall comply with the requirements of the Security Rule applicable to Business Associate including those set forth at 45 C.F.R. parts 164.306, 164.308, 164.310, 164.312 and 164.316 to prevent the use or disclosure of PHI other than

as permitted by this Agreement. Business Associate shall document and keep current its policies to safeguard PHI, and will provide a copy of such policies to Covered Entity upon request.

2.4 Mitigation. Business Associate agrees to mitigate, to the extent practicable, any harmful effect that is known to Business Associate resulting from a use or disclosure of PHI by Business Associate in violation of the requirements of HIPAA.

2.5 Reporting to Covered Entity.

(a) Breach and Other Privacy Rule Violations. Business Associate shall report to Covered Entity any use or disclosure of PHI not permitted by this Agreement, the Services Agreement, or that is in violation of any provision of HIPAA, including any Breach of unsecured PHI as required by 45 C.F.R. § 164.410, within five (5) calendar days after the date on which Business Associate learns or should have learned of such occurrence. In its report to Covered Entity, Business Associate will identify, at a minimum (i) the nature of the non-permitted use or disclosure; (ii) the PHI used or disclosed; (iii) the party or parties who made the non-permitted use or received the non-permitted disclosure; (iv) what corrective action Business Associate took or will take to prevent further non-permitted uses or disclosures; (v) what Business Associate did or will do to mitigate any harmful effect of the non-permitted use or disclosure; (vi) such other information, including a written report, as Covered Entity may request; and (vii) such other information as HHS may prescribe by regulation.

(b) Security Incidents. Business Associate shall report all Security Incidents to Covered Entity, in accordance with the following reporting procedures for (i) Security Incidents that result in unauthorized access, use, disclosure, modification or destruction of electronic PHI ("***ePHI***") or interference with system operations ("***Successful Security Incidents***"); and (ii) Security Incidents that do not result in unauthorized access, use, disclosure, modification or destruction of ePHI or interference with system operations ("***Unsuccessful Security Incidents***").

(i) Successful Security Incidents. Business Associate shall provide notice to Covered Entity of any Successful Security Incident of which it becomes aware within five (5) calendar days. At a minimum, such report shall contain the following information: (A) date and time when the Security Incident occurred and/or was discovered; (B) names of systems, programs, or networks affected by the Security Incident; (C) preliminary impact analysis; (D) description of and scope of ePHI used, disclosed, modified, or destroyed; and (E) any mitigation steps taken by Business Associate.

(ii) Unsuccessful Security Incidents. To avoid unnecessary burden on either party, Business Associate shall report to Covered Entity any Unsuccessful Security Incident of which it becomes aware only upon request of Covered Entity. The frequency, content and the format of the report of Unsuccessful Security Incidents shall be mutually agreed upon by

the parties. If the definition of "Security Incident" is amended under the Security Rule to remove the requirement for reporting "unsuccessful" attempts to use, disclose, modify or destroy ePHI, then this Section 2.5(b)(ii) shall no longer apply as of the effective date of such amendment.

2.6 Use of Subcontractors. Business Associate shall not use any Subcontractor to assist Business Associate with the provision of the Services under the Services Agreement without the prior consent of Covered Entity. Business Associate may disclose PHI to a Subcontractor only to the extent expressly permitted by the Services Agreement and subject to the terms of this Agreement. Prior to the disclosure of PHI to any Subcontractor, Business Associate shall cause each such Subcontractor to agree in writing to the same restrictions, conditions and requirements that apply to the Business Associate with respect to such PHI. Upon request, Business Associate shall provide to Covered Entity a copy of the written contract with the Subcontractor. Furthermore, Business Associate shall disclose to its Subcontractors only the Minimum Necessary to perform such Services as are delegated to the Subcontractor by the Business Associate.

2.7 Authorized Access to PHI. At the request of Covered Entity and within ten (10) calendar days of such request, Business Associate shall make available to Covered Entity (or to the Individual at the direction of Covered Entity) for inspection and copying, any PHI about an Individual which Business Associate created or received for or from Covered Entity and that is in the custody or control of Business Associate as required by 45 C.F.R. § 164.524. To enable Covered Entity to fulfill its obligations that pertain to an Individual's request for an electronic copy of his or her PHI that is used or maintained in an Electronic Health Record, to the extent Business Associate uses or maintains PHI in an Electronic Health Record, Business Associate shall provide Covered Entity with a copy of such information in electronic format, at Covered Entity's expense, within five (5) calendar days of a request by Covered Entity.

2.8 Amendment of PHI. Business Associate shall, at the request of Covered Entity, within twenty (20) calendar days, amend PHI in accordance with the instructions provided by Covered Entity or permit Covered Entity access to amend any portion of the PHI which Business Associate created or received from or on behalf of Covered Entity, as required by 45 C.F.R. §164.526.

2.9 Accounting of Disclosures of PHI.

(a) Disclosure Tracking. Business Associate shall retain a record of each disclosure of PHI that Business Associate makes to a third party to the extent required by HIPAA, including (i) the disclosure date; (ii) the name and (if known) address of the person or entity to whom Business Associate made the disclosure; (iii) a brief description of the PHI disclosed; and (iv) a brief statement of the purpose of the disclosure.

(b) Disclosure Accounting. Business Associate shall provide an accounting of disclosure of PHI to Covered Entity (or to an individual, is so directed by Covered Entity) (i) no later than twenty (20) calendar days after receipt of a written request

for such disclosure accounting by Covered Entity pursuant to 45 C.F.R. § 164.528, or (ii) in accordance with HIPAA.

2.10 Performance of Obligations of Covered Entity. To the extent Business Associate is to carry out an obligation of Covered Entity under the Privacy Rule, Business Associate shall comply with the requirements of the Privacy Rule that apply to Covered Entity in performance of such obligation.

2.11 Inspection of Books and Records. Business Associate shall make its internal practices, books, and records, relating to the use and disclosure of all such PHI, available to Covered Entity and to HHS to determine Covered Entity's and Business Associate's compliance with HIPAA.

ARTICLE III

TERM AND TERMINATION

3.1 Term. The term of this Agreement shall commence as of the Effective Date of this Agreement and shall continue in effect until terminated in accordance with Section 3.2

3.2 Termination. This Agreement shall terminate upon the earlier to occur of: (i) termination of the Services Agreement or (ii) receipt by Business Associate of Covered Entity's notice to terminate in the event Business Associate breaches a material term of this Agreement pursuant to Section 3.3.

3.3 Right to Terminate for Breach. Covered Entity has the right to terminate this Agreement immediately if Covered Entity determines, in its reasonable discretion that Business Associate has breached any material term of this Agreement. Following Covered Entity's determination that Business Associate has breached a material term of this Agreement, in lieu of immediate termination, Covered Entity may elect, in its sole discretion, to provide Business Associate with written notice of its determination, and afford Business Associate an opportunity to cure such alleged breach. In the event that Business Associate fails to cure said breach to the reasonable satisfaction of Covered Entity within such time frame as is designated by Covered Entity, Covered Entity may immediately terminate this Agreement and the Services Agreement.

3.4 Return or Destruction of PHI.

(a) Upon termination of this Agreement for any reason, Business Associate shall automatically return, at its cost, all PHI or any copies thereof received from Covered Entity that Business Associate or its agents or Subcontractors still maintain in any form. Prior to the return of PHI to Covered Entity, Business Associate may submit to Covered Entity a written request for permission to destroy PHI, and such request may be approved or denied in the sole discretion of Covered Entity.

(b) Business Associate shall not retain any copies of PHI unless Covered Entity expressly permits it to do so in writing.

3.5 Continuing Privacy and Security Obligation. If return or destruction of the PHI is not feasible, as determined by Covered Entity, Business Associate shall extend the protections of this Agreement for as long as necessary to protect the PHI and to limit any further use or disclosure. Business Associate shall only use or disclose such PHI for those purposes that make return or destruction infeasible.

3.6 Injunctive Relief. In the event of a breach of any material term of this Agreement, Covered Entity has a right to obtain injunctive relief to prevent future disclosure of PHI.

ARTICLE IV

INDEMNIFICATION

4.1 Indemnification. Business Associate shall indemnify and hold harmless Covered Entity and any Covered Entity affiliate, officer, director, employee, subcontractor, agent, or other members of its workforce, from and against any claim, cause of action, liability, damage, fine, penalty, cost or expense (including without limitation, attorney fees, and costs related to notifications required under 45 CFR §§ 164.400 - 164.408, arising out of or in connection with any non-permitted use or disclosure of PHI or other breach of this Agreement by Business Associate or any subcontractor, affiliate, or agent therefore, including but not limited to any Subcontractor, that provides services described in or relating to the Services Agreement. Covered Entity shall control the defense of any claim indemnified hereunder at the expense of Business Associate. Notwithstanding any provision of the Services Agreement to the contrary, Business Associate's responsibility for indemnification arising out of or in connection with this Agreement will be governed solely by this Section 4.1 and no provision set forth in the Services Agreement, including indemnification provisions thereunder or any terms that define, restrict or limit the types or amounts of damages, costs or expenses, will in any way alter, expand, restrict or limit Business Associate's indemnification liability hereunder. The provisions of this Section 4.1 shall survive the termination of this Agreement.

4.2 Insurance. Business Associate represents and warrants that Business Associate has, and will maintain, at Business Associate's own expense, liability insurance covering breach of Business Associate's requirements under this Agreement and Business Associate's negligent or intentional disclosure or Breach of PHI covered by this Agreement. At the request of Covered Entity, Business Associate shall provide to Covered Entity proof of insurance coverage required by this Section 4.2.

ARTICLE V

MISCELLANEOUS

5.1 Amendments. The parties acknowledge that state and federal laws relating to data security and privacy are rapidly evolving and that amendment of this Agreement may be required to provide for procedures to ensure compliance with such developments. The parties specifically agree to take such action as is necessary to implement the standards

and requirements of HIPAA and other applicable laws relating to the security or confidentiality of PHI.

5.2 No Third Party Beneficiaries. Nothing express or implied in this Agreement is intended to confer, nor shall anything herein confer, upon any person other than Covered Entity, Business Associate and their respective successors or assigns, any rights, remedies, obligations or liabilities whatsoever.

5.3 Conflicts. The terms and conditions of this Agreement will override and control any conflicting term or condition of any other agreements that may be in place between the parties. All non-conflicting terms and conditions of this Agreement and any other agreement between the parties remain in full force and effect.

5.4 Construction. This Agreement shall be construed as broadly as necessary to implement and comply with HIPAA. Any ambiguity in this Agreement shall be resolved in favor of a meaning that complies with HIPAA.

5.5 Subpoenas. Business Associate shall provide written notice to Covered Entity of any subpoena or other legal process seeking PHI received from or created on behalf of Covered Entity, or otherwise relating to the provision of Services by Business Associate. Such written notice shall be provided within three (3) business days of receipt of a subpoena or other legal process.

5.6 Notices. All notices, records, or reports required to be given to either party under this Agreement will be in writing and sent by traceable carrier to each party's address indicated below, or such other address as a party may indicate by at least ten (10) business days' prior written notice to the other party. Notices will be effective upon receipt.

COVERED ENTITY:

DIALYZE DIRECT NY, LLC

BUSINESS ASSOCIATE:

Loretto Health & Rehabilitation

5.7 Counterparts. This Agreement may be executed in two or more counterparts and each such counterpart executed shall for all purposes be deemed an original, and all counterparts together shall constitute but one and the same instrument. This shall be binding upon all signatories hereof who sign below.

5.8 Survival. The rights and obligations of Business Associate under Sections 2.9, 3.5, 3.6, 4.1, 4.2, and Article V of this Agreement shall survive the termination of this Agreement.

5.9 **Governing Law.** This Agreement shall be governed by and interpreted in accordance with the laws of the State of New York. Jurisdiction and venue for any dispute relating to this Agreement shall rest exclusively with the state and federal courts of the State of New York.

[SIGNATURE PAGE FOLLOWS]

RN Education and Experience Requirements

Education

- BS in Nursing;
- AA or Diploma from School of Nursing Experience;
- Registered professional nurse who meets the licensure and practice requirements of New York State; and
- At least 12 months experience of providing nursing care and at least three months experience working as a hemodialysis nurse.

Skills

- Assess patient status and take appropriate action;
- Able to function at a high level with little operational oversight;
- Exemplary interpersonal skills; able to effectively communicate (verbal and written) with diverse backgrounds and different organizational levels; and
- Able to define problems and present solutions;

Licenses, Certifications

- Valid New York State Nursing License required;
- Current CNN or CDN required or must be obtained within one (1) year from date of hire;
- Current BLS certification required; and
- Current driver's license.

Facility Id. 10004
Certificate No. 7001147R

State of New York
Department of Health
Office of Primary Care and Health Systems Management

OPERATING CERTIFICATE

Diagnostic and Treatment Center

Effective Date: 01/17/2017
Expiration Date: NONE

Dialyze Direct NY, LLC
4714 16th Avenue
Brooklyn, New York 11204

Operator: Dialyze Direct NY, LLC
Operator Class: Proprietary LLC

Has been granted this Operating Certificate pursuant to Article 28

of the Public Health Law for the service(s) specified:

Home Hemodialysis Training and Support

Keith W. Servis

Deputy Director Office of Primary Care and Health Systems Management

Howard Zucker M.D.

Commissioner

20170118

This certificate must be conspicuously displayed on the premises.

Policies and Procedures	**Policy/Procedure #**
Staffing (RN in room at all times, RN initiating and terminating treatments, qualifications of staff)	NY-CS-7001
Emergency Preparedness (including a plan for backup dialysis that does not rely on an ER)	DD-EP-7488
Medical Emergencies	DD-EP-2469
Oversight of Water Treatment Systems	DD-CS-0242
Reconciliation of Supplies Ordered	DD-CS-0184
Monthly Physician Consult of the Home Dialysis Patient	DD-MR-0167
Home Evaluation Prior to Accepting Patient into Program (include testing feed water)	DD-CS-2825
Infection Control (include isolation, PPE use, storage of infectious waste, disinfection of machines and equipment)	DD-IC-0267
Communication (ESRD staff must provide names and phone #s of on call staff available to NH 24/7)	DD-EP-7488
Competency verification by visual audits of ESRD staff in NH while performing treatments (state frequency of audits)	DD-SE-1338
Patient Assessment (Include timing of assessment by RN if patient has catheter vs fistula, and afterwards if patient shows signs of decompensating, include frequency of vital signs, call to the MD, communication between ESRD and NH staff)	DD-CS-0153
Patient Plan of Care (include frequency of treatments, time of day for treatments, if resident refuses treatment, collaboration of IDT)	DD-MR-0167
Care of the Dialysis Patient at Home	DD-CS-1347
Providing Care for the Dialysis Patient during an Outbreak/Quarantine	DD-IC-0095
Water Emergencies (Emergencies that interrupt water service prior to or during treatment)	DD-EP-2469
Allowing a personal home dialysis caregiver/ care partner, who previously assisted the resident in their home with dialysis, to assist the resident with dialysis in the nursing home.	N/A

Compliance with ESRD CfC 42 CFR 494.1-494.180 (related to care of residents receiving treatments in a nursing home).	Section 3(L)
Coordination between the ESRD Interdisciplinary Care Team (IDT) (MSW, RD, RN) and the Nursing Home IDT regarding the provision of dialysis treatments and ongoing communication regarding the resident's condition and treatments. Provide consult with nursing home IDT regarding resident condition and provide face to face meeting if necessary.	Section 3, Section 6
Coordination with the nursing home to ensure that a RN trained in hemodialysis employed by the ESRD provider provides on-site supervision of the dialysis treatment.	Section 3(F)
Coordination with the nursing home to ensure qualified administering dialysis personnel employed by the ESRD provider remain in visual contact with the resident throughout the dialysis treatment.	Section 3(I)
Initial/on-going verification of competencies of the dialysis administering personnel including documented evidence of ESRD staff training in fire safety and medical emergencies prior to the start of initiation of patient care.	Section 3(H)
Ordering/providing dialysis supplies/medications.	Section 3(D)
Communication regarding the safety/cleanliness of the nursing home dialysis environment and resolution.	Section 11
Provision of emergency care during dialysis in accordance with resident wishes and advanced directives.	Section 6(B)
Immediate reporting of any unexpected/adverse events during dialysis to the resident, their nephrologist, nursing home medical and nursing staff, and their responsible party.	Section 3(K)
Following the dialysis prescription, the dialysis related medications, communicating all changes in the orders to the dialysis administering personnel and nursing home IDT.	Section 2, Section 6(C)
Review of treatment records to ensure accurate documentation of delivered dialysis treatments and effects on the resident during dialysis, including adverse events.	Section 14
Monitoring lab values related to dialysis and acting upon them, if indicated.	Section 3(B)
Ensuring all dialysis equipment is maintained in good working order.	Section 3(D)
Testing and monitoring the water and dialysate quality for HD equipment.	Section 9
Monthly visits with nephrologist or the practitioner treating the resident.	Section 2
Providing periodic training to the nursing home staff regarding basic care of the dialysis patient.	Section 3(C)
Incorporation of services provided to residents into ESRD facility QAPI program.	Section 3(B)
Providing a safe and sanitary environment for dialysis including: infection control practices, room type specifics (isolation/roommate selection), monitoring/mitigating hazards, prohibiting intrusions into dialysis environment during treatment, and cleaning/disinfecting all dialysis equipment and usable supplies.	Section 3(M)(i)
Protecting the personal dialysis equipment/supplies of the resident from unauthorized access.	Section 9
All supportive care of the resident (monitoring weight, dietary/fluid intake, conditions related to fluid overload/depletion/infection/electrolyte imbalance post dialysis)	Section 7(A)
Written communication between the NH and ESRD on dialysis treatment orders, medication orders, patient assessment, and any changes in the patient condition.	Section 6

Reviewing NH and ESRD plans of care and making collaborative revisions to ensure that the resident's needs are met, and their goals are attained.	Section 2
Documentation that assessments, care provided, interventions by both facilities is complete, timely, and accurate.	Section 14
Training and competency credential files for dialysis administering personnel are maintained by ESRD facility and NH.	Section 3(H)
Attestation that only an RN employed by the ESRD provider can initiate and discontinue dialysis and must be present throughout the entire dialysis treatment	Section 3(F)

	TITLE: INTRADIALYTIC ASSESSMENT AND MONITORING PROCEDURE	REFERENCE: #DD-CS-0153
CATEGORY: CLINICAL SERVICES		
REPLACING: #DDCS0459		PAGE: 1 OF: 2
APPROVED REVISION: 3/31/2017		EFFECTIVE: 12/01/2014

POLICY:

Dialyze Direct Facility shall routinely monitor the patient's response to hemodialysis treatment and the accuracy of the machine functions.

PROCEDURE:

- The Dialysis Services Staff RN shall be responsible for evaluating the patient's response to the dialysis treatment, performing patient assessment, including blood pressure, fluid status, pulse and respiration.
- The steps in this procedure shall be completed every half hour, unless more frequent monitoring is required due to the condition of the patient.
- The following machine parameters shall be checked:
  - Arterial pressure
  - Venous pressure
  - Fluid removal
  - Dialysate flow
  - Blood flow
  - Visual check of dialyzer, blood tubing and connections
  - Visual checks of machine monitor setting
  - Visual check of air/foam alarm status
  - Visual check of patient's access (needles are visible and secure)
- The patient assessment shall include:
  - General condition and response of patient to procedure
  - Signs and symptoms, including nausea, apprehensions, shortness of breath, restlessness, agitation, irritability, itching, flushing twitching, irrational behavior, sensation of faintness, complaints of pain
- Record the patient assessment and machine checks in the patients EMR.
- Notify nephrologist of any unusual issues prior to patient discharge

- For staff-assisted home hemodialysis in the skilled nursing facility, communication shall take place between Dialyze Direct and skilled nursing facility during patient hand offs. Additionally, any adverse occurrences during dialysis treatments shall be communicated immediately to skilled nursing facility leadership. Dialysis Facility shall follow procedures in accordance with Hand Off Communication with Long Term Care Facility Policy- #DDCS0331 and Emergency Medical Response in the Long Term Care Facility - #DDCS0260.
- If patient shows signs of decompensating, Dialyze Direct shall follow the policy and procedure Emergency Response in the Long Term Care Facility - #DDCS0260.

REFERENCE:

Review of Hemodialysis for Nurses and Dialysis Personnel, 7th Edition,
Judith Z. Kallenbach, MSN, RN, CNN; Charles F. Gutch, MD, FACP; Martha H. Stoner, RN, PhD; Anna L. Corea, MN, RN, CNAA

	TITLE: HOME HEMODIALYSIS HHD SUPPLIES MANAGEMENT POLICY	REFERENCE: #DD-CS-0184
CATEGORY: CLINICAL SERVICES		
REPLACING: #DDCS0387		PAGE: 1 OF: 1
APPROVED REVISION: 3/31/2017		EFFECTIVE:12/01/2014

POLICY:

- Dialyze Direct Dialysis Services Facility is responsible for the oversight and overall management of the home dialysis patient, including assuring that the patient is provided with functional, prescribed equipment and supplies.

- Dialyze Direct Dialysis Services Facility has a written agreement with Nxstage inc DME Company. This agreement outlines the responsibilities of this facility and the DME Company.

- All machines and equipment shall be repaired and routine preventive maintenance completed in accordance with the manufacturer's recommendations.

    - The preventive maintenance and repair logs for the equipment in use at patients' homes documents that the manufacturer's directions were adhered to for periodic preventive maintenance.

- This dialysis facility maintains records of preventive maintenance and repairs, performed by a DME supplier.

    - If the facility staff members are responsible for performing the maintenance and repair on the home dialysis equipment, personnel file review shall show evidence of training and competency verification for all of the different systems the facility maintains.

- Dialyze Direct maintains a log of the serial numbers of all equipment in use at patients' homes; these logs are updated to reflect any exchange of equipment.

	TITLE: WATER AND DIALYSATE EVALUATION AND TESTING GUIDELINES FOR PUREFLOW SL POLICY – SKILLED NURSING FACILITY	REFERENCE: #DD-CS-0242
CATEGORY: CLINICAL SERVICES		
REPLACING: #DDLP1749		PAGE: 1 OF: 6
APPROVED REVISION: 3/31/2017		EFFECTIVE:12/01/2014

PURPOSE:

To provide guidelines for testing, evaluating, and monitoring the quality of water and dialysate when using the PureFlow SL with the NxStage System One (known to CMS as preconfigured system) for compliance with the CMS Conditions for Coverage. **NOTE:** In Center dialysis treatments will use only premixed dialysate solution bags provided by NxStage therefore do not require water and dialysate testing. The Pureflow SL training equipment will be set up and tested prior to use.

This document reflects policy for staff-assisted home hemodialysis in the long-term care or skilled nursing facility.

POLICY:

Water and dialysate testing and documentation will meet NxStage, CMS, and AAMI standards and guidelines. Documentation of testing, results, and interventions will be maintained at the home training center.

TESTING OVERVIEW:

TAG	Sample	Frequency of Draw	Test Performed
593/ 594	Source water: Municipal	Initially to verify source water is within range for the use of PureFlow SL. Annually thereafter	Chemical analysis of the standard AAMI test panel contaminants to ensure product manufacturer's specifications are met. See PFSL User's Guide 4), Section 10: Specifications for Source Water Purity Limits.
593/ 594	Source water: Well	Initially to verify source water is within range for the use of PureFlow SL, then as necessary to reflect seasonal variations.	Chemical analysis of the standard AAMI test panel contaminants to ensure product manufacturer's specifications are met. See PFSL User's Guide 04), Section 10: Specifications for Source Water Purity Limits.
594/ 276	Product water	For PAK produced at skilled nursing facility only:	Chemical analysis of the standard AAMI test panel contaminates to

		Monthly: All PAKs will be tested monthly. More frequently if needed to verify results are within the AAMI limits.	ensure AAMI specifications are met.
595	Product water	Each batch, prior to use of the batch. will be tested for chlorine / chloramines	Analysis of chlorine / chloramines levels to ensure the AAMI and manufacturer's specifications are met.
595	Dialysate	Initially: test within the first month of initializing PureFlow SL machine, near the estimated end of a batch. Monthly: re-test dialysate monthly near the estimated end of a batch (1 SAK per PAK) More frequently if needed to verify results are within the AAMI limits.	Bacteriological and endotoxin analysis to ensure AAMI specifications are met.
	Dialysate	None	No independent testing of dialysate for conductivity/pH is required.

	TITLE: WATER AND DIALYSATE EVALUATION AND TESTING GUIDELINES FOR PUREFLOW SL POLICY – SKILLED NURSING FACILITY	REFERENCE: #DD-CS-0242
CATEGORY: CLINICAL SERVICES		
REPLACING: #DDLP1749		PAGE: 3 OF: 6
APPROVED REVISION: 3/31/2017		EFFECTIVE:12/01/2014

Tag Number	Regulation	Interpretive Guidance
V593/594 **Source water - municipal** **Source water - well**	Monitoring of the quality of water and dialysate used by ESRD unit/home hemodialysis including conducting an onsite evaluation and testing of the water and dialysate system in accordance with: (A) The recommendations specified in the manufacturer's instructions; and (B) The system's FDA – approved labeling for preconfigured systems designed, tested, and validated to meet AAMI quality (which includes standards for chemical and chlorine/chloramines testing) water and dialysate.	The facility home training staff must conduct on-site evaluations of the ESRD unit/home hemodialysis patient's water supply prior to selecting a water treatment system for home hemodialysis. There should be evidence the source water to be used meets the minimum requirements specified by the manufacturer of the water treatment components or of the integrated system, if such is in use. Because of the variables with regulation of the water supply to a home for safe drinking water standards, annual analysis of the quality of the product water may not be sufficient, since the quality of water from the well may change over time and since private wells are not routinely monitored. More frequent analysis may be needed if the well is subjected to seasonal changes or contamination from sources such as septic tanks, underground fuel storage tanks, or agricultural waste and chemicals. The additional monitoring might not need to be the full AAMI analysis if only certain contaminants are known to be of concern.

NXSTAGE TECHNICAL CLARIFICATION:

- Obtain source water sample from patient's home prior to completion of patient training to ensure source water does not exceed PureFlow SL (PFSL) maximum level of contaminants.
- Water quality can be confirmed for all new PureFlow SL patients by performing a standard AAMI test panel then comparing each contaminate level to the corresponding PureFlow SL User Guide Section 10: Specifications for source water purity limits (reprinted below).
- Verify with the patient, if the patient's source water changes (i.e. moving to another home location or significant changes in plumbing) that source water is re-verified.

	Contaminant	Source Water (mg/L)	Product Water (mg/L) ANSI/AAMI/ISO 13959:2009
Contaminants with documented toxicity in hemodialysis	Aluminum*	0.2	0.01
	Chloramines**	4.0	Not specified*
	Free Chlorine**	4.0	Not specified*
	Total Chlorine	4.0	0.1
	Copper	1.3	0.1
	Fluoride	4.0	0.2
	Lead	0.015	0.005
	Nitrates (as N)	10	2
	Sulfate*	250	100
	Zinc*	5	0.1
Normally included in dialysate	Calcium	No limit	2
	Magnesium	No limit	4
	Potassium	No limit	8
	Sodium	No limit	70

Other Contaminants	Antimony	0.006	0.006
	Arsenic	0.01	0.005
	Barium	2	0.1
	Beryllium	0.004	0.004
	Cadmium	0.005	0.001
	Chromium	0.1	0.014
	Mercury	0.002	0.0002
	Selenium	0.05	0.09
	Silver*	0.1	0.005
	Thallium	0.002	0.002

- Source water pressure must be between 20 – 80 psi or 20 to 120 psi with a Pressure Regulator.
- Source water flow must be at least 150ml/min or greater.
- Results of source water may be recorded on Water and Dialysate Testing Log (TM0427) available from NxStage Home Hemodialysis NxDocuments.

IF RESULTS ARE OUT OF RANGE:

AAMI Testing:

- If tests are out of range, redraw within 24hours x1.
    - If PAK/SAK results are out of range again, change PAK
    - Patients may not be initiated using PureFlow until labs are in range. If necessary, filters will be installed to treat water prior to reaching the PAK to enable source water to reach an acceptable limit.

Bacteriological and Endotoxin Testing:

- If tests are out of range, change PAK and draw new sample x1.
- Follow protocol in **Bacteriological and Endotoxin Testing Policy**- out of range results require:
    - Patient evaluation
    - Notify patient's physician/Dialyze Direct medical director
    - Other interventions per Dialyze Direct policy

	TITLE: WATER AND DIALYSATE EVALUATION AND TESTING GUIDELINES FOR PUREFLOW SL POLICY – SKILLED NURSING FACILITY	**REFERENCE: #DD-CS-0242**
CATEGORY: CLINICAL SERVICES		
REPLACING: #DDLP1749		**PAGE: 6 OF: 6**
APPROVED REVISION: 3/31/2017		**EFFECTIVE:12/01/2014**

REFERENCES:

CMS 42 CFR Parts 494 Conditions for Coverage for End-Stage Renal Disease Facilities and related CMS ESRD Program Interpretive Guidance (October 3, 2008)

Dialysate Preparation Primer Chronic Hemodialysis with the NxStage PureFlow SL
PureFlow SL User's Guide

AAMI/FDS-RD52:2004/A1 Dialysate for Hemodialysis, Amendment 1- Annex C; Special Considerations for Home Hemodialysis

	TITLE: STAFF ASSISTED HOME HEMODIALYSIS IN THE LONG TERM CARE FACILITY	REFERENCE: #DD-CS-1347
CATEGORY: CLINICAL SERVICES		
REPLACING: DDCS-0698		PAGE: 1 OF: 2
APPROVED REVISION: 3/31/2017		EFFECTIVE: 12/01/2014

PURPOSE:

The purpose of this policy is to provide guidance and direction for managing patients receiving Staff Assisted Home Hemodialysis in a Long Term Care Facility (LTCF) in the State of New York.

PERFORMED BY:

Facility Home Therapy Staff/ Staff Assist Home Caregiver

OVERVIEW:

If the **patient is a resident of a Long Term Care Facility**, Dialyze Direct will provide a qualified and trained Caregiver to provide the patient's treatment at the Long Term Care Facility.

The Dialyze Direct Home Dialysis Team will work in collaboration with the Long Term Care Facility to assure quality services that meet all CMS Conditions of the End Stage Renal Disease Program are provided, along with consistent and quality services that take into consideration individual patient needs and preferences while complying with all licensing /state regulations.

POLICY:

The Dialyze Direct Staff Assisted Home Hemodialysis Program provides the following range of services to all qualified patients.

- Services are provided by trained and certified Dialyze Direct personnel
- The patient is considered a member of the Interdisciplinary Team and is encouraged to participate in his/her own care to extent possible. The patient's authorized representative may also participate in the Care Planning process. Refer to the **Comprehensive Assessment Policy.** Dialyze Direct will collaborate with long term care staff in planning patient care.
- All services have established guidelines, policies, and procedures that have been reviewed and approved by the Facility Governing Body
- At least one registered nurse shall be on duty for the first nine patients receiving dialysis services on the premises and an additional registered nurse shall be on duty for each additional nine patients, or any portion thereof.

- At least one registered nurse or licensed practical nurse shall be on duty for every two patients receiving dialysis services.
- Additionally a qualified licensed nurse with home dialysis experience is on-call for home support 24/7 and may be reached by calling: (800) 673-4225
- Dialyze Direct policies and procedures are reviewed at least every two years. This includes policies and procedures related to Staff Assisted Home Hemodialysis in a Long Term Care Facility (patient's residence)
- Revisions to policies and services provided may take place as necessary with review and approval from the CEO/ Chief Executive Officer, Medical Director and Facility Governing Body.

REFERENCES:

Department of Health & Human Services Centers for Medicare & Medicaid Services 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

	TITLE: BEDSIDE HOME HEMODIALYSIS ENVIRONMENT ASSESSMENT POLICY	**REFERENCE: # DD-CS-2825**
CATEGORY: CLINICAL SERVICES		
REPLACING: #NONE		**PAGE: 1 OF: 1**
APPROVED REVISION		**EFFECTIVE:12/31/2018**

PURPOSE:

- Prior to commencing bedside home hemodialysis treatments in a nursing home, Dialyze Direct shall evaluate each bedside home dialysis setting to ensure the setting is suitable for the safe provision of home hemodialysis treatments.

POLICY:

A. Every bedside home hemodialysis setting within a nursing home must maintain the bedside room must:

   i. maintain a secured storage location for dialysis equipment and supplies;

   ii. maintain proper space requirements to ensure avoidance of infection control issues;

   iii. maintain a designated location to place biohazard waste;

   iv. meet requirements listed in policy and procedure DD-CS-0242, Water and Dialysate Evaluation and Testing Guidelines for Pureflow SL Policy – Skilled Nursing Facility;

   v. maintain access to a scale to ensure dialysis patient can be weighed pre and post dialysis treatments.

	TITLE: AFTER HOURS AND EMERGENCY COVERAGE IN THE LONG TERM CARE SETTING POLICY	REFERENCE: #DD-EP-7488
CATEGORY: EMERGENCY PREPAREDNESS		
REPLACING:		PAGE: 1 OF: 2
APPROVED REVISION:		EFFECTIVE:8/30/2018

PURPOSE:

To provide guidelines for after hours and emergency medical care coverage for all patients residing in the long term care setting after normal facility operating hours.

POLICY:

1. Dialyze Direct provides staff-assisted home hemodialysis services to patients residing in the long term care setting between the hours of 8 am and 5 pm Monday through Friday.

2. For after-hours emergent issues, dial 911 or contact the physician of record.

3. For non-emergent issues, call (800) 673-4225 for assistance after normal operating hours.

4. The procedure for healthcare/emergency medical access after normal operating hours will be clearly communicated to the skilled nursing facility during orientation.

5. Dialyze Direct will have a written agreement with a hospital that can provide acute dialysis services, inpatient treatment, other hospital services as well as emergency medical care 24 hours a day, seven (7) days a week.
    a. The agreement will:
        i. Verify that hospital services are available to Dialyze Direct's patients when needed.
        ii. Include reasonable assurances that patients from Dialyze Direct are accepted and treated in emergencies.
6. Dialyze Direct shall provide long-term care facility with their facility's lead dialysis RN's name and phone number for purposes of providing 24/7 availability and handling non-emergency dialysis related questions and issues.

	TITLE: AFTER HOURS AND EMERGENCY COVERAGE IN THE LONG TERM CARE SETTING POLICY	**REFERENCE: #DD-EP-0901**
CATEGORY: EMERGENCY PREPAREDNESS		
REPLACING:		**PAGE: 2 OF: 2**
APPROVED REVISION:		**EFFECTIVE:8/30/2018**

	TITLE: TRANSMISSION BASED (CONTACT, DROPLET, ISOLATION) PRECAUTIONS POLICY, PROCEDURE	REFERENCE: #DD-IC-0095
CATEGORY: INFECTION CONTROL		
REPLACING: #DDCS0743		PAGE: 1 OF: 7
APPROVED REVISION: 3/31/2017		EFFECTIVE:12/01/2014

PURPOSE:

Transmission-Based Precautions are to be used in addition to Standard Precautions for patients with documented or suspected infection or colonization with highly transmissible or epidemiologically-important pathogens for which additional precautions are needed to prevent transmission.

POLICY:

- Transmission-Based Precautions shall be used in addition to Standard Precautions to prevent the spread of infection throughout the facility.
- Transmission-Based Precautions include:
  - Contact Precautions
  - Droplet Precautions

CONTACT PRECAUTIONS:

- Contact Precautions shall be used for patients with known or suspected infections or evidence of syndromes that represent an increased risk for contact transmission. See also CDC pathogen-specific recommendations.
- Discontinue Contact Precautions after signs and symptoms of the infection have resolved or according to CDC pathogen-specific recommendations.
  - Patient Placement:
    - Patients who require Contact Precautions shall be placed in a single-patient room when available.

- When single-patient rooms are in short supply, apply the following principles for making decisions on patient placement shall be used:
  - Patients with conditions that may facilitate transmission (i.e., uncontained drainage, stool incontinence) shall be prioritized for single-patient room placement.
  - Patients who are infected or colonized with the same pathogen and are suitable roommates shall be placed together (cohorted).
  - If it becomes necessary to place a patient who requires Contact Precautions in a room with a patient who is not infected or colonized with the same infectious agent, the following principles shall be followed:
    - Avoid placing patients on Contact Precautions in the same room with patients who have conditions that may increase the risk of adverse outcome from infection or that may facilitate transmission (i.e., those who are immunocompromised, have open wounds, or have anticipated prolonged lengths of stay).
  - Change protective attire and perform hand hygiene between contact with patients in the same room, regardless of whether one or both patients are on Contact Precautions.

- Personal Protective Equipment:
  - Gloves shall be worn whenever touching the patient's intact skin or surfaces and articles in close proximity to the patient (i.e., medical equipment, bed rails). Gloves shall be donned upon entry into the patient's room or cubicle.
  - Gowns shall be worn whenever it is anticipated that clothing will have direct contact with the patient, or potentially contaminated environmental surfaces or equipment in close proximity to the patient. Gown shall be donned upon entry into the room or cubicle. Gown shall be removed and hand hygiene performed before leaving the patient-care environment.

- unavoidable, equipment shall be cleaned and disinfected prior to use on another patient.

- Environmental Measures:

  - Rooms for patients on Contact Precautions shall be prioritized for frequent cleaning and disinfection (i.e., at least daily), with a focus on frequently-touched surfaces (i.e., bed rails, overbed table, bedside commode, lavatory surfaces in patient bathrooms, doorknobs) and equipment in the immediate vicinity of the patient.

DROPLET PRECAUTIONS:

- Droplet Precautions shall be used in accordance with CDC Recommendations for patients known or suspected to be infected with pathogens transmitted by respiratory droplets (i.e., large-particle droplets greater than 5µ in size) that are generated by a patient who is coughing, sneezing or talking.

- Droplet Precautions shall be discontinued after signs and symptoms have resolved or according to CDC pathogen-specific recommendations.

  - Patient Placement:

    - Patients who require Droplet Precautions shall be placed in a single-patient room when available.

    - When single-patient rooms are in short supply, the following principles for making decisions on patient placement shall be used:

      - Prioritize patients who have excessive cough and sputum production for single-patient room placement

      - Place together in the same room (cohort) patients who are infected with the same pathogen and are suitable roommates

- ♦ If it becomes necessary to place patients who require Droplet Precautions in a room with a patient who does not have the same infection:
  - □ Avoid placing patients on Droplet Precautions in the same room with patients who have conditions that may increase the risk of adverse outcome from infection or that may facilitate transmission (i.e., those who are immunocompromised, have or have anticipated prolonged lengths of stay).
  - □ Ensure that patients are physically separated (i.e., greater than three [3] feet apart) from each other. Draw the privacy curtain between beds to minimize opportunities for close contact.
  - □ Change protective attire and perform hand hygiene between contact with patients in the same room, regardless of whether one patient or both patients are on Droplet Precautions.

- Personal Protective Equipment:
  - ■ A face mask shall be donned upon entry into the patient room or cubicle.
  - ■ For patients with suspected or proven SARS, avian influenza or pandemic influenza, refer to the CDC website for the most current recommendations.
- Patient Transport:
  - ■ Patient transport shall be limited to transport and movement of patients outside of the room for medically-necessary purposes only.
  - ■ If transport or movement in any healthcare setting is necessary, the patient shall be instructed to wear a face mask and follow Respiratory Hygiene/Cough Etiquette.

AIRBORNE PRECAUTIONS:

- Airborne Precautions shall be used in accordance with CDC recommendations for patients known or suspected to be infected with infectious agents transmitted person-to-person by the airborne route (i.e., *M tuberculosis*, measles, chickenpox, disseminated herpes zoster).
    - When an AIIR is not available therefore, the patient shall be transferred to a facility that has an available AIIR.
    - In the event of an outbreak or exposure involving large numbers of patients who require Airborne Precautions, the following should be considered:
        - Cohort patients who are presumed to have the same infection (based on clinical presentation and diagnosis when known) in areas of the facility that are away from other patients, especially patients who are at increased risk for infection (i.e., immunocompromised patients).

- Staff Restrictions:
    - Susceptible healthcare staff shall be restricted from entering the rooms of patients known or suspected to have measles (rubeola), varicella (chickenpox), disseminated zoster or smallpox, if other immune healthcare staff are available.

- Use of PPE:
    - A surgical mask shall be worn for respiratory protection when entering the area of a patient when the following diseases are suspected or confirmed:
        - Infectious pulmonary or laryngeal tuberculosis, or when infectious tuberculosis skin lesions are present, and procedures that would aerosolize viable organisms (i.e., irrigation, incision and drainage, whirlpool treatments) are performed
        - Smallpox (vaccinated and unvaccinated)

- Respiratory protection is recommended for all healthcare staff, including those with a documented “take” after smallpox vaccination, due to the risk of a genetically engineered virus against which the vaccine may not provide protection, or of exposure to a very large viral load (i.e., from high-risk aerosol-generating procedures, immunocompromised patients, hemorrhagic or flat smallpox.

- Patient Transport:
  - Patients requiring Airborne Precautions will be transferred to another facility that will be able to meet the needs of the patient.
  - When transport or movement outside an AIIR is necessary, patients shall be instructed to wear a surgical mask, if possible, and observe Respiratory Hygiene/Cough Etiquette.
  - For patients with skin lesions associated with varicella or smallpox, or draining skin lesions caused by *M. tuberculosis*, the affected area shall be covered to prevent aerosolization or contact with the infectious agent in skin lesions.

- Exposure Management:
  - Susceptible persons shall be offered immunization or provided with the appropriate immune globulin as soon as possible following unprotected contact (i.e., exposed) to a patient with measles, varicella or smallpox.
    - Administration of measles vaccine (at any interval following exposure) or immune globulin (within six [6] days of exposure, particularly contacts less than or equal to six [6] months of age, pregnant women, and immunocompromised people, for whom the risk of complications is highest) to susceptible contacts.

- Varicella vaccine should be administered to exposed susceptible persons within 120 hours after the exposure, or administer varicella immune globulin (VZIG or alternative product), when available, within 96 hours for high-risk persons in whom vaccine is contraindicated (i.e., immunocompromised patients, pregnant women, newborns whose mother's varicella onset was less than five [5] days before or within 48 hours after delivery).

- Smallpox vaccine should be administered to exposed susceptible persons within four (4) days after exposure.

REFERENCE:

Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee, 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings, June 2007

	TITLE: INFECTION PREVENTION AND CONTROL PRACTICES	REFERENCE: #DD-IC-0267
CATEGORY: INFECTION CONTROL		
REPLACING: #DDCS0419		PAGE: 1 OF: 3
APPROVED REVISION: 3/31/2017		EFFECTIVE: 12/01/2014

POLICY:

- Dialyze Direct Dialysis Services Facility shall provide and monitor a sanitary environment to minimize the transmission of infectious agents within the between this facility and any adjacent hospital or other public areas.
- Standard Precautions shall be followed by all staff.
- Staff shall wear gowns, face shields, eye wear or masks to protect themselves and prevent soiling of clothing when performing procedures during which spurting or spattering of blood might occur (i.e., during initiation and termination of dialysis, cleaning of dialyzers, centrifugation of blood).
    - Such protective clothing or gear shall be changed if it becomes soiled with blood, body fluids, secretions or excretions.
- Staff members shall not eat, drink or smoke in the dialysis treatment area or in the laboratory.
- Transmission-Based Precautions (Isolation Precautions) shall be followed by all staff, as applicable.
- Specific infection prevention and control precautions followed to prevent the transmission of bloodborne viruses and pathogenic bacterial among patients include:
    - Routine serologic testing for hepatitis B virus infections
    - Vaccination of susceptible patients against hepatitis B
    - Isolation of patients who test positive for hepatitis B surface antigen
    - Surveillance for infections and other adverse events
    - Staff Infection prevention and control training and education
    - Patient and family education
- Hand hygiene shall be followed by all staff.
- Hands always shall be washed after gloves are removed and between patient contacts, as well as after touching blood, body fluids, secretions, excretions and contaminated items.

- Patients are encouraged to wash extremity with soap and water upon arrival for dialysis, if able. If patient unable to wash access site, patient care staff will clean access extremity with skin cleansing agent and pat dry.

- Patients are encouraged to remove gloves and wash hands after holding access post dialysis.
- Non-sterile gloves shall be required whenever caring for a patient or touching a patient's equipment.
- A supply of clean non-sterile gloves and a glove discard container shall be placed near each dialysis station.
- Any item taken to a patient's dialysis station, including those placed on top of dialysis machines, shall either be disposed of, dedicated for use only on a single patient, or cleaned and disinfected before being returned to a common clean area or used for other patients.
- Unused medications or supplies (i.e., syringes, alcohol swabs) taken to the patient's station shall not be returned to a common clean area or used on other patients.
- All medications shall be prepared in a room or area separated from the patient treatment area and designated only for medications.
- Intravenous medication vials labeled for single use, including erythropoietin, shall not be punctured more than once. Once a needle has entered a vial labeled for single use, the sterility of the product can no longer be guaranteed.
    - According to the CDC, once a needle has entered a vial labeled for single use, the sterility of the product can no longer be guaranteed. Residual medication from two (2) or more vials shall not be pooled into a single vial.
    - Single-use vials/ampules must be used for only one (1) patient, shall not be entered more than once, and if entered, may not be stored for future use.
    - Staff shall only enter vials with a new sterile syringe and needle. If both vials are single-use and are discarded after the single entry into each, the same syringe may be used. If either vial is multiple dose, a different syringe must be used for entry into each vial.
- Hand hygiene shall be performed after contact with the chair-side computer keyboards/ screens.

- All surface areas and equipment shall be cleaned and disinfected with an facility approved disinfectant and according to manufacturers instructions.
    - Clean areas shall be clearly designated for the preparation, handling and storage of medications and unused supplies and equipment. Clean areas shall be clearly separated from contaminated areas where used supplies and equipment are handled.
    - Do not handle and store medications or clean supplies in the same or an adjacent area to that where used equipment or blood samples are handled.
    - When multiple dose medication vials are used (including vials containing diluents), prepare individual patient doses in a clean (centralized) area away from dialysis stations and deliver separately to each patient.
    - Do not carry multiple dose medication vials from station to station.
    - Do not use common medication carts to deliver medications to patients. If trays are used to deliver medications to individual patients, they must be cleaned between patients.
- Disposal of Waste:
    - All blood contaminated or infectious waste shall be disposed of in accordance with Dialyze Direct Dialysis Services Facility protocol for biohazardous waste

SURVEILLANCE FOR INFECTIONS AND OTHER ADVERSE EVENTS:

- A staff person shall be designated to promptly review the results of routine testing each time such testing is performed, and periodically review recorded episodes of bacteremia or vascular access infections.
- In consultation with the Medical Director and Dialysis Services Nurse Manager, actions shall be taken when changes occur in test results or in the frequency of episodes of bacteremias or vascular access loss because of infection.
- Logs shall be maintained that include for each patient for each dialysis session:
    - Dialysis station
    - Machine number
    - Staff connecting patient to machine
    - Staff de-connecting patient from machine

	TITLE: PATIENT PLAN OF CARE POLICY, PROCEDURE	REFERENCE: #DD-MR-0167
CATEGORY: MEDICAL RECORDS		
REPLACING: #DDCS0793		PAGE: 1 OF: 4
APPROVED REVISION: 3/31/2017		EFFECTIVE: 12/01/2014

POLICY:

A written, individualized comprehensive plan of care that specifies the services necessary to address the Home and LTC dialysis patient's needs, as identified by the comprehensive assessment and changes in the patient's condition, including measurable and expected outcomes and estimated timetables to achieve these outcomes, shall be developed by the interdisciplinary team.

PROCEDURE:

- The plan of care shall be completed by the interdisciplinary team, including the patient if the patient desires.
- The complete plan of care shall be signed by team members, including the patient or the patient's designee.
    - If the patient chooses not to sign the plan of care, this choice shall be documented on the plan of care, along with the reason the signature was not provided.
- Implementation of the initial plan of care shall begin within the latter of 30 calendar days after admission to the Dialysis Services Facility or 13 outpatient hemodialysis sessions beginning with the first outpatient dialysis session.
- Implementation of monthly or annual updates of the plan of care shall be performed within 15 days of the completion of the additional patient assessments.
- The plan of care must address, but not be limited to, the following:
    - Dose of dialysis:
        - The necessary care and services, including the prescribed frequency of dialysis treatments, to manage the patient's volume status; and achieve and sustain the prescribed dose of dialysis to meet a hemodialysis Kt/V of at least 1.2, or meet an alternative equivalent professionally-accepted clinical practice standard for adequacy of dialysis.
    - Nutritional status:
        - The necessary care and counseling services to achieve and sustain an effective nutritional status. A patient's albumin level and body weight shall

be measured at least monthly. Additional evidence-based professionally-accepted clinical nutrition indicators may be monitored, as appropriate.

- Mineral metabolism:
  - The necessary care to manage mineral metabolism and prevent or treat renal bone disease.
- Anemia:
  - The necessary care and services to achieve and sustain the clinically appropriate hemoglobin/hematocrit level. The patient's hemoglobin/ hematocrit shall be measured at least monthly.
    - For home dialysis patients, the Dialysis Services Facility shall evaluate whether the patient can safely, aseptically and effectively administer erythropoiesis-stimulating agents and store this medication under refrigeration, if necessary.
    - The patient's response to erythropoiesis-stimulating agent(s), including blood pressure levels and utilization of iron stores, shall be monitored on a routine basis.
- Vascular access:
  - Vascular access monitoring and appropriate, timely referrals to achieve and sustain vascular access shall be provided. The hemodialysis patient shall be evaluated for the appropriate vascular access type, taking into consideration co-morbid conditions, other risk factors and whether the patient is a potential candidate for arteriovenous fistula placement. The patient's vascular access shall be monitored to prevent access failure, including monitoring of arteriovenous grafts and fistulae for symptoms of stenosis.
- Psychosocial status:
  - The necessary monitoring and social work interventions, including counseling services and referrals for other social services, to assist the patient in achieving and sustaining an appropriate psychosocial status as measured by a standardized mental and physical assessment tool chosen by the social worker at regular intervals, or more frequently on an as-needed basis.
- Modality:

- Home dialysis:
  - The interdisciplinary team must identify a plan for the patient's home dialysis or explain why the patient is not a candidate for home dialysis.
  - If home dialysis is determined to be modality of choice, the IDT team will inform the patient of dialysis treatment scheduling.
- Transplantation status:

- When the patient is a transplant referral candidate, the interdisciplinary team shall develop plans for pursuing transplantation. The patient's plan of care must include documentation of:
  - Plan for transplantation, if the patient accepts the transplantation referral
  - Patient's decision, if the patient is a transplantation referral candidate but declines the transplantation referral
  - Reason(s) for the patient's nonreferral as a transplantation candidate.
  - The interdisciplinary team shall track the results of each kidney transplant center referral, monitor the status of any facility patients who are on the transplant wait list, and communicate with the transplant center regarding patient transplant at least annually, and when there is a change in transplant candidate status.
- Rehabilitation status:
  - Assisting the patient in achieving and sustaining an appropriate level of productive activity, as desired by the patient, and making rehabilitation and vocational rehabilitation referrals, as appropriate.
- Patient/family education:
  - The patient care plan shall include, as applicable, education and training for patients and family members or caregivers or both, in aspects of the dialysis experience, dialysis management, infection prevention and control, and personal care, home dialysis and self care, quality of life, rehabilitation, transplantation, and the benefits and risks of various vascular access types.

- Implementation:

- If the expected outcome(s) are not achieved, the interdisciplinary team shall adjust the patient's plan of care to achieve the specified goals. When a patient is unable to achieve the desired outcomes, the team will:
  - Adjust the plan of care to reflect the patient's current condition
  - Document in the record the reasons why the patient was unable to achieve the goals
  - Implement plan of care changes to address the issues identified
- The Dialysis Services Facility must ensure that all dialysis patients are seen by a physician, nurse practitioner, clinical nurse specialist or physician's assisting providing ESRD care at least monthly, as evidenced by a monthly progress note placed in the medical record, and periodically while the hemodialysis patient is receiving in-facility dialysis.

- Transfer:
  - When the patient is transferred from Dialyze Direct the care plan will be sent with the patient or will follow within one working day of the transfer.

- Patient Refusal of Dialysis Treatment
  - In the event patient refuses dialysis treatment against medical advice, Dialyze Direct shall following DDCC1014NY Patient Refusing Treatment or Leaving Facility Against Medical Advice (AMA) policy and procedure.

	TITLE: EMERGENCY AND DISASTER PLAN IN THE LONG TERM CARE SETTING POLICY, PROCEDURE	REFERENCE: #DD-EP-2469
CATEGORY: EMERGENCY PREPAREDNESS		
REPLACING: #NJPC1070		PAGE: 1 OF: 5
APPROVED REVISION: 8/31/2018		EFFECTIVE:12/01/2014

Policy: In the event of a medical emergency that requires activation of 911 emergency response services, Dialyze Direct staff will activate the Long term Care Facility's Emergency Response Plan.

All Dialyze Direct Staff will be trained by Dialyze Direct and deemed competent in activating the Long Term Care Emergency Response System prior to being scheduled to work in each Long Term Care (LTC) setting. In addition, Dialyze Direct staff will participate in the ongoing mock codes and mock drills in the long-term care facility.

Purpose: To provide guidelines for the Dialyze Direct Staff to follow in the event of an emergency involving any home hemodialysis patient receiving dialysis treatment in the long term care setting.

Procedure: Response to a Medical Emergency:

1. Dialyze Direct trained and qualified staff will discontinue the dialysis treatment and initiate emergency response procedures as per Dialyze Direct policy and procedure.

2. Dialyze Direct trained and qualified staff will activate the Long-Term Care Facility's Emergency Response System.

3. Dialyze Direct trained and qualified staff will initiate emergency procedures i.e. CPR until the arrival of the Emergency Response System (911).

4. Dialyze Direct Licensed Professional Nurse (RN) will complete the Universal Transfer Form (if required by State).

5. The patient's nephrologist will be notified and the event will be documented in the medical record utilizing electronic medical record system.

6. Dialyze Direct Licensed Professional Nurse (RN) will complete the following:

    a. Notify NxStage Technical Support
    b. Complete the NxStage Patient Request for Information Form

c. Record serial # of the cycler
d. Record serial # of the Pureflow
e. Record SAK lot #
f. Place cartridge /lines in a red biohazard bag and place in the lab refrigerator until contents ready to be sent to NxStage.
g. Patient cycler will be removed from the treatment area.

DOCUMENTATION:

Dialyze Direct Licensed Registered Nurse (RN) will document the patient event in the medical record using the electronic medical record (EMR).

1. Dialyze Direct Licensed Registered Nurse (RN) is responsible for completing the Hand off Communication form to be sent to the Long Term Care Emergency Response Team.

2. Dialyze Direct Licensed Registered Nurse (RN) is responsible for completing the Incident Report.

3. Dialyze Direct Licensed Registered Nurse (RN) is responsible for completing the NxStage Request for Patient Information form.

Procedure: Response to a Non-Medical Emergency or Disaster:

1. In the event of a FIRE: The Long-Term Care Facility fire plan will be activated, the proper response to fire is R.A.C.E.
    - **R** = **Rescue** patients immediately from fire or smoke area
    - **A** = **Pull fire alarm** station and call emergency number and give location
    - **C** = **Contain** the smoke or fire by closing all doors to rooms and corridors
    - **E** = **Extinguish** the fire (when it is safe to do so)

2. All staff must report to the treatment area for implementation of the Emergency Evacuation procedure.

    a. Emergency take off procedure will be instructed by the Charge Nurse.

b. Staff will assist patients that are unable to perform Emergency Take off Procedure.

- Ambulatory patients will be instructed to evacuate the facility and proceed to the designated meeting place.
- Non-ambulatory patients must be accompanied by a staff member to the designated meeting place.

c. The charge nurse will be responsible to ensure that the home dialysis room is clear of all patients and staff prior to proceeding to the meeting place.

3. Designated Meeting Place:

a. The Charge Nurse will be responsible for roll call once all patients and staff have arrived at the designated meeting place.

b. The Charge Nurse will notify the Nurse Manager, Administrator and Medical Director that evacuation has taken place.

c. The RN will assess all patients to determine the need for the patient to be transported to the hospital
   - Administration of IV fluids
   - Removal of AVF/AVG needles

d. Direct patient care staff will provide comfort to patients once outside

<u>After Hours and Emergency Coverage (staffing):</u>

- Patients residing in the long term care facility: for after hours emergent issues, dial 911 or contact the physician of record.
- Contact the after-hours call number (800) 673-4225 for other issues and assistance after normal operating hours.
- In the event of a disaster or emergency where dialysis cannot be performed in the long term care setting, patients will receive treatment utilizing one of the following plans:
  a. Dialyze Direct will collaborate with the skilled nursing facility to transfer the patient to another location where Dialyze Direct provides services; OR

b. Dialyze Direct staff will transport equipment and supplies to the patient's new location to perform dialysis; OR
c. Patients will be diverted to a contracted outpatient hemodialysis facility; OR
d. Patients will be diverted to a contracted hospital

- The home dialysis program will have a written agreement with a hospital that can provide acute dialysis services, inpatient treatment, other hospital services as well as emergency medical care 24 hours a day, seven (7) days per week.

Procedure: Shelter in Place:

1. To Shelter-in-Place means to remain in your workplace during an emergency, and protect yourself there. Sheltering-in-Place is the first action you should take during most types of emergencies. While Sheltering-in-Place you should listen to your local radio or TV stations for the latest updates. Emergency management officials may use radio broadcasts to give you further instructions. They will also let you know when the emergency has passed. If an emergency is taking place and you are unsure what to do, first Shelter-in-Place. Then listen to the radio for instructions from emergency management officials.

2. **In the Long Term Care facility, coordinate with the nursing supervisor or administrative staff for instructions on the Shelter-in-Place procedure and identified safe rooms.**

    a. Interior rooms above the ground floor with the fewest amount of windows or vents are best. Avoid overcrowding by selecting several rooms if necessary. Conference rooms without exterior windows, copy rooms, pantries, utility rooms and large storage closets work well. Avoid selecting a room with mechanical equipment such as ventilation blowers or pipes, because this equipment may not be able to be sealed from the outdoors. It is ideal to have a hard-wired telephone in the room(s) you select. Cellular telephone equipment may be overwhelmed or damaged during an emergency.

Procedure: Back up supplies:

1. Dialyze Direct will maintain 7 days of reserve supplies on hand in case of emergency at all times, including pre-mixed 209 bags in case of any water disruption or other emergencies.

2. Additional supplies are available to be delivered within 24 hours as needed.

	TITLE: HAND OFF COMMUNICATION WITH LONG TERM CARE FACILITY POLICY, PROCEDURE	REFERENCE: #DD-CS-0149
CATEGORY: CLINICAL SERVICES		
REPLACING: #DDCS0331		PAGE: 1 OF: 4
APPROVED REVISION: 3/31/2017		EFFECTIVE:12/01/2014

PURPOSE:

To provide guidelines for the Dialyze Direct Staff to follow when using the hand off communication form.

POLICY:

- "Hand-off" communication form is intended for use as an internal communication process between Long Term Care Staff and Dialyze Direct Staff.
- Hand-off" communication will take place whenever there is a change in the patient's caregivers. Caregivers include all clinical staff and physicians
- The licensed nurse is responsible for completing the Hand-Off Communication Form.
- "Hand-off" communication shall include:
  - Accurate patient information regarding care, treatment and services
  - Patient's current condition and diagnosis
  - Recent or anticipated changes in the patient's condition
- All information will be presented in a clear, concise manner using the "Hand – Off Communication Form. For patient being transfer from dialysis area back to their prospective rooms with in the Long Term Care Facility.
- Healthcare professionals shall be allotted the time to "hand-off" patient communication and to ask and answer questions with minimal interruption. It is hoped that this will lessen the amount of information that might be forgotten or simply not conveyed.
- Examples of patient care transitions where "hand-off" communication will take place:
  - At the change of shift between nurses

- A written or verbal report is a form of "hand-off" communication as long as the individual receiving the information can ask questions of the individual who wrote or tape recorded the information.

- When a nurse leaves the facility for a period of time, such as lunch
  - Temporary responsibility of the patients, under the care of the departing nurse, is given to another licensed nurse.
- When a physician transfers complete responsibility for a patient
- When physicians are transferring on-call responsibilities
- Critical Clinical Laboratory and Imaging/Radiology results sent/called to physicians' offices

PROCEDURE:

- Caregivers shall find a quiet area to give a verbal report (hand-off communication) to ensure accurate, clear and concise information is given with a minimum of interruptions.
- Caregivers will give each other the opportunity to ask questions, answer questions and read-back or repeat-back information, as needed.
- The receiver of patient information shall be given the opportunity to review applicable patient historical data regarding care, treatment and services.
- Information provided during hand-off communications will include at a minimum (this information will be discipline-specific):
  - Patient's name and location
  - Patient's physician

- Date of admission
- Summary of the patient's current physical and mental health condition may include:
  - Current medications and when they were last given
  - IVs present: hep- lock and/or IV solution, rate of infusion
  - Most recent vital signs

- Input and output, when applicable
- Oxygen
- Wound dressings, drains, etc.
- Emotional status
- Pain assessment and management

- Allergies
- Recent or anticipated changes in the patient's condition
- Pertinent past medical and surgical history
- The patient's resuscitation status
- Results of recent Clinical Laboratory and diagnostic tests
- Patient problem list
- Treatment, care and services that need to be completed (to-do list)
- Any other information which is important to the patient's care

DIALYZEDIRECT
DIALYSIS HANDOFF COMMUNICATION FORM

RESIDENT _____ **DATE** _____

Code Status _____

Mental Status _____ Allergies _____

Vital Signs T _____ P _____ R _____ BP _____

Current Diet/Fluid Restrictions _____

Resident Compliance with Diet/Fluids _____

New Medications Since Last Dialysis _____

Medical Problems Since Last Dialysis YES _____ NO _____

_____

Skin Issues _____

Condition of Access Site Prior to Leaving for Dialysis

Location/Type of Access Site _____

Bruit Present NO _____ YES _____ N/A _____

Thrill Present NO _____ YES _____ N/A _____

Signs/Symptoms of Infection NO _____ YES _____

Nurse's Signature _____

SECTION TO BE COMPLETED BY DIALYSIS UNIT AND RETURNED WITH RESIDENT

Pre-Dialysis Weight _____ Post-Dialysis Weight _____

Problems During Dialysis _____

Amount of Fluid Removed _____

Post-Tx Vitals T _____ P _____ R _____ BP: *Sitting* _____ *Standing* _____

Labs Drawn _____

***Please attach copies of the lab results*

Did Dietician Make Recommendations? _____

Did Social Worker Make Recommendations? _____

Food/Fluid Consumed During Dialysis _____ % Meal Consumed _____ Fluids Consumed

Medications Given During Dialysis _____

Additional Comments _____

Dialysis Nurse's Signature _____ Date _____

NURSING HOME USE ONLY – UPON RETURN TO FACILITY FOLLOWING DIALYSIS

Bruit Present NO _____ YES _____ N/A _____

Thrill Present NO _____ YES _____ N/A _____

Signs/Symptoms of Infection NO _____ YES _____

Additional Comments _____

Nurse's Signature _____ Date/Time _____

	TITLE: INTERDISCIPLINARY TEAM IN THE LONG TERM CARE SETTING POLICY	REFERENCE: #DD-CS-1187
CATEGORY: CLINICAL SERVICES		
REPLACING: #DDCS2042		PAGE: 1 OF: 2
APPROVED REVISION: 3/31/2017		EFFECTIVE: 12/01/2014

PURPOSE:

To establish guidelines as to the collaboration process between the Dialyze Direct Interdisciplinary Team (IDT) and the Long Term Care Interdisciplinary Team (IDT).

POLICY:

- Dialyze Direct Dialysis Services Facility shall have a systematic process for gathering pertinent information about the patient's treatment for end stage renal disease.
- The Interdisciplinary Team at Dialyze Direct Dialysis Services Facility is responsible for providing each patient with an individualized and comprehensive assessment of his/her needs.
- The Interdisciplinary Team at Dialyze Direct Dialysis Services will work collaboratively with the Interdisciplinary Team of the Long Term Care (LTC) facility. Telephone Conferences and or schedule meetings will be arranged to discuss patient status and the evolving plan of care
- The comprehensive assessment is used to develop the patient's treatment plan and expectations for care(refer to Comprehensive Assessment Policy)
- The interdisciplinary team consists of, at a minimum:
  A. Patient or the patient's designee (if the patient chooses)
  B. Registered nurse
  C. Physician treating the patient for ESRD
  D. Social worker
  E. Registered Dietitian
  F. Transplant Designee (*Applies to New Jersey Only*)

Patients shall be given the option to, and shall be encouraged to, participate in their assessment and care planning process.

- Interdisciplinary team member shall conduct one-on-one interviews with the patient or may opt to set-up team meetings which would include the patient, and for patients who reside in a LTC facility our Interdisciplinary team will work in collaboration with the facilities team

	TITLE: INTERDISCIPLINARY TEAM IN THE LONG TERM CARE SETTING POLICY	REFERENCE: #DD-CS-1187
CATEGORY: CLINICAL SERVICES		
REPLACING: #DDCS2042		PAGE: 2 OF: 2
APPROVED REVISION: 3/31/2017		EFFECTIVE: 12/01/2014

	TITLE: PATIENT PLAN OF CARE POLICY, PROCEDURE	REFERENCE: #DD-MR-0167
CATEGORY: MEDICAL RECORDS		
REPLACING: #DDCS0793		PAGE: 1 OF: 4
APPROVED REVISION: 3/31/2017		EFFECTIVE: 12/01/2014

POLICY:

A written, individualized comprehensive plan of care that specifies the services necessary to address the Home and LTC dialysis patient's needs, as identified by the comprehensive assessment and changes in the patient's condition, including measurable and expected outcomes and estimated timetables to achieve these outcomes, shall be developed by the interdisciplinary team.

PROCEDURE:

- The plan of care shall be completed by the interdisciplinary team, including the patient if the patient desires.
- The complete plan of care shall be signed by team members, including the patient or the patient's designee.
  - If the patient chooses not to sign the plan of care, this choice shall be documented on the plan of care, along with the reason the signature was not provided.
- Implementation of the initial plan of care shall begin within the latter of 30 calendar days after admission to the Dialysis Services Facility or 13 outpatient hemodialysis sessions beginning with the first outpatient dialysis session.
- Implementation of monthly or annual updates of the plan of care shall be performed within 15 days of the completion of the additional patient assessments.
- The plan of care must address, but not be limited to, the following:
  - Dose of dialysis:
    - The necessary care and services to manage the patient's volume status; and achieve and sustain the prescribed dose of dialysis to meet a hemodialysis Kt/V of at least 1.2, or meet an alternative equivalent professionally-accepted clinical practice standard for adequacy of dialysis.
  - Nutritional status:
    - The necessary care and counseling services to achieve and sustain an effective nutritional status. A patient's albumin level and body weight shall be measured at least monthly. Additional evidence-based professionally-accepted clinical nutrition indicators may be monitored, as appropriate.

- Mineral metabolism:
  - The necessary care to manage mineral metabolism and prevent or treat renal bone disease.
- Anemia:
  - The necessary care and services to achieve and sustain the clinically appropriate hemoglobin/hematocrit level. The patient's hemoglobin/ hematocrit shall be measured at least monthly.
    - For home dialysis patients, the Dialysis Services Facility shall evaluate whether the patient can safely, aseptically and effectively administer erythropoiesis-stimulating agents and store this medication under refrigeration, if necessary.
    - The patient's response to erythropoiesis-stimulating agent(s), including blood pressure levels and utilization of iron stores, shall be monitored on a routine basis.
- Vascular access:
  - Vascular access monitoring and appropriate, timely referrals to achieve and sustain vascular access shall be provided. The hemodialysis patient shall be evaluated for the appropriate vascular access type, taking into consideration co-morbid conditions, other risk factors and whether the patient is a potential candidate for arteriovenous fistula placement. The patient's vascular access shall be monitored to prevent access failure, including monitoring of arteriovenous grafts and fistulae for symptoms of stenosis.
- Psychosocial status:
  - The necessary monitoring and social work interventions, including counseling services and referrals for other social services, to assist the patient in achieving and sustaining an appropriate psychosocial status as measured by a standardized mental and physical assessment tool chosen by the social worker at regular intervals, or more frequently on an as-needed basis.
- Modality:
  - Home dialysis:

- The interdisciplinary team must identify a plan for the patient's home dialysis or explain why the patient is not a candidate for home dialysis.

- Transplantation status:

- When the patient is a transplant referral candidate, the interdisciplinary team shall develop plans for pursuing transplantation. The patient's plan of care must include documentation of:
  - Plan for transplantation, if the patient accepts the transplantation referral
  - Patient's decision, if the patient is a transplantation referral candidate but declines the transplantation referral
  - Reason(s) for the patient's nonreferral as a transplantation candidate.
  - The interdisciplinary team shall track the results of each kidney transplant center referral, monitor the status of any facility patients who are on the transplant wait list, and communicate with the transplant center regarding patient transplant at least annually, and when there is a change in transplant candidate status.

- Rehabilitation status:
  - Assisting the patient in achieving and sustaining an appropriate level of productive activity, as desired by the patient, and making rehabilitation and vocational rehabilitation referrals, as appropriate.

- Patient/family education:
  - The patient care plan shall include, as applicable, education and training for patients and family members or caregivers or both, in aspects of the dialysis experience, dialysis management, infection prevention and control, and personal care, home dialysis and self care, quality of life, rehabilitation, transplantation, and the benefits and risks of various vascular access types.

- Implementation:
  - If the expected outcome(s) are not achieved, the interdisciplinary team shall adjust the patient's plan of care to achieve the specified goals. When a patient is unable to achieve the desired outcomes, the team will:

- Adjust the plan of care to reflect the patient's current condition
- Document in the record the reasons why the patient was unable to achieve the goals
- Implement plan of care changes to address the issues identified

- The Dialysis Services Facility must ensure that all dialysis patients are seen by a physician, nurse practitioner, clinical nurse specialist or physician's assisting providing ESRD care at least monthly, as evidenced by a monthly progress note placed in the medical record, and periodically while the hemodialysis patient is receiving in-facility dialysis.

- Transfer:
  - When the patient is transferred from Dialyze Direct the care plan will be sent with the patient or will follow within one working day of the transfer.

	TITLE: EMERGENCY MEDICAL RESPONSE IN THE LONG TERM CARE FACILITY POLICY, PROCEDURE	REFERENCE: #DD-EP-1184
CATEGORY: EMERGENCY PREPAREDNESS		
REPLACING: #DDCS0260		PAGE: 1 OF: 2
APPROVED REVISION: 3/31/2017		EFFECTIVE:12/01/2014

PURPOSE:

To provide guidelines for the Dialyze Direct Staff to follow in the event of an emergency involving any home hemodialysis patients receiving dialysis treatment in the long term care setting.

POLICY:

In the event of a medical emergency that requires the activation of 911 emergency response services, Dialyze Direct Staff will activate the Long Term Care Facility's Emergency Response Services.

1. All Dialyze Direct Staff will be trained by Dialyze Direct and deemed competent in activating the Long Term Care Emergency Response System prior to being scheduled to work in the each Long Term Care (LTC) Setting.

PROCEDURE:

1. Dialyze Direct trained and qualified staff will discontinue the dialysis treatment and initiate emergency procedures as per Dialyze Direct appropriate policy and procedure. Refer to DDCS0159 "Code Blue During Dialysis".

2. Dialyze Direct trained and qualified staff will activate the Emergency Response System within the Long Term Care Setting.

3. Dialyze Direct trained and qualified staff will initiate emergency procedures i.e. (CPR) until the arrival of the Emergency Response System (911)

4. Dialyze Direct Licensed Professional Registered Nurse (RN) complete the NxStage Request for Patient Information Form.

5. The patient's nephrologist will be notified and the patient's event will be documented in the medical record utilizing the electronic medical records system.

6. Dialyze Direct Licensed Professional Registered Nurse (RN) will then complete the following:
    - Notify NxStage Technical Support
    - Complete "NxStage Patient Request For Information"
    - Record serial # of cycler
    - Record serial # of Pure Flow
    - Record SAK Lot #
    - Place Cartridge/Lines and Dialyzer in a red biohazard bag and place in laboratory refrigerator until contents ready to be sent to NxStage.
    - Patient Cycler will be removed from the treatment area

DOCUMENTATION:

Dialyze Direct License Registered Nurse (RN) will document patient event in patient medical record using the electronic medical record (EMR).

1. Dialyze Direct Licensed Professional Registered Nurse (RN) is responsible for completing the Incident Report. Refer to DDCS0415: " Incident Reporting"

2. Dialyze Direct Licensed Professional Registered Nurse (RN) is responsible for completing "Nx Stage Request for Patient Information.

MOCK CODE EVALUATION FORM

Location: _____ **Date/Time:** _____

STEPS	YES	NO	COMMENTS
Staff identifies patient as unconscious or pulseless. Notifies RN and begins CPR (Follows CAB: compressions > airway > breathing)			
RN directs staff member to initiate code alert as per Nursing Home policy (e.g. Call operator or call assigned extension)			
HD treatment ended, blood returned at a rate of 200 ml/min, lines flushed, capped and secured. Fistula needles are not removed.			
RN verifies patient is not DNR, verifies area is clear to allow access for code team and code cart, floor is dry			
Compression-to-ventilation ratio should occur at rate of 30:2. With a compression rate 100/min			
Code team responds with Crash cart. Backboard placed correctly and CPR continued. Report given to code team and 911 on their arrival.			
AED applied. CPR resumed after rhythm evaluated.			
Ambu-bag applied with O2 set at 10-15L/min Ventilations are given at a rate of 2 ventilations after every 30 compressions			
RN assigns a staff member to document. Use of CPR record for documentation.			
RN assigns Direct Patient Caregiver to monitor other patients			
Staff aware of their role in a Cardiac or Respiratory Arrest			
RN notifies Nurse Manager, Nephrologist and Medical Director.			
Privacy screen utilized			
Post 'Code Blue' 1. RN documents event in the EMR 2. Incident Report completed 3. Lines & dialyzer are red bagged, labeled and refrigerated until instructed to ship or dispose. 4. Remove and isolate NxStage cycler & Pureflow from treatment area. 5. Notify NxStage Technical Support 6. Complete the NxStage "request for Patient Information Form"			

	TITLE: EMERGENCY AND DISASTER PLAN IN THE LONG TERM CARE SETTING POLICY, PROCEDURE	REFERENCE: #DD-EP-2469
CATEGORY: EMERGENCY PREPAREDNESS		
REPLACING: #NJPC1070		PAGE: 1 OF: 4
APPROVED REVISION: 3/31/2017		EFFECTIVE:12/01/2014

Policy: In the event of a medical emergency that requires activation of 911 emergency response services, Dialyze Direct staff will activate the Long term Care Facility's Emergency Response Plan.

All Dialyze Direct Staff will be trained by Dialyze Direct and deemed competent in activating the Long Term Care Emergency Response System prior to being scheduled to work in each Long Term Care (LTC) setting.

Purpose: To provide guidelines for the Dialyze Direct Staff to follow in the event of an emergency involving any home hemodialysis patient receiving dialysis treatment in the long term care setting.

Procedure: Response to a Medical Emergency:

1. Dialyze Direct trained and qualified staff will discontinue the dialysis treatment and initiate emergency response procedures as per Dialyze Direct policy and procedure.
2. Dialyze Direct trained and qualified staff will activate the Emergency Response System within the Long Term Care Setting.
3. Dialyze Direct trained and qualified staff will initiate emergency procedures i.e. CPR until the arrival of the Emergency Response System (911).
4. Dialyze Direct Licensed Professional Nurse (RN) will complete the Universal Transfer Form (if required by State).
5. The patient's nephrologist will be notified and the event will be documented in the medical record utilizing electronic medical record system.
6. Dialyze Direct Licensed Professional Nurse (RN) will complete the following:
    a. Notify NxStage Technical Support
    b. Complete the NxStage Patient Request for Information Form
    c. Record serial # of the cycler
    d. Record serial # of the Pureflow
    e. Record SAK lot #
    f. Place cartridge /lines in a red biohazard bag and place in the lab refrigerator until contents ready to be sent to NxStage.
    g. Patient cycler will be removed from the treatment area.

DOCUMENTATION:

Dialyze Direct Licensed Registered Nurse (RN) will document the patient event in the medical record using the electronic medical record (EMR).

1. Dialyze Direct Licensed Registered Nurse (RN) is responsible for completing the Hand off Communication form to be sent to the Long Term Care Emergency Response Team.

2. Dialyze Direct Licensed Registered Nurse (RN) is responsible for completing the Incident Report.

3. Dialyze Direct Licensed Registered Nurse (RN) is responsible for completing the NxStage Request for Patient Information form.

Procedure: Response to a Non-Medical Emergency or Disaster:

1. In the event of a FIRE: The fire plan will be activated, the proper response to fire is R.A.C.E.
   - **R** = **Rescue** patients immediately from fire or smoke area
   - **A** = **Pull fire alarm** station and call emergency number and give location
   - **C** = **Contain** the smoke or fire by closing all doors to rooms and corridors
   - **E** = **Extinguish** the fire (when it is safe to do so)

2. All staff must report to the treatment area for implementation of the Emergency Evacuation procedure.

   a. Emergency take off procedure will be instructed by the Charge Nurse.

   b. Staff will assist patients that are unable to perform Emergency Take off Procedure.

      - Ambulatory patients will be instructed to evacuate the facility and proceed to the designated meeting place.

      - Non-ambulatory patients must be accompanied by a staff member to the designated meeting place.

   c. The charge nurse will be responsible to ensure that the home dialysis room is clear of all patients and staff prior to proceeding to the meeting place.

3. Designated Meeting Place:

    a. The Charge Nurse will be responsible for roll call once all patients and staff have arrived at the designated meeting place.

    b. The Charge Nurse will notify the Nurse Manager, Administrator and Medical Director that evacuation has taken place.

    c. The RN will assess all patients to determine the need for the patient to be transported to the hospital
        - Administration of IV fluids
        - Removal of AVF/AVG needles

    d. Direct patient care staff will provide comfort to patients once outside

Procedure: Response to Power Failure:

1. Emergency Generator will provide power to the facility in the event of power failure. All staff must report to the hemodialysis room.

    - In the event that the generator has exceeded the allotment time and power has not been restored, all blood will be returned, treatment terminated and treatments will be rescheduled.

    - The Charge Nurse will be responsible for contacting the patient's nephrologist to notify them of early termination of treatment.

2. The Nurse Manager will coordinate with the Long Term Care Facility to reschedule treatments.

After Hours and Emergency Coverage (staffing):

- A Home Hemodialysis Nurse (RN) providing on call will be assigned duties based upon education, training and competencies and in accordance with the home dialysis nurse job description. Staff members on call must return calls within 30 minutes.

- Contact the emergency call number (800) 673-4225 for assistance after normal operating hours.

- The home dialysis program will have a written agreement with a hospital that can provide acute dialysis services, inpatient treatment, other hospital services as well as emergency medical care 24 hours a day, seven (7) days per week.

Procedure: Shelter in Place:

1. To Shelter-in-Place means to remain in your workplace during an emergency, and protect yourself there. Sheltering-in-Place is the first action you should take during most types of emergencies. While Sheltering-in-Place you should listen to your local radio or TV stations for the latest updates. Emergency management officials may use radio broadcasts to give you further instructions. They will also let you know when the emergency has passed. If an emergency is taking place and you are unsure what to do, first Shelter-in-Place. Then listen to the radio for instructions from emergency management officials.
2. **In the Long Term Care facility, coordinate with the nursing supervisor or administrative staff for instructions on the Shelter-in-Place procedure and identified safe rooms.**
    a. Interior rooms above the ground floor with the fewest amount of windows or vents are best. Avoid overcrowding by selecting several rooms if necessary. Conference rooms without exterior windows, copy rooms, pantries, utility rooms and large storage closets work well. Avoid selecting a room with mechanical equipment such as ventilation blowers or pipes, because this equipment may not be able to be sealed from the outdoors. It is ideal to have a hard-wired telephone in the room(s) you select. Cellular telephone equipment may be overwhelmed or damaged during an emergency.

Procedure: Back up supplies:

1. Dialyze Direct will maintain 7 days of reserve supplies on hand in case of emergency at all times.
2. Additional supplies are available to be delivered within 24 hours as needed.

DialyzeDirect
DIALYSIS WITH DIGNITY

Patient Label

INITIAL AND QUARTERLY PATIENT EMERGENCY DRILL INSTRUCTIONS FOR LTC

IN CASE OF FIRE:

1. A fire is designated as CODE RED.
2. The fire emergency will be announced through a member of the staff. The staff will announce the location of the fire and the procedure to follow.
3. If the fire is in another area of the building:
   a. Remain in your chair with you and continue your dialysis treatment *b.* The staff will close all doors *c.* The staff will stay
4. If the fire is in the dialysis unit or in close proximity:
   a. Remain in your chair *b.* The staff will close all doors *c.* The staff will terminate your treatment as soon as possible by:
   1) Clamp each blood line and access line. 2) Close thumb clamps 3) Disconnect blood and access line-lock end. 4) If time permits, tape access line securely.

   After disconnecting from the machine, go to the designated area as instructed. Unstable patients will be assisted by the staff of the designated area.

1. Do not remove access needles until evaluated by the medical personnel.
2. Under no circumstances, should any medical personnel unfamiliar with your dialysis status place or inject anything into your vascular access (catheter, fistula, or graft).
3. After transferring patient to a safe designated area, the medical staff will assess each patient's condition including vital signs, condition of vascular access and subjective complaints. A normal saline infusion may be used for volume replacement if necessary.
4. Respective nephrologists will be notified of the early termination of dialysis.
5. If stable, fistula needles will be removed for patients with permanent access.
6. Catheter will be flushed with saline and be capped off for patients with temporary catheter or permacath.
7. Treatment will be arranged elsewhere for patients whose treatment should be completed due to dialysis related issues.

IN CASE OF ELECTRICAL AND EQUIPMENT MALFUNCTION:

a. Remain in your chair.
b. The staff will terminate your treatments as appropriate.
c. The staff will direct you regarding what to do.

Initial instructions given by:

Patient's signature: _____

Date: _____

QUARTERLY INSTRUCTIONS

Date instructions Given:				
Instructions given by:				
Patient signature				

#DD-EP-0879

	TITLE: EMERGENCY PROCEDURE FOR INCAPACITATED DIALYSIS NURSE IN THE LONG TERM CARE SETTING POLICY, PROCEDURE	REFERENCE: #DD-CS-7323
CATEGORY: CLINICAL SERVICES		
REPLACING:		PAGE: 1 OF: 2
APPROVED REVISION:		EFFECTIVE: 8/01/2017

PURPOSE:

To provide guidance in order to ensure patient safety in circumstances when the dialysis nurse becomes incapacitated during a treatment.

OVERVIEW:

In the event that a dialysis nurse is providing treatment in a setting away from other dialysis staff (such as in isolation), and becomes incapacitated, non-dialysis nursing staff will be provided instructions on how to respond in order to ensure patient safety.

POLICY:

- Emergency dialysis disconnect instructions will be clearly visible anywhere a patient is dialyzing.

- Non-dialysis nursing staff should follow the following instructions:
  1. Call for medical assistance to treat incapacitated dialysis nurse. Move the dialysis nurse away from treatment area.
  2. On the dialysis machine, immediately flip the power switch to the OFF position (located on the BACK of the NxStage System One cycler).
  3. Clamp each blood line (4 clamps total).
     - Catheter- clamp each catheter lumen (2), and the blood tubing red and blue pinch clamps (2) that are connected to the catheter.
     - Fistula or graft- clamp each fistula needle pinch clamp (2), and the blood tubing red and blue pinch clamps (2) they are connected to. Make sure tubing is taped securely to the patient's arm to prevent needle dislodgement.
  4. Unplug the NxStage machine from the wall.
  5. Contact DialyzeDirect staff on site for further instruction.
  6. Leave the patient connected to the machine until dialysis staff can assist or give direction.

7. **DO NOT ATTEMPT TO RETURN THE BLOOD TO THE PATIENT! YOU RISK THE POSSIBILITY OF A LIFE-THREATENING AIR EMBOLISM BY IMPROPER BLOOD RETURN!**

DIALYSIS EMERGENCY DISCONNECT PROCEDURE

IN CASE OF INCAPACITATED DIALYSIS NURSE

1

Call for medical assistance to treat incapacitated dialysis nurse. Move the dialysis nurse away from treatment area.

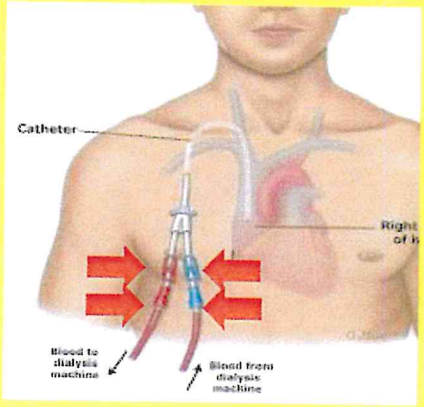
2

On the dialysis machine, immediately flip the power switch to the OFF position (located on the BACK of the NxStage System One cycler). Unplug the NxStage Machine from the wall.

CONTINUED ON BACK

DO NOT ATTEMPT TO RETURN THE BLOOD TO THE PATIENT! YOU RISK THE POSSIBILITY OF A LIFE-THREATENING AIR EMBOLISM BY IMPROPER BLOOD RETURN!

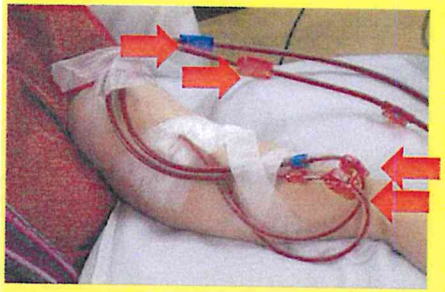
DIALYSIS EMERGENCY DISCONNECT PROCEDURE- CONTINUED



3

Clamp each blood line (4 clamps total).

Catheter- clamp each catheter lumen (2), and the blood tubing red and blue pinch clamps (2) that are connected to the catheter.



Fistula or graft- clamp each fistula needle pinch clamp (2), and the blood tubing red and blue pinch clamps (2) they are connected to. Make sure tubing is taped securely to the patient's arm to prevent needle dislodgement.

4

Contact DialyzeDirect staff on site for further instruction. Leave the patient connected to the machine until dialysis staff can assist.

DO NOT ATTEMPT TO RETURN THE BLOOD TO THE PATIENT! YOU RISK THE POSSIBILITY OF A LIFE-THREATENING AIR EMBOLISM BY IMPROPER BLOOD RETURN!

	TITLE: INFECTION PREVENTION AND CONTROL PROGRAM	REFERENCE: #DD-IC-1309
CATEGORY: INFECTION CONTROL		
REPLACING: #DDCS0423		PAGE: 1 OF: 9
APPROVED REVISION: 3/31/2017		EFFECTIVE: 12/01/2014

PURPOSE:

The purpose of this policy and procedure is to provide guidance and direction to ensure that all Dialyze Direct patient care staff, patients and caregivers are educated, trained and compliant with the Dialyze Direct Infection Prevention and Control Program.

PERFORMED BY:

All Dialyze Direct staff, Patients and Caregivers

OVERVIEW:

Infection Control (494.30) is a Centers for Medicare & Medicaid Services (CMS) Condition for Coverage. This Condition incorporates two Centers for Disease Control and Prevention (CDC) documents as regulations, and CMS developed regulations. These infection control requirements apply to both chronic dialysis in-center facilities and any home program facilities.

POLICY:

- Dialyze Direct Dialysis Services Facility' s Governing Body is responsible for the organization wide Infection Prevention and Control Program, and shall develop and implement infection prevention and control policies and procedures for the entire healthcare organization.
- Dialyze Direct Dialysis Services Facility's Infection Prevention and Control Program shall be integrated into the facility wide Continuous Quality Improvement and Performance Improvement (CQI/PI) program.
- All facility staff shall participate and support the Infection Prevention and Control Program through compliance with infection prevention and control practices, policies and procedures, reporting infection prevention and control concerns.
- Dialyze Direct shall provide the necessary equipment and supplies to maintain consistent observance of Standard Precautions, including hand hygiene products and personal protective equipment.

INFECTION PREVENTION AND CONTROL COMMITTEE AND INFECTION PREVENTIONIST:

- There shall be collaboration between a Certified (CBIC) Infection Control Consultant and the facility to identify any Healthcare Associated Infections (HAI) trends or patterns that may occur, as well as identification of opportunities to improve outcomes in the reduction and control of infections.
- The Infection Preventionist/designee shall:
  - Be responsible for the oversight of the Infection Prevention and Control Program as delegated by the Governing Body
  - Have the authority to take immediate action and institute control measures to prevent or control the spread of infection when identified
  - Develop, review, implement and evaluate policies and procedures governing infections and communicable diseases
  - Develop and maintain a system for identifying, reporting, investigating and controlling infections and communicable diseases
  - Comply with the reporting of communicable diseases, outbreaks in the facility and HAI data to local and state agencies, as applicable
  - Maintain a log of incidents related to infections and communicable diseases, including (HAIs) and infections identified through employee health services
  - Prepare monthly reports for the Governing Body
  - Be a consultant for all medical and clinical staff
  - Assist with staff infection prevention and control education
  - Inform the receiving healthcare organization of any infections a patient may have at the time of transfer
  - Report lab results, indicating an infection, to the attending physician or receiving healthcare organization if the lab results are received after patient has been discharged/transferred
  - Inform the referring healthcare organization of any patient, admitted to this facility, who has an infection at the time of admission
  - Work in collaboration with all staff regarding infection prevention and control processes

- The Infection Preventionist and Infection Control Committee shall be responsible for identifying, investigating, reporting, preventing and controlling infections and communicable diseases through the following activities:
  - Maintenance of a sanitary facility environment
  - Development and implementation of infection prevention and control measures related to facility staff, including contract workers (i.e., housekeeping staff)
  - Evaluate facility staff immunization status for designated infectious diseases, as recommended by the CDC and its Advisory Committee on Immunization Practices (ACIP)
  - Development and implementation of policies articulating the authority and circumstances under which the facility screens facility staff for infections likely to cause significant infectious disease or other risk to the exposed individual, and for reportable diseases, as required under local, state, or federal public health authority
  - Development and implementation of policies articulating when infected facility staff are restricted from providing direct patient care and/or are required to remain away from the healthcare facility entirely
  - Development of new employee and regular update training in preventing and controlling healthcare associated infections and methods to prevent exposure to and transmission of infections and communicable diseases
  - Evaluates staff and volunteers exposed to patients with infections and communicable disease
  - Communication to staff, including medical staff addressing infection prevention and control processes or a practice change

Mitigation of risks associated with patient infections present upon admission:

- Development of systems for early detection and management (i.e., use of appropriate infection prevention and control measures, including isolation precautions, PPE) of potentially infectious persons at the time of admission to the facility
  - Measures for the early identification of patients who require isolation in accordance with CDC guidelines
  - Appropriate use of personal protective equipment, including gowns, gloves, masks and eye protection devices

- Use and techniques for "isolation" precautions as recommended by the CDC

Mitigation of risks contributing to healthcare associated infections:

- Other facility healthcare associated infection risk mitigation measures:
  - Promotion of hand washing hygiene among staff and employees, including utilization of alcohol-based hand sanitizers
  - Measures specific to prevention of infections caused by organisms that are antibiotic-resistant
  - Measures specific to prevention of device-associated bloodstream infection (BSI), such as a protocol for reducing infections of central venous catheters specifying aseptic precautions for line insertions, care of inserted lines and prompt removal when a line is no longer needed
  - Measures specific to prevention of other device-associated infections, i.e., tube feeding, indwelling urinary catheters
  - Isolation procedures and requirements for highly immunosuppressed patients who require a protective environment
  - Requiring disinfectants, antiseptics and germicides to be used in accordance with the manufacturers' instructions
  - Adherence to nationally recognized infection prevention and control precautions, such as current CDC guidelines and recommendations, for infections/communicable diseases identified as present in the facility
  - Educating patients, visitors, caregivers and staff, as appropriate, about infections and communicable diseases and methods to reduce transmission in the facility and in the community

Monitoring compliance with all policies, procedures, protocols and other Infection Prevention and Control Program requirements:

- Infection Prevention and Control Program evaluation and revision of the program annually and when indicated
- Coordination as required by law with federal, state and local emergency management and health authorities to address communicable disease threats, bioterrorism and outbreaks

Infection Prevention and Control Program:

- The Infection Prevention and Control Program at Dialyze Direct Dialysis Services Facility incorporates and documents the following on an ongoing basis:
  - The Infection Preventionist/designee shall be responsible for conducting surveillance within the organization, in consultation with staff as needed.
  - Surveillance shall be conducted to determine rate of infections so that trends can be identified and investigated, and appropriate prevention strategies can be initiated.
  - Monitoring shall include comprehensive surveillance for limited periods of time or targeted surveillance to describe infection risk related to high-risk procedures, patient populations or locations within the facility.

Active Surveillance:

- Monitoring patients and care team members for acquisition of infection and/or colonization
- Conducting surveillance (reliable sampling or other mechanism) on a facility-wide basis in order to identify infectious risks or communicable disease problems at any particular location
- Conducting surveillance activities in accordance with infection prevention and control surveillance practices utilized by the CDC's National Healthcare Safety Net (NHSN) and shall include infection detection, data collection and analysis, monitoring, and evaluation of preventive interventions
- Methods for obtaining and reviewing data on infections/communicable diseases selected for monitoring
- Methods for monitoring and evaluating practices of asepsis
- Authority and indications for obtaining microbiological cultures from patients and the environment as indicated
- Provisions to monitor compliance with all policies, procedures, protocols and other infection prevention and control program requirements
- Provision for program evaluation and revision of the program, when indicated

- Policies and procedures developed in coordination with federal, state and local emergency preparedness and health authorities to address communicable disease threats, bioterrorism and outbreaks

- Procedures for meeting the reporting requirements of the local health authority
- Measurement and analysis of infections and communicable diseases to identify any patterns or trends
- Certain infections shall be monitored regularly, including:
  - MRSA
  - VRE
  - Employee health infections/trends
- Certain areas shall be monitored and risk mitigation plans developed for:
  - Patient infections present upon admission
  - Factors contributing to healthcare associated infection
  - Surgery-related infection risks
- Data quality shall be ensured through the use of inter-rater reliability among the reviewers and by controlled re-review of a test population periodically.
- Standardized activities for each indicator monitored shall be specified in writing and shall be followed exactly as described to ensure that appropriate analysis and comparison can be made.
- **Investigation:**
  - Identification and analysis of infection prevention and control problems or undesirable trends
- **Prevention:**
  - Implementation of measures to prevent transmission of infectious agents and to reduce risks for device- and procedure-related infections
- **Control:**
  - Evaluation and management of outbreaks
- **Reporting:**
  - Provision of information to external agencies as required by state and federal law and regulation

COMMUNICABLE DISEASE OUTBREAKS:

- Infection Control Consultant shall work closely with facility leadership to ensure that Dialyze Direct Dialysis Services Facility is prepared to address the following issues that may arise during a communicable disease outbreak:
  - Preventing transmission among patients, healthcare staff and visitors
  - Identifying persons who may be infected and exposed
  - Providing treatment or prophylaxis to large numbers of people
  - Logistics issues (staff, medical supplies, re-supply, continued operations and capacity)
- Infection Control Consultant, as directed by facility leadership, shall work with local, state and federal public health agencies to identify likely communicable disease threats and develop appropriate preparedness and response strategies.

EDUCATION OF STAFF, PATIENTS AND VISITORS:

- Education addressing the principles and practices for preventing transmission of infectious agents shall be provided to all facility staff, as well as anyone who may have direct or indirect contact with patients or medical equipment.
- All staff, including the medical staff, shall receive infection prevention and control education at the time of orientation, annually and whenever needed.
- Patients and families shall also receive infection prevention and control education, as applicable and appropriate.

PERFORMANCE IMPROVEMENT/EVALUATION:

- A Plan shall be in place in order to evaluate the Infection Prevention and Control Program and Plan, and to ensure continuous improvement in the prevention and control of infections throughout the organization. (See **Performance Improvement Plan**)
- The Infection Prevention and Control Plan shall be evaluated annually and whenever risks have significantly changed. Revisions shall be made as appropriate.

- Performance improvement activities shall evaluate how successful the Infection Prevention and Control Program is at addressing the prioritized risks and meeting goals, objectives, and strategies and then revising the strategies and the plan as needed.
- Performance measures will be identified based on the infection risk assessment and shall be approved by Governing Body.
- Performance measures with related performance outcomes shall be reported to the Governing Body as prescribed by the facility's Performance Improvement Plan. Infection Control Consultant is responsible for reporting performance measurement results to facility leadership.
- Any problems identified through performance measurement shall be addressed with a written corrective action plan.
- Corrective action plans shall be reported to the CEO and Governing Body, who shall hold joint responsibility for linking the Infection Prevention and Control Program with the facility wide performance improvement program.
- Facility leadership shall be explicitly responsible for implementing successful corrective action plans by monitoring adherence to corrective action plans, as well as assessing the effectiveness of actions taken, with implementation of revised corrective actions as needed.

SUPPLIES:

Infection Prevention and Control Program

PROCEDURE:

Follow the steps in the table below to **provide** education, training and implementation of the Infection Control Practices:	
1	Ensure the Infection Prevention and Control Program has been reviewed by the Medical Director and approved by the Governing Body.
2	Review the Infection Prevention and Control Program with the Dialyze Direct staff, patients, and caregivers as appropriate.
3	Provide infection control and prevention training using the Dialyze Direct Infection Prevention & Control Training program to all employees on hire and then review annually thereafter.
4	Provide education and training on the Infection Prevention and Control Program to patients and caregivers as part of the Home Program dialysis training.
5	Ensure education and training in Infection Prevention & Control Program has been documented in the Dialyze Direct employee personnel files and in the patient's

	training records.
6	Ensure infection prevention and control policies and procedures are accessible to all employees in the Dialyze Direct Policy & Procedure Manual.

REFERENCES:

- Federal Register (April 2008). Centers for Medicare & Medicaid Services (CMS), Conditions for Coverage, 494.180 Governance
- Federal Register (April 2008). Centers for Medicare & Medicaid Services (CMS), Conditions for Coverage, 494.30 Infection Control
- U.S. Department of Health and Human Services, Center for Disease Control & Prevention (CDC), Guidelines Recommendations for preventing transmission of infections among chronic hemodialysis patients. *Morbidity and Mortality Weekly Report,* April 27, 2001/Vol. 50/No. RR-5.
- U.S. Department of Health and Human Services, Center for Disease Control & Prevention (CDC), Guidelines for Environmental Infection Control in Health Care Facilities. *Morbidity and Mortality Weekly Report,* June 6, 2003/Vol. 52/No. RR-10

RELATED DOCUMENTS:

- Governing Body policy
- Infection Prevention and Control Practices
- Performance Improvement Plan

	TITLE: INFECTION PREVENTION AND CONTROL PRACTICES	REFERENCE: #DD-IC-0267
CATEGORY: INFECTION CONTROL		
REPLACING: #DDCS0419		PAGE: 1 OF: 3
APPROVED REVISION: 3/31/2017		EFFECTIVE: 12/01/2014

POLICY:

- Dialyze Direct Dialysis Services Facility shall provide and monitor a sanitary environment to minimize the transmission of infectious agents within the between this facility and any adjacent hospital or other public areas.
- Standard Precautions shall be followed by all staff.
- Staff shall wear gowns, face shields, eye wear or masks to protect themselves and prevent soiling of clothing when performing procedures during which spurting or spattering of blood might occur (i.e., during initiation and termination of dialysis, cleaning of dialyzers, centrifugation of blood).
    - Such protective clothing or gear shall be changed if it becomes soiled with blood, body fluids, secretions or excretions.
- Staff members shall not eat, drink or smoke in the dialysis treatment area or in the laboratory.
- Transmission-Based Precautions (Isolation Precautions) shall be followed by all staff, as applicable.
- Specific infection prevention and control precautions followed to prevent the transmission of bloodborne viruses and pathogenic bacterial among patients include:
    - Routine serologic testing for hepatitis B virus infections
    - Vaccination of susceptible patients against hepatitis B
    - Isolation of patients who test positive for hepatitis B surface antigen
    - Surveillance for infections and other adverse events
    - Staff Infection prevention and control training and education
    - Patient and family education
- Hand hygiene shall be followed by all staff.
- Hands always shall be washed after gloves are removed and between patient contacts, as well as after touching blood, body fluids, secretions, excretions and contaminated items.

- Patients are encouraged to wash extremity with soap and water upon arrival for dialysis, if able. If patient unable to wash access site, patient care staff will clean access extremity with skin cleansing agent and pat dry.

- Patients are encouraged to remove gloves and wash hands after holding access post dialysis.
- Non-sterile gloves shall be required whenever caring for a patient or touching a patient's equipment.
- A supply of clean non-sterile gloves and a glove discard container shall be placed near each dialysis station.
- Any item taken to a patient's dialysis station, including those placed on top of dialysis machines, shall either be disposed of, dedicated for use only on a single patient, or cleaned and disinfected before being returned to a common clean area or used for other patients.
- Unused medications or supplies (i.e., syringes, alcohol swabs) taken to the patient's station shall not be returned to a common clean area or used on other patients.
- All medications shall be prepared in a room or area separated from the patient treatment area and designated only for medications.
- Intravenous medication vials labeled for single use, including erythropoietin, shall not be punctured more than once. Once a needle has entered a vial labeled for single use, the sterility of the product can no longer be guaranteed.
    - According to the CDC, once a needle has entered a vial labeled for single use, the sterility of the product can no longer be guaranteed. Residual medication from two (2) or more vials shall not be pooled into a single vial.
    - Single-use vials/ampules must be used for only one (1) patient, shall not be entered more than once, and if entered, may not be stored for future use.
    - Staff shall only enter vials with a new sterile syringe and needle. If both vials are single-use and are discarded after the single entry into each, the same syringe may be used. If either vial is multiple dose, a different syringe must be used for entry into each vial.
- Hand hygiene shall be performed after contact with the chair-side computer keyboards/ screens.

- All surface areas and equipment shall be cleaned and disinfected with an facility approved disinfectant and according to manufacturers instructions.
    - Clean areas shall be clearly designated for the preparation, handling and storage of medications and unused supplies and equipment. Clean areas shall be clearly separated from contaminated areas where used supplies and equipment are handled.
    - Do not handle and store medications or clean supplies in the same or an adjacent area to that where used equipment or blood samples are handled.
    - When multiple dose medication vials are used (including vials containing diluents), prepare individual patient doses in a clean (centralized) area away from dialysis stations and deliver separately to each patient.
    - Do not carry multiple dose medication vials from station to station.
    - Do not use common medication carts to deliver medications to patients. If trays are used to deliver medications to individual patients, they must be cleaned between patients.
- Disposal of Waste:
    - All blood contaminated or infectious waste shall be disposed of in accordance with Dialyze Direct Dialysis Services Facility protocol for biohazardous waste

SURVEILLANCE FOR INFECTIONS AND OTHER ADVERSE EVENTS:

- A staff person shall be designated to promptly review the results of routine testing each time such testing is performed, and periodically review recorded episodes of bacteremia or vascular access infections.
- In consultation with the Medical Director and Dialysis Services Nurse Manager, actions shall be taken when changes occur in test results or in the frequency of episodes of bacteremias or vascular access loss because of infection.
- Logs shall be maintained that include for each patient for each dialysis session:
    - Dialysis station
    - Machine number
    - Staff connecting patient to machine
    - Staff de-connecting patient from machine

	TITLE: INFECTION PREVENTION AND CONTROL – STAFF EDUCATION	REFERENCE: #DD-IC-0080
CATEGORY: INFECTION CONTROL		
REPLACING: #DDCS0427		PAGE: 1 OF: 1
APPROVED REVISION: 3/31/2017		EFFECTIVE: 12/01/2014

POLICY:

- Staff shall receiving Infection Prevention and Control training at the time of orientation and annually thereafter.
- The topics that will be addressed include (not all inclusive):
  - Standard Precautions
  - Transmission Based Precautions (Isolation Precautions)
  - Bloodborne pathogens
  - Proper hand hygiene technique
  - Proper use of personal protective equipment
  - Special precautions for HBsAg-positive patients
  - Proper infection prevention and control techniques for initiation, care and maintenance of access sites
  - Modes of transmission for bloodborne viruses, pathogenic bacteria and other microorganisms, as appropriate
  - Proper handling, preparation, and administration of parenteral medications maintaining aseptic technique
  - Proper methods to clean and disinfect equipment and environmental surfaces to minimize transmission of microorganisms
- Staff must demonstrate knowledge of infection prevention and control policies and procedures. Educational records shall be maintained as a part of each staff member's personnel record.

	TITLE: CARE OF THE HBV-POSITIVE PATIENT RESIDING IN THE LONG TERM CARE SETTING POLICY	REFERENCE: #DD-CS-1183
CATEGORY: CLINICAL SERVICES		
REPLACING: #DDCS0133		PAGE: 1 OF: 1
APPROVED REVISION: 3/31/2017		EFFECTIVE: 12/01/2014

PURPOSE:

To establish guidelines on how to care for the Hepatitis B positive patients residing in the long term care setting.

POLICY:

- Patients that are HBV+ that reside in the long term care setting will be dialyzed at the bedside in a private room.
- Only HBV immune staff will be assigned to care for the HBV+ patient.
- While patient is receiving their dialysis treatment staff must wear personal protective equipment (PPE). Refer to "PERSONAL PROTECTIVE EQUIPMENT POLICY" and "INFECTION CONTROL POLICY"
- Anyone entering the patient room while patient is receiving their dialysis treatment must wear personal protective equipment (PPE). Refer to "PERSONAL PROTECTIVE EQUIPMENT POLICY" and "INFECTION CONTROL POLICY"
- Personal Protect Equipment (PPE) must be removed and hands washed prior to leaving the patient's room.
- Equipment used for the HBV+ patient should be reserved for the HBV+ patients unless repair or maintenance is needed or until all HBV+ patients have been discharged.
- Separate dedicated and marked supplies and equipment, including blood glucose monitors must be used to provide care to the HBV+ patient.
- All supplies used in the patient room such as clamps, blood- pressure cuffs, testing reagent, etc. will be kept in patient room.

	TITLE: TRANSMISSION BASED (CONTACT, DROPLET, ISOLATION) PRECAUTIONS POLICY, PROCEDURE	REFERENCE: #DD-IC-0095
CATEGORY: INFECTION CONTROL		
REPLACING: #DDCS0743		PAGE: 1 OF: 7
APPROVED REVISION: 3/31/2017		EFFECTIVE:12/01/2014

PURPOSE:

Transmission-Based Precautions are to be used in addition to Standard Precautions for patients with documented or suspected infection or colonization with highly transmissible or epidemiologically-important pathogens for which additional precautions are needed to prevent transmission.

POLICY:

- Transmission-Based Precautions shall be used in addition to Standard Precautions to prevent the spread of infection throughout the facility.
- Transmission-Based Precautions include:
  - Contact Precautions
  - Droplet Precautions

CONTACT PRECAUTIONS:

- Contact Precautions shall be used for patients with known or suspected infections or evidence of syndromes that represent an increased risk for contact transmission. See also CDC pathogen-specific recommendations.
- Discontinue Contact Precautions after signs and symptoms of the infection have resolved or according to CDC pathogen-specific recommendations.
  - Patient Placement:
    - Patients who require Contact Precautions shall be placed in a single-patient room when available.

- When single-patient rooms are in short supply, apply the following principles for making decisions on patient placement shall be used:
  - Patients with conditions that may facilitate transmission (i.e., uncontained drainage, stool incontinence) shall be prioritized for single-patient room placement.
  - Patients who are infected or colonized with the same pathogen and are suitable roommates shall be placed together (cohorted).
  - If it becomes necessary to place a patient who requires Contact Precautions in a room with a patient who is not infected or colonized with the same infectious agent, the following principles shall be followed:
    - Avoid placing patients on Contact Precautions in the same room with patients who have conditions that may increase the risk of adverse outcome from infection or that may facilitate transmission (i.e., those who are immunocompromised, have open wounds, or have anticipated prolonged lengths of stay).
  - Change protective attire and perform hand hygiene between contact with patients in the same room, regardless of whether one or both patients are on Contact Precautions.

- Personal Protective Equipment:
  - Gloves shall be worn whenever touching the patient's intact skin or surfaces and articles in close proximity to the patient (i.e., medical equipment, bed rails). Gloves shall be donned upon entry into the patient's room or cubicle.
  - Gowns shall be worn whenever it is anticipated that clothing will have direct contact with the patient, or potentially contaminated environmental surfaces or equipment in close proximity to the patient. Gown shall be donned upon entry into the room or cubicle. Gown shall be removed and hand hygiene performed before leaving the patient-care environment.

- unavoidable, equipment shall be cleaned and disinfected prior to use on another patient.

- Environmental Measures:
  - Rooms for patients on Contact Precautions shall be prioritized for frequent cleaning and disinfection (i.e., at least daily), with a focus on frequently-touched surfaces (i.e., bed rails, overbed table, bedside commode, lavatory surfaces in patient bathrooms, doorknobs) and equipment in the immediate vicinity of the patient.

DROPLET PRECAUTIONS:

- Droplet Precautions shall be used in accordance with CDC Recommendations for patients known or suspected to be infected with pathogens transmitted by respiratory droplets (i.e., large-particle droplets greater than 5μ in size) that are generated by a patient who is coughing, sneezing or talking.

- Droplet Precautions shall be discontinued after signs and symptoms have resolved or according to CDC pathogen-specific recommendations.

  - Patient Placement:
    - Patients who require Droplet Precautions shall be placed in a single-patient room when available.
    - When single-patient rooms are in short supply, the following principles for making decisions on patient placement shall be used:
      - Prioritize patients who have excessive cough and sputum production for single-patient room placement
      - Place together in the same room (cohort) patients who are infected with the same pathogen and are suitable roommates

- If it becomes necessary to place patients who require Droplet Precautions in a room with a patient who does not have the same infection:
  - Avoid placing patients on Droplet Precautions in the same room with patients who have conditions that may increase the risk of adverse outcome from infection or that may facilitate transmission (i.e., those who are immunocompromised, have or have anticipated prolonged lengths of stay).
  - Ensure that patients are physically separated (i.e., greater than three [3] feet apart) from each other. Draw the privacy curtain between beds to minimize opportunities for close contact.
  - Change protective attire and perform hand hygiene between contact with patients in the same room, regardless of whether one patient or both patients are on Droplet Precautions.

- Personal Protective Equipment:
  - A face mask shall be donned upon entry into the patient room or cubicle.
  - For patients with suspected or proven SARS, avian influenza or pandemic influenza, refer to the CDC website for the most current recommendations.
- Patient Transport:
  - Patient transport shall be limited to transport and movement of patients outside of the room for medically-necessary purposes only.
  - If transport or movement in any healthcare setting is necessary, the patient shall be instructed to wear a face mask and follow Respiratory Hygiene/Cough Etiquette.

AIRBORNE PRECAUTIONS:

- Airborne Precautions shall be used in accordance with CDC recommendations for patients known or suspected to be infected with infectious agents transmitted person-to-person by the airborne route (i.e., *M tuberculosis*, measles, chickenpox, disseminated herpes zoster).
    - When an AIIR is not available therefore, the patient shall be transferred to a facility that has an available AIIR.
    - In the event of an outbreak or exposure involving large numbers of patients who require Airborne Precautions, the following should be considered:
        - Cohort patients who are presumed to have the same infection (based on clinical presentation and diagnosis when known) in areas of the facility that are away from other patients, especially patients who are at increased risk for infection (i.e., immunocompromised patients).

- Staff Restrictions:
    - Susceptible healthcare staff shall be restricted from entering the rooms of patients known or suspected to have measles (rubeola), varicella (chickenpox), disseminated zoster or smallpox, if other immune healthcare staff are available.

- Use of PPE:
    - A surgical mask shall be worn for respiratory protection when entering the area of a patient when the following diseases are suspected or confirmed:
        - Infectious pulmonary or laryngeal tuberculosis, or when infectious tuberculosis skin lesions are present, and procedures that would aerosolize viable organisms (i.e., irrigation, incision and drainage, whirlpool treatments) are performed
        - Smallpox (vaccinated and unvaccinated)

- Respiratory protection is recommended for all healthcare staff, including those with a documented "take" after smallpox vaccination, due to the risk of a genetically engineered virus against which the vaccine may not provide protection, or of exposure to a very large viral load (i.e., from high-risk aerosol-generating procedures, immunocompromised patients, hemorrhagic or flat smallpox.

- Patient Transport:
  - Patients requiring Airborne Precautions will be transferred to another facility that will be able to meet the needs of the patient.
  - When transport or movement outside an AIIR is necessary, patients shall be instructed to wear a surgical mask, if possible, and observe Respiratory Hygiene/Cough Etiquette.
  - For patients with skin lesions associated with varicella or smallpox, or draining skin lesions caused by *M. tuberculosis*, the affected area shall be covered to prevent aerosolization or contact with the infectious agent in skin lesions.

- Exposure Management:
  - Susceptible persons shall be offered immunization or provided with the appropriate immune globulin as soon as possible following unprotected contact (i.e., exposed) to a patient with measles, varicella or smallpox.
    - Administration of measles vaccine (at any interval following exposure) or immune globulin (within six [6] days of exposure, particularly contacts less than or equal to six [6] months of age, pregnant women, and immunocompromised people, for whom the risk of complications is highest) to susceptible contacts.

- Varicella vaccine should be administered to exposed susceptible persons within 120 hours after the exposure, or administer varicella immune globulin (VZIG or alternative product), when available, within 96 hours for high-risk persons in whom vaccine is contraindicated (i.e., immunocompromised patients, pregnant women, newborns whose mother's varicella onset was less than five [5] days before or within 48 hours after delivery).

- Smallpox vaccine should be administered to exposed susceptible persons within four (4) days after exposure.

REFERENCE:

Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee, 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings, June 2007

	TITLE: BIOHAZARDOUS WASTE HANDLING AND DISPOSAL POLICY, PROCEDURE	REFERENCE: #DD-IC-0075
CATEGORY: CLINICAL SERVICES		
REPLACING: #DDCS0327		PAGE: 1 OF: 3
APPROVED REVISION: 3/31/2017		EFFECTIVE:12/01/2014

PURPOSE:

To provide guidelines for the handling and disposal of ALL waste, in accordance with the State Health and Safety Code.

DEFINITION:

- Clinical Laboratory wastes, including cultures of etiologic agents, which poses substantial threat to health, due to their volume and virulence.
- Pathologic specimens, including tissues, blood elements, excreta and secretions, which contain etiologic agents.
- Equipment, instruments, utensils, dressing and other disposable materials which are likely to transmit etiologic agents.
- Any other material which presents a significant danger of infection because it is contaminated with, or may reasonably be expected to be contaminated with, etiologic agents.

POLICY:

- All requirements set forth by the Health and Safety Code on Infectious Waste shall be followed as outlined in state and local regulations and shall be applied to all biohazardous waste generated (may vary state to state).
    - Infectious sharps shall be contained for disposal in leak proof, rigid and puncture resistant containers, such as plastic or metal, which are taped closed or tightly lidded to preclude loss of the contents.
    - Cultures of viable etiologic agents shall be rendered noninfectious before disposal to landfill by heating the culture in a steam sterilizer, by incineration or by another sterilization technique approved in writing by the facility.
        - Standard Precautions are utilized during the handling of all bio hazardous waste.
        - Biohazardous waste shall be segregated from other non biohazardous medical waste, at the point of origin.

- Containers used for biohazardous waste shall be so secured as to deny access to unauthorized persons.
- Biohazardous waste shall not be stored for more than one (1) day, other than needles and sharps.
- All biohazardous waste, except needles and sharps, will be single bagged prior to disposal.
- The following items are considered biohazardous and disposed of according to this procedure:
  - Three-quarters (3/4) full needle and syringe rigid collection containers
  - Blood and blood products (i.e., lab specimens)
  - Used disposable surgical blades
  - Used culture plates - taped closed
  - Used culture swabs
  - Any materials in contact with either blood or bloody drainage (i.e., gauze, dressings and surgical drapes) (single-bagged)
  - Any disposable item in direct contact with a wound or person with communicable disease (single-bagged)
- Dispose of all biohazardous wastes in plastic bags located in designated covered waste containers with foot pedals.

PROCEDURE:

- Disposal of Biohazardous Waste:
  - Urine can be poured down the sink or toilet, followed by copious amounts of water. Urine containers are to be rinsed out and thrown into regular trash.
  - Fresh stools are to be flushed down the toilet. The containers can be rinsed and thrown out with the regular trash
- Disposal of Sharps:
  - Biohazardous sharps waste disposal containers for disposing of needles, sharps and blood specimens will be used.

- Used needles, syringes, lancets and scalpels are disposed of in the hard plastic biohazardous waste container
  - Never recap a contaminated needle.
  - Drop used syringe, scalpel or lancet into the container.
  - Never reach inside the container.
  - Snap on or tape the lid of a three-quarters (3/4) filled container, prior to discarding.
- Never dispose of syringes or needles in general trash receptacle.
- Follow needle puncture policy, if punctured by contaminated needle.

- Single Bagging:
  - When the bag is full and/or at the end of each shift, follow bagging procedure:
    - While wearing gloves, remove bag and contents from the container and closes securely.
    - Unfold cuff and tie securely closed, being careful not to touch inside of bag.
    - Place bag (now "clean" on the outside) next to trash container to be picked up by Environmental Services staff.
    - Carefully pick up clean bag set out earlier and lines trash container with it.
    - Maintain container in readiness for contaminated material. Protect contaminated biohazardous wastes identified for special handling. If outer bag punctures, repeat the procedure.
    - Remove gloves and throw in contaminated container.
    - Wash hands.

	TITLE: WATER AND DIALYSATE EVALUATION AND TESTING GUIDELINES FOR PUREFLOW SL POLICY – SKILLED NURSING FACILITY	REFERENCE: #DD-CS-0242
CATEGORY: CLINICAL SERVICES		
REPLACING: #DDLP1749		PAGE: 1 OF: 6
APPROVED REVISION: 3/31/2017		EFFECTIVE:12/01/2014

PURPOSE:

To provide guidelines for testing, evaluating, and monitoring the quality of water and dialysate when using the PureFlow SL with the NxStage System One (known to CMS as preconfigured system) for compliance with the CMS Conditions for Coverage. **NOTE:** In Center dialysis treatments will use only premixed dialysate solution bags provided by NxStage therefore do not require water and dialysate testing. The Pureflow SL training equipment will be set up and tested prior to use.

This document reflects policy for staff-assisted home hemodialysis in the long-term care or skilled nursing facility.

POLICY:

Water and dialysate testing and documentation will meet NxStage, CMS, and AAMI standards and guidelines. Documentation of testing, results, and interventions will be maintained at the home training center.

TESTING OVERVIEW:

TAG	Sample	Frequency of Draw	Test Performed
593/ 594	Source water: Municipal	Initially to verify source water is within range for the use of PureFlow SL. Annually thereafter	Chemical analysis of the standard AAMI test panel contaminants to ensure product manufacturer's specifications are met. See PFSL User's Guide 4), Section 10: Specifications for Source Water Purity Limits.
593/ 594	Source water: Well	Initially to verify source water is within range for the use of PureFlow SL, then as necessary to reflect seasonal variations.	Chemical analysis of the standard AAMI test panel contaminants to ensure product manufacturer's specifications are met. See PFSL User's Guide 04), Section 10: Specifications for Source Water Purity Limits.
594/ 276	Product water	For PAK produced at skilled nursing facility only:	Chemical analysis of the standard AAMI test panel contaminates to

		Monthly: All PAKs will be tested monthly. More frequently if needed to verify results are within the AAMI limits.	ensure AAMI specifications are met.
595	Product water	Each batch, prior to use of the batch. will be tested for chlorine / chloramines	Analysis of chlorine / chloramines levels to ensure the AAMI and manufacturer's specifications are met.
595	Dialysate	Initially: test within the first month of initializing PureFlow SL machine, near the estimated end of a batch. Monthly: re-test dialysate monthly near the estimated end of a batch (1 SAK per PAK) More frequently if needed to verify results are within the AAMI limits.	Bacteriological and endotoxin analysis to ensure AAMI specifications are met.
	Dialysate	None	No independent testing of dialysate for conductivity/pH is required.

	TITLE: WATER AND DIALYSATE EVALUATION AND TESTING GUIDELINES FOR PUREFLOW SL POLICY – SKILLED NURSING FACILITY	REFERENCE: #DD-CS-0242
CATEGORY: CLINICAL SERVICES		
REPLACING: #DDLP1749		PAGE: 3 OF: 6
APPROVED REVISION: 3/31/2017		EFFECTIVE:12/01/2014

Tag Number	Regulation	Interpretive Guidance
V593/594 **Source water - municipal** **Source water - well**	Monitoring of the quality of water and dialysate used by ESRD unit/home hemodialysis including conducting an onsite evaluation and testing of the water and dialysate system in accordance with: (A) The recommendations specified in the manufacturer's instructions; and (B) The system's FDA – approved labeling for preconfigured systems designed, tested, and validated to meet AAMI quality (which includes standards for chemical and chlorine/chloramines testing) water and dialysate.	The facility home training staff must conduct on-site evaluations of the ESRD unit/home hemodialysis patient's water supply prior to selecting a water treatment system for home hemodialysis. There should be evidence the source water to be used meets the minimum requirements specified by the manufacturer of the water treatment components or of the integrated system, if such is in use. Because of the variables with regulation of the water supply to a home for safe drinking water standards, annual analysis of the quality of the product water may not be sufficient, since the quality of water from the well may change over time and since private wells are not routinely monitored. More frequent analysis may be needed if the well is subjected to seasonal changes or contamination from sources such as septic tanks, underground fuel storage tanks, or agricultural waste and chemicals. The additional monitoring might not need to be the full AAMI analysis if only certain contaminants are known to be of concern.

NXSTAGE TECHNICAL CLARIFICATION:

- Obtain source water sample from patient's home prior to completion of patient training to ensure source water does not exceed PureFlow SL (PFSL) maximum level of contaminants.
- Water quality can be confirmed for all new PureFlow SL patients by performing a standard AAMI test panel then comparing each contaminate level to the corresponding PureFlow SL User Guide Section 10: Specifications for source water purity limits (reprinted below).
- Verify with the patient, if the patient's source water changes (i.e. moving to another home location or significant changes in plumbing) that source water is re-verified.

	Contaminant	Source Water (mg/L)	Product Water (mg/L) ANSI/AAMI/ISO 13959:2009
Contaminants with documented toxicity in hemodialysis	Aluminum*	0.2	0.01
	Chloramines**	4.0	Not specified*
	Free Chlorine**	4.0	Not specified*
	Total Chlorine	4.0	0.1
	Copper	1.3	0.1
	Fluoride	4.0	0.2
	Lead	0.015	0.005
	Nitrates (as N)	10	2
	Sulfate*	250	100
	Zinc*	5	0.1
Normally included in dialysate	Calcium	No limit	2
	Magnesium	No limit	4
	Potassium	No limit	8
	Sodium	No limit	70

Other Contaminants	Antimony	0.006	0.006
	Arsenic	0.01	0.005
	Barium	2	0.1
	Beryllium	0.004	0.004
	Cadmium	0.005	0.001
	Chromium	0.1	0.014
	Mercury	0.002	0.0002
	Selenium	0.05	0.09
	Silver*	0.1	0.005
	Thallium	0.002	0.002

- Source water pressure must be between 20 – 80 psi or 20 to 120 psi with a Pressure Regulator.
- Source water flow must be at least 150ml/min or greater.
- Results of source water may be recorded on Water and Dialysate Testing Log (TM0427) available from NxStage Home Hemodialysis NxDocuments.

IF RESULTS ARE OUT OF RANGE:

AAMI Testing:

- If tests are out of range, redraw within 24hours x1.
  - If PAK/SAK results are out of range again, change PAK
  - Patients may not be initiated using PureFlow until labs are in range. If necessary, filters will be installed to treat water prior to reaching the PAK to enable source water to reach an acceptable limit.

Bacteriological and Endotoxin Testing:

- If tests are out of range, change PAK and draw new sample x1.
- Follow protocol in **Bacteriological and Endotoxin Testing Policy**- out of range results require:
  - Patient evaluation
  - Notify patient's physician/Dialyze Direct medical director
  - Other interventions per Dialyze Direct policy

REFERENCES:

CMS 42 CFR Parts 494 Conditions for Coverage for End-Stage Renal Disease Facilities and related CMS ESRD Program Interpretive Guidance (October 3, 2008)

Dialysate Preparation Primer Chronic Hemodialysis with the NxStage PureFlow SL
PureFlow SL User's Guide

AAMI/FDS-RD52:2004/A1 Dialysate for Hemodialysis, Amendment 1- Annex C; Special Considerations for Home Hemodialysis

	TITLE: EQUIPMENT STORAGE IN LONG TERM CARE FACILITIES POLICY, PROCEDURE	REFERENCE: #DD-E-0792
CATEGORY: EQUIPMENT		
REPLACING: #DDCS0267		PAGE: 1 OF: 1
APPROVED REVISION: 3/31/2017		EFFECTIVE:12/01/2014

POLICY:

Dialysis equipment when not in use must be stored in a safe and secure location. Only Dialyze Direct staff should have access to this storage area.

PROCEDURE:

NxStage System One Cyclers along with The PureFlow Units will be stored in a locked clean utility room. The PureFlow Units will remain plugged in and in operation mode at all times while being stored with a BATCH. Each patient will have equipment that is dedicated for their use only.

	TITLE: MEDICAL STORAGE: IN THE LONG TERM CARE FACILITY LTC POLICY, PROCEDURE	REFERENCE: #DD-CS-0790
CATEGORY: CLINICAL SERVICES		
REPLACING: #DDCS0523		PAGE: 1 OF: 2
APPROVED REVISION: 3/31/2017		EFFECTIVE: 12/01/2014

PURPOSE:

The purpose of this policy and procedure is to provide guidance and direction for storing medications securely in the Long Term Care Facility (LTCF).

OVERVIEW:

All medications in the Long Term Care Facility will be secured in a dedicated locked refrigerator and/or locked cabinet in the medication/work room for Dialyze Direct.

POLICY:

- Medications will be locked and secured at all times in the Long Term Care Facility.
- All End Stage Renal Disease (ESRD) medications will be administered by Dialyze Direct employed staff.
- Oral, intravenous and external medications will be labeled and separated.
- Medications that require refrigeration are stored in a dedicated locked refrigerator in the dialysis treatment area. Medication refrigerator temperature will be checked daily and recorded on the temperature log sheet. Refer to the policy, **Medication Refrigerator Policy** for more information.
    - No food is allowed to be stored in the medication refrigerator.

PROCEDURE:

1	Ensure medications are stored appropriately to prevent medication errors due to confusion of labels and types of medications.
2	Ensure the medication area in the LTCF is secure and locked when medications are not being prepared and at the end of the day.
3	Ensure the medication refrigerator temperature is checked and recorded on the appropriate Medication Refrigerator Log daily.
4	Report temperatures not within the acceptable range for storing medications to the appropriate LTCF staff.

REFERENCES:

- Counts, C. (2008). Core Curriculum for Nephrology Nursing, Fifth Ed., Anthony J. Jannetti, Inc., Pitman, NJ.

RELATED DOCUMENTS:

- MEDICATION REFRIGERATOR POLICY
- MEDICATION REFRIGERATOR LOG

	TITLE: INITIAL ORIENTATION AND ANNUAL CLINICAL STAFF TRAINING AND COMPETENCY POLICY	REFERENCE: #DD-SE-1338
CATEGORY: GENERAL FACILITY		
REPLACING: # DDCS-0701		PAGE: 1 OF: 3
APPROVED REVISION: 8/27/2018		EFFECTIVE: 12/01/2014

PURPOSE:

The purpose of this policy is to define the Orientation, Training and Education Program and annual competency validation provided by Dialyze Direct for all Clinical Staff.

PERFORMED BY:

Dialyze Direct clinical staff as assigned.

OVERVIEW:

Employees who have received job-specific training are more productive and confident. Both clinical and administrative staff benefit from ongoing education and improving practice stability. Learning and education foster a positive motivated staff committed to the organization's goals. Most importantly, staff education and supported training affects the safety of the patient, who benefits from the employee's skills, attitude, and efficiency.

Comprehensive Staff Education and Training may include a formal orientation program, cross-functional training and ongoing review of professional and job related skills.

POLICY:

- Dialyze Direct employs an organized and written plan for Staff Education that includes but is not limited to:
    - Orientation of all staff to the Facility and services provided, policies and procedures specific to the employee's job description
    - Use of all patient care and clinical policies and procedures, as applicable, related to equipment management, training in water and dialysate systems as applicable and clinical care management
    - Medical Record Management, Compliance and HIPPA

- Quality Assessment and Performance Improvement
- Infection Control
- Dialyze Direct Safety Plan
- Adverse Event Reporting
- Emergency Preparedness

- Dialyze Direct provides for the educational needs of its staff based on assessment of staff performance and competency that is completed on an annual basis, and more often as indicated by employee performance.
- Dialyze Direct has an established process for evaluating staff competencies, for all job categories and is performed and documented on an annual basis.
- Dialyze Direct maintains a record of attendance for each educational program provided and records of in-service participation for each staff member as applicable.

For staff providing care in the long-term care setting:

- All RN, LVN, nurse aides, or trained caregivers providing care in the SNF receive training that is:
  - (1) Equivalent to the ESRD facility training and competency verification for home dialysis patients at §494.100 (a)(3)(i-viii) and §494.100 (b)(1).
  - (2) Approved by the ESRD facility medical director and governing body;
  - (3) Administered under the direction of a home dialysis training nurse meeting the qualifications at §494.140(b)(2) and;
  - (4) Specific to the dialysis modality.
- The training program must include at least the subject matter listed at §494.100 (a)(3)(i-viii).
- Dialyze Direct will designate a lead dialysis RN on a site by site basis within each long-term care facility who on a continual and ongoing basis will monitor competencies of trained dialysis caregivers to ensure quality and safety of dialysis treatments.

SUPPLIES:

- Clinical Staff Training Schedule
- NxStage NxSteps Training Program

PROCEDURE:

See Clinical Staff Orientation and Training Schedule

Annual Competency:

Maintaining competency levels for all staff is essential in providing excellent patient care. Annual staff competencies will be validated by (but not limited to) the following:

- AVF checklist
- Graft checklist
- Catheter checklist
- Annual HealthStream education as assigned
    - Rapid Regulatory Compliance (“Clinical I and II”)
    - Recognizing and Reporting Suspected Child, Adult, Disabled Person or Elderly Abuse/Neglect/Exploitation
    - HIPPA / Corporate Compliance
    - Dealing with Difficult Patients
    - Fire Safety
    - Mock code / Emergency Preparedness
    - Infection Control

RELATED DOCUMENTS:

- STAFF TRAINING FOR WATER AND DIALYSATE SYSTEMS
- TRAINING CLINICIANS TO TEACH HOME DIALYSIS
- SKILLS ORIENTATION CHECKLIST
- NEW EMPLOYEE SCAVENGER HUNT

	TITLE: NURSING SERVICES POLICY	REFERENCE: #NY-CS-7001
CATEGORY: CLINICAL SERVICES		
REPLACING: #		PAGE: 1 OF: 2
APPROVED REVISION: 8/27/2018		EFFECTIVE:12/01/2014

POLICY:

- Dialyze Direct Facility employs a Nurse Manager who is responsible for nursing services in the facility.

- The Dialysis Services Nurse Manager provides oversight and direction to all direct care staff who provide dialysis and nursing care in the facility, including input into hiring, evaluating and terminating these staff.

- Two (2) or more qualified nurses may share this responsibility, but the facility must designate one (1) of these nurses as primarily responsible

- The same registered nurse(s) who meets these requirements may fulfill multiple nursing roles in the dialysis facility as long as the facility has an adequate number of qualified nurses present while patients are dialyzing to meet patients' clinical needs for the level of dialysis care provided

- The Dialysis Services Nurse Manager qualifications include:

  (a) Full-time employee
  (b) Registered Nurse
  (c) Have at least 12 months of experience in clinical nursing, and an additional six (6) months of experience in providing nursing care to patients on maintenance dialysis.

- There is a registered nurse on duty and available at all times when in-center dialysis patients are being treated including the beginning and end of the treatment day.

- When staff assisted dialysis is provided, a licensed professional registered nurse (RN) will be present at all times, including at the bedside in the long term care setting.

- Dialyze Direct LLC, will have a Dialyze Direct, employed registered nurse (RN) on duty at the LTC facility any time dialysis services are being provided and will fully comply with the staffing requirements. The RN will either directly provide the dialysis services, or, if a licensed practical nurse (LPN) is providing the dialysis

services, the RN will be on duty during the provision of dialysis services for immediate supervision and oversight of direct patient care.

- All personnel who initiate and discontinue hemodialysis treatments are RNs who meet the practice requirements in the state s/he is employed.

Long Term Care Facility:

- All RN/LVN, nurse aides, or trained caregivers **providing care in the SNF** receive training that is:
  - (1) Equivalent to the ESRD facility training and competency verification for home dialysis patients at §494.100 (a)(3)(i-viii) and §494.100 (b)(1).
  - (2) Approved by the ESRD facility medical director and governing body;
  - (3) Administered under the direction of a home dialysis training nurse meeting the qualifications at §494.140(b)(2) and;
  - (4) Specific to the dialysis modality.

  The training program must include at least the subject matter listed at §494.100 (a)(3)(i-viii)

	TITLE: BIOHAZARDOUS WASTE HANDLING AND DISPOSAL POLICY, PROCEDURE	**REFERENCE: #DD-IC-0075**
CATEGORY: CLINICAL SERVICES		
REPLACING: #DDCS0327		**PAGE: 1 OF: 2**
APPROVED REVISION: 7/1/2020		**EFFECTIVE:12/01/2014**

PURPOSE:

To provide guidelines for the handling and disposal of biohazardous waste, in accordance with applicable guidelines and regulations.

POLICY:

1. All requirements set forth regarding the handling and disposal of biohazardous waste shall be followed as outlined in federal, state, and local regulations and shall be applied to all biohazardous waste generated (may vary state to state).

2. Standard Precautions are to be utilized during the handling of all biohazardous waste.

3. Biohazardous waste will be segregated from other, non-biohazardous waste, at the point of origin.

4. Infectious sharps shall be contained for disposal in leak proof, rigid and puncture resistant containers, which are tightly lidded and securely closed to prevent loss of the contents.

5. Containers used for biohazardous waste shall be so secured as to deny access to unauthorized persons.

6. Biohazardous waste shall not be stored for more than one (1) day, other than needles and sharps.

7. All biohazardous waste, except needles and sharps, will be placed in plastic bags located in designated covered waste containers for disposal.

8. The following items are considered biohazardous and are to be disposed of in compliance with this procedure:
    a Three-quarters (3/4) infectious sharps rigid collection containers
    b Blood and blood products (i.e., lab specimens)
    c Any disposable materials in contact with either blood or bloody drainage

	TITLE: BIOHAZARDOUS WASTE HANDLING AND DISPOSAL POLICY, PROCEDURE	REFERENCE: #DD-IC-0075
CATEGORY: CLINICAL SERVICES		
REPLACING: #DDCS0327		PAGE: 2 OF: 2
APPROVED REVISION: 7/1/2020		EFFECTIVE:12/01/2014

PROCEDURE:

1. Disposal of Sharps:
    a Place sharps in rigid, puncture-proof, waste disposal containers designated for disposing of needles, sharps and blood specimens.
        - Never recap a contaminated needle.
        - Drop used syringe or needle into the container.
        - Never reach inside the container.

    b Snap on or tape the lid of a three-quarters (3/4) filled container, prior to discarding.

2. Disposal of all other biohazardous wastes:
    a When the bag is full and/or at the end of each shift, follow bagging procedure:
        - While wearing appropriate PPE, remove bag and contents from the container and close the bag securely.
        - Unfold cuff and tie securely closed, being careful not to touch inside of bag.
        - If the bag is punctured or leaking, place the bag in an additional bag as necessary to contain waste or fluid.

    b Place bag (now "clean" on the outside) next to trash container to be picked up by Environmental Services staff.

    c Obtain a clean bag and line biohazardous waste container with it.

    d Maintain container in readiness for receipt of contaminated material.

    e Remove and discard PPE.

    f Wash hands.

	TITLE: EMERGENCY AND DISASTER PLAN IN THE LONG TERM CARE SETTING POLICY, PROCEDURE	REFERENCE: #DD-EP-2469
CATEGORY: EMERGENCY PREPAREDNESS		
REPLACING: #NJPC1070		PAGE: 1 OF: 3
APPROVED REVISION: 6/1/2020		EFFECTIVE:12/01/2014

PURPOSE:

To provide guidelines for the Dialyze Direct Staff to follow in the event of an emergency involving any home hemodialysis patient receiving dialysis treatment in the long-term care setting.

POLICY:

All Dialyze Direct Staff will be trained by Dialyze Direct and deemed competent in activating the Dialyze Direct Emergency Preparedness Plan as well as the Long-Term Care facility's Emergency Response System prior to being scheduled to work in each Long-Term Care (LTC) setting.

In the event of a medical emergency that requires activation of emergency response services, Dialyze Direct staff will activate the Long-Term Care Facility's Emergency Response Plan as described in DD-EP-1184 Emergency Medical Response in the Long-Term Care Facility Policy, Procedure.

The home dialysis program will have a written agreement with a hospital that can provide acute dialysis services, inpatient treatment, other hospital services as well as emergency medical care 24 hours a day, seven (7) days per week.

PROCEDURE:

FIRE EMERGENCY:

1. **In the event of a FIRE**: The fire plan will be activated, the proper response to fire is R.A.C.E.
    - **R** = **Rescue** patients immediately from fire or smoke area
    - **A** = **Pull fire alarm** station and call emergency number and give location
    - **C** = **Contain** the smoke or fire by closing all doors to rooms and corridors
    - **E** = **Extinguish** the fire (when it is safe to do so)

2. All staff must report to the treatment area for implementation of the Emergency Evacuation procedure.

a. Emergency take off procedure will be instructed by the Charge Nurse.
b. Staff will assist patients that are unable to perform Emergency Take off Procedure
c. Ambulatory patients will be instructed to evacuate the facility and proceed to the designated meeting place
d. Non-ambulatory patients must be accompanied by a staff member to the designated meeting place.
e. The charge nurse will be responsible to ensure that the home dialysis room is clear of all patients and staff prior to proceeding to the meeting place.

3. Designated Meeting Place:
   a. The Charge Nurse will be responsible for roll call once all patients and staff have arrived at the designated meeting place.
   b. The Charge Nurse will notify the Nurse Manager, Administrator and Medical Director that evacuation has taken place.
   c. The RN will assess all patients to determine the need for the patient to be transported to the hospital
      - Administration of IV fluids
      - Removal of AVF/AVG needles
   d. Direct patient care staff will provide care and comfort to patients once outside the building.

POWER FAILURE EMERGENCY;

1. Emergency Generator will provide power to the facility in the event of power failure. All staff must report to the hemodialysis room.

   - In the event that the generator has exceeded the allotment time and power has not been restored, all blood will be returned, treatment terminated and treatments will be rescheduled.
   - The Charge Nurse will be responsible for contacting the patient's nephrologist to notify them of early termination of treatment.

2. The Nurse Manager will coordinate with the Long-Term Care Facility to reschedule treatments.

SHELTER IN PLACE EMERGENCY:

In the Long Term Care facility, coordinate with the nursing supervisor or administrative staff for instructions on the Shelter-in-Place procedure and identified safe rooms.

BACK-UP SUPPLIES PROCEDURE:

1. Dialyze Direct will maintain a 7 day reserve of supplies on hand in case of emergency at all times.
2. Additional supplies are available to be delivered within 24 hours as needed.

Additional disaster response procedures are described in each Dialyze Direct Facility's Emergency Operations Plan, and include procedures for responding to the following potential emergencies:

Active Shooter Emergency
Bomb Threat
Civil Disturbance
Earthquake
External Hazmat Incident
Fire
Flooding
Hurricane
IT System Failure
Internal Chemical Spill
Pandemic Disease Outbreak
Power Failure
Severe Weather Watch/Warning/Incident
Telephone System Failure
Water Treatment System Failure/Water Service Interruption
Winter Storms

	TITLE: EMERGENCY MEDICAL RESPONSE IN THE LONG TERM CARE FACILITY POLICY, PROCEDURE	REFERENCE: #DD-EP-1184
CATEGORY: EMERGENCY PREPAREDNESS		
REPLACING: #DDCS0260		PAGE: 1 OF: 2
APPROVED REVISION: 3/1/2020		EFFECTIVE:12/01/2014

PURPOSE:

To provide guidelines for the Dialyze Direct Staff to follow in the event of an emergency involving any home hemodialysis patients receiving dialysis treatment in the long-term care setting.

POLICY:

In the event of a medical emergency that requires the activation of 911 emergency response services, Dialyze Direct Staff will activate the Long-Term Care Facility's Emergency Response Services.

1. All Dialyze Direct Staff will be trained by Dialyze Direct and deemed competent in activating the Long-Term Care Emergency Response System prior to being scheduled to work in the Long-Term Care (LTC) Setting.

PROCEDURE:

1. Dialyze Direct trained and qualified staff will discontinue the dialysis treatment and initiate emergency procedures as per Dialyze Direct appropriate policy and procedures. Refer to the appropriate Dialyze Direct procedure for the identified medical emergency.

2. Dialyze Direct trained and qualified staff will activate the long-term care facility Emergency Response System.

3. Dialyze Direct trained and qualified staff will initiate emergency procedures i.e. (CPR) as indicated until the arrival the long-term care facility's emergency response personnel or external EMS providers.

4. Dialyze Direct Licensed Professional Registered Nurse (RN) contacts NxStage Technical Support and completes the NxStage Request for Patient Information Form, when applicable.

5. The patient's nephrologist will be notified and the patient's event will be documented in the medical record utilizing the electronic medical records system.

6. An Adverse Occurrence Report will be completed by the Dialyze Direct RN and forwarded to Quality Improvement.

7. Dialyze Direct Licensed Professional Registered Nurse (RN) will then complete the following when necessary:

- Notify NxStage Technical Support or biomed (when applicable)
- Complete "NxStage Patient Request for Information" (when applicable)
- Record serial # of cycler
- Record serial # of Pure Flow
- Record SAK Lot #
- Place Cartridge/Lines and Dialyzer in a red biohazard bag and place in laboratory refrigerator until contents ready to be sent to NxStage.
- Patient cycler/dialysis machine will be removed from the treatment area

DOCUMENTATION:

Dialyze Direct License Registered Nurse (RN) will document patient event in patient medical record using the electronic medical record (EMR).

1. Dialyze Direct Licensed Professional Registered Nurse (RN) is responsible for completing the Adverse Occurrence Report. Refer to DD-CS-4640 Incident and Adverse Event Reporting and DD-CS-0129 Security, Medical, Employee Incident Report

2. Dialyze Direct Licensed Professional Registered Nurse (RN) is responsible for completing "Nx Stage Request for Patient Information" when applicable.

	TITLE: HAND OFF COMMUNICATION WITH LONG TERM CARE FACILITY POLICY, PROCEDURE	REFERENCE: #DD-CS-0149
CATEGORY: CLINICAL SERVICES		
REPLACING: #DDCS0331		PAGE: 1 OF: 2
APPROVED REVISION: 7/1/2020		EFFECTIVE:12/01/2014

PURPOSE:

To provide guidelines for the Dialyze Direct Staff to follow in implementing hand off communication.

POLICY:

- Hand-off communication will take place whenever there is a change in the patient's caregivers, including when patient is transferred from dialysis area back to their prospective rooms within the long-term care facility or when the patient's care is temporarily assumed by another dialysis caregiver i.e., during a lunch break, or at the change of shifts.
- Healthcare professionals shall be allotted the time for hand-off patient communication and to ask and answer questions with minimal interruption. It is hoped that this will lessen the amount of information that might be forgotten or simply not conveyed.
- The Dialysis Hand Off Communication Form is intended for use as an internal communication process between Long Term Care Staff and Dialyze Direct Staff.
- The licensed nurse is responsible for completing the Hand Off Communication Form.
- Hand-off communication shall include:
    - Changes in the patient's condition or plan of care since the previous dialysis treatment
    - Accurate patient information regarding care, treatment and services provided
    - Patient's current condition

PROCEDURE:

When transferring care between Dialyze Direct caregivers:

- Dialysis personnel shall find a quiet area to give a verbal report (hand-off communication) to ensure accurate, clear and concise information is given
- Caregivers will give each other the opportunity to ask questions, answer questions and read-back or repeat-back information, as needed.

- Information provided during hand-off communications will include at a minimum (this information will be discipline-specific):
    - Recent or anticipated changes in the patient's condition
    - Treatment, care and services that need to be completed (to-do list)
    - Any other information which is important to the patient's care

When receiving the patient from Long-Term Care Facility personnel or transferring care from Dialyze Direct caregivers to Long-Term Care Facility personnel:

- The Dialysis Hand Off Communication Form is to be initiated by the long-term care caregiver prior to the patient's scheduled dialysis treatment
- The Dialyze Direct nurse will review the information prior to the initiation of the patient's dialysis treatment
- The Dialyze Direct nurse will complete the Dialysis Hand Off Communication Form after the patient's treatment and forward the form to the patient's long-term care facility nurse

	TITLE: INFECTION PREVENTION AND CONTROL PROGRAM	REFERENCE: #DD-IC-1309
CATEGORY: INFECTION CONTROL		
REPLACING: #DDCS0423		PAGE: 1 OF: 5
APPROVED REVISION: 6/1/2020		EFFECTIVE: 12/01/2014

PURPOSE:

The purpose of this policy and procedure is to provide guidance and direction to ensure that all Dialyze Direct patient care staff, patients and caregivers are educated, trained and compliant with the Dialyze Direct Infection Prevention and Control Program.

PERFORMED BY:

All Dialyze Direct staff, Patients and Caregivers

OVERVIEW:

Infection Control (494.30) is a Centers for Medicare & Medicaid Services (CMS) Condition for Coverage. This Condition incorporates two Centers for Disease Control and Prevention (CDC) documents as regulations, and CMS developed regulations. These infection control requirements apply to both chronic dialysis in-center facilities and home program facilities.

POLICY:

- The Dialyze Direct Facility' s Governing Body is responsible for oversight of the Infection Prevention and Control Program, to include development and implementation of; and monitoring compliance with; infection prevention and control policies and procedures as necessary.
- The Dialyze Direct Facility's Infection Prevention and Control Program shall be integrated into the facility's Quality Assessment and Performance Improvement (QAPI) program.
- All facility staff shall participate and support the Infection Prevention and Control Program through compliance with infection prevention and control practices, policies and procedures, and reporting infection prevention and control concerns.
- Dialyze Direct shall provide the necessary equipment and supplies to maintain consistent observance of Standard Precautions, including hand hygiene products and personal protective equipment.

- The Infection Prevention and Infection Program shall include identifying, investigating, reporting, preventing and controlling infections and communicable diseases through the following activities:

  - Maintenance of a sanitary facility environment
  - Evaluation and monitoring of facility staff and patient immunization status for designated infectious diseases, including Hepatitis B and Hepatitis C, as recommended by the CDC and its Advisory Committee on Immunization Practices (ACIP)
  - Implementation of policies under which the facility screens facility staff and patients for infections with potential to cause significant infectious disease and for reportable diseases, as required under local, state, or federal public health authority
  - Implementation of policies articulating when infected facility staff are restricted from providing direct patient care and/or are required to remain away from the healthcare facility entirely
  - Conducting new employee and regular update training in preventing and controlling healthcare associated infections and methods to prevent exposure to and transmission of infections and communicable diseases
  - Ensures evaluation of staff exposed to patients with infections and communicable disease when necessary
  - Communication to staff, addressing infection prevention and control processes or any practice changes
  - Ensures early identification of patients who require isolation in accordance with CDC dialysis guidelines
  - Ensures appropriate use of personal protective equipment, including gowns, gloves, masks and eye protection devices

- Promotion of hand-washing and hand hygiene among staff, including utilization of alcohol-based hand sanitizers
- Implements measures specific to prevention of device-associated bloodstream infection (BSI), such as a procedures specific to reducing infections of central venous catheters
- Ensures disinfectants, antiseptics and germicides are used in accordance with the manufacturers' instructions
- Ensures adherence to nationally recognized infection prevention and control precautions, such as current CDC guidelines and recommendations.
- Educating patients, visitors, caregivers and staff, as appropriate, about infections and communicable diseases and methods to reduce transmission in the facility and in the home

- The Infection Prevention and Control Program incorporates and documents the following on an ongoing basis:

  - Surveillance of infections within the organization so that trends can be identified and investigated, and appropriate prevention strategies initiated when indicated

  - Recommendations and action plans to minimize infection transmission and promote immunizations

  - Monitoring shall include:
    - Monitoring patients for acquisition of infection and/or colonization
    - Conducting surveillance on a facility-wide basis in order to identify infectious risks or communicable disease problems at any particular location
    - Conducting surveillance activities in accordance with infection prevention and control surveillance practices utilized by the CDC's National Healthcare Safety Net (NHSN), as required, and shall include infection detection, data collection and analysis, monitoring, and evaluation of preventive interventions
    - Provisions to monitor compliance with all policies, procedures, protocols and other infection prevention and control program requirements
    - 🕐 Methods for monitoring and evaluating aseptic technique practices
- 🕐

COMMUNICABLE DISEASE OUTBREAKS:

- The Infection Prevention and Control Program will ensure that the Dialyze Direct Dialysis Facility is prepared to address the following issues that may arise during a communicable disease outbreak:
  - Preventing transmission among patients, healthcare staff, and visitors
  - Identifying persons who may be infected and exposed
  - Facilitating access to treatment or prophylaxis to patients and staff
  - Logistics issues (staff, medical supplies, re-supply, continued operations and capacity)
- The Infection Prevention and Control Program shall coordinate with local, state and federal public health agencies to identify likely communicable disease threats and develop appropriate preparedness and response strategies.

EDUCATION OF STAFF, PATIENTS AND VISITORS:

- Education addressing the principles and practices for preventing transmission of infections shall be provided to all facility staff
- All staff shall receive infection prevention and control education at the time of orientation, annually and whenever needed.
- Patients and families shall also receive infection prevention and control education, as applicable and appropriate.

PERFORMANCE IMPROVEMENT/EVALUATION:

- Infection data and other surveillance activities shall be reviewed with the QAPI Committee monthly, at minimum.
- Any problems identified shall be addressed with an Action Plan
- The Governing Body maintains repsonsibility for evaluation and revision of the program when indicated

- Facility leadership shall be responsible for implementing successful corrective action plans by monitoring adherence to corrective action plans, as well as assessing the effectiveness of actions taken, with implementation of revised corrective actions as needed.

REFERENCES:

Federal Register (April 2008). Centers for Medicare & Medicaid Services (CMS), Conditions for Coverage, 494.180 Governance

Federal Register (April 2008). Centers for Medicare & Medicaid Services (CMS), Conditions for Coverage, 494.30 Infection Control

U.S. Department of Health and Human Services, Center for Disease Control & Prevention (CDC), Guidelines Recommendations for preventing transmission of infections among chronic hemodialysis patients. Morbidity and Mortality Weekly Report, April 27, 2001/Vol. 50/No. RR-5.

	TITLE: QUALITY ASSESSMENT AND PERFORMANCE IMPROVEMENT (QAPI) POLICY	REFERENCE: #DD-GF-0304
CATEGORY: GENERAL FACILITY		
REPLACING: #DDSS2053		PAGE: 1 OF: 3
APPROVED REVISION: 7/1/2020		EFFECTIVE:12/01/2014

PURPOSE:

To establish guidelines for the development, implementation, maintenance, and evaluation of an effective, data-driven Quality Assessment and Performance Improvement Program.

POLICY:

1. The dialysis facility will develop, implement, maintain and evaluate an effective, data-driven quality assessment and performance improvement program with participation by the professional members of the Interdisciplinary Team (IDT).
2. Professional members of the facility's interdisciplinary team participating in the Quality Assessment and Performance Improvement activities must minimally include, but not be limited to, a physician (Medical Director), a registered nurse (Nurse Manager), a masters-prepared social worker, and a registered dietician.
3. Quality Assessment and Performance Improvement program activities must include continuous activities designed to achieve measurable improvements in health outcomes and the prevention and reduction of medical errors by ongoing monitoring and review of performance measures and indicators associated with:
    - Measurable improvements in patient health outcomes, and
    - Reduction of medical errors
4. The QAPI program will utilize the Measures Assessment Tool (MAT) to monitor data/ information, prioritize areas for improvement, determine potential root causes, develop, implement, evaluate and revise plans that result in improvement of the care provided by the facility.
5. The Governing Body will appoint a Quality Assessment and Performance Improvement Committee, maintain oversight of the function and performance of the committee, and receive annual reports of the committee's activities and outcomes.
6. Members of the QAPI Committee will be responsible for the implementation of comprehensive data collection, as well as monitoring and improvement activities including, but not limited to, measurement, evaluation, and analysis of the data related to the following items; and the development of improvement plans for the following measures when indicated:

a. Health Outcomes: Physical and Mental Functioning
b. Health Outcomes: Patient Hospitalization
c. Health Outcomes: Patient Survival
d. Hemodialysis Adequacy
   - Target Kt/V: Home/Out-Patient Hemodialysis: NxStage: $\geq$ 2.0
   - Target Kt/V: Home/Out-Patient Hemodialysis: conventional machines: $\geq$ 1.2

e. Peritoneal Dialysis Adequacy: Target Kt/V $\geq$ 1.7
f. Nutritional Status
   - Albumin: $\geq$ 3.4g/dL

g. Mineral Metabolism
   - Corrected Calcium: 8.4 – 10.2mg/dL
   - Phosphorus: 3.5 – 5.5mg/dL
   - iPTH: 150 – 600pg/ml

h. Anemia Management
   - Hemoglobin: 9.0 – 11.0g/dL
   - Transferrin Saturation: 30 – 50%
   - Ferritin: 200 – 1200ng/ml (optimal: 500 – 800ng/ml)

i. Vascular Access
   - Patients with Central Venous Catheters > 90 days: < 10%
   - Patients with AV Fistula: > 65%

j. Medical Injuries and Errors Identification
k. Patient Satisfaction and Grievances
l. Infection Control and Surveillance
m. Vaccinations
n. Technical Operations and Water/Dialysate Monitoring

7. The QAPI Committee will meet monthly to review the QAPI data for the prior month, verifying measures where goals are met, and identifying areas not meeting the expected thresholds where improvement plans may be indicated.

8. Action plans to improve outcomes will be developed and implemented by the QAPI committee as necessary. Plans will be reviewed monthly, and revised as necessary after review and analysis of the current outcome data.

9. The QAPI Committee will share clinical outcomes data monthly with the SNF clinical management staff.

10. The QAPI Committee will ensure that all coordination agreements with long-term care facilities are reviewed annually.

DOCUMENTATION:

Dialyze Direct Facility QAPI Meeting Minutes

REFERENCES:

Conditions for Coverage for End Stage Renal Disease Facilities, Interpretive Guidance, Centers for Medicare and Medicaid Services, 2008

Measures Assessment Tool, Centers for Medicare and Medicaid Services, Version 2.5

DIALYSIS CARE

POLICY: Residents receiving dialysis will have the care plan "The resident requires dialysis" initiated. All dialysis observation/assessment and care must be documented in the medical record on each dialysis day, prior to dialysis and upon return.

PROCEDURE: The Nurse Manager/ANM/CC/Designee will:

1. Review admission screen for dialysis information.
2. Verify dialysis unit, days of treatment, time of dialysis, transportation arrangements.
3. Arrange transportation.
4. Inform patient and/or family of dialysis schedule to include dialysis unit, days and times of dialysis, and transportation arrangements.
5. Document in appointment book:
    a. Name of dialysis unit
    b. Phone number of dialysis unit
    c. Scheduled days/time of dialysis
    d. Transportation arrangements
    e. Specific name/phone number of individual who transports or specific name/phone number of transport company and pick up time
6. Initiate the care plan "The Resident required dialysis". Include all appropriate interventions, including the intervention that flows to the Kardex "Resident attends dialysis": Specifying:
    a. name of dialysis unit
    b. scheduled days/time
    c. transportation pick up time

7. Provide a bag meal, as dialysis centers allow, otherwise the resident will be provided a snack or their meal before leaving or upon return.

8. Set up "dialysis book"- on front and spine of book write:
    a. Patient name
    b. Name, address, phone number of dialysis unit, days and times of treatment
    c. Pick up time and with whom/or with which transportation company

Dialysis Day:

9. Place inside the "dialysis book" and send with resident:
    a. A copy of the current MAR (with each change)
    b. Interfacility Transfer Patient Report form: complete prior to each treatment and check after each treatment. Document in dialysis book any correspondence to the dialysis unit. Form will be uploaded into the medical record.

10. VS will be obtained before and after treatment. Blood Pressure will be done in extremity, which is not affected by the vascular access. No blood pressures are to be done in the vascular access extremity.

11. The *Dialysis Observation/Assessment* UDA will be completed on each dialysis day, prior to dialysis and upon return.

12. The procedure for examination of the vascular access site will be done each day of dialysis.
    a. Observe/assess for adequate circulation in the vascular access and in the distal portion of the vascular access extremity.
        -To assess for bruit (circulation) place stethoscope over vascular access and listen for a "blowing noise."
        -To palpate for thrill you will feel an abnormal tremor movement over the vascular access.

    b. The distal portion of the extremity should be examined for adequate circulation – warm, not cool, normal color, no swelling, redness or evidence of discoloration.

13. Determine resident's level of consciousness (i.e. alert, oriented, confused, etc.).

14. Document transportation to dialysis and back including type of transport (name of transport agency) in the Sign Out/Sign In Book.

15. Note in progress notes, any dialysis communication in dialysis book, or via telephone conversation, in relation to how dialysis was tolerated.

Dialysis Observation/Assessment - V 1

Client:	**Effective Date:**	**Location:**
Initial Admission:	**Admission:**	**Date of Birth:**
Score: NA	**Category:** NA	**Physician:**

Reason for Observation/Assessment

1. Reason for Observation/Assessment
   - ○ a. Pre-dialysis treatment
   - ○ b. Post-dialysis treatment

1a. Scheduled dialysis time: **(S)**

1b. Returned to facility time:

A. Vital Signs

1. Most Recent Blood Pressure
   Blood Pressure: _____ Date: _____
   Position: _____
2. Most Recent Temperature
   Temperature: _____ Date: _____
   Route: _____
3. Most Recent Pulse
   Pulse: _____ Date: _____
   Pulse Type: _____
4. Most Recent Respiration
   Respiration: _____ Date: _____

B. Orientation/Cognition

1. Oriented to
   - ☐ a. Person
   - ☐ b. Place
   - ☐ c. Time
   - ☐ d. Confused
   - ☐ e. Disoriented
2. ☐ Agitated
3. ☐ Drowsy
4. ☐ Depressed
5. ☐ Combative
6. ☐ Somnolent

C. Access Observation/Assessment

1. ☐ Graft/Fistula
2. ☐ Other type of vascular access

1a. Extremity/Location of graft/fistula

Observe/assess the vascular access site for adequate circulation in the vascular access and in the distal portion of the vascular access extremity:

1b. Bruit: place stethoscope over vascular access and listen for "blowing noise"
   - ○ a. bruit present

Client:

- b. bruit not present- notify medical provider

1c. Thrill: to palpate for thrill, feel for abnormal tremor movement over the vascular access

- a. thrill present
- b. thrill not present- notify medical provider

1d. Circulation to distal portion of extremity

- a. Warm (normal)
- b. Normal color
- c. No redness or evidence of discoloration
- d. No swelling present
- e. Adverse signs noted, notify medical provider

e1. Adverse signs noted

2a. Type of vascular access:

- a. Permcath
- b. Subclavian
- c. IJ

2b. Dressing/Caps/Clamps

- a. Dressing dry and intact
- b. Caps on
- c. Clamps secured

Hemodialysis Access Sites

Policy:
Hemodialysis provides temporary support for patients with acute reversible renal failure. It is also used for regular long-term treatment of patients with chronic end stage renal disease. The patient's rate of urea generation and weight gain are used to determine the number and duration of hemodialysis treatments.

PROCEDURE

Permacath/Subclavian or Jugular central line/femoral catheter

1. Care and Monitoring
    a. Protect the catheter from being accidentally pulled out or damaged. The catheter must be secure.
    b. Do not touch catheter Caps.
    c. May shower with an occlusive dressing over dialysis catheter site.
    d. Dressing Changes can only be done at Hemodialysis. You may reinforce dressing as needed.
    e. If catheter starts to come out call MD, Hemodialysis Center or 911. DO NOT push in or pull out catheter – if catheter does come out apply pressure if bleeding – call MD or 911.
    f. Check permacath/subclavian or jugular central line/femoral catheter site every shift for signs and symptoms of infection, bleeding, and catheter is intact.

Arteriovenous Fistula, Graft

1. Arteriovenous Fistula – sides of an artery and a vein in the wrist are incised and sutured together to make a common opening.
2. Arteriovenous graft – incision is made in forearm, upper arm, or thigh. A synthetic or natural graft is then tunneled under the skin and sutured with the distal end to an artery and the proximal end to a vein.
3. Care and monitoring of arteriovenous, fistula, or graft.
    a. Check site every shift for signs and symptoms of infection such as redness, warmth, tenderness, purulent drainage, open sores, or swelling. Patients with end-stage kidney disease are at increased risk of infection.
    b. Graft, or fistula may be covered with a dressing – for dressing changes contact hemodialysis for specific orders.
    c. No BP or venipunctures of arm with fistula, graft. Must be noted on resident care sheet.
    d. Auscultate the vascular access with a stethoscope to detect a bruit or "swishing" sound that indicates patency.
    e. Check the patient's circulation by palpating pulses distal to the vascular access; observing capillary refill in his fingers; and assessing for

numbness, tingling, altered sensation, coldness, and pallor in the affected extremity.

f. Notify the MD promptly if you suspect clotting.
g. When you move the patient or help with ambulation, avoid trauma to or excessive pressure on the affected arm.
h. Assess for blebs (ballooning or bulging) of the vascular access that may indicate an aneurysm that can rupture and cause hemorrhage.
i. After dialysis, assess the vascular access for any bleeding or hemorrhage.
j. Document all hemodialysis information on hemodialysis treatment sheet and progress notes.

Loretto

INTERFACILITY TRANSFER PATIENT REPORT DATE: _____

FACILITY REPORT TO DIALYSIS UNIT
Patient Name: _____
Facility Name: _____
Telephone #: _____

Patient Assessment:
Access Eval: (graft/fistula)
BP _____ Bruit/Thrill Present _____
Temp _____ Appearance _____
Resp _____

If permcath/subclavian/IJ:
Dressing: Dry _____ Intact _____
Caps on & clamps secured: _____

Mentation:
A&O _____ Confused _____
Agitated _____ Combative _____
Drowsy _____ Somnolent _____
Depressed _____ Disoriented _____

MEDICATIONS prior to transport:
_____
_____
_____
_____
_____
_____
_____
_____
_____

REPORTS (Sig change, New Orders, ,)
_____
_____
_____
_____
_____
_____
_____

Nurse Completing report:
_____

Please attach a copy of any pertinent labs/test results

DIALYSIS REPORT TO FACILITY
Post treatment patient assessment:
BP Standing: _____ BP sitting: _____
Pulse: _____ Temp: _____
Breath Sounds: _____
Post tx wgt: _____
Pre tx wgt: _____

Access Eval: (Graft/fistula)
Bruit/Thrill present _____
Appearance: _____

Hemostasis achieved _____
Prolonged bleeding _____
Drsg in place, dry, intact _____
Permcath/Subclavian/IJ: _____
Exit site appearance: _____
_____
_____

Clamps secured: _____
Caps secured: _____
Heparinized w/1: _____
_____ ml _____ml(L)

Mentation:
A&O Mentation:
A&O _____ Confused _____
Agitated _____ Combative _____
Drowsy _____ Somnolent _____
Depressed _____ Disoriented _____

Medications during/after:
_____
_____
_____

REPORTS
_____
_____
_____
_____

Nurse Completing report:
_____

Limited Review Application

State of New York Department of Health/Office of Health Systems Management

Schedule LRA 2

Total Project Cost

ITEM		ESTIMATED PROJECT COST
1.1 Land Acquisition (*attach documentation*)		-
1.2 Building Acquisition		-
1.1-1.2 Subtotal:	**$**	**-**
2.1 New Construction		-
2.2 Renovation and Demolition		213,175
2.3 Site Development		-
2.4 Temporary Power		-
2.1-2.4 Subtotal:	**$**	**213,175**
3.1 Design Contingency		21,318
3.2 Construction Contingency		21,318
3.1-3.2 Subtotal:	**$**	**42,636**
4.1 Fixed Equipment (NIC)		-
4.2 Planning Consultant Fees		-
4.3 Architect/Engineering Fees (incl. computer installation, design, etc.)		18,120
4.4 Construction Manager Fees		5,329
4.5 Capitalized Licensing Fees		-
4.6 Health Information Technology Costs		-
4.6.1 Computer Installation, Design, etc.		-
4.6.2 Consultant, Construction Manager Fees, etc.		-
4.6.3 Software Licensing, Support Fees		-
4.6.4 Computer Hardware/Software Fees		-
4.7 Other Project Fees (Consultant, etc.)		5,000
4.1-4.7 Subtotal:	**$**	**28,449**
5.1 Movable Equipment **		31,945
6.1 Total Basic Cost of Construction	**$**	**316,205**
7.1 Financing Cost (points, fees, etc.)		-
7.2 Interim Interest Expense - Total Interest on Construction Loan: Amount $ 0 @ 0 % for 0 months		-
7.3 Application Fee		1,000
8.1 Estimated Total Project Cost (Total 6.1 – 7.3)	**$**	**317,205**

**** Please refer to the LRA Schedule 2 Attachment**

If this project involves construction enter the following anticipated construction dates on which your cost estimates are based.

Construction Start Date 11/1/2025 (on or before)

Construction Completion Date 5/1/2026 (on or before)

SCHEDULE LRA 2 ATTACHMENT

Equipment List

LRA 2A

MOVABLE EQUIPMENT
Loretto Health and Rehabilitation Center
700 East Brighton Ave
Syracuse, New York 13205
Onondaga County

Proposed Hemodialysis Den (4 Chairs)
(December 2024)

A.	Dialysis Chairs	$ 16,800		
B.	TVs	3,000		
C.	Cubicle Curtains	4,500		
D.	Subtotal (A-C)		$ 24,300	
E.	Freight (10%)		2,430	
F.	Installation (5%)		1,215	
G.	Subtotal (D-F)			$ 27,945
H.	Contingency			4,000
I.	**Total Movable Equipment**			**$ 31,945**

Limited Review Application

State of New York Department of Health/Office of Health Systems Management

Schedule LRA 3

Proposed Plan for Project Financing

A. LEASE ☐

If any portion of the cost for land, building or Equipment is to be financed through a lease, rental agreement or lease/purchase agreement, complete the chart at the right.

A complete copy of each proposed lease must be submitted.

Attachment # _____

ITEM	COST AS IF PURCHASED	
	$	
	$	
	$	
	$	
	$	

B. CASH ☒

If cash is to be used, complete the chart at the right.

Attach a copy of the latest certified financial Statement and interim monthly or quarterly financial reports to cover the balance of time to date.

Attachment # **Sch LRA 3 Attachment**

Accumulated Funds	$	
Sale of Existing Assets	$	
Other – (i.e. gifts, grants, etc.)*	$	$317,205
TOTAL CASH	$	$317,205

*** Mother Cabrini Health Foundation, Inc. grant funds**

*Attach a full and complete description of the assets to be sold.

Attachment # N/A

** If grants, attach a description of the source of financial support

Attachment # **Sch LRA 3 Attachment**

C. DEBT FINANCING ☐

If the project is to be financed by debt of any type, complete the chart at the right.

Attach a copy of the proposed letter of interest From the intended source of permanent financing. **This letter must include an estimate of the Principal, term, interest rate and pay-out period presently being considered.**

Attachment # _____

Principal	$
Interest Rate	%
Term	Yrs
Pay-out Period	Yrs
Type *	

* Commercial, Dormitory Authority Bonds, Dormitory Authority, TELP Lease, Industrial Development Agency Bonds, Other (identify).

Schedule LRA 4/Schedule 7
CON Forms Regarding
Environmental issues

Contents:

Environmental Assessment

Part I.	The following questions help determine whether the project is "significant" from an environmental standpoint.	Yes	No
1.1	If this application involves establishment, will it involve more than a change of name or ownership only, or a transfer of stock or partnership or membership interests only, or the conversion of existing beds to the same or lesser number of a different level of care beds? **NOT APPLICABLE**	☐	☐
1.2	Does this plan involve construction and change land use or density?	☐	☒
1.3	Does this plan involve construction and have a permanent effect on the environment if temporary land use is involved?	☐	☒
1.4	Does this plan involve construction and require work related to the disposition of asbestos?	☐	☒
Part II.	If any question in Part I is answered "yes" the project may be significant, and Part II must be completed. If all questions in Part II are answered "no" it is likely that the project is not significant	**Yes**	**No**
2.1	Does the project involve physical alteration of ten acres or more?	☐	☒
2.2	If an expansion of an existing facility, is the area physically altered by the facility expanding by more than 50% and is the total existing and proposed altered area ten acres or more?	☐	☐ N/A
2.3	Will the project involve use of ground or surface water or discharge of wastewater to ground or surface water in excess of 2,000,000 gallons per day?	☐	☒
2.4	If an expansion of an existing facility, will use of ground or surface water or discharge of wastewater by the facility increase by more than 50% and exceed 2,000,000 gallons per day?	☐	☐ N/A
2.5	Will the project involve parking for 1,000 vehicles or more?	☐	☒
2.6	If an expansion of an existing facility, will the project involve a 50% or greater increase in parking spaces and will total parking exceed 1000 vehicles?	☐	☐ N/A
2.7	In a city, town, or village of 150,000 population or fewer, will the project entail more than 100,000 square feet of gross floor area?	☐	☒
2.8	If an expansion of an existing facility in a city, town, or village of 150,000 population or fewer, will the project expand existing floor space by more than 50% so that gross floor area exceeds 100,000 square feet?	☐	☐ N/A
2.9	In a city, town or village of more than 150,000 population, will the project entail more than 240,000 square feet of gross floor area?	☐	☐ N/A
2.10	If an expansion of an existing facility in a city, town, or village of more than 150,000 population, will the project expand existing floor space by more than 50% so that gross floor area exceeds 240,000 square feet?	☐	☐ N/A
2.11	In a locality without any zoning regulation about height, will the project contain any structure exceeding 100 feet above the original ground area?	☐	☐ N/A
2.12	Is the project wholly or partially within an agricultural district certified pursuant to Agriculture and Markets Law Article 25, Section 303?	☐	☒
2.13	Will the project significantly affect drainage flow on adjacent sites?	☐	☒

2.14	Will the project affect any threatened or endangered plants or animal species?	☐	☒
2.15	Will the project result in a major adverse effect on air quality?	☐	☒
2.16	Will the project have a major effect on visual character of the community or scenic views or vistas known to be important to the community?	☐	☒
2.17	Will the project result in major traffic problems or have a major effect on existing transportation systems?	☐	☒
2.18	Will the project regularly cause objectionable odors, noise, glare, vibration, or electrical disturbance as a result of the project's operation?	☐	☒
2.19	Will the project have any adverse impact on health or safety?	☐	☒
2.20	Will the project affect the existing community by directly causing a growth in permanent population of more than five percent over a one-year period or have a major negative effect on the character of the community or neighborhood?	☐	☒
2.21	Is the project wholly or partially within, or is it contiguous to any facility or site listed on the National Register of Historic Places, or any historic building, structure, or site, or prehistoric site, that has been proposed by the Committee on the Registers for consideration by the New York State Board on Historic Preservation for recommendation to the State Historic Officer for nomination for inclusion in said National Register?	☒	☐
2.22	Will the project cause a beneficial or adverse effect on property listed on the National or State Register of Historic Places or on property which is determined to be eligible for listing on the State Register of Historic Places by the Commissioner of Parks, Recreation, and Historic Preservation?	☐	☒
2.23	Is this project within the Coastal Zone as defined in Executive Law, Article 42? If Yes, please complete Part IV.	☐	☒
Part III.		**Yes**	**No**
3.1	Are there any other state or local agencies involved in approval of the project? If so, fill in Contact Information to Question 3.1 below.	☒	☐
	Agency Name:	City of Syracuse, Building Dept	
	Contact Name:	Brian Thompson	
	Address:	300 South State Street	
	State and Zip Code:	Syracuse, New York 13202	
	E-Mail Address:	bthompson@syr.gov	
	Phone Number:	315-448-8607	
	Agency Name:		
	Contact Name:		
	Address:		
	State and Zip Code:		
	E-Mail Address:		
	Phone Number:		
	Agency Name:		
	Contact Name:		

	Address:			
	State and Zip Code:			
	E-Mail Address:			
	Phone Number:			
	Agency Name:			
	Contact Name:			
	Address:			
	State and Zip Code:			
	E-Mail Address:			
	Phone Number:			
3.2	Has any other agency made an environmental review of this project? If so, give name, and submit the SEQRA Summary of Findings with the application in the space provided below.		**Yes** ☐	**No** ☒
	Agency Name:			
	Contact Name:			
	Address:			
	State and Zip Code:			
	E-Mail Address:			
	Phone Number:			
3.3	Is there a public controversy concerning environmental aspects of this project? If yes, briefly describe the controversy in the space below.		**Yes** ☐	**No** ☒
Part IV.	**Storm and Flood Mitigation**			
	Definitions of FEMA Flood Zone Designations			
	Flood zones are geographic areas that the FEMA has defined according to varying levels of flood risk. These zones are depicted on a community's Flood Insurance Rate Map (FIRM) or Flood Hazard Boundary Map. Each zone reflects the severity or type of flooding in the area.			
	Please use the FEMA Flood Designations scale below as a guide to answering all Part IV questions regardless of project location, flood and or evacuation zone.		**Yes**	**No**
4.1	Is the proposed site located in a flood plain? If Yes, indicate classification below and provide the Elevation Certificate (FEMA Flood Insurance).		☒	☐
	Moderate to Low Risk Area		**Yes**	**No**
	Zone	**Description**	☒	☐
	In communities that participate in the NFIP, flood insurance is available to all property owners and renters in these zones:			
	B and X	Area of moderate flood hazard, usually the area between the limits of the 100-year and 500-year floods. Are also used to designate base floodplains of lesser hazards, such as areas protected by levees from 100-year flood, or shallow flooding areas with average depths of less than one foot or drainage areas less than 1 square mile.	☒	

	C and X	Area of minimal flood hazard, usually depicted on FIRMs as above the 500-year flood level.	☐	
	High Risk Areas		**Yes**	**No**
	Zone	**Description**	☐	☒
	In communities that participate in the NFIP, mandatory flood insurance purchase requirements apply to all these zones:			
	A	Areas with a 1% annual chance of flooding and a 26% chance of flooding over the life of a 30-year mortgage. Because detailed analyses are not performed for such areas; no depths or base flood elevations are shown within these zones.	☐	
	AE	The base floodplain where base flood elevations are provided. AE Zones are now used on new format FIRMs instead of A1-A30.	☐	
	A1-30	These are known as numbered A Zones (e.g., A7 or A14). This is the base floodplain where the FIRM shows a BFE (old format).	☐	
	AH	Areas with a 1% annual chance of shallow flooding, usually in the form of a pond, with an average depth ranging from 1 to 3 feet. These areas have a 26% chance of flooding over the life of a 30-year mortgage. Base flood elevations derived from detailed analyses are shown at selected intervals within these zones.	☐	
	AO	River or stream flood hazard areas, and areas with a 1% or greater chance of shallow flooding each year, usually in the form of sheet flow, with an average depth ranging from 1 to 3 feet. These areas have a 26% chance of flooding over the life of a 30-year mortgage. Average flood depths derived from detailed analyses are shown within these zones.	☐	
	AR	Areas with a temporarily increased flood risk due to the building or restoration of a flood control system (such as a levee or a dam). Mandatory flood insurance purchase requirements will apply, but rates will not exceed the rates for unnumbered A zones if the structure is built or restored in compliance with Zone AR floodplain management regulations.	☐	
	A99	Areas with a 1% annual chance of flooding that will be protected by a Federal flood control system where construction has reached specified legal requirements. No depths or base flood elevations are shown within these zones.	☐	
	High Risk Coastal Area		**Yes**	**No**
	Zone	**Description**		
	In communities that participate in the NFIP, mandatory flood insurance purchase requirements apply to all these zones:			
	Zone V	Coastal areas with a 1% or greater chance of flooding and an additional hazard associated with storm waves. These areas have a 26% chance of flooding over the life of a 30-year mortgage. No base flood elevations are shown within these zones.	☐	☒
	VE, V1 - 30	Coastal areas with a 1% or greater chance of flooding and an additional hazard associated with storm waves. These areas have a 26% chance of flooding over the life of a 30-year mortgage. Base flood elevations derived from detailed analyses are shown at selected intervals within these zones.	☐	
	Undetermined Risk Area		**Yes**	**No**
	Zone	**Description**	☐	☒

	D	Areas with possible but undetermined flood hazards. No flood hazard analysis has been conducted. Flood insurance rates are commensurate with the uncertainty of the flood risk.		
4.2	Are you in a designated evacuation zone?		☐	☒
	If Yes, the Elevation Certificate (FEMA Flood Insurance) shall be submitted with the application.			
	If yes which zone is the site located in?			
4.3	Does this project reflect the post Hurricane Lee, and or Irene, and Superstorm Sandy mitigation standards?		☐	☒
	If Yes, which floodplain?	100 Year	☐	
		500 Year	☐	

The Elevation Certificate provides a way for a community to document compliance with the community's floodplain management ordinance.

FEMA **Elevation_Certificate_** and Instructions

Schedule LRA 6 Attachment

Limited Review Application

Schedule LRA 5

State of New York Department of Health/Office of Health Systems Management

Space & Construction Cost Distribution

☐ New

■ Alteration

LOCATION			Code and Functional Category Description	Functional Gross SF	Construction Cost per SF	Total Construction Cost	(ALT) Scope of Work
Bldg. No.	Floor No.	Sect. No.					
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
Main	1	--	Nursing Home Hemodialysis	2,517	$ 84.69	$ 213,175	C
			Total Construction	**2,517**	**$ 84.69**	**$ 213,175**	**C**

1. If new construction is involved, is it "freestanding"? **N/A** Yes ☐ No ☐

2. (Check where applicable) The facilities to be affected by this project are located in a:

☐ Dense Urban Area ■ Other Metropolitan or Suburban Area ☐ Rural Area

3. This submission consists of: ☐ New Construction Report Number of pages _____

■ Alteration Construction Report Number of pages 1

Do not use the master copy. Photocopy master and then complete copy if this schedule is required.

(Rev. 7/7/2010)

Schedule 6
Architectural/Engineering Submission

Contents:

New York State Department of Health Certificate of Need Application

Schedule 6

Architectural Submission Requirements for Contingent Approval and Contingency Satisfaction

Schedule applies to all projects with construction, including Articles 28 & 40, i.e., Hospitals, Diagnostic and Treatment Centers, Residential Health Care Facilities, and Hospices.

Instructions

- Provide Architectural/Engineering Narrative using the format below.
- Provide Architect/Engineer Certification form:
  - Architect's Letter of Certification for Proposed Construction or Renovation for Projects That Will Be Self-Certified. Self-Certification Is Not an Option for Projects over $15 Million, or Projects Requiring a Waiver (PDF)
  - Architect's Letter of Certification for Proposed Construction or Renovation Projects to Be Reviewed by DOH or DASNY. (PDF) (Not to Be Submitted with Self-Certification Projects)
  - Architect's Letter of Certification for Completed Projects (PDF)
  - Architect's or Engineer's Letter of Certification for Inspecting Existing Buildings (PDF)
- Provide FEMA BFE Certificate. Applies only to Hospitals and Nursing Homes.
  - FEMA Elevation Certificate and Instructions.pdf
- Provide Functional Space Program: A list that enumerates project spaces by floor indicating size by gross floor area and clear floor area for the patient and resident spaces.
- For projects with imaging services, provide Physicist's Letter of Certification and Physicist's Report including drawings, details and supporting information at the design development phase.
  - Physicist's Letter of Certification (PDF)
- Provide Architecture/Engineering Drawings in PDF format created from the original electronic files; scans from printed drawings will not be accepted. Drawing files less than 100 MB, and of the same trade, may be uploaded as one file.
  - NYSDOH and DASNY Electronic Drawing Submission Guidance for CON Reviews
  - DSG-1.0 Schematic Design & Design Development Submission Requirements
- Refer to the Required Attachment Table below for the Schematic Design Submission requirements for Contingent Approval and the Design Development Submission requirements for Contingency Satisfaction.
  - Attachments must be labeled accordingly when uploading in NYSE-CON.
  - Do not combine the Narrative, Architectural/Engineering Certification form and FEMA BFE Certificate into one document.
  - If submitted documents require revisions, provide an updated Schedule 6 with the revised information and date within the narrative.

Architecture/Engineering Narrative

Narrative shall include but not limited to the following information. Please address all items in the narrative including items located in the response column. Incomplete responses will not be accepted.

Project Description	
Schedule 6 submission date: 12/18/2024	Revised Schedule 6 submission date: NA Click to enter a date.
Does this project amend or supersede prior CON approvals or a pending application? No If so, what is the original CON number? Click here to enter text.	
Intent/Purpose: It is proposed to convert an existing and vacant 2,517 sf former adult day health care space on the first floor of the existing 12 story licensed RHCF to a 4-chair dialysis den with expansion space for additional chairs should the Department's policy on the number of chairs change in the future. To minimize conversion costs, all existing walls and ceilings within the area will be salvaged with minimal change. The size of the space	

allows for toilet facilities, recharge stations, and emergency supply closets to be located within the den. The only required ancillary spaces located outside the den is the janitor's closet (located across the hall) and the proposed dialysis resident isolation room. The Dialysis Den location requires no intrusion thru an existing nursing unit, and resident access to the den is via (3) existing elevators located across the hall from the den entry. The den is proposed for inpatient use only.	
Site Location: Loretto Health and Rehabilitation, 700 East Brighton Avenue, Syracuse, NY 13205	
Brief description of current facility, including facility type: The existing Facility is a licensed 583 bed RHCF. The structure is 12 stories plus penthouse and basement. The construction type is NFPA I (332). The Facility Type is existing healthcare. Resident common area services are located on the first floor while all upper floors are resident nursing units. The basement houses the non-resident services.	
Brief description of proposed facility: The existing Facility (site and building) will remain unchanged except for the internal conversion of the 2,517 sf first floor area to a 4 chair dialysis den.	
Location of proposed project space(s) within the building. Note occupancy type for each occupied space. The dialysis den will be located on the first floor which houses the main public entry and such resident communal areas as central dining, therapy, treatment center, and other such spaces.	
Indicate if mixed occupancies, multiple occupancies and or separated occupancies. Describe the required smoke and fire separations between occupancies: NA, the Facility is not a mixed occupancy. Click here to enter text.	
If this is an existing facility, is it currently a licensed Article 28 facility?	Yes
Is the project space being converted from a non-Article 28 space to an Article 28 space? The space was a former, now vacant, adult day care center.	No
Relationship of spaces conforming with Article 28 space and non-Article 28 space: The former adult day health care space occupies a central location on the first floor.	
List exceptions to the NYSDOH referenced standards. If requesting an exception, note each on the Architecture/Engineering Certification form under item #3. NONE	
Does the project involve heating, ventilating, air conditioning, plumbing, electrical, water supply, and fire protection systems that involve modification or alteration of clinical space, services or equipment such as operating rooms, treatment, procedure rooms, and intensive care, cardiac care , other special care units (such as airborne infection isolation rooms and protective environment rooms), laboratories and special procedure rooms, patient or resident rooms and or other spaces used by residents of residential health care facilities on a daily basis? If so, please describe below. There will be very limited plumbing and electric modifications to provide for the services to the new dialysis chair locations, recharge station, and emergency storage rooms. The HVAC, fire protection, and life safety systems will all remain unchanged.	Yes
Provide brief description of the existing building systems within the proposed space and overall building systems, including HVAC systems, electrical, plumbing, etc. All systems are Municipally provided electric, gas, water, sanitary. All central systems will remain unchanged.	
Describe scope of work involved in building system upgrades and or replacements, HVAC systems, electrical, Sprinkler, etc. There is no anticipated HVAC or sprinkler changes or upgrades. These will remain unchanged. Plumbing and electric and data changes will be minimal and only as required to provide for the equipment and layout needs of the dialysis den.	
Describe existing and or new work for fire detection, alarm, and communication systems: All is anticipated to remain unchanged.	
If a hospital or nursing home located in a flood zone, provide a FEMA BFE Certificate from www.fema.gov, and describe the work to mitigate damage and maintain operations during a flood event. Refer to the environmental section 4/7. The Facility is in FEMA zone X with no mitigation requirements.	

Does the project contain imaging equipment used for diagnostic or treatment purposes? If yes, describe the equipment to be provided and or replaced. Ensure physicist's letter of certification and report are submitted. No imaging equipment is proposed
Does the project comply with ADA? If no, list all areas of noncompliance. Yes,
Other pertinent information: none

Project Work Area	**Response**
Type of Work	Alteration
Square footages of existing areas, existing floor and or existing building.	30,000 sf +
Square footages of the proposed work area or areas. Provide the aggregate sum of the work areas.	2,517 sf
Does the work area exceed more than 50% of the smoke compartment, floor or building?	Less than 50% of the floor
Sprinkler protection per NFPA 101 Life Safety Code	Sprinklered throughout
Construction Type per NFPA 101 Life Safety Code and NFPA 220	Type 1 (332)
Building Height	160' +
Building Number of Stories	13
Which edition of FGI is being used for this project?	2018 Edition of FGI
Is the proposed work area located in a basement or underground building?	Grade Level
Is the proposed work area within a windowless space or building?	Yes
Is the building a high-rise?	Yes
If a high-rise, does the building have a generator?	Yes
What is the Occupancy Classification per NFPA 101 Life Safety Code?	Chapter 18 New Health Care Occupancy
Are there other occupancy classifications that are adjacent to or within this facility? If yes, what are the occupancies and identify these on the plans. Click here to enter text.	No
Will the project construction be phased? If yes, how many phases and what is the duration for each phase? Click here to enter text.	No
Does the project contain shell space? If yes, describe proposed shell space and identify Article 28 and non-Article 28 shell space on the plans. Click here to enter text.	No
Will spaces be temporarily relocated during the construction of this project? If yes, where will the temporary space be? Click here to enter text.	No
Does the temporary space meet the current DOH referenced standards? If no, describe in detail how the space does not comply. Click here to enter text.	Not Applicable
Is there a companion CON associated with the project or temporary space? If so, provide the associated CON number. Click here to enter text.	No
Will spaces be permanently relocated to allow the construction of this project? If yes, where will this space be? Click here to enter text.	No
Changes in bed capacity? If yes, enumerate the existing and proposed bed capacities. Click here to enter text.	No Change
Changes in the number of occupants? If yes, what is the new number of occupants? Click here to enter text.	No
Does the facility have an Essential Electrical System (EES)? If yes, which EES Type? Type 2	Yes
If an existing EES Type 1, does it meet NFPA 99 -2012 standards?	Yes
Does the existing EES system have the capacity for the additional electrical loads? Click here to enter text.	Yes
Does the project involve Operating Room alterations, renovations, or rehabilitation? If yes, provide brief description.	No

Click here to enter text.	
Does the project involve Bulk Oxygen Systems? If yes, provide brief description. Click here to enter text.	No
If existing, does the Bulk Oxygen System have the capacity for additional loads without bringing in additional supplemental systems?	Not Applicable
Does the project involve a pool?	No

REQUIRED ATTACHMENT TABLE			
SCHEMATIC DESIGN SUBMISSION for **CONTINGENT APPROVAL**	DESIGN DEVELOPMENT SUBMISSION (State Hospital Code Submission) for **CONTINGENCY SATISFACTION**	**Title of Attachment**	**File Name in PDF format**
•		Architectural/Engineering Narrative	A/E Narrative.PDF
•		Functional Space Program	FSP.PDF
•		Architect/Engineer Certification Form	A/E Cert Form. PDF
•		FEMA BFE Certificate	FEMA BFE Cert.PDF
•		Article 28 Space/Non-Article 28 Space Plans	
•	•	Site Plans	
•	•	Life Safety Plans including level of exit discharge, and NFPA 101-2012 Code Analysis	LSC100.PDF
•	•	Architectural Floor Plans, Roof Plans and Details. Illustrate FGI compliance on plans.	A100.PDF
•	•	Exterior Elevations and Building Sections	
•	•	Vertical Circulation	
•	•	Reflected Ceiling Plans	A400.PDF
optional	•	Wall Sections and Partition Types	
optional	•	Interior Elevations, Enlarged Plans and Details	
	•	Fire Protection	
	•	Mechanical Systems	
	•	Electrical Systems	
	•	Plumbing Systems	
	•	Physicist's Letter of Certification and Report	

SCHEDULE LRA 6 ATTACHMENT

Architectural Information

SELF-CERTIFICATION FORM FOR ARCHITECTS AND ENGINEERS

Date:	December 18, 2024
CON Number:	TBD
Facility Name:	Loretto Health and Rehabilitation Center
Facility ID Number:	0648
Facility Address:	700 East Brighton Avenue, Syracuse, New York 13205

NYS Department of Health/Office of Health Systems Management
Center for Health Care Facility Planning, Licensure and Finance
Bureau of Architectural and Engineering Review
ESP, Corning Tower, 18th Floor
Albany, New York 12237
To The New York State Department of Health:

I hereby certify that:

1. I have been retained by the above-named facility, to provide services related to the design and preparation of construction documents and specifications for the aforementioned construction project, and, as applicable, to make periodic visits to the site during construction, and perform such other required services to familiarize myself with the general progress, quality and conformance of the work.

2. I have ascertained that, to the best of my knowledge, information and belief, the completed structure will be designed. and constructed, in accordance with the programmatic requirements for the aforementioned and in accordance with any project definitions, modifications and or revisions approved or required by the New York State Department of Health.

3. The above-referenced construction project will be designed and constructed in compliance with all applicable local codes, statutes, and regulations, and the applicable provisions of the State Hospital Code -- 10 NYCRR Part 711 (General Standards for Construction) and Parts (check all that apply):

    a. __712 (Standards of Construction for General Hospital Facilities)
    b. X 713 (Standards of Construction for Nursing Home Facilities)
    c. __714 (Standards of Construction for Adult Day Health Care Program Facilities)
    d. __715 (Standards of Construction for Freestanding Ambulatory Care Facilities)
    e. __716 (Standards of Construction for Rehabilitation Facilities)
    f. __717 (Standards of Construction for New Hospice Facilities and Units)

4. I understand that as the design of this project progresses, if a component of this project is inconsistent with the State Hospital Code (10 NYCRR Parts 711 or 713), I shall bring this to the attention of Bureau of Architecture and Engineering Review (BAER) of the New York State Department of Health prior to or upon submitting final drawings for compliance resolution.

5. I understand that upon completion of construction, the costs of any subsequent corrections necessary to address the preopening survey findings of deficiencies by the NYSDOH Regional Office, to achieve compliance with applicable requirements of 10 NYCRR Parts 711 and 713, when the prior work was not completed properly as certified herein, may not be considered allowable costs for reimbursement under 10 NYCRR Part 86.

6. I have reviewed and acknowledged the Supplemental Self-Certification Eligibility Checklist Page 4 of this document and evaluated and determined this project does meet the prerequisite requirements for Self-Certification. I understand

and agree, if the project is deemed by NYSDOH not meeting the criteria allowable for self-certification, I will be required to be resubmit the project documents for an AER review.

This self-certification is being submitted to facilitate the Architectural CON process and is in lieu of a plan review. It is understood that an electronic copy of final Construction Documents on CD, meeting the requirements of DSG-05 must be submitted to PMU for all projects, including limited, administrative, full review, self-certification and reviews performed and completed by DASNY, prior to construction.

Project Eligibility Checklist for Architectural/Engineering Self-Certification			
	Does the project include any of the following?	**YES** If Yes, project is not eligible for SelfCertification and is required to be submitted for an AER review.	**NO**
1.	Is a waiver or exceptions required?		X
2.	Will the project costs exceed $15,000,000.00 (fifteen million dollars.)?		X
3.	Is Bulk Oxygen /Medical Gas Storage associated with this project? Examples of Bulk Oxygen /Medical Gas Storage projects include but not limited to the following:		X
	a. Hyperbaric Chambers		
	b. Bulk Systems include Nitrous Oxide System and Oxygen System: Definitions as defined below:		
	Bulk Nitrous Oxide System. An assembly of equipment as described in the definition of bulk oxygen system that has a storage capacity of more than 3200 lb (1452 kg) [approximately 28,000 ft3 (793 m3) (NTP)] of nitrous oxide. (PIP)ground		
	Bulk Oxygen System* An assembly of equipment such as oxygen storage containers, pressure regulators, pressure relief devices, vaporizers, manifolds, and interconnecting piping that has a storage capacity of more than 20,000 ft3 (566 m3) of oxygen (NTP) including unconnected reserves on hand at the site. The bulk oxygen system terminates at the point where oxygen at service pressure first enters the supply line. (PIP)		
4.	Will this project have Locked or Secured Units? Examples of Locked or Secured Units include but not limited to the following;		X
	a. Observation Units for behavioral health in ED's.		
	b. Behavioral health located within inpatient settings.		
	c. Nursing Homes or other facilities with Dementia Units that are locked.		
	d. Corrections and Detention Facilities located in Hospitals, Ambulatory Health Care Occupancies and Business Occupancies where healthcare is provided.		
5.	Will this project involve construction of new procedure rooms, new operating rooms, renovations and or alterations to existing procedure rooms and or operating rooms, including modifications made to existing support systems, including, but not limited to heating, cooling, plumbing, electrical systems, medical gas systems, fire detection and fire protection systems, located in hospitals and existing ambulatory surgery centers? Examples, include but not limited to the following.		X
	a. Endoscopy Procedure Rooms		
	b. Procedure Rooms		
	c. Operating Rooms		
	d. Interventional Imaging *i.* Located in procedure rooms *ii.* Located in operating rooms		
6.	Is this a project requiring construction that is required to comply with New Ambulatory Health Care Occupancies as indicated in Chapter 20 of NFPA 101, 2012 edition requirements? Examples, include but not limited to the following:		X
	a. New Ambulatory Surgery Center		X
	b. Endoscopy Centers and or Other Procedure Rooms		X
	c. Free Standing Emergency Departments providing Definitive Care.		X
7.	Is this project intended to provide Ventilator units for patients located in nursing homes?		X
8.	Does this project involve Airborne infection isolation (AII) room?		X
9.	Does this project involve Protective environment (PE) room?		X

Project Name:	**Loretto Health and Rehabilitation Center**
Location:	300 East Brighton Ave, Syracuse, New York 13205
Description:	Create a 4-Chair Dialysis Den

Signature of NYS Licensed Architect/Engineer

David A Schlosser

Name of Architect/Engineer (Print)

013298

Professional New York State License Number

1111 James Street, Syracuse, New York 13203

Business Street Address, City, State, Zip Code

Architectural or Engineering Professional Stamp

The undersigned applicant understands and agrees that, notwithstanding this architectural/engineering certification the Department of Health shall have continuing authority to (a) review the plans submitted herewith and/or inspect the work with regard thereto, and (b) withdraw its approval thereto. The applicant shall have a continuing obligation to make any changes required by the Division to comply with the above-mentioned codes and regulations, whether or not physical plant construction or alterations have been completed.

Margaret Lally
Authorized Signature for Applicant

6/17/2025
Date

MARGARET LALLY VP FINANCE
Name (Print) Title

Notary signing required for the applicant

STATE OF NEW YORK)
) SS:
County of ONONDAGA)

On the 17TH day of JUNE 2025 before me personally appeared MARGARET LALLY, to me known, who being by me duly sworn, did depose and say that he/she is the VP OF FINANCE of the LORETTO HEALTH & REHABILITATION, the facility described herein which executed the foregoing instrument; and that he/she signed his/her name thereto by order of the governing authority of said facility.

(Notary) Lorry Marie Abel

Lorry Marie Abel
Notary Public, State of New York
Reg. No. 01AB4986344
Qualified in Madison County
Commission Expires 09/09/2025

LRA 6A
FUNCTIONAL SPACE PROGRAM
12/18/2024

Proposed Hemodialysis Den
Loretto Health and Rehabilitation Center
700 East Brighton Ave
Syracuse, New York 13205

A. INTENT/PURPOSE:

1. Loretto Health and Rehabilitation Center is a 583-bed licensed RHCF (#3301327N; PFI 0648).
2. The facility is a 12-story plus mechanical penthouse and is constructed as an NFPA Construction Type I (332).
3. The first floor of the facility provides the following functions:
   - Main public entry.
   - Central dining.
   - Therapy.
   - Exam and treatment areas.
   - Shipping/receiving.
   - Other central service areas.
4. In the center of the first floor is a vacant 2,320 SF area that formally served as the activity center for adult day health care program. This location is proposed for the new dialysis den.
5. The proposed den, while quite large for a 4-chair facility, it provides substantial area for additional dialysis stations should the department change its maximum capacity policy in the future. Additionally, the area provides all accessory spaces (toilet facilities and dialysis storage) without any significant construction change.

B. FUNCTIONAL SPACE PROGRAM:

1.	Dialysis Den:	SF
	• Entry	60
	• Treatment	333
	• Work area	1,360
	• Recharge (2)	187
	• Supply storage (2)	198
	• Toilets (2)	97
	• Misc storage (3)	85
	• Total Den	2,320
2.	Isolation room	134 SF
3.	Janitors closets (2)	63 SF
	TOTAL	2,517

Limited Review Application

State of New York Department of Health/Office of Health Systems Management

Schedule LRA 8

Staffing

Staffing Categories	Number of FTEs to the Nearest Tenth		
	Current Year*	First Year of implementation	Third Year of implementation
Health Providers:**			
Registered Nurse	N/A	1.0	1.0
Patient Care Technician	N/A	1.0	1.0
Support Staff*:**			
Total Number of Employees			

* Last complete year prior to submitting application

** "Health Providers" includes <u>all</u> providers serving patients at the site. A Health Provider is any staff who can provide a billable service – physician, dentist, dental hygienist, podiatrist, physician assistant, physical therapist, etc.

*** All other staff.

Describe how the number and mix of staff were determined:

No nursing home staff; Dialyze Direct employs staff.

PLEASE COMPLETE THE FOLLOWING:

1. Are staff paid and on payroll? ☐ Yes ☒ No **Dialyze Direct employs staff.**
2. Provide copies of contracts for any independent contractor. **Please refer to the Sch. LRA CS Attachment for Dialyze Direct contract.**
3. Please attach the Medical Doctors C.V. **Please refer to the Sch. LRA 8 Attachment.**
4. Is this facility affiliated with any other facilities? (If yes, please describe affiliation and/or agreement.) ☐ Yes ☒ No

Limited Review Application

State of New York Department of Health/Office of Health Systems Management

Schedule LRA 10

The Sites Tab in NYSE-CON has replaced Schedule LRA 10. Schedule LRA 10 is only to be used when submitting a Modification, in hardcopy, after approval or contingent approval. ***However, due to programming issues, you may still be required to upload a blank Schedule LRA 10 to submit a Service Delivery LRA application.***

Impact of Limited Review Application on Operating Certificate (services specific to the site)

NOT APPLICABLE

Instructions:
"Current" Column: Mark "x" in the box only if the service currently appears on the operating certificate (OpCert) not including requested changes
"Add" Column: Mark "x" in the box this CON application seeks to add.
"Remove" Column: Mark "x" in the box this CON application seeks to decertify.
"Proposed" Column: Mark "x" in the box corresponding to all the services that will ultimately appear on the OpCert.

Category/Authorized Service	Code	Current	Add	Remove	Proposed
		☐	☐	☐	☐
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		☐	☐	☐	☐

Does the applicant have any previously submitted Certificate of Need (CON) applications that have not been completed involving addition or decertification of beds?

☐ No

☐ Yes (*Enter CON numbers to the right*) ______ ______ ______