Pacific Medical Dialysis Services, LLC

Exemption of Certificate of Need for Dialysis services

Certificate of Need Program
Washington State Department of Health
Attn: Eric Hernandez, Program Manager
PO Box 47852
Olympia, WA 98504-7852

Date: 3/15/2023

Dear Mr. Hernandez:

I am writing to you on behalf of our company, Pacific Medical Dialysis Services, LLC, and our site for our service, **Park Rose Care Center,** to request an exemption from needing a Certificate of Need (CON), and that Pacific Medical Dialysis Services, LLC planned Home Hemodialysis ("HHD") standalone program to provide dialysis in SNF/NF is not subject to CON review.

The proposed HHD Program will NOT provide in-center dialysis, rather it will provide home hemodialysis services to residents within the SNF/NF that would contract out our services.

We are also requesting this review to go through the expedited review process, in accordance with the WAC 246-310-150.

A check for the review fee of $1,925.00, per WAC 246-310-990(1), has been mailed separately.

About Park Rose Care Center

Park Rose Care Center is a 139 bed Skill Nursing facility located at 3919 S. 19th Street, Tacoma. We serve a diverse populatin of vulneratble adults, many of whom require ventilator and tracheostomy care and services. This type of care is only avaible at six facilities in the state of Washington.

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About Pacific Medical Dialysis Services, LLC (Pac MSG)

We are part of a multispecialty group, called Pacific Medical Specialty Group LLC (providing multispecialty care to SNF/NF residents), and we provide home hemodialysis services strictly to SNF/NF residents. The idea for this service was born after observing a need in a specific population that wasn't being met on many levels. To start, the ESRD population within the SNF/NF have to be transported to and from an outpatient dialysis center at least three times a week, which is not only time consuming and tiresome for patients, but also carries the risk of complications during transport. From the SNF/NF standpoint, this is also a huge financial burden to provide transportation, staffing, etc. Our hope is to bridge this gap for the patients as well as the facilities while providing a better continuity of care.

A Description of the Services Proposed:

In the US, patients over 65 make up 52% of the annual incident dialysis patients as per USRDS Renal data Extraction and referencing system. In 2015-2017, it was noted that 6.9% of ESRD patients resided in a skilled nursing facility, which is likely an underestimate. However, much of the medical literature is virtually blind to SNF dialysis residents, and the dialysis care for these patients are very heterogeneous. Dialysis delivered in a SNF/NF is defined by the Centers for Medicare & Medicaid Services (CMS) ESRD Conditions for Coverage (CfC) as home dialysis.[1] Our goal is to provide comprehensive care for these residents with cooperative care from the primary care providers and other subspecialties. We are proposing a service for the SNF/NF using the home dialysis model. As you are aware, by definitions outlined by the SSA (Social Security Act) 1919, which defines people occupying a nursing facility or skilled nursing care as "residents," or the Oxford dictionary which also defines a resident as "a person who lives somewhere permanently or on a long-term basis," this would conclude that a person who resides in a SNF/NF is no different than someone who resides in their respective home/apartment/place of residence. To carry out our proposal, we will work with the SNF/NF to train and educate the employee designated and hired by the SNF/NF to perform dialysis duties. The training and education will be provided by the staff of Pac MSG on how to perform individual dialysis on SNF/NF patients. For each individual SNF/NF patient, they will have individualized home hemodialysis education by our dialysis education staff/Nurse (Pac MSG). We will monitor their techniques and analyze their troubleshooting of dialysis related problems so that they can independently run dialysis for these patients 3-4/week pending prescription. Staff of Pac MSG will continue with our monthly visits with each patient and his/her caregiver/dialysis performer and will be available for any questions if any issues arise.

During the SNF/NF stay, we will also plan to do joint IDT monthly meetings with SNF/NF staff, dietician, social worker, and PacMSG dialysis staff/including MD, to provide comprehensive care for our ESRD patients. I think this will bring a better awareness of caring for ESRD populations in the SNF/NF staffs.

We will be using Outset Tablo machines, FDA approved for in-facility and home dialysis, which will use tap water through the built-in internal water purification system to generate on-demand dialysate. These machines will provide mobile dialysis capability to SNF/NF dialysis residents allowing for treatments at bedside within the SNF/NF.

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[1] Center for Clinical Standards and Quality, CMS QSO 18-22-ESRD https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/QSO18-22-ESRD.pdf

New proposed/planned additional services:
For patients who are newly diagnosed with ESRD, if the hospital social worker is NOT able to find a suitable outpatient dialysis placement for the patient and the patient is then transferred out to the SNF/NF, we will work with the SNF/NF social worker to help continue the search for placement into their outpatient dialysis units. The ESRD patients will not be able to be discharged from SNF/NF until outpatient placement is determined and confirmed.

Our additional proposed service also includes identification of residents/patients with capability and/or family support to transition to home dialysis at their permanent residence. We are planning to provide home training to patients and their care partners at our office in **3919 S 19th St, Tacoma, WA 98405**, to help the family member/care-taker to be fully trained for home hemodialysis, if they desire. After this training and transition takes place, they will follow up with their respective outpatient nephrologist. Increasing access to home dialysis aligns with CMS initiatives to encourage its use through the End Stage Renal Disease (ESRD) Treatment Choices (ETC) model which was derived from the Federal government's Advancing American Kidney Health (AAKH) initiative. This will allow enhanced rehabilitation and autonomy for ESRD patients.

In the case that we identify a possible home hemodialysis candidate, and they are motivated and capable for most of the treatment but will still need assistance, and we aren't able to secure a care partner/care-taker/family member, we will work with the social worker to explore all options for the patient to be able to go home as a home hemodialysis patient. This could include searching for possible grant options through the RRF/Foundation for Aging to finance a care-taker.

We are also planning to help with respite care for our dialysis caretaker both at home and SNF/NF. If a need arises where the SNF/NF dialysis administrator, or home dialysis care-taker needs vacation/respite care, we will coordinate care with PacMSG staff/locums to help cover those days.

Where it is performed:
In each SNF/NF, dialysis machines will be brought to each SNF/NF, and the SNF/NF staff will perform the dialysis.

Who performs the treatment:
During the SNF/NF stay, the SNF/NF staff will provide the ESRD residents with hemodialysis at the convenience of their "home". We will have policies in places to work collaboratively with SNF/NF nurses/staff, in case of emergencies, medication distribution, vitals, etc. We will provide our own staff/nurse to educate SNF/NF staff regarding dialysis and troubleshooting as defined by above. We will work collaboratively with SNF/NF social workers and dietician/nutritionist to provide comprehensive care to the ESRD SNF/NF residents.

Estimated Cost of the Proposed Project:
We are planning to start off at one location in Burien with two dialysis machines from Outset. We will start out initially by securing one nurse and one technician/facility administrator, as well as securing supplies for dialysis, as well as catheter care, and AVF/AVG care pre- and post-dialysis. We are planning

to start off with 2 patients, up to a maximum of 4 patients. We will also have to secure bundled payment medications. We will not have any facility build out costs as part of this model. We are projecting an annual expense of $500,000.

Description of the Service Area:
During the SNF/NF stay, the ESRD residents will get dialysis bedside or in the comfort of their room.

Reason For Our Request of Exemption from CON Review

The Department may only require a CON for those activities identified in the CON statutes. CON-reviewable activities include (1) "[t]he construction, development, or other establishment of a new health care facility," RCW 70.38.105(4)(a), which includes "kidney disease treatment centers," RCW 70.38.025(6) (defining "health care facility"), and (2) "[a]ny increase in the number of dialysis stations in a kidney disease center." RCW 70.38.105(4)(h). "Kidney disease treatment center" is not defined in the CON statutes, but it is defined by the Department in regulation, as "any place, institution, building or agency or a distinct part thereof equipped and operated to provide services, including outpatient dialysis." WAC 246-310-800(10) (emphasis added).

Therefore, the plain language of the regulatory definition is directed at "outpatient dialysis" facilities that provide in-center dialysis care and stations, not dialysis to be provided at "home". "Home" is defined as a place of residency of which a SNF/NF qualifies as such under the CMS ESRD CfCs. The Department defines "Nursing Home" as "home, place or institution which operates or maintains facilities providing convalescent or chronic care, or both, for a period in excess of twenty-four consecutive hours for three or more patients not related by blood or marriage to the operator, who by reason of illness or infirmity, are unable properly to care for themselves." Convalescent and chronic care may include but not be limited to any or all procedures commonly employed in waiting on the sick, such as administration of medicines, preparation of special diets, giving of bedside nursing care, application of dressings and bandages, and carrying out of treatment prescribed by a duly licensed practitioner of the healing arts", RCW 18.51.010 (3), which can mean that these are considered the place of residence and thus likely will be "Home" for these residents. Additionally, "a term in a regulation should not be read in isolation but rather within the context of the regulatory and statutory scheme as a whole." Odyssey Healthcare Operating BLP v. Wash. State Dept. of Health, 145 Wn. App. 131, 142 (2008) (interpreting CON rules governing hospice agencies). The context of the dialysis rules makes it overwhelmingly clear that the "kidney disease treatment centers" subject to CON review are in-center outpatient dialysis facilities. Everything in the CON rules is based around determining the need for in-center hemodialysis stations and approving a sufficient number of in-center stations to meet that need.

Stations are a concept applicable to in-center hemodialysis; methodology in the WAC used for calculating patient need describes the number of patients per station and pertains to in-center hemodialysis patients. Stations are not part of our proposed "Home" SNF/NF treatments; instead, our services are to provide a service/hemodialysis in the comfort of the patient's "Home".

The code ensures an appropriate level of statewide in-center hemodialysis services through a rigorous station need methodology described in WAC 246-310-812. It starts by defining that the need methodology relates to "applications for new stations' ' in WAC 246-310-812 (1). WAC 246-310-812 (2) then clearly defines the in-center hemodialysis patient census information that determines the need for CON applications: "Data used to project station need must be the most recent five-year resident end-of year in-center patient data available from the Northwest Renal Network...". This explicitly focuses the application on in-center hemodialysis projects and explicitly excludes "Home SNF/NF HD" patients and the programs which serve from the needs build-up.

The ensuing statutes in WAC 246-310-812 make extensive and consistent references to the detailed methodology that solely references in-center hemodialysis. For example, the statutes determine "the number of dialysis stations projected as needed in a planning area" (246-310-812(4)) and the department criteria for approving "new in-center kidney dialysis stations" in two types of planning areas that are defined based on utilization of in-center kidney dialysis stations(246-310-812(5) and (6)). Additional areas of code also highlight that need is based on in-center station availability WAC 246-310-818, WAC 246-310-821, and WAC 246-310-824 and thus irrelevant for home dialysis.

In our technical assistance conversation with the Department to prepare this determination request, ESRD network mentioned that "Stand-alone Home HD unit" was specifically taken out of the methodology used for calculating and addressing in-center hemodialysis needs.

The above regulatory analysis should be sufficient to determine that Pacific Medical Dialysis Services LLC is not CON reviewable, and that our goal is to provide overall better patient care in our vulnerable ESRD population in SNF/NF setting.

Aside from the convenience aspect of the patients and SNF/NF, we as providers are fully aware of the increased risk of exposure to transmittable diseases that are highly susceptible to our elderly ESRD patient population with multiple co-morbidities. Especially now, as the world is still adjusting to the reality of living in an on-going pandemic, it is even more critical and essential to eliminate any areas of increased exposure not only to COVID-19, but other viruses that can be lethal to this population such as flu to name a few. Another ripple effect of the pandemic that all healthcare facilities and hospitals are facing and struggling with is the shortage of staff and resources. By providing "home hemodialysis" within the SNF/NF, our hope is to relive some of this burden for the staff so they can focus on better patient care and outcomes. This benefit should also extend out to the hospital and in-center dialysis facilities that are over-burdened with the increasing need for outpatient in-center placement while juggling shortage of staff, providers, and resources. We are hopeful that this balance will help relive provider fatigue, facility burden and restore better patient outcomes and satisfaction.

Aside from these logistical benefits by implementing our model/system, we also cannot stress enough the improvement of cardiovascular surrogates (names LV mass), as well as quality-of-life indicators for these more frequently dialyzed home hemodialysis vs conventional thrice weekly in-center dialysis.[2]

[2] J Am Soc Nephrol. 2012 May; 23(5): 895–904, Survival in Daily Home Hemodialysis and Matched Thrice-Weekly In-Center Hemodialysis Patients, E.D. Weinhandl, J. Liu, D.T. Gilbertson, T.J Arneson, and A.J. Collins

These may be small things, but to our vulnerable ESRD populations with multiple co-morbid conditions, these small things matter in their quality-of-life, which is my main belief in my care of my patients.

CONCLUSION

In conclusion, based on the totality of information provided, including a review of Chapter 70. 38 RCW and WAC 246-310, the HHD-only at SNF/NF program proposed by Pacific Medical Dialysis Services LLC is not included under the definition of "kidney disease treatment center" and is therefore not subject to CON review. This decision is limited to the facts presented in this determination of reviewability. The above analysis is applicable under the current kidney dialysis rules. We look forward to your participation as a part of this dynamic discussion.

If you have any questions about this project, or if the Department needs any additional information to make our requested reviewability determination, please do not hesitate to contact me.

Sincerely,

Charles Minn, MD, FASN, FACP
Senior VP & Clinical Specialty Services
Pacific Medical Dialysis Services LLC/Pacific Medical Specialty Group LLC

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