

DEPARTMENT OF HEALTH

Olympia, Washington 98504

STATE OF WASHINGTON

May 3, 2019

CERTIFIED MAIL # 7018 2290 0001 8591 8315

Evan Moore, Special Projects Director DaVita, Inc.-North Star Division Office 32275 – 32nd Avenue South Federal Way, Washington 98001

RE: CN Application #18-58 – Green Lake Dialysis Center

Dear Mr. Moore:

We have completed review of the Certificate of Need application submitted by DaVita, Inc. proposing to establish a 19-station dialysis center in King County planning area #1. Enclosed is a written evaluation of the application.

For the reasons stated in this evaluation, the department has concluded that the project is not consistent with the Certificate of Need review criteria identified below, and a Certificate of Need is denied.

Washington Administrative Code 246-310-240

Cost Containment

This decision may be appealed. The two appeal options are listed below.

Appeal Option 1:

You or any person with standing may request a public hearing to reconsider this decision. The request must state the specific reasons for reconsideration in accordance with Washington Administrative Code 246-310-560. A reconsideration request must be received within 28 calendar days from the date of the decision at one of the following addresses:

Mailing Address:
Department of Health
Certificate of Need Program
Mail Stop 47852
Olympia, WA 98504-7852

Physical Address
Department of Health
Certificate of Need Program
111 Israel Road SE
Tumwater, WA 98501

Evan Moore, Special Projects Director DaVita, Inc.-North Star Division Office Certificate of Need Application #18-58 May 3, 2019 Page 2 of 2

Appeal Option 2:

You or any person with standing may request an adjudicative proceeding to contest this decision within 28 calendar days from the date of this letter. The notice of appeal must be filed according to the provisions of Revised Code of Washington 34.05 and Washington Administrative Code 246-310-610. A request for an adjudicative proceeding must be received within the 28 days at one of the following addresses:

> Mailing Address: Department of Health Adjudicative Service Unit Mail Stop 47879

Olympia, WA 98504-7879

Physical Address Department of Health Adjudicative Service Unit

111 Israel Road SE Tumwater, WA 98501

If you have any questions, or would like to arrange for a meeting to discuss our decision, please contact the Certificate of Need Program at (360) 236-2955.

Sincerely,

Nancy Tyson, Executive Director

Health Facilities and Certificate of Need

Enclosure

YEAR 2018 CYCLE 1 NON-SPECIAL CIRCUMSTANCE EVALUATION DATED MAY 3, 2019, FOR THE FOLLOWING THREE CERTIFICATE OF NEED APPLICATIONS PROPOSING TO ADD DIALYSIS STATION CAPACITY IN KING COUNTY PLANNING AREA #1

- NORTHWEST KIDNEY CENTERS PROPOSING TO ADD 19 DIALYSIS STATIONS TO NKC LAKE CITY KIDNEY CENTER IN LAKE FOREST PARK
- PUGET SOUND KIDNEY CENTERS PROPOSING TO ESTABLISH A 19-STATION DIALYSIS CENTER IN SHORELINE
- DAVITA, INC PROPOSING TO ESTABLISH A 19-STATION DIALYSIS CENTER IN SEATTLE

APPLICANT DESCRIPTIONS

Northwest Kidney Centers

Northwest Kidney Centers (NKC) is a private, not-for-profit corporation, incorporated in the state of Washington. Established in 1962, NKC operates as community based dialysis program working to meet the needs of dialysis patients and their physicians. A volunteer board of trustees governs NKC and the board is comprised of medical, civic and business leaders from the community. An appointed Executive Committee of the Board oversees operating policies, performance and approves capital expenditures for all of its facilities. [source: CN historical files and Application, p3 and Exhibits 1 and 2]

NKC provides dialysis services through its facilities located in King, Clallam, and Pierce counties and does not own or operate any healthcare facilities outside of Washington State. In Washington State, NKC is approved to own and operated 17 kidney dialysis facilities.¹ Of the 17 facilities, 15 are located within King County; one in Pierce County; and one in Clallam.² Below is a listing of NKC's dialysis facilities in Washington. [source: Application, Exhibit 3 and CN historical files]

King County

Auburn Kidney Center
Broadway Kidney Center
Elliot Bay Kidney Center
Enumclaw Kidney Center
Federal Way Kidney Center
Kent Kidney Center
Kirkland Kidney Center
Lake City Kidney Center

King County

Lake Washington Kidney Center
Renton Kidney Center
Scribner Kidney Center
Seattle Kidney Center
SeaTac Kidney Center
Snoqualmie Ridge Kidney Center
West Seattle Kidney Center

Clallam County

Port Angeles Kidney Center

Pierce County

Fife Kidney Center

Puget Sound Kidney Centers

Puget Sound Kidney Centers (PSKC) is a not-for-profit entity that provides kidney dialysis services in Washington State. PSKC was established in 1981 as a community-based provider in northern Snohomish County, and is governed by a board of directors and 5-member executive team that includes the

¹ The department acknowledges that NKC has submitted an application to establish an additional dialysis center in Everett, within Snohomish County (CN Application #18-50). As of the writing of this evaluation, a decision on the Snohomish County project has not been released.

² Of the 17 Northwest Kidney Center facilities two are recently CN approved and not yet operational. The two facilities are Federal Way Kidney Center and Fife Kidney Center.

president/CEO, chief financial officer, chief operating officer, chief medical officer, and an executive director for the PSKC Foundation. [source: PSKC website and application, pdf5]

PSKC provides dialysis services through its facilities located in Island, Skagit, and Snohomish counties and does not own or operate any healthcare facilities outside of Washington State. In Washington State, PSKC is approved to own and operated a total of seven dialysis facilities. Of the seven facilities, one is located in Island County, one in Skagit County, and five are in Snohomish County. PSKC also operates a mobile dialysis service that provides dialysis services to patients in area hospitals. Below is a listing of the PSKC dialysis facilities in Washington. [source: Application, pdf6]

Skagit	Snohomish
PSKC – Anacortes	PSKC – Everett
	PSKC – Monroe
Island	PSKC - Lakewood
PSKC – Whidbey Island	PSKC – South
	PSKC – Smokey Point

DaVita, Inc.

DaVita submitted this application under its subsidiary of Total Renal Care, Inc. For Certificate of Need purposes, DaVita, Inc. is the applicant. DaVita is a national provider of dialysis services operating in 45 states and the District of Columbia. In Washington State, DaVita is approved to own and operate a total of 42 dialysis centers in 19 separate counties. Listed on the following page are the names of the facilities owned or operated by DaVita in Washington State. [source: CN historical files and Application, pp5-8]

Benton	Pierce
Chinook Dialysis Center	Graham Dialysis Center
Kennewick Dialysis Center	Lakewood Community Dialysis Center
•	Parkland Dialysis Center
Clark	Puyallup Community Dialysis Center
Vancouver Dialysis Center	Rainier View Dialysis Center
Battle Ground Dialysis Center	Tacoma Dialysis Center
·	•

ChelanSkagitWenatchee Valley Dialysis CenterCascade Dialysis Center

³ The department acknowledges that PSKC has submitted applications to establish additional dialysis centers in the counties of Thurston (#19-31) Kitsap (#18-52), King (#18-53), and another center in Snohomish (#18-55). As of the writing of this evaluation, decisions on these projects have not been released.

⁴ Of the seven Puget Sound Kidney Center facilities, PSKC Lakewood is recently CN approved and not yet operational.

⁵ DaVita operates in 45 states and the District of Columbia. The five states where DaVita is not located are: Alaska, Delaware, Mississippi, Vermont, and Wyoming.

⁶ The department acknowledges that DaVita has submitted applications to establish additional dialysis centers in the counties of Cowlitz (#19-37), King (#18-59 & #19-39), Kitsap (#19-38), Snohomish (#18-63), Spokane (#18-62), and Thurston (#18-60). As of the writing of this evaluation, decisions on these projects have not been released.

Douglas

East Wenatchee Dialysis Center

Franklin

Mid-Columbia Kidney Center

Island

Whidbey Island Dialysis Center

King

Bellevue Dialysis Center Federal Way Dialysis Center Kent Dialysis Center Olympic View Dialysis Center Renton Dialysis Center Redondo Heights Dialysis Center Westwood Dialysis Center

Kittitas

Ellensburg Dialysis Center

Lewis

Cooks Hill Dialysis Center

Mason

Belfair Dialysis Center

Pacific

Seaview Dialysis Center

Snohomish

Everett Dialysis Center Lynnwood Dialysis Center Mill Creek Dialysis Center Pilchuck Dialysis Center

Spokane

Downtown Spokane Renal Center North Spokane Renal Center Spokane Valley Renal Center

Stevens

Echo Valley Dialysis Center

Thurston

Olympia Dialysis Center Tumwater Dialysis Center

Whatcom

Mount Baker Kidney Center

Yakima

Mt. Adams Dialysis Center Union Gap Dialysis Center Wapato Dialysis Center Yakima Dialysis Center Zillah Dialysis Center

PROJECT DESCRIPTIONS

Note – each application refers to a 19-station need in King County planning area #1 and frequently refers to this figure. Based on WAC 246-310-800(9), exempt isolation stations are not counted in the methodology. Shortly following the department's first screening, the department sent out a supplemental screening asking all applicants to clarify whether their isolation stations would meet the definition under WAC 246-310-800(9). Though this evaluation will consistently refer to a 19-station need, the approved project(s) would reflect one additional exempt isolation station if identified by the applicant in response to screening.

Northwest Kidney Centers

This project focuses Lake City Kidney Center located at 14524 Bothell Way Northeast in Lake Forrest Park within King County planning area #1. The dialysis center currently provide the following services:

- Outpatient maintenance hemodialysis.
- Isolation in a private room.
- A bed for patients who are unable to dialyze in an upright position.
- Home peritoneal and home hemodialysis training.
- Back up support treatments for both home hemodialysis and home peritoneal dialysis patients.
- Hemodialysis services for visitors.
- Shift beginning after 5:00 PM.

The addition of 19 stations to Lake City Kidney Center will not change the services currently provided. [source: Application, p6]

In order to add the 19 dialysis stations to Lake City Kidney Center, NKC will first relocate administrative and support services located at the center to a new site. The administrative and support space will then be remodeled to accommodate 10 of the 19 stations. The 10 new stations are expected to be operational by the end of April 2021. Remodel of new space at Lake City Kidney Center is necessary to accommodate the remaining 9 stations. NKC expects the 9 stations would be operational by the end of June 2021. [source: Application, p4 and July 31, 2018, screening response, pp1-2]

At project completion, Lake City Kidney Center would be operating a total of 35 in-center dialysis stations and three isolation stations. Within the application, NKC acknowledged that only one of the three isolation stations will not be counted in the numeric methodology as allowed under WAC 246-310-809. [source: Application, p4]

The total capital expenditure for this project is \$11,238,608, which includes costs for relocation of the administrative and support services and the addition of 19 stations. [source: Application, p18 and July 31, 2018, screening response, p4]

Public Comment

During the review of NKC's project, DaVita expressed two concerns with the process NKC used to submit its project. DaVita's concerns are: 1) NKC's project is phased; and 2) NKC's project and the letter of intent submitted for the project are inconsistent. [source: DaVita September 5, 2018, public comment, pp1-3]

Phased Project

"NKC proposes an expansion by nineteen stations from its existing eighteen-station facility in Lake City, King County ESRD Planning Area #1, to a 37 (38 with exempt isolation station)-station facility, to be done in three phases. In the Department's decision in Pierce County Planning Area #5, issued March 30, 2017, the department allowed applicants to propose phased projects, due to the unusual size of the 44-station award, as an exception to its general policy of not allowing phased dialysis facility projects. As the Department stated in its evaluation, quoting its memorandum dated March 29, 2016:

... It should be noted, the department does not ordinarily accept phased projects or subprojects within applications for kidney dialysis facilities. The department's decision to accept these phased applications was based on the unusually high need specific to the Pierce #5 planning area. It should not be assumed the department will accepted phased kidney dialysis applications in the future.

In NKC's case, it has explicitly rejected the two options of a smaller facility remodel, or a new facility in the planning area. It has also specifically proposed a three-phase project, when the Department has clearly indicated these projects are not normally accepted within applications for kidney dialysis facilities. Therefore, not only has NKC rejected two options to provide a smaller facility favored by the Department, but it has explicitly proposed a multi-phased project in direct contradiction with the Department's explanation of its normal procedure outlined in the Pierce 5 decision. The Department should reject NKC's application in King County Planning Area #1 due to this inconsistency.

Letter of Intent and Project are Inconsistent

In its LOI, NKC simply proposed "to add 19 stations" to its facility. (NKC application, Ex. 4.) It said nothing about sub-projects, i.e., discreet phases within the proposed expansion.

The Program recently denied DaVita applications in King 10 and Pierce 4 because DaVita's applications included smaller alternatives not identified in the respective LOIs. Specifically, the Program denied those DaVita applications because the inclusion of a smaller alternative in an application "proposes a project that is significantly different than proposed in the letter of intent," under WAC 246-310-080(3), making "the application the letter of intent," which means the application is untimely under the concurrent review schedule for dialysis applications.

NKC was the beneficiary of the Department's actions in King 10 and Pierce 4. Its competing applications were approved. Yet here, NKC has effectively done the same thing DaVita did in King 10 and Pierce 4, which resulted in the denial of DaVita's application.

In its May 1 letter of intent, NKC described its project as follows: "NKC is proposing to add 19 stations to the existing NKC Lake City Kidney Center dialysis facility." (Application, Ex. 4.)

In its June 1 application, NKC described its project as a three-phase expansion. Phase 1 would involve continuing to operate 18 stations, but in a different location. Phase 2 would involve expanding the facility by 10 stations, thus allowing the operation of a 28-station facility for a period of time. Phase 3 would involve adding 9 additional stations, thus allowing the operation of a 37-station facility. (Application, pp.3-4.) In King 10 and Pierce 4, DaVita's applications were consistent with its LOIs in terms of the total number of stations, but its applications included smaller alternatives. The Department determined that this was impermissible. Here, NKC's application is consistent with its LOI in terms of the total number of stations, but its application includes three smaller phases. This is an even more significant difference than was the case for DaVita's applications. In King 10 and Pierce 4, DaVita's "plan A" in its application was exactly the project described in its LOI. Here, the only plan in NKC's application is different from its LOI; indeed, its 18-station, 10-station, and 9-station phases are not even referenced in its LOI.

Again, this is not Pierce 5. There, the Department explicitly allowed phased projects, so no applicant could have been surprised if a competitor followed this advice and included phasing in its application. Here, if NKC wished to pursue a phased project, in contravention of the Department's stated policy that phasing and sub-projects "ordinarily" will not be allowed for dialysis facilities, at minimum NKC should have disclosed this in its LOI. Because it did not do so, its application proposes a project "significantly different" than that described in the LOI, and therefore its application becomes the LOI, which is untimely under the concurrent-review schedule.

The Department must be consistent in its application of its rules. Accordingly, it should deny NKC's application here for the same reason it denied DaVita's applications (and approved NKC's competing applications) in King 10 and Pierce 4."

PSKC also provided comments on NKC's application that focus on the phases and the timeline for opening the new facility. PSKC's comments are restated below. [source: PSKC September 5, 2018, public comment, p7]

"NKC proposes a three-phased renovation of its existing NKC Lake City facility. The total capital expenditure of the renovation is \$11,238,608. Phase 1 of their project will be completed by March 2020, but this Phase does not increase station capacity. Phases 2 and 3 will be completed in 2021. NKC's application states that its stations will be prepared for survey by June 2021. Per WAC 246-310-812, there is need in King 1 in 2018 for 12 additional stations, and 16 of the 19 needed stations are needed by 2020."

Rebuttal Comment

NKC provided rebuttal comments in response to the two topics above. [source: NKC, October 5, 2018, pp2-3]

Phased Project

"In its application and screening responses, NKC explained- in detail- how it plans to convert its existing 18-station Lake City facility to a state of the art 37-station facility that will provide a superior care environment and meet the need for 19 new stations in the King One planning area. In its comments, DaVita criticizes NKC's detailed explanation of its project, arguing that the Program should reject NKC's application as "inconsistent" with the Program's "general policy" against "phased" projects.

DaVita's attack is mistaken. NKC's project will add 19 stations to the existing complement in the King 1 planning area by June 2021, all in strict compliance with the requirements in WAC 246-310-200 through 240. NKC's Lake City facility includes both clinical and non-clinical spaces. In the first phase, we are building and relocating all 18 existing stations into another part of our same building before constructing the space for the new 19 stations within our application. We identified this "phase" in order to provide a completely transparent roadmap of the process. The remaining two "phases" represent less than a 60-90 day process in the staging or "phasing" of the delivery of the new stations during the course of a single construction project. This does not in any way affect the project's compliance with the CN rules- it simply notes when the stations are expected to come online. Had NKC stated that **all** of the stations would be available in June 2021, DaVita would have no complaint; the fact that approximately half of the new stations will be available a few months earlier does not change the substance of the project or its compliance with the CN laws. DaVita does not cite any requirement that is violation by NKC's detailed disclosures, nor does it cite any precedent for rejecting a project like NKC's. DaVita invites the Program to commit legal error for no apparent reason other than advancing its own economic interest.

Ironically, DaVita itself proposes a "phased" project in Snohomish Two. Here, DaVita proposes to relocate its existing facility to Mukilteo and then add 9 stations. DaVita's screening response indicates that the existing facility will be operational until January 2021 and the new facility will be operational by February 2021."

Letter of Intent and Project are Inconsistent

"Still stinging from errors in the letters of intent that it submitted in the King Ten and Pierce Four planning areas (in which DaVita submitted LOIs for projects that were **larger** than the indicated need, defects that it then tried to cure by presenting compliant "alternatives" in its applications), DaVita argues that the Program should reject NKC's application on the grounds that it impermissibly includes "three smaller phases." Da Vita's critique is without merit.

As DaVita reluctantly acknowledges, "NKC's application is consistent with its LOI in terms of the total number of stations." Da Vita's applications in King Ten and Pierce Four were not. NKC's LOI stated its intent to add 19 stations to its Lake City facility; its application proposes a project to add 19 stations to its Lake City facility. NKC's application does not "propose" a project that is significantly different than that proposed in the letter of intent," WAC 246-310-080(3) (emphasis added), and there is no colorable argument that its identically-sized project can be considered a new letter of intent under the applicable law. An application that is "consistent" with an "LOI" is, by definition, not significantly different. Da Vita's argument fails."

Department Evaluation of Public Comment

In the application, NKC presented the project in the three phases described below:

- Phase one is the relocation of the administrative and support services to a new site;
- Phase two is the remodel of space and the addition of ten stations.
- Phase three is the remodel of space and the addition of nine stations.

Regardless of how the project is presented, the department does not consider it a phased project. This rationale is two-fold. First, the relocation of the administrative and support services does not require prior Certificate of Need review and approval. Internal information obtained from the Department of Health's Office Health Systems Oversight confirms that while administrative and support services are required to be available, they are not required to be on-site at a dialysis center. NKC's explanation of the 'phase one' clarifies that they intend to build out space and relocate all 18 existing stations into another part of the building before constructing the space for the new 19 stations. Again, this action does not require prior Certificate of Need review and approval because it is not the relocation of a dialysis center as described in WAC 246-310-830. The costs for this portion of the project must be included in the capital expenditure because it is necessary to complete this portion before the 19 stations can be added.

Second, NKC projects that the first 10 stations would be operational in April 2021 and the remaining 9 stations would be operational two months later—in June 2021. A 60 day difference in adding stations under one construction project is not a phased project.

For comparison purposes, DaVita submitted an application in May 2016 proposing to add 15 dialysis stations to its existing Lakewood Community Dialysis Center. The project was approved in March 2017 and CN #1597 was issued on April 12, 2017. Contrary to the project description provided in the application, DaVita implemented its project similar to NKC's project at Lake City Kidney Center. DaVita added 14 dialysis stations by the end of June 2017 and then added the 15th station by the end of December 2017. [source: September and December 2017 progress reports for CN #1597] The department did not consider the implementation of DaVita's project to be phased, nor was the project presented as phased in the application.

Focusing on the comments regarding the inconsistency between the NKC letter of intent and the application, the department disagrees with DaVita's assertions. The example provided by DaVita is not an apples-to-apples comparison. In DaVita's example, a letter of intent was submitted for the establishment of a dialysis center with 13 stations. In contrast, the application that was submitted requested either a 13 station facility or a 10 station facility. NKC is not requesting to add 10 stations or 19 stations, the application requests to add 19 stations.

In conclusion, the NKC project is not a phased project because, if approved, the department would approve the addition of 19 stations, not a lesser number. Further, the NKC's letter of intent and application are consistent. The two concerns are not grounds for denial of NKC's project.

Puget Sound Kidney Centers

PSKC proposes to establish a new 19-station dialysis center at 355 Richmond Beach Road in Shoreline [98177] within King County planning area #1. The new center would be known as PSKC Richmond Beach. Services to be provided at the new dialysis center include in-center hemodialysis, home hemodialysis and

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⁷ Certificate of Need application #16-34 submitted May 31, 2016.

⁸ For demonstrative purposes the department uses the Pierce County planning area #4 example. It is noted that the King County planning area #10 issue was similar, with the exception of a letter of intent for 11 new stations and the application requested either 11 stations or 9 stations. [March 10, 2017, letter to DaVita and NM2017-349 Initial Order dated July 12, 2017 and Final Order dated March 6, 2018.]

home peritoneal dialysis training, isolation capabilities, and a permanent bed station. There will also be a patient shift starting after 5pm. [source: Application, pdf7]

If approved, PSKC expects the 19-station dialysis center would be operational by the end of October 2020. [source: Application, pdf7]

The total capital expenditure for this project is \$8,538,099, which includes costs for purchasing the building and construction costs, equipment, and associated fees and taxes. [source: Application, pdf21]

Public Comment

During the review of PSKC's project, DaVita expressed concerns with the data PSKC used in its application. DaVita's concerns are restated below. [source: DaVita September 5, 2018, public comment, p2]

PSKC's Application Violates WAC 246-310-827(3)(c)

"PSKC's application violates WAC 246-310-827(3)(c), which provides: "The number of applications per concurrent review cycle that rely on the same three comparables is limited to two." This limitation is clear and unambiguous. Yet PSKC filed four applications relying on the same three comparables during this cycle, including this one.

The CON dialysis rules, including the limitation set forth in 827(3)(c), were developed with the input of the existing dialysis providers, including PSKC. All providers other than PSKC have complied with this rule and refrained from filing more than two applications relying upon the same three comparables. Unlike all of the other applicants, PSKC chose not to comply with the limitation set forth in 827(3)(c). Instead, PSKC chose to violate the regulation by filing four applications relying on the same three comparables.

If the Program were to allow PSKC to "withdraw" two of its applications at this time, this would reward PSKC for violating the Department's rules and give it an unfair advantage over the other applicants, each of whom complied with the 2-application rule. Specifically, PSKC now has the benefit of not only knowing where other providers have applied, but also having the opportunity to review the applications with which it would have to compete in these planning areas, the screening questions and responses relating to those competing applications, and even competitors' comments on PSKC's own applications. Therefore, PSKC would be able to choose where to move forward based on this information. If PSKC were allowed to ignore the 827(3)(c) limitation and then "correct" this by later withdrawing applications, this would set a destructive precedent and lay the following blueprint for future application cycles: Providers should file as many applications as they can relying upon the same three comparables and then, when they see where others have applied and have assessed the strength of those competing applications, they should strategically withdraw some of their applications to bring two into compliance with 827(3)(c). This would distort what is supposed to be a fair and transparent process where applicants cannot file more than two applications relying on the same three comparables.

The Program has a history of strictly enforcing the CON rules governing dialysis applications. For example, the Program recently rejected DaVita's applications in King 10 and Pierce 4 because smaller options identified as alternatives in the applications were not identified in DaVita's LOIs, which the Program determined was inconsistent with WAC 246-310-080. Consistent with its past practice, and in the interest of fairness, the Program should deny PSKC's application here under 827(3)(c)."

Rebuttal Comment

[source: PSKC October 5, 2018, rebuttal comment, pp5-6]

"PSKC submitted a total of five applications in Cycle 1 2018. One of these five applications (Snohomish 1) uses a different set of three closest facilities than do the other four. Another application (Kitsap) did not face any competing applications. We thus believed that neither of those applications (Snohomish 1 and Kitsap) were subject to the limitations of WAC 246-310-827(3)(c).

Of the three remaining PSKC applications, one (Clark) is competing only against a provider (Fresenius) that has facilities in the same planning area, but they are operating below 4.5; as such, we believed that their competing application should have been withdrawn, but in any case, we fully expect that the CN Program will conclude that the Fresenius application fails on the basis of WAC 246-310-240 without any need to reach the superiority analysis of WAC 246-310-827. As such, we were and remain confident that we did not have more than two applications that would be subjected to a superiority analysis relying on the same three closest facilities.

In recent conversation with the CN Program, we have been advised that the CN Program does not in fact intend to ask Fresenius to withdraw its Clark application prior to its final analysis, despite the obvious failures of their application. The CN Program has further indicated that, notwithstanding whether the Clark applications will be resolved without resort to the superiority factors, if at the time of the CN Program's analysis of King 1 (projected to be prior to the analysis of Clark) there are still two additional applications relying on the same three closest facilities, the CN Program would reject the King 1 application under WAC 246-310-827(3)(c)- even though, were the order reversed and the Clark application resolved first, there would be no such barrier to both applications being approved.

PSKC disagrees with this interpretation of the rule. We were actively involved in the nearly three years of rulemaking that resulted in these current rules. We retained a very complete and comprehensive set of notes from that process. Our review of the discussion was that the rule was intended to stop applicants from submitting multiple applications in the same planning area, and then "pulling" all but one of them after the close of rebuttal-a cynical and wasteful gamesmanship strategy historically relied upon by DaVita in particular. The rule was never intended to prevent legitimate growth by well-qualified providers. The irony of DaVita's purported concerns about gamesmanship by other applicants is not lost on PSKC.

That said, PSKC respects its longstanding relationship with the CN Program and wishes to avoid the legal complications and delays that often follow disagreements of this sort. PSKC has been in conversation with the CN Program and we have received confirmation that they concur that PSKC can voluntarily remove two of its applications from consideration, such that no more than two applications have the same three closest facilities, and that doing so will fully remedy any potential WAC 246-310-827(3)(c) issues in the remaining three applications. Accordingly, and in reliance on those communications from the CN Program, PSKC is taking all necessary steps to withdraw its Cycle 1 2018 applications for the Kitsap and Clark planning areas. This renders DaVita's ironic concern moot."

Department Evaluation of Public Comment

To evaluate the concerns raised by DaVita, the department reviewed the PSKC applications submitted during the 2018 cycle 1 review. In fact, PSKC did submit five separate CN applications during the 2018 cycle 1 review. One of the applications was submitted for Clark County. In the August 31, 2018,

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⁹ At the time the 2018 cycle 1 applications were submitted, there were three active analysts in the Certificate of Need Program. PSKC's five applications were distributed as follows: Analyst BH-1 application; Analyst KN-2 applications, and Analyst PA-2 applications. With this distribution, each analyst was not aware that other PSKC

screening for the Clark County project, the department noted that PSKC had used the same comparable facilities in four of the five applications submitted. The comparable facilities are: PSKC Everett, PSKC South, and PSKC Monroe. The department's screening question is restated below. [source: August 31, 2018, DOH screening for CN App #18-54, question #6]

"WAC 246-310-827(3)(b) and (c) provides the following guidance for new facilities.

- (3) When available, Washington facilities must be used as comparables, as follows:
 - (b) For new kidney dialysis facilities, use data for the next three closest facilities as comparables owned by or affiliated with the applicant as measured by a straight line from the proposed new kidney dialysis facility location. Straight lines will be calculated using "Google Maps" or equivalent mapping software (mileage calculated out to two decimal points, no rounding).
 - (c) <u>The number of applications per concurrent review cycle that rely on the same three comparables is limited to two</u>." [emphasis added]

The three facilities used for this Clark County project are PSKC Everett, PSKC South, and PSKC Monroe. These same three facilities were used in four of five PSKC applications submitted under the year 2018 Nonspecial Circumstance Cycle 1 concurrent review cycle. Please explain how this approach by PSKC is consistent with the rule under WAC 246-310-827(3)(c).

Please explain how this approach by PSKC is consistent with the rule under WAC 246-310-827(3)(c)."

In response to the question above, PSKC withdrew two of the five applications (#18-52-Kitsap County and #18-54-Clark County). This action by PSKC resulted in two of three PSKC applications relying on the same comparable facilities which is consistent with WAC 246-310-827(3)(c) above.

DaVita appears to assert that PSKC's application should be denied because it was not consistent with WAC 246-310-827(3)(c) when it was submitted. If PSKC had not withdrawn applications, this application would be denied. However, once PSKC withdrew two applications, the comparable issue no longer exists. As a result, the department concludes that DaVita's rationale to deny PSKC's application under this standard is no longer applicable to this project.

DaVita, Inc.

DaVita proposes to establish a new 19-station dialysis center at 8901 Greenwood Avenue North in Seattle [98103], within King County planning area #1. The new center would be known as DaVita Green Lake Dialysis Center. Services to be provided at the new dialysis center include:

- Hemodialysis patients who dialyze in the chronic setting,
- Hemodialysis patients requiring isolation,
- Hemodialysis patients requiring dialysis in a permanent bed station,
- Hemodialysis patients requiring treatment shifts that begin after 5:00 PM.

Additional services provided will include:

- Treatment for visiting hemodialysis patients from other areas outside King 1, and
- Community education for patients recently diagnosed with Chronic Kidney Disease (CKD).

[source: Application, p8 & p10]

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applications relied on the same comparable facilities. The duplicates of comparables was recognized in the Clark County project and addressed during the screening of the application.

If approved, DaVita expects the 19-station dialysis center would be operational by September 2020. [source: Application, p10]

The total capital expenditure for this project is \$3,252,406, which includes construction costs, equipment, and associated fees and taxes. [source: Application, p18]

Public Comment

NKC and PSKC questioned the reliability of DaVita's timeline to open its new facility in King County planning area #1. PSKC's comments are restated below. [source: PSKC September 5, 2018, public comment, pp5-6]

"PSKC and DaVita received CN approval on October 24, 2016, to add stations in adjacent planning area Snohomish 3. PSKC was approved to expand its existing facility by four stations and DaVita was approved to establish a new three station facility. At the time we submitted the CN for new stations, PSKC's Snohomish 3 facility, PSKC South, had operated in excess of 90% occupancy for years. PSKC made its four stations operational **immediately** upon CN approval and by early 2017 returned to occupancy levels exceeding 80% even with the addition of the four additional stations.

In September 2017, due to scheduling difficulties for new patients, PSKC sent a letter to the CN Program requesting to be allowed, temporarily, to put into operation the three stations that had been approved for DaVita Lynnwood until their facility was certified. In November 2017, PSKC received a response from the CN Program indicating that the DaVita Lynnwood facility was 'operational.' Although not defined by the CN Program, PSKC thought that this meant the facility was actually admitting and caring for patients. PSKC's request was denied.

Today - nearly one year after performing its first treatment, DaVita Lynnwood is still not "operating," or accepting patients, and occupancy of our Snohomish 3 facility is such that timely access for patients is compromised. PSKC requested and received from the CN Program copies of DaVita Lynnwood's progress reports. A summary of the information contained in the progress reports submitted for the last three quarters is included in **Table 2**.

Applicant's Table

Table 2
DaVita Lynnwood Certificate of Need Progress Report Summaries

Date of Progress Report	Activity to Date	
December 2017 (submitted	Certificate of Occupancy received	
1/31/2018)	9/20/17.	
	1 st Treatment 10/24/17	
	Request for initial survey submitted to	
	the Washington Department of Health	
	Request for expedited survey submitted	
	to the Washington Department of Health	
	Private -pay patients only currently	
	treating at DVA Lynnwood facility	
March 2018 (submitted	Project was completed on 9/20/17 and is	
4/30/2018)	currently treating one patient while	
	awaiting survey.	
June 2018 (submitted 8/9/2018)	No reportable activity. Awaiting CMS	
	survey	

Source: DaVita Lynnwood CN Progress Reports

PSKC has not experienced any survey delays such as DaVita outlines. Proactively working with the State Department of Health, our practice is to explain when we will be ready for initial survey, and the State Surveyors respond timely; we have received surveys without delay. The net effect is that DaVita-Lynnwood's operations have negatively affected patient access and today--one year after receiving a certificate of occupancy--only commercial patients still have access to treatment at DaVita Lynnwood DaVita should not be allowed to create a new facility in an adjacent planning area when its Lynnwood facility has been "sitting virtually closed for operations" and limiting access to governmental payers for nearly a year, at the expense of PSKC, referring doctors, and most importantly, patients."

NKC's comments are restated below. [source: NKC September 5, 2018, public comment, p9]

<u>DaVita's Timeline to Opening</u>: DaVita offers no explanation in its application as to why it has assumed that the facility would be constructed but not meet the definition of operational per WAC 246-310-800(12) until 15 months later. No explanation is given for the long delay.

<u>DaVita Lynnwood Still Awaiting Certification</u>: DaVita's application indicates that its Lynnwood facility is still awaiting survey despite having met the definition of 'operational' last year. NKC does not understand this long delay as we had our NKC Federal Way East Kidney Center surveyed within 7 days of being operational (the facility became operational in March 2018). Note that effective August 10th, 2018 CMS published a memo outlining that all new centers will be surveyed within 90 days. See **Exhibit 5**.

Rebuttal Comment

[source: DaVita October 5, 2018, rebuttal comments, p15]

"NKC and PSKC criticize DaVita for the timing of its Lynnwood facility. However, as the Department knows that facility is simply waiting for CMS inspection and certification. DaVita has requested this but has no control over the CMS's inspection schedule. Obviously there is no benefit to DaVita of a delay in certification. DaVita would like its facility to be certified as soon as possible.

After giving the Department of Investigations and Inspections forewarning of Lynnwood's impending opening, DaVita contacted the Department on 10/26/2017 with Lynnwood's water validations and a notice that the facility was ready for survey (the first patient treated, and the center became operational, on 10/24/2017). DaVita repeated this request formally on 1/18/2018, 4/9/2018, and 7/31/2018, as well as numerous telephonic and in-person follow-up requests.

DaVita made its Lynnwood facility operational consistent with the timeline in its original application, and has made repeated attempts to elevate initial survey on the Department of Investigations Inspections' priority list."

Department Evaluation of Public Comment

NKC and PSKC assert that the department should deny DaVita's King 1 application because DaVita did not meet its timeline to open its Lynnwood Dialysis Center. PSKC and DaVita both received approval on the same day (October 24, 2016) to add dialysis stations to Snohomish County planning area #3. PSKC has already added its approved dialysis capacity to PSKC-South located in Mukilteo. NKC and PSKC assert that DaVita's Lynnwood Dialysis Center has yet to open its approved capacity.

In turn, DaVita states Lynnwood Dialysis Center's four stations have been ready for survey since late October 2017 and DaVita notified DOH three times since October 2017 that it was ready for survey.

The department's internal files show that Lynnwood Dialysis Center's CMS survey was completed November 2018—more than 12 months from the time it was ready. [source: December 2018, progress report for CN #1588]

While the department agrees that DaVita's Lynnwood Dialysis Center did not become operational within the timeline identified by DaVita in the application, the current kidney dialysis rules do not contemplate any penalty—or praise—for meeting, or not meeting, an operational timeline. The 'penalty' or 'praise' is recognized in WAC 246-310-812(5)(b) for 4.8 planning areas and (6)(b) for 3.2 planning areas.

WAC 246-310-812(5)(b) states:

"Before the department approves new in-center kidney dialysis stations in a 4.8 planning area, all certificate of need counted stations at each facility in the planning area must be operating at 4.5 in-center patients per station. However, when a planning area has one or more facilities with stations not meeting the in-center patients per stations standard, the department will consider the 4.5 in-center patients per station standard met for those facilities when: ...(b) Certificate of need approved stations for a facility have not become operational within the timeline as represented in the approved application. For example, an applicant states the stations will be operational within eight months following the date of the certificate of need approval. The eight months would start from the date of an uncontested certificate of need approval. If the certificate of need approval is contested, the eight months would start from the date of the final department or judicial order. However, the department, at its sole discretion, may approve a one-time modification of the timeline for purposes of this subsection upon submission of documentation that the applicant was prevented from meeting the initial timeline due to circumstances beyond its control.

Both resident and nonresident patients using the kidney dialysis facility are included in this calculation. Data used to make this calculation must be from the most recent quarterly modality report from the Northwest Renal Network as of the letter of intent submission date."

The department disagrees with PSKC and NKC that DaVita's King #1 project should be denied because it did not meet its operational timeline at Lynnwood Dialysis Center.

Department Information on Timelines for Completion of the Projects

Each of the applicants identified a timeline for completion of their respective projects based on a December 2018 evaluation release date. Due to delays in releasing this evaluation, each applicant's timeline may not be achievable or accurate. Regardless of which applicant is approved in this review, the department will adjust the operational timeline to account for the additional days of delay of the release of this evaluation.

APPLICABILITY OF CERTIFICATE OF NEED LAW

Northwest Kidney Centers project is subject to Certificate of Need review as the increase in the number of dialysis stations in a kidney disease center under Revised Code of Washington (RCW) 70.38.105(4)(h) and Washington Administrative Code (WAC 246-310-020(1)(e).

For Puget Sound Kidney Centers and DaVita, Inc., the two projects are subject to Certificate of Need review as the construction, development, or other establishment of a new health care facility under the provisions of RCW 70.38.105(4)(a) and WAC 246-310-020(1)(a).

EVALUATION CRITERIA

WAC 246-310-200(1)(a)-(d) identifies the four determinations that the department must make for each application. WAC 246-310-200(2) provides additional direction on how the department is to make its determination. It states:

"Criteria contained in this section and in WAC 246-310-210, 246-310-220, 246-310-230, and 246-310-240 shall be used by the department in making the required determinations.

- (a) In the use of criteria for making the required determinations, the department shall consider:
 - (i) The consistency of the proposed project with services or facility standards contained in this chapter;
 - (ii) In the event the standards contained in this chapter do not address in sufficient detail for a required determination the service or facilities for health services proposed, the department may consider standards not in conflict with those standards in accordance with subsection (2)(b) of this section; and
 - (iii) The relationship of the proposed project to the long-range plan (if any) of the person proposing the project."

In the event WAC 246-310 does not contain service or facility standards in sufficient detail to make the required determinations, WAC 246-310-200(2)(b) identifies the types of standards the department may consider in making its required determinations. Specifically WAC 246-310-200(2)(b) states:

- (b) The department may consider any of the following in its use of criteria for making the required determinations:
 - (i) Nationally recognized standards from professional organizations;
 - (ii) Standards developed by professional organizations in Washington State;
 - (iii) Federal Medicare and Medicaid certification requirements;
 - (iv) State licensing requirements
 - (v) Applicable standards developed by other individuals, groups, or organizations with recognized expertise related to a proposed undertaking; and
 - (vi) The written findings and recommendations of individuals, groups, or organizations with recognized expertise related to a proposed undertaking, with whom the department consults during the review of an application.

To obtain Certificate of Need approval, an applicant must demonstrate compliance with the applicable criteria found in WAC 246-310-210 (need); 246-310-220 (financial feasibility); 246-310-230 (structure and process of care); and 246-310-240 (cost containment).

Each application must also demonstrate compliance with applicable kidney disease treatment center criteria outlined in WAC 246-310-800 through 833. For these three ESRD applications submitted under WAC 246-310-806 Nonspecial Circumstance, the following review criteria do not apply and will not be discussed in this evaluation.

WAC 246-310-809	One-time exempt isolation station reconciliation
WAC 246-310-818	Special circumstances one- or two-station expansion—Eligibility criteria and
	application process
WAC 246-310-821	Kidney disease treatment facilities—Standards for planning areas without an
	existing facility
WAC 246-310-824	Kidney disease treatment centers—Exceptions
WAC 246-310-830	Kidney disease treatment facilities—Relocation of facilities
WAC 246-310-833	One-time state border kidney dialysis facility station relocation

WAC 246-310-803

WAC 246-310-803 requires an applicant to submit specific data elements to the Certificate of Need Program. For the 2018 concurrent review cycle, the data must be received <u>before</u> February 16, 2018. Each applicant submitted the data elements on February 15, 2018. This data is used to calculate superiority in the event that more than one application meets the applicable review criteria. Consistent with WAC 246-

310-827, these data elements are the only means by which two or more applications may be compared to one another.

WAC 246-310-803 and WAC 246-310-827 allow for public review and correction to data submissions prior to any concurrent review cycle. Therefore, if the department receives public comments related to data submission under WAC 246-310-803 or WAC 246-310-827 during a review, the comments will not be considered and discussed.

TYPE OF REVIEW

As directed under WAC 246-310-806, the department accepted these three applications under the Kidney Disease Treatment Centers-Nonspecial Circumstances Concurrent Review Cycle #1 for calendar year 2018. Below is the chronological summary of the review timelines.

APPLICATION CHRONOLOGY

Action	NKC	PSKC	DaVita, Inc.
Letter of Intent Submitted	May 1, 2018	May 1, 2018	May 1, 2018
Application Submitted	June 1, 2018 June 1, 2018 June 1, 20		
Department's pre-review activities			
DOH Screening Letter	June 29, 2018	June 29, 2018	June 29, 2018
Applicant's Responses Received	July 31, 2018	July 31, 2018	July 31, 2018
Beginning of Review	August 6, 2018		
End of Public Comment			
 Public comments accepted through the end of public comment 	September 5, 2018		
No public hearing requested or conducted			
Rebuttal Comments Submitted	October 5, 2018		
Department's Initial Anticipated Decision Date	December 19, 2018		
Department's Anticipated Decision Date with 150-day extension 10	May 20, 2019		
Department's Actual Decision Date	May 3, 2019		

AFFECTED PERSONS

Washington Administrative Code 246-310-010(2) defines "affected" person as:

- "...an "interested person" who:
 - (a) Is located or resides in the applicant's health service area;
 - Testified at a public hearing or submitted written evidence; and *(b)*
 - Requested in writing to be informed of the department's decision."

As noted above, WAC 246-310-010(2) requires an affected person to first meet the definition of an 'interested person.' WAC 246-310(34) defines "interested person" as:

The applicant; (a)

- (b) Health care facilities and health maintenance organizations providing services similar to the services under review and located in the health service area;
- Third-party payers reimbursing health care facilities in the health service area; (c)
- Any agency establishing rates for health care facilities and health maintenance organizations in the health service area where the proposed project is to be located;

¹⁰ Thirty day extension letters were sent to the applicants on December 20, 2018, January 18, 2019, February 20, 2019, March 19, 2019, and April 12, 2019.

- (e) Health care facilities and health maintenance organizations which, in the twelve months prior to receipt of the application, have submitted a letter of intent to provide similar services in the same planning area;
- (f) Any person residing within the geographic area to be served by the applicant; and
- (g) Any person regularly using health care facilities within the geographic area to be served by the applicant.

For these three projects, each applicant is an affected person for the other two competing applications. Two entities sought interested persons for the three projects, but no other entities sought affected person status.

SOURCE INFORMATION REVIEWED

- Northwest Kidney Centers Certificate of Need application received June 1, 2018
- Northwest Kidney Centers screening responses received July 31, 2018
- Puget Sound Kidney Centers Certificate of Need application received June 1, 2018
- Puget Sound Kidney Centers screening responses received July 31, 2018
- DaVita, Inc. Certificate of Need application received June 1, 2018
- DaVita, Inc. screening response received July 31, 2018
- Public comments accepted through September 5, 2018
- Rebuttal comments received on October 5, 2018
- Years 2012 through 2017 historical kidney dialysis data obtained from the Northwest Renal Network
- Department of Health's ESRD Need Projection Methodology for King County planning area #1 posted to its website March 2018
- Licensing data provided by the Medical Quality Assurance Commission, Nursing Quality Assurance Commission, and Health Systems Quality Assurance Office of Customer Service
- Compliance history obtained from the Washington State Department of Health Office of Health Systems Oversight
- Centers for Medicare and Medicaid website at www.medicare.gov/dialysisfacilitycompare
- Certificate of Need historical files

CONCLUSIONS

Northwest Kidney Centers

For the reasons stated in this evaluation, the department has concluded that the Northwest Kidney Centers project is not consistent with the Certificate of Need review, and a Certificate of Need is denied.

Puget Sound Kidney Centers

For the reasons stated in this evaluation, the application submitted by Puget Sound Kidney Centers proposing to establish a 19-station dialysis center in King County planning area #1 is consistent with applicable criteria of the Certificate of Need Program, provided Puget Sound Kidney Centers agrees to the following in its entirety.

Project Description:

This certificate approves the establishment of a 19-station dialysis center to be located at 355 Richmond Beach Road in Shoreline [98177] within King County planning area #1. The table below provides a breakdown of the total number of stations at project completion.

	CMS Certified Stations	Stations Counted in Methodology
General Use In-Center Stations	18	18
Permanent Bed Station	1	1
Private Isolation Station ¹¹	1	0
Total Stations	20	19

Services to be provided at the new dialysis center include in-center hemodialysis, home hemodialysis and home peritoneal dialysis training, isolation capabilities, and a permanent bed station. There will also be a patient shift starting after 5pm.

Conditions:

- 1. Approval of the project description as stated above. Puget Sound Kidney Centers further agrees that any change to the project as described in the project description is a new project that requires a new Certificate of Need.
- 2. Puget Sound Kidney Centers shall finance this project consistent with the financing described in the application.
- 3. Prior to providing services at the new dialysis center, Puget Sound Kidney Centers will provide a copy of the executed medical director agreement for review and approval. The executed agreement will be consistent with the draft agreement provided in the application.
- 4. Prior to providing services at the new dialysis center, Puget Sound Kidney Centers will provide a copy of the executed Patient Transfer Agreement with language that includes this new dialysis center.

Approved Capital Expenditure:

The total capital expenditure for this project is \$8,538,099, which includes costs for purchasing the building and construction costs, equipment, and associated fees and taxes.

DaVita, Inc.

For the reasons stated in this evaluation, the department has concluded that the DaVita, Inc. project is not consistent with the Certificate of Need review, and a Certificate of Need is denied.

¹¹ DaVita has not yet completed the administrative station adjustment as allowed under Washington Administrative Code 246-310-809.

CRITERIA DETERMINATIONS

A. Need (WAC 246-310-210)

Northwest Kidney Centers

Based on the source information reviewed the department concludes that Northwest Kidney Centers has met the need criteria in WAC 246-310-210. The kidney disease treatment center specific numeric methodology applied is detailed under WAC 246-310-812(4). WAC 246-310-210(1) criteria is also identified in WAC 246-310-812(5) and (6).

Puget Sound Kidney Centers

Based on the source information reviewed the department concludes that Puget Sound Kidney Centers has met the need criteria in WAC 246-310-210. The kidney disease treatment center specific numeric methodology applied is detailed under WAC 246-310-812(4). WAC 246-310-210(1) criteria is also identified in WAC 246-310-812(5) and (6).

DaVita, Inc.

Based on the source information reviewed, the department concludes that DaVita Inc. has met the need criteria in WAC 246-310-210. The kidney disease treatment center specific numeric methodology applied is detailed under WAC 246-310-812(4). WAC 246-310-210(1) criteria is also identified in WAC 246-310-812(5) and (6).

(1) The population served or to be served has need for the project and other services and facilities of the type proposed are not or will not be sufficiently available or accessible to meet that need.

WAC 246-310-812 requires the department to evaluate kidney disease treatment centers applications based on the population's need for the service and determine whether other services and facilities of the type proposed are not, or will not, be sufficiently available or accessible to meet that need as required in WAC 246-310-210. The kidney disease treatment center specific numeric methodology is applied and detailed under WAC 246-310-812(4). WAC 246-310-210(1) criteria and also identified in WAC 246-310-812(5) and (6).

WAC 246-310-812 Kidney Disease Treatment Center Numeric Methodology

WAC 246-310-812 contains the methodology for projecting numeric need for dialysis stations within a planning area. This methodology projects the need for kidney dialysis treatment stations through a regression analysis of the historical number of dialysis patients residing in the planning area using verified utilization information obtained from the Northwest Renal Network (NWRN). 12

The first step in the methodology calls for the determination of the type of regression analysis to be used to project resident in-center station need. [WAC 246-310-812(4)(a)] This is derived by calculating the annual growth rate in the planning area using the year-end number of resident in-center patients for each of the previous six consecutive years, concluding with the base year.¹³

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¹² NWRN was established in 1978 and is a private, not-for-profit corporation independent of any dialysis company, dialysis unit, or transplant center. It is funded by Centers for Medicare and Medicaid Services, Department of Health and Human Services. Northwest Renal Network collects and analyzes data on patients enrolled in the Medicare ESRD programs, serves as an information resource, and monitors the quality of care given to dialysis and transplant patients in the Pacific Northwest. [Source: Northwest Renal Network website]

¹³WAC 246-310-280 defines base year as the most recent calendar year for which December 31 data is available as of the first day of the application submission period from the *Northwest Renal Network's Modality Report* or successor report." For this project, the base year is 2017.

In planning areas experiencing high rates of growth in the dialysis population (6% or greater growth in each of the last five annual change periods), the method uses exponential regression to project future need. In planning areas experiencing less than 6% growth in any of the last five annual change periods, linear regression is used to project need.

Once the type of regression is determined as described above, the next step in the methodology is to determine the projected number of resident in-center stations needed in the planning area based on the planning area's previous five consecutive years NWRN data, again concluding with the base year. [WAC 246-310-812(4)(b) and (c)]

[WAC 246-310-812(5)] identifies that for all planning areas except Adams, Columbia, Douglas, Ferry, Garfield, Jefferson, Kittitas, Klickitat, Lincoln, Okanogan, Pacific, Pend Oreille, San Juan, Skamania, Stevens, and Wahkiakum counties, the number of projected patients is divided by 4.8 to determine the number of stations needed in the planning area. For the specific counties listed above, the number of projected patients is divided by 3.2 to determine needed stations. Additionally, the number of stations projected as needed in the target year is rounded up to the nearest whole number.

Finally, once station need has been calculated for the project years, the number of CN approved incenter stations are then subtracted from the total need, resulting in a net need for the planning area. [WAC 246-310-812(4)(d)] The department calculates the numeric methodology for each of the 57 planning areas and posts the results to its website. Below is a discussion of the numeric methodology submitted by each applicant.

Northwest Kidney Centers

NKC proposes to add 19 dialysis stations to Lake City Kidney Center located in Lake Forest Park. NKC submitted the numeric methodology posted to the department's website for King County planning area #1. The methodology projected need for 19 stations in year 2018.

Public Comment

None

Rebuttal Comment

None

Puget Sound Kidney Centers

PSKC proposes to establish a 19-station dialysis center to be located in Shoreline. PSKC relied on the numeric methodology posted to the department's website for King County planning area #1. The methodology projected need for 19 stations in year 2018.

Public Comment

None

Rebuttal Comment

None

DaVita, Inc.

PSKC proposes to establish a 19-station dialysis center to be located in Shoreline. PSKC relied on the numeric methodology posted to the department's website for King County planning area #1. The methodology projected need for 19 stations in year 2018.

Public Comment None

Rebuttal Comment

None

Department Evaluation of the Numeric Methodology for King County Planning Area #1

The department calculates the numeric methodology for each of the 57 ESRD planning areas in Washington and posts each of the results to its website. The department's year 2018 numeric methodology was posted in March 2018 and it will be used for evaluating these three projects.

Based on the calculation of the annual growth rate in the planning area, the department used the linear regression to determine numeric need. The number of projected patients was divided by 4.5 to determine the number of stations needed in King County planning area #1. A summary of the department's numeric methodology is shown in Table 1 below.

Department's Table 1 King County Planning area #1 Numeric Methodology Summary

6	4.5 in-center patients per station		
	2022 Projected # of stations	Minus Current # of stations	2022 Net Need or (Surplus)
DOH Methodology Posted to Website	59	40	19

As shown in the table above, once the 40 existing stations are subtracted from the projected need, the result is a net need of 19 stations. The department's methodology is included in this evaluation as Appendix A. The department concludes all three applicants **meet the numeric methodology standard**.

In addition to the numeric need, the department must determine whether other services and facilities of the type proposed are not or will not be sufficiently available or accessible to meet the dialysis station need. ¹⁴ The department uses the standards in WAC 246-310-812(5) and WAC 246-310-812(6).

WAC 246-310-812(5)

Before the department approves new in-center kidney dialysis stations in a 4.8 planning area, all certificate of need counted stations at each facility in the planning area must be operating at 4.5 incenter patients per station. However, when a planning area has one or more facilities with stations not meeting the in-center patients per stations standard, the department will consider the 4.5 in-center patients per station standard met for those facilities when:

- (a) All stations for a facility have been in operation for at least three years; or
- (b) Certificate of need approved stations for a facility have not become operational within the timeline as represented in the approved application.

...Both resident and nonresident patients using the kidney dialysis facility are included in this calculation. Data used to make this calculation must be from the most recent quarterly modality report from the Northwest Renal Network as of the letter of intent submission date.

For King County planning area #1, WAC 246-310-812(5) requires all CN approved stations in the planning area be operating at 4.5 in-center patients per station. Below is a discussion of the information submitted by each applicant for this standard.

¹⁴ WAC 246-310-210(1)(b).

Northwest Kidney Centers

There are two dialysis centers currently operating in King County planning area #1. NKC provided a table showing that both centers were operating above the 4.5 standard. [source: Application, p10]

Public Comment

None

Rebuttal Comment

None

Puget Sound Kidney Centers

PSKC provided a table showing that both centers were operating above the 4.5 standard. [source: Application, pdf12]

Public Comment

None

Rebuttal Comment

None

DaVita, Inc.

DaVita provided a table showing that both centers were operating above the 4.5 standard. [source: Application, p13]

Public Comment

None

Rebuttal Comment

None

Department Evaluation

WAC 246-310-812(5) states that the "data used to make this calculation must be from the most recent quarterly modality report from the Northwest Renal Network as of the letter of intent submission date." The date of the letter of intent is May 1, 2018. The data available as of May 1, 2018, is December 31, 2017, end of year data that was available on February 15, 2018. The utilization of the two existing dialysis centers located in King County planning area #1 is shown below.

Department's Table 2 December 31, 2017, Utilization Data King County Planning Area #1

Facility Name	# of Stations	# of Patients	Patients/Station
NKC Lake City Kidney Center	18	93	5.16
NKC Scribner Kidney Center	22	129	5.86

As shown in the table above, both facilities meet the utilization requirement and this standard is met for all three applicants.

(2) <u>All residents of the service area, including low-income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly are likely to have adequate access to the proposed health service or services</u>

To evaluate this sub-criterion, the department evaluates an applicant's admission policies, willingness to serve Medicare and Medicaid patients, and to serve patients that cannot afford to pay for services.

The admission policy provides the overall guiding principles of the facility as to the types of patients that are appropriate candidates to use the facility and assurances regarding access to treatment. The admission policy must also include language to ensure all residents of the planning area would have access to the proposed services. This is accomplished by providing an admission policy that states patients would be admitted without regard to race, ethnicity, national origin, age, sex, pre-existing condition, physical, or mental status.

Medicare certification is a measure of an agency's willingness to serve the elderly. With limited exceptions, Medicare is coverage for individuals age 65 and over. It is also well recognized that women live longer than men and therefore more likely to be on Medicare longer. One of the exceptions is Medicare coverage for patients with permanent kidney failure. Patients of any age with permanent kidney failure are eligible for Medicare coverage.

Medicaid certification is a measure of an agency's willingness to serve low income persons and may include individuals with disabilities.

A facility's charity care policy should show a willingness of a provider to provide services to patients who have exhausted any third-party sources, including Medicare and Medicaid, and whose income is equal to or below 200% of the federal poverty standards, adjusted for family size or is otherwise not sufficient to enable them to pay for the care or to pay deductibles or coinsurance amounts required by a third-party payer. With the passage of the Affordable Care Act (ACA), the amount of charity care is expected to decrease, but not disappear. The policy should also include the process one must use to access charity care at the facility.

Northwest Kidney Centers

In response to this sub-criterion, NKC provided the following statements. [source: Application, p15]

"NKC is undertaking this project and adding stations to assure that no factors restrict patient access to dialysis services. NKC has a long-established history of developing and providing services that meet the dialysis needs of the communities it serves. NKC Lake City, as with all other NKC facilities, is committed to providing services to all patients regardless of race, color, ethnic origin, religious belief, sex, age or lack of ability to pay. Copies of the admission policies and procedures and the charity care policy for the existing NKC Lake City are included in Exhibit 8."

NKC also provided the following policies for this project. [source: Application, Exhibit 8]

- New Patient Admission Policy
- Charity Policy
- Patient Compliance Policy

Public Comment

DaVita provided public comments stating that NKC is not available to all residents of the services area. DaVita's public comments are restated below. [source: DaVita September 5, 2018, public comment, pp4-5]

¹⁵ WAC 246-453-010(4).

"NKC's application should be denied because its facility will not accept all planning-area residents as patients. WAC 246-310-210(2) requires that "all residents of the service area ... are likely to have adequate access to the proposed health service or services." (Emphasis added.) As of October 2017, NKC did not accept all planning-area residents as new patients. NKC informed physicians at that time as follows:

Therefore, we have made the following admissions policy decisions:

We will accept new in-center patients with ESRD and AKI who reside in King or Clallam counties and are covered by Medicare, Medicaid and commercial insurance with whom we have a contract. (We do not have contracts with Kaiser Permanente, Veterans Administration or Humana outside of Washington.)

We will not accept new in-center patients who reside in Pierce or Snohomish County. We will accept PD and home hemodialysis patients from all counties.

We will place a mobile in-center patient in a bed, if that is where a slot is available. We will not accept visitors to whom we have not yet made a commitment, including pretransplant patients.

Source: NKC's newsletter.

If this is still NKC's policy, NKC does not accept (1) uninsured patients, (2) patients covered by insurers with which NKC does not have contracts, or (3) patients who reside in Pierce or Snohomish Counties. Even if NKC responds that it has since changed this policy, that NKC placed these restrictions in effect at least for a period of time (presumably without informing the Department of Health) should cause concern that it may do so again in the future.

We fully understand that a particular dialysis facility may be unable to accept new patients if it is full and there are no spaces available for <u>anyone</u>, but this is not what NKC is doing. In its new policy, NKC states that it <u>will</u> continue to accept new patients who (1) have certain insurance and (2) do not reside in Pierce or Snohomish Counties, but <u>will not</u> accept new patients who (1) are uninsured altogether or are not insured by insurers with which NKC has a contract or (2) reside in Pierce or Snohomish Counties.

So that there is no confusion, DaVita confirms that <u>all</u> of its Washington facilities will accept <u>all</u> patients regardless of insurance status or ability to pay if they have a space available, and will work to accept a patient in a nearby facility with space and waitlist the patient at his or her preferred facility if not. Unlike NKC, DaVita does not turn away ESRD patients based on where they live or what insurance they have.

NKC's new policies do not comport with the access requirement set forth in 210(2), which states that a CON application will not be approved unless all residents of a service area will have adequate access to the proposed facility. Accordingly, NKC's application should be denied because all residents of the service area will not have adequate access to NKC's proposed facility. Indeed, if they have the "wrong" address or insurance, or no insurance at all, they apparently will be automatically excluded pursuant to NKC's stated new policies."

[source: NKC October 5, 2018, rebuttal comments, pp4-5]

"NKC Does Not Discriminate and Will Accept All Planning Area Residents

"DaVita cites WAC 246-310-210(2) which requires that all residents of the service area (emphasis added) are likely to have adequate access, and then concludes that NKC should be denied because of an October 2017 article in the NKC Physician newsletter about the influx of patients from outlying counties. DaVita has cherry-picked and purposefully misconstrued the position in the newsletter. NKC is a community-based provider and accepts all patients. The entire article is included in Attachment 1 and the purpose of the newsletter is restated below:

From Physician Update, Oct. 20, 2017

Regional shortage of dialysis capacity prompts new admitting policies

We recently surveyed dialysis facilities in King, south Snohomish and Pierce counties. We found many have waiting lists and none other than Northwest Kidney Centers state they are accepting new patients.

We have open slots, although our South and North End units are quite full. In a Recent two-week period, we received almost as many referrals as in a typical month.

Therefore, we have made the following admissions policy decisions:

- 1. We will accept new in-center patients with ESRD and AKI who reside in King or Clallam counties and are covered by Medicare, Medicaid and commercial insurance with whom we have a contract. (We do not have contracts with Kaiser Permanente, Veterans Administration or Humana outside of Washington.)
- 2. We will not accept new in-center patients who reside in Pierce or Snohomish County.
- 3. We will accept PD and home hemodialysis patients from all counties.
- 4. We will place a mobile in-center patient in a bed, if that is where a slot is available.
- 5. We will not accept visitors to whom we have not yet made a commitment, including pre-transplant patients.

Holding slots:

- 1. Referral for admission The unit will hold a slot for one week.
- 2. Starting PD or home hemo The unit will hold a slot for two weeks while patient trains.
- 3. Transplant The unit will hold the slot for two weeks post-transplant.
- 4. Long-term hospitalization The unit will release the slot after 30 days in the hospital.
- 5. Hospice The unit will release the slot after the patient is admitted to hospice and has withdrawn from dialysis.
- 6. AKI The unit will hold the slot for one week.
- 7. Snowbirds The unit will release the slot after the patient moves for the season.

If you have questions or concerns, please contact Dr. Bonnie Collins, associate chief medical officer.

Specifically, the article was NKC's response to an extraordinary circumstance occurring in several adjacent planning areas. The entire purpose of the notification was to assure providers that patients (ESRD and AKI) residing in the NKC primary planning areas would continue to be well served.

DaVita neglected to provide in its public comment the context for the change in practice. Further, it neglected to explain that the extraordinary circumstance was in large part, prompted by the fact that DaVita had closed to new patients in some of its own facilities in adjacent planning areas in Pierce County and Snohomish County even though it had capacity. The patients needed a facility and were overflowing into our King County facilities; our article was in response to this fact.

NKC does not have a "new policy" and continues to provide access to ALL patients regardless of payer, sex, handicap, etc. within our Planning Areas. NKC currently operates 16 units in two Counties- King and Clallam Counties.

In addition, we are preparing to open the NKC-Federal Way West Campus unit in the King Five planning area and are currently awaiting survey. Nevertheless, NKC accepts all ESRD patients from King Five planning area and serves them at NKC facilities in other King County planning areas. Our NKC Port Angeles unit in Clallam County accepts all patients from that county.

NKC does not operate units in Pierce and Snohomish County or any other counties in the State today. Of course, dialysis patients seek care close to home, so it makes sense they would seek care from providers in their own communities. The two national for-profit dialysis companies have dialysis units throughout the State. Thus, these companies may be able to refer new patients to far-off units that they operate in other planning areas if they do not have capacity close to the patient's home. NKC does not have that option and thus serves ESRD patients where we operate units, i.e. King and Clallam counties."

Department Evaluation

In its public comment, DaVita asserts that the information released by NKC to mitigate its overcrowding at its facilities in King and Clallam counties is limiting access to dialysis services in NKC facilities. However, what DaVita does not acknowledge is NKC did not operate dialysis facilities in Pierce or Snohomish County when the notice was released. With that information in mind, NKC is correct in its rebuttal that the notice was simply a reminder that its King and Clallam facilities were reaching capacity and NKC intended to ensure that the residents of King and Clallam counties had access to dialysis services in a facility within the planning area.

Additionally, DaVita does not factor in that the numeric methodology identifies need based on planning area residents. The numeric methodology does not contemplate in-migration at the level that NKC has experienced at it King and Clallam County facilities. If NKC is experiencing a large number of Pierce or Snohomish County patients traveling to its King or Clallam County dialysis centers, this could impact the availability of dialysis stations for planning area residents.

In conclusion, submission of the October 20, 2017, NKC notification by DaVita without context could be misconstrued as an access to care issue by NKC. In this instance, it is not proof of an access to care issue at NKC's facilities and is not grounds for denial of NKC's application for King County planning area #1.

NKC provided copies of the necessary policies used at all NKC dialysis centers, including the existing Lake City Kidney Center.

Medicare and Medicaid Programs

NKC currently participates in the Medicare and Medicaid programs for its operational dialysis centers, including Lake City Kidney Center. NKC provided its Medicare and Medicaid provider numbers for Lake City Kidney Center.

Medicare Provider Number: 502536 Medicaid Provider Number: 3990785

As directed WAC 246-310-815, NKC based its payer mix on the existing payer mix of Lake City Kidney Center. NKC provided a table showing the current payer mix Lake City Kidney Center. The information is summarized below. [source: Application, pdf23]

Department's Table 3 NKC Lake City Kidney Center Current and Projected Payer Mix

Source	Percentage of Revenue by Payer	Percentage of Patients by Payer
Medicare (includes managed care)	62.3%	84.5%
Medicaid	5.1%	8.2%
Other: Commercial	32.6%	7.3%
Total	100.0%	100.0%

Based on the information above, the department concludes that NKC's application meets this subcriterion.

Puget Sound Kidney Centers

In response to this sub-criterion, PSKC provided the following statements. [source: Application, pdf17]

"As noted above, all individuals in need of dialysis services have access to PSKC's dialysis centers. PSKC's Community Service Statement policy, attached as Exhibit 4, prohibits discrimination on the basis of race, income, ethnicity, sex, or handicap. PSKC reinvests in the community and does not turn patients away on the basis of income or payment resources. PSKC is committed to caring for the underserved and is truly a nonprofit provider in every sense of the word. Our policy differentiates us from many other dialysis providers in that we identify patients prospectively and qualify them as eligible for charity care (as opposed to re-categorizing bad debt). We are extremely proud of our policy and appreciate how well it has benefited dialysis patients over the years."

PSKC also provided the following policies for this project. [source: Application, Exhibit 4]

- Community Service Statement Administrative/General
- New Patient Admission Policy Administrative/General
- Patient's Rights and Responsibilities Clinical/General
- Patient Transfer and Discharge Clinical/General

Public Comment

None

Rebuttal Comment

None

Department Evaluation

PSKC provided copies of the necessary policies used at all PSKC dialysis centers, including the proposed Richmond Beach facility.

Medicare and Medicaid Programs

PSKC currently participates in the Medicare and Medicaid programs for its operational dialysis centers.

As directed WAC 246-310-815, PSKC based its payer mix on PSKC's three closest facilities. All three facilities are located in Snohomish County. They are: PSKC Everett located in Everett; PSKC South located in Mountlake Terrace; and PSKC Monroe located in Monroe. For the proposed Richmond Beach facility, PSKC provided a table showing the proposed percentages of revenues by payer and revenues by patient for the new facility. The information is summarized below. [source: Application, pdf23]

Department's Table 4 PSKC Projected Payer Mix

Source	Percentage of Revenue by Payer	Percentage of Patients by Payer
Medicare (includes managed care)	64.1%	75.6%
Medicaid	7.8%	12.1%
Other: Commercial	28.1%	12.3%
Total	100.0%	100.0%

Based on the information above, the department concludes that PSKC's application meets this subcriterion.

DaVita, Inc.

DaVita provided the following information for this sub-criterion. [source: Application, p16]

"DaVita's history of providing dialysis services at numerous locations throughout Washington State shows that all persons, including the underserved groups identified in WAC 246-310-210(2), have adequate access to DaVita's facilities, as required by the regulation. We have provided as Appendix 14 copies of the applicable admission, patient financial evaluation, and patient involuntary transfer policies. Additionally, the pro forma the funds that have been budgeted to provide charity care."

DaVita also provided the following policies for this project. [source: Application, Exhibit 14]

- Accepting End State Renal Disease Patients for Treatment
- Patient Behavior Agreements, 30 Day Discharge, Involuntary Discharge or Involuntary Transfer
- Patient Financial Evaluation Policy
- Patient Rights

Public Comment

In its public comment, NKC expressed concerns regarding whether DaVita is available to all residents of the service area. NKC's comments are below. [source: NKC September 5, 2018, public comment, pp2-5]

"DaVita projects to have a census of 23 patients by the end of 2021 and 95 by the end of year 3. DaVita identified its three closest facilities to be its Olympic View, Bellevue and Westwood Dialysis Centers. DaVita noted on page 20 of its application that the inclusion of Olympic View, increases the category

of "commercial, HMO, Other Government other" to be higher than normally seen at a DaVita Center1. It then provided payor mix data for just Bellevue and Westwood. The payer mix (by Patient) for all three centers is approximately 35% Medicare, 2% Medicaid and 63% commercial. For just the two centers, the payer mix (by Patient) is approximately 43% Medicare, 3% Medicaid and 54% commercial. In addition, in its screening response, DaVita also provided payer mix including its Mill Creek facility and excluding Olympic View (the three closest facilities being Bellevue, Westwood and Mill Creek). The payer mix for these three facilities, depicted in Table 11b, was 47% Medicare, 3% Medicaid and 51% commercial.

WAC 246-310-210 (2) requires the Program to find that:

All residents of the service area, including low-income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly are likely to have adequate access to the proposed health service or services... Such consideration shall include an assessment of the following: (a) The extent to which medically underserved populations currently use the applicant's services in comparison to the percentage of the population in the applicant's service area which is medically underserved, and the extent to which medically underserved populations are expected to use the proposed services if approved. (bold added)

Historically, for any project type, to measure conformance to this WAC, the Program has evaluated whether the facility maintains a Medicare and Medicaid contract and then considered how the facility performs in terms of serving such patients compared to other providers serving the Planning Area. While DaVita Green Lake proposes to secure Medicare and Medicaid contracts, by virtue of how different it's proposed payer mix is to NKC's experience in King 1, and in fact, in comparison to all dialysis providers statewide, it fails to demonstrate access.

Medicare began coverage for persons, regardless of age who have ESRD in 1972. Today, Medicare coverage generally starts on the first day of the fourth month of a patient's dialysis treatments. If an ESRD patient has coverage under an employer or individual plan, that plan is typically the only payer for the first 3 months of dialysis, and the patient experiences some out-of-pocket costs. Once the patient with employer coverage becomes eligible for Medicare, there is still a period of time, called a "coordination period," when the employer plan continues to pay. If the employer plan does not pay 100%, Medicare will pay up to the Medicare allowable amounts (this is referred to as "coordination of benefits," the Plan pays "first" and Medicare "pays second"). If the patient is indigent and does not have an employer-sponsored plan, Medicaid pays for dialysis for the first 90 days and then the patient is covered by Medicare. At the end of 33 months, nearly all patients are on Medicare. In fact, and according to the Northwest Renal Network's Annual Reports, in Washington State, 84% of all dialysis patients in 2015 were covered by Medicare. In 2016, 81% of patients were covered by Medicare.

Anecdotally, over the years, and during the course of review on numerous dialysis CN applications, existing dialysis providers suggested that DaVita prioritizes admission to commercial pay patients. The new data collected under WAC 246-310-827 and the payer mix information provided in each DaVita application helps to provide clarity.

On February 15, 2018, consistent with the requirements of WAC 246-310-803, DaVita filed data with the Program for its 38 facilities currently in operation in Washington, and for which data was available. This data shows that DaVita consistently has some of the highest net revenue per treatment in Washington State (of the 20 facilities with the highest net revenue per treatment in the State, 10 were DaVita facilities). Of note, none of the highest net revenue facilities were not-for-profit providers. Included in **Exhibit 1** is a comparison of DaVita Net Revenue per treatment with Puget Sound Kidney Centers in similar markets to highlight the differences between providers.

As Medicare and Medicaid pay cost, or less than the cost, the driver of high net revenue is commercial payers. **Table 1** compares DaVita's proposed payer mix in King 1 to the actual payer mix of NKC's two facilities:

Northwest Kidney Centers Table

Table 1 Payer Mix, by Patient

Facility	Medicare	Medicaid	Commercial, HMO, Other Government and Other
DaVita- 3 closest, less			
Olympic View;	43.02%	3.39%	53.59%
NKC Lake City	84.5%	8.2%	7.3%
NKC Scribner	78.2%	8.4%	13.4%

Source: DaVita Application, Table 11 and DaVita Screening Response, Table 11b, NKC Lake City, Application, Table 10 and NKC Scribner internal data.

As depicted in **Exhibit 2**, of the eight applications DaVita filed on June 1, the percent of Medicare patients ranged from a low of 35% to a high of 69%, and its Medicaid ranged from 2% to 4%. This compares to 74% to 85% for Medicare and 4% to 12% for Medicaid for the 10 applications filed by all other providers. The pattern of significantly higher commercial or significantly lower Medicare and Medicaid rates is pervasive in the CN applications DaVita has submitted in 2018.

The question must be asked: Why is DaVita's payer mix always significantly higher for commercial and its Medicare and Medicaid consistently lower? DaVita is increasingly under scrutiny for its premium assistance practices that ultimately result in patients being steered to commercial insurance plans. DaVita apparently donates funds to cover the premiums for these plans for which DaVita ultimately collects significantly higher payment. According to an April 2018 report from America's Health Insurance Plan's Center for Policy and Research, the impact of this practice "...raises overall health system costs and results in significant increases in premiums for the entire commercial population, not just those with ESRD needs". Out of pocket expenses for these patients could increase in direct proportion. A number of articles have been published in the past year regarding this issue and are included in **Exhibit 3**. These articles include statements such as the April 18th, 2018 statement in the Healthcare Dive brief:

"The practice allows dialysis providers to pay premiums through the American Kidney Fund, increasing overall healthcare costs to the system and threatening the sustainability of the marketplaces and employer plans' risk pools".

Most relevant in Washington State was the Office of the Insurance Commissioner's (OIC) May 5, 2017 order to DaVita to cease and desist in insurance activities for which it was not licensed. The OIC issued the cease and desist after receiving complaints that DaVita was directing Medicaid patients to enroll in a Plan that paid higher insurance benefits than did Medicaid.

DaVita and the OIC ultimately entered into a Settlement Agreement, dated November 8, 2017 (see **Exhibit 3**). While DaVita did not acknowledge any wrongdoing in the Settlement, the data collected by the Program, and per WAC must be used in the review of Cycle 1 Non-Special Circumstance CN applications, demonstrates that DaVita has exponentially higher commercial rates and its applications demonstrate that is has exponentially lower percentages of Medicaid patients than other dialysis providers in the State.

DaVita itself acknowledges its high rate of commercial patients:

.... we note that DaVita's other Seattle-area facilities treat a high percentage of commercial, HMO, and other government patients, as evidenced in Table 11A, meaning Olympic View is not an extreme outlier in that regard. (question 3, screening response)

In the Green Lake screening response, DaVita revised its payer mix for the three closest facilities in King 1 to include Mill Creek instead of Olympic View. Mill Creek is one of the three comparables cited in this application for WAC 246-310-827. Including Mill Creek actually increased the percentage of commercial patients for the combined three facilities.

In a competitive review, DaVita not only fails WAC 246-310-210 (2), it also fails WAC 246-310-220 (2), which states:

The determination of financial feasibility of a project shall be based on the following criteria.

2) The costs of the project, including any construction costs, will probably not result in an unreasonable impact on the costs and charges for health services.

The higher payments paid by insurance companies for services that Medicare and Medicaid otherwise pay for at cost or less. increases costs to the overall health care system. Further, out of pocket costs borne by commercial patients that are otherwise eligible for government programs. These costs are unnecessary."

Rebuttal Comment

[source: DaVita October 5, 2018, rebuttal comments, pp3-5]

"At every one of its facilities in Washington, including those used as comparables for this application, DaVita accepts all patients regardless of insurance status or ability to pay. As noted in DaVita's comments on NKC's application, this is not true of NKC: in October 2017, NKC informed physicians that it no longer would be accepting new patients who are uninsured or covered by, among other payors, the Veterans Administration.

Although DaVita accepts all patients, NKC attempts to make the case that DaVita has an inordinate number of commercially-insured patients, by asserting that the identified payer mix for DaVita's three comparable facilities "is approximately 35% Medicare, 2% Medicaid and 63% commercial." PSKC makes a similar claim. But this is inaccurate. Table 11 in DaVita's application identifies 63% "Commercial, HMO, Other Government, and Other." NKC has conveniently omitted everything after the word "commercial."

NKC's attempt to compare these figures with its own Lake City payor mix is a classic apples-vs.-oranges situation. The "Commercial, HMO, Other Government, and Other" identified in DaVita's Table 11 includes, among other things, Medicare Advantage and managed Medicaid. NKC apparently bundles Medicare Advantage with Medicare and managed Medicaid with fee-for-service Medicaid in its own payor mix categories. But this does not mean that DaVita is obligated to do so.

To make something closer to an apples-to-apples comparison, although still not exact, the Department could use the company-wide figures reported in DaVita's Form 10-K, which as a public company DaVita is required to file with the U.S. Securities and Exchange Commission and that is attached as an appendix to Davita's application. In its annual report for 2017, DaVita disclosed that approximately 89.5% of its total dialysis patients are covered by government-based programs. Notably, this is right between the percentages referenced by NKC (92.7%) and PSKC (87.7%) in their applications. The

remaining 10.5% of DaVita's total dialysis patients are associated with commercial payors. This also is between the percentages referenced by NKC (7.3%) and PSKC (12.3%) in their applications.

Similarly, approximately 67% of DaVita's total dialysis revenue comes from government-based programs. This is nearly identical to NKC's figure (67.4%). The remaining 33% of DaVita's total dialysis revenue comes from commercial payors. This also is nearly identical to NKC's figure (32.6%).

But it is not even necessary to look at DaVita's company-wide payor-mix figures. In response to NKC's criticism, we have gone back to the data for the comparable facilities specifically (Table 11 includes Olympic View, Table 11b, Mill Creek in its place at the Department's request), to determine how much of the "Commercial, HMO, Other Government, and Other" category is attributable to Medicare Advantage, managed Medicaid, and one other important "Other Government" payor-the Veterans Administration. VA-insured patients are a particularly important category to consider because NKC apparently does not accept them. Here is a payor mix with the categories adjusted to be more similar to NKC's categories:

DaVita's Table 11-Reallocated Green Lake Dialysis Center Projected Payer Mix

	Percentage by Revenue	Percentage by Patient
Medicare(including Medicare Advantage)	43.68%	70.84%
Medicaid (including Managed Medicaid)	3.15%	6.56%
Commercial, HMO, Other Government, and Other	53.17%	22.60%
Total	100.00%	100.00%
Note: VA (included in 'other government')	0.76%	1.09%

DaVita's Table 11B-Reallocated Green Lake Dialysis Center Projected Payer Mix

	Percentage by Revenue	Percentage by Patient
Medicare(including Medicare Advantage)	37.21%	68.04%
Medicaid (including Managed Medicaid)	3.87%	8.35%
Commercial, HMO, Other Government, and Other	58.92%	23.62%
Total	100.00%	100.00%
Note: VA (included in 'other government')	2.12%	3.27%

As can be seen in the above table, the percentage of DaVita's patients covered by Medicare (including Medicare Advantage), Medicaid (including managed Medicaid), and the VA adds up to either 78.49% or 79.66%--which is in the ballpark of NKC's figure (and still excludes other government programs). Furthermore, these figures tend to vary by provider location: the 20.44-21.51% of DaVita's patients within "Commercial, HMO, Other Government, and Other," excluding the VA, is similar to NKC's "Commercial" figure in Enumclaw, where NKC has attested to a commercial patient total of 18.5% in its Special Circumstances application filed in Cycle 1, 2018.

NKC attempts to create an issue where none exists, by making misleading comparisons between different statistics. NKC goes so far as to edit DaVita's "Commercial, HMO, Other Government, and Other" category to read "Commercial," which is a blatant misrepresentation of the application record. The fact of the matter is that overall payor mix is pretty consistent across dialysis providers, given how dialysis treatment is reimbursed. Although it certainly can vary between individual facilities for particular periods of time, the fact that DaVita's company-wide government and commercial revenue

percentages (67% and 33%) are nearly identical to the corresponding percentages at NKC's Lake City facility (67.4% and 32.6%) illustrates this neatly.

DaVita accepts all patients regardless of insurance status or ability to pay. NKC and PSKC provide no evidence whatsoever for their false claims to the contrary."

Department Evaluation

DaVita provided copies of the necessary policies used at all DaVita dialysis centers, including the proposed Green Lake facility.

Medicare and Medicaid Programs

DaVita currently participates in the Medicare and Medicaid programs for its operational dialysis centers. As directed WAC 246-310-815, DaVita based its payer mix on DaVita's three closest facilities. All three facilities are located in King County. They are: DaVita Olympic View Dialysis Center located in Seattle, DaVita Bellevue Dialysis Center located in Bellevue; and DaVita Westwood Dialysis Center located in Seattle.

For the proposed Green Lake facility, DaVita provided a table showing the proposed percentages of revenues by payer and revenues by patient for the new facility. The information is summarized below. [source: Application, p20]

Department's Table 5
DaVita Projected Paver Mix

Source	Percentage of Revenue by Payer	Percentage of Patients by Payer
Medicare (includes managed care)	17.67%	34.69%
Medicaid	0.94%	2.09%
Other: Commercial	81.39%	63.22%
Total	100.00%	100.0%

Because DaVita's Olympic View Dialysis Center serves a high percentage of HMO/Kaiser Permanente patients, the department requested DaVita provide an alternative to Olympic View Dialysis Center. In response, DaVita provided the alternative information and clarification to the as a demonstrative example, but did not change its payer mix in the application or in its pro forma financial statements. [source: July 31, 2018, screening response, pp3-4]

"As a preliminary matter, we understood that we were required to use Olympic View Dialysis Center as one of the three comparable facilities under WAC 246-310-815(c)(i) ("Revenue projections must be based on the net revenue per treatment of the applicant's three closest dialysis facilities."). Additionally, we note that DaVita's other Seattle-area facilities treat a high percentage of commercial, HMO, and other government patients, as evidenced in Table 11A, meaning Olympic View is not an extreme outlier in that regard. Furthermore, a substantial number of the patients treating at DaVita Olympic View Dialysis Center are indeed Kaiser Permanente of Washington patients, but are covered under Kaiser Permanente Medicare Advantage plans. As Medicare patients treating in urban Seattle, these patients are of a similar age profile, and may have many similar transportation, socio-economic, and comorbidity similarities with the patient population expected to treat in DaVita Green Lake Dialysis Center. These patient similarities provide ample reason to believe that Olympic View Dialysis is an appropriate comparable for DaVita Green Lake Dialysis Center when viewed in combination with DaVita's facilities in Westwood and Bellevue.

The next-nearest dialysis center for which data is available is DaVita Mill Creek Dialysis Center, although its community is more suburban in character than DaVita's Seattle facilities and Bellevue. Table 11b, below, shows the calculation using Mill Creek Dialysis Center. We further note that use of Mill Creek as a comparable adjusts the revenue calculations (and most expense line items excluding the lease expense, medical director expense, and depreciation expense, when used as a comparable). In light of this, in an abundance of caution, we provide attached Appendix 23, "Detailed Projected Operating Statement (Pro Forma) – Mill Creek as Comparable" for the Department's use should it decide Olympic View Dialysis Center is not a comparable facility. Appendix 23 uses Westwood, Bellevue, and Mill Creek as comparables."

WAC 246-310-815(1) is restated below in its entirety.

- "(1) The kidney dialysis facility must demonstrate positive net income by the third full year of operation.
 - (a) The calculation of net income is subtraction of all operating and non-operating expenses, including appropriate allocated and overhead expenses, amortization and depreciation of capital expenditures from total revenue generated by the kidney dialysis facility.
 - (b) Existing facilities. Revenue and expense projections for existing facilities must be based on that facility's current payor mix and current expenses.
 - (c) New facilities.
 - (i) Revenue projections must be based on the net revenue per treatment of the applicant's three closest dialysis facilities.
 - (ii) Known expenses must be used in the pro forma income statement. Known expenses may include, but are not limited to, rent, medical director agreement, and other types of contracted services.
 - (iii) All other expenses not known must be based on the applicant's three closest dialysis facilities.
 - (iv) If an applicant has no experience operating kidney dialysis facilities, the department will use its experience in determining the reasonableness of the pro forma financial statements provided in the application.
 - (v) If an applicant has one or two kidney dialysis facilities, revenue projections and unknown expenses must be based on the applicant's operational facilities."

For this project, sub-sections (1)(a) and (c) apply. Contrary to public comments, the rule does not exclude use of a 'closest' dialysis center as a comparable because of its patient mix. Based on the information above, the comments are not grounds for denial of this project.

PSKC provided public comment that questioned the appropriateness of the payer mix for DaVita—not specific to this proposed facility, but rather to an alleged practice organization-wide, in which Medicaid patients are inappropriately steered into commercial insurance plans. The article provided by PSKC, while full of information regarding steps that are being taken to request action from the Department of Health and Human Services, does not include or point to conclusive evidence that DaVita has denied access to any patients based on payer source. The payer mix table above identifies that approximately 0.94% of revenue is from Medicaid, representing approximately 2.09% of patients. There were approximately 2,160,000 King County residents in 2018, of which approximately 398,000 were enrolled in some form of Medicaid program – approximately 18.5% of the population. While 18.5% is more than the 0.94% identified in the application, this has not been adjusted for age or any other factors and is not concerning to the CN program without additional evidence showing denial of access.

PSKC did not provide sufficient evidence for the department to conclude that DaVita's patients on Medicaid have been DaVita is not accessible to Medicaid patients. So far as the reimbursement is concerned, this issue is addressed under WAC 246-310-827 – superiority. If more thanThis analysis can be found under WAC 246-310-240 towards the conclusion of this evaluation.

NKC's concerns regarding whether DaVita's existing dialysis centers are available and accessible to all residents of the service area cannot be substantiated by the documents provided by NKC during this review. A simple comparison of payer mix percentages does not substantiate NKC's assertions under this review sub-criterion. NKC's comments are not grounds for denial of DaVita's project.

Based on the information above, the department concludes that **DaVita's application meets this sub-**criterion.

- (3) The applicant has substantiated any of the following special needs and circumstances the proposed project is to serve.
 - (a) The special needs and circumstances of entities such as medical and other health professions schools, multidisciplinary clinics and specialty centers providing a substantial portion of their services or resources, or both, to individuals not residing in the health service areas in which the entities are located or in adjacent health service areas.
 - (b) The special needs and circumstances of biomedical and behavioral research projects designed to meet a national need and for which local conditions offer special advantages.
 - (c) <u>The special needs and circumstances of osteopathic hospitals and non-allopathic services.</u>
- (4) The project will not have an adverse effect on health professional schools and training programs. The assessment of the conformance of a project with this criterion shall include consideration of:
 - (a) The effect of the means proposed for the delivery of health services on the clinical needs of health professional training programs in the area in which the services are to be provided.
 - (b) <u>If proposed health services are to be available in a limited number of facilities, the extent to which the health professions schools serving the area will have access to the services for training purposes.</u>
- (5) The project is needed to meet the special needs and circumstances of enrolled members or reasonably anticipated new members of a health maintenance organization or proposed health maintenance organization and the services proposed are not available from nonhealth maintenance organization providers or other health maintenance organizations in a reasonable and cost-effective manner consistent with the basic method of operation of the health maintenance organization or proposed health maintenance organization.

Department Evaluation

WAC 246-310-210(3), (4), and (5) do not apply to any of the three dialysis projects under review.

B. Financial Feasibility (WAC 246-310-220)

Northwest Kidney Centers

Based on the source information reviewed the department concludes that Northwest Kidney Centers has met the financial feasibility criteria in WAC 246-310-220 and WAC 246-310-815.

Puget Sound Kidney Centers

Based on the source information reviewed the department concludes that Puget Sound Kidney Centers has met the financial feasibility criteria in WAC 246-310-220 and WAC 246-310-815.

DaVita, Inc.

Based on the source information reviewed the department concludes that DaVita, Inc. has met the financial feasibility criteria in WAC 246-310-220 and WAC 246-310-815.

(1) The immediate and long-range capital and operating costs of the project can be met.

WAC 246-310-815 outlines the financial feasibility review requirements for dialysis projects. For this project, each applicant must demonstrate compliance with the following sub-sections of WAC 246-310-815(1).

WAC 246-310-815(1)

- (1) The kidney dialysis facility must demonstrate positive net income by the third full year of operation.
- (a) The calculation of net income is subtraction of all operating and non-operating expenses, including appropriate allocated and overhead expenses, amortization and depreciation of capital expenditures from total revenue generated by the kidney dialysis facility.
- (b) Existing facilities. Revenue and expense projections for existing facilities must be based on that facility's current payer mix and current expenses.
- (c) New facilities.
 - (i) Revenue projections must be based on the net revenue per treatment of the applicant's three closest dialysis facilities.
 - (ii) Known expenses must be used in the pro forma income statement. Known expenses may include, but are not limited to, rent, medical director agreement, and other types of contracted services.
 - (iii) All other expenses not known must be based on the applicant's three closest dialysis facilities.
 - (iv) If an applicant has no experience operating kidney dialysis facilities, the department will use its experience in determining the reasonableness of the pro forma financial statements provided in the application.
 - (v) If an applicant has one or two kidney dialysis facilities, revenue projections and unknown expenses must be based on the applicant's operational facilities.

Northwest Kidney Centers

For NKC's project, sub-sections (a) and (b) of WAC 246-310-815(1) apply. NKC provided the following information related to this sub-criterion. [source: Application, p16, p20, and Exhibit 9]

"The requested pro forma financial information is included in Exhibit 9. As required by WAC 246-310-815 (1) the calculation of net income is subtraction of all operating and non-operating expenses, including appropriate allocated and overhead expenses, amortization and depreciation from total revenue, and because NKC Lake City is an existing facility, revenue and expense projections are based on current payer mix and current expenses.

- 1. The Pro forma is completed based on a June 30 fiscal year. The implementation year is assumed to be the 12 months ending June 30, 2021.
- 2. Volumes
 - a. Patient In-Center Census: Census is expected to reach 178 by June 30, 2024. The initial increase in census will result from a shift in the planning area from facilities that are operating above capacity as Lake City will have more desirable run times. Growth beyond that is assumed to meet the projected need in the area.
 - b. Treatments are calculated based on 13 treatments per month and a 5% no-show rate.
- 3. Gross Revenue

- a. Medicare: The modeled weighted average charge per treatment for all billable services is reflective of the actual average amount for the existing facility for the first 9 months of fiscal year 2018.
- b. Medicaid: The modeled weighted average charge per treatment for all billable services is reflective of the actual average amount for the existing facility for the first 9 months of fiscal year 2018.
- c. Medicaid: The modeled weighted average charge per treatment for all billable services is reflective of the actual average amount for the existing facility for the first 9 months of fiscal year 2018.
- d. Total Gross Revenue is the weighted average of the above gross revenue relative to the patient payer mix which is reflective of the actual average payer mix for the existing facility for the first 9 months of the fiscal 2018.
- 4. Deductions from Gross Revenue
 - a. Total Contractual Deductions is the weighted average is reflective of the actual average payer mix for the existing facility for the first 9 months of fiscal year 2018.
 - b. Bad Debt is reflective of the actual average bad debt write-off for the existing facility per treatment for the first 9 months of fiscal year 2018.
 - c. Charity is reflective of the actual average bad debt write-off for the existing facility per treatment for the first 9 months of fiscal year 2018.
- 5. Direct Expenses: All direct expenses are modeled based on the actual average amount per treatment for the existing facility for the first 9 months of fiscal year 2018.
 - a. No inflation has been assumed in the forecast period
 - b. Medical Director is based on contracted amount
 - c. Depreciation has been increased by \$111,173 in the implementation year for new construction costs associated with the project
 - d. Interest Expenses is assumed to be 3.8% and with a bond amortization period of 25 years. Interest is would be capitalized into the project until the unit is operational.
 - e. Other Supplies refers to office supplies, janitorial supplies, building and plant supplies
 - f. Other Purchased Services refers to language interpretation services, freight, landscaping, window washing and pest control.
- 6. Overhead: is based on the organization-wide operating budget for fiscal year 2018. Overhead included administrative and support services.

"NKC Lake City's current payer mix is detailed in Table 10. No change in payer mix is assumed for this project."

Applicant's Table 10

Table 10 NKC Lake City Kidney Center Current and Projected Payer Mix

Davies Miss	Percentage	Percentage
Payer Mix	by Revenue	by Patient
Medicare	62.3%	84.5%
Medicaid	5.1%	8.2%
Commercial	32.6%	7.3%
Total	100.0%	100.0%

Source: Applicant

Using the assumptions stated above, NKC projected the end-of-year number of in-center dialyses and patients for fiscal years 2018 through 2024. Fiscal years 2020 through 2024 are shown in the table below. ¹⁶ [source: Application, p14]

Department's Table 6 NKC Auburn Kidney Center Projected Patients and Dialyses for Fiscal Years 2020 – 2024

	FY 2020	FY 2021	FY 2022	FY 2023	FY 2024
Number of Stations	18	37	37	37	37
Total In center Patients	93	108	135	155	178
Total In center Treatments	13,783	13,875	18,006	21,478	24,635

NKC also projected the revenue, expenses, and net income for fiscal years 2018 through 2024. Fiscal years 2020 through 2024 are shown in the table below. [source: Application, Appendix 9]

Department's Table 7 NKC Auburn Kidney Center

Projected Revenue and Expenses for Fiscal Years 2020 - 2024

-	FY 2020	FY 2021	FY 2022	FY 2023	FY 2024
Net Revenue	\$5,574,719	\$5,612,183	\$7,283,101	\$8,687,121	\$9,964,128
Total Expenses	\$5,368,891	\$5,440,918	\$7,341,005	\$8,580,152	\$9,706,896
Net Profit / (Loss)	\$205,828	\$171,265	(\$57,904)	\$106,969	\$257,232

The 'Net Revenue' line item is gross in-center and training revenue, minus deductions for contractual allowances, bad debt, and charity care.

The 'Total Expenses' line item includes all expenses related to the operation of the projected 37-station facility in years 2020 through 2024. The expenses also include allocated costs consistent with historical percentages. Medical director costs are currently \$75,000 annually for the existing 18-station center. As a 34-station center, the annual medical director costs will increase to \$220,000 annually consistent with the executed Medical Director Agreement provided in the application.

Public Comment

None

Rebuttal Comment

None

Department Evaluation

NKC's Lake City Kidney Center is currently operating with 18 dialysis stations. NKC based its projected utilization of Lake City Kidney Center on its current utilization, plus 19 additional stations consistent with WAC 246-310-815(1)(a) and (b). Based on a review of the assumptions used for projecting utilization of the 37 station dialysis center, the department concludes they are reasonable.

NKC provided a detailed description of the assumptions used for projecting revenue, expenses, and net income of Lake City Kidney Center with 37 stations. The department concludes they are reasonable.

¹⁶ NKC's fiscal years begins July 1 and ends June 30. [source: Application, p14]

Since the site for Lake City Kidney Center is currently owned by NKC, no lease or rent costs are included in the statement. The facility operates with an executed Medical Director Agreement that substantiates the costs identified in the pro form revenue and expense statement.

For NKC's project, the department concludes this sub-criterion is met.

Puget Sound Kidney Centers

For PSKC's project, sub-sections (a) and (c) of WAC 246-310-815(1) apply. PSKC provided the following information related to this sub-criterion. [source: Application, pdf19, pdf22, pdf23 and Exhibit 6]

"The requested pro forma financial statements, utilization projections and financial assumptions are included in Exhibit 6. The three closest facilities are detailed in Table 11.

Applicant's Table

Table 11

Puget Sound Kidney Centers' Three Closest Facilities to PSKC Richmond

Beach

Beach					
Facility	Address	Distance to PSKC Richmond Beach(straight line)	PSKC Facilities Used for "Three Closest Calculation		
PSKC Everett	1005 Pacific Avenue Everett, WA 98201	16.18 miles	X		
PSKC South	21309 44th Ave W. Mountlake Terrace, WA 98043	4.39 miles	Х		
PSKC Smokey Point	18828 Smokey Point Blvd Arlington, WA 98223	29.12 miles			
PSKC Whidbey Island	430 SE Midway Blvd Oak Harbor, WA 98277	38.95 miles			
PSKC Anacortes	809 31st Street Anacortes, WA 98221	51.99 miles			
PSKC Monroe	18121 149th St. SE Monroe, WA 98272	18.76 miles	Х		

Source: Applicant and Google Maps

1. Volumes

- A. Patients In-Center. Census was based on the assumptions outlined below: PSKC has assumed that 18 patients transfer from PSKC South upon opening; and an additional 8 new patients are added (due to the increase projected, in part, from application of the methodology). In 2021, an additional 28 patients are added due to the full operation of PSKC Richmond. In 2022 and in 2023, 19 new patients are expected in each year.
- B. Patients Home Program. Increases in patient census by modality were projected based upon PSKC's historical experience.
- C. Treatments In-Center. Treatments were assumed to average 148 treatments per patient annually to account for missed treatments.
- D. Treatments Home Program. Treatments were based on PSKC experience and assumed an average of 360 treatments per PD patient per year and 156 treatments per HHD patient per year.

2. Revenues

A. Revenues and current payer mix were based on the current experience of three closest PSKC facilities (PSKC Everett, PSKC South, and PSKC Monroe) for all modalities. Payer mix by patient

and revenue was provided in Table 10 of the application. Net revenue per treatment is assumed to be \$312.31 for in-center treatments and per WAC 246-310-812 (c)(i) is the average of the three closest facilities. Net revenue per treatment for home treatments is based upon the net revenue by modality for home hemodialysis (\$393.12) and peritoneal dialysis treatments (\$167.59).

- *B.* Charity care is assumed to be 0.88% of net revenue based on the three closest facilities.
- C. Bad debts are assumed to be 1.1% of net revenue based on the three closest facilities.

3. Direct Expenses

Per the requirement of WAC 246-310-815 (1)(iii) unless otherwise stated, 'all other expenses' have been calculated based on the average cost per treatment of the three closest facilities (total expenses/total treatments) to the proposed PSKC Richmond Beach.

- A. Salaries and wages: information regarding the number of FTEs and average salary was provided in Table 12.
- B. Benefits were assumed to be 24.63%, which is based on the average benefit percentages of the three closest facilities.
- C. Medical Director fees are based on medical director agreement applicable to PSKC Richmond Beach (see Exhibit 7 of the application; \$50,000/year).
- D. Medical supplies: average cost per treatment based on the three closest facilities (\$29.74 for incenter and \$52.04 for home treatments).
- E. Pharmacy and EPO: based on the average cost per treatment of the three closest facilities.
- F. Office and miscellaneous expenses include office supplies, small equipment, information technology expenses (including licenses, software maintenance, and IT-related supplies), equipment rent, and other miscellaneous expenses. These expenses were based on the cost per treatment experience for PSKC's three closest facilities. In year 2020, the first partial year of operation for PSKC Richmond Beach, the expense was increased to include the cost of small equipment not eligible for capitalization.
- G. Repairs and Maintenance include maintenance agreements and parts for various operating equipment. These expenses were based on the cost per treatment experience of PSKC's three closest facilities.
- H. Housekeeping: These expenses were based on the cost per treatment experience of PSKC's three closest facilities.
- I. Building repairs and maintenance, and utilities. Building maintenance was estimated using the cost per square foot average of PSKC's three closest facilities.
- J. Utilities were based on the cost per treatment experience of PSKC's three closest facilities.
- K. Communication expenses include telephone (both land and cell), postage, connectivity, and internet costs. They were estimated based on the average costs of PSKC's three closest facilities.
- L. Laboratory expenses were based on the rate charged for each bundled patient and was assumed to be \$750/patient.
- M. Training: These expenses were based on the cost per treatment experience at PSKC's three closest facilities.
- N. Interest: PSKC intends to finance the proposed facility construction. The required interest expense incurred for this project has been reflected according to the terms of the bank letter.
- O. Depreciation expenses were estimated based on the actual useful lives PSKC assigned to certain equipment classifications. Classifications are as follows:

Building	40 years
Building improvements	15 years
Medical equipment	7 years
Furniture and office equipment	7 years

4. Overhead

- A. Indirect expenses are allocated based on a cost per patient treatment (equivalent in-center treatments) for the proposed PSKC Richmond Beach using 2017 actuals.
- B. The Corporate Medical Director fees are allocated based on a cost per patient treatment (equivalent in-center treatments).

PSKC Richmond Beach's proposed payer mix is detailed in Table 10. PSKC has based the proposed payer mix on the existing payer mix of PSKC's three closest facilities as required by WAC 246-310-815 (c)(i).

Applicant's Table

Table 10
PSKC Richmond Beach Kidney Center
Projected Paver Mix

Payer Mix	Percentage by Revenue	Percentage by Patient
Medicare	48.7%	59.7%
Medicare Managed Care	15.4%	15.9%
Medicaid	7.8%	12.1%
Other: Commercial	28.1%	12.3%
Total	100.0%	100.0%

Source: Applicant

Using the assumptions stated above, PSKC projected the end-of-year number of in-center dialyses and patients for fiscal years 2020 through 2023, which are shown in the table below.¹⁷ [source: Application, p16]

Department's Table 8
PSKC Richmond Beach Kidney Center
Projected Patients and Dialyses for Fiscal Years 2020 – 2023

	FY 2020	FY 2021	FY 2022	FY 2023
Number of Stations	19	19	19	19
Total In center Patients	26	54	73	92
Total In center Treatments	962	7,992	10,804	13,616

PSKC also projected the revenue, expenses, and net income for fiscal years 2020 through 2023, which are shown in the table below. [source: Application, Appendix 9]

Department's Table 9
PSKC Richmond Beach Kidney Center
Projected Revenue and Expenses for Fiscal Years 2020 - 2023

	FY 2020	FY 2021	FY 2022	FY 2023
Net Revenue	\$354,118	\$2,744,199	\$3,753,357	\$4,762,518
Total Expenses	\$534,753	\$2,814,702	\$3,669,549	\$4,330,861
Net Profit / (Loss)	(\$180,635)	(\$70,503)	\$83,808	\$431,657

¹⁷ PSKC's fiscal years begins January 1 and ends December 31. [source: July 31, 2018, screening response, p3]

The 'Net Revenue' line item is gross in-center revenue, minus deductions for bad debt and charity care.

The 'Total Expenses' line item includes all expenses related to the operation of the projected 19-station facility in fiscal years 2020 through 2023. The expenses also include allocated costs consistent with historical PSKC percentages. Medical director costs are \$50,000 annual and consistent with the draft agreement in the application. Since the site would be purchased by PSKC, there are no costs associated with rent or lease for the building.

Public Comment

None

Rebuttal Comment

None

Department Evaluation

PSKC proposes a new 19 station dialysis center in King County planning area #1. PSKC based its projected utilization of the new Richmond Beach facility consistent with WAC 246-310-815(1)(a) and (c). Based on a review of the assumptions used for projecting utilization of the 19 station dialysis center, the department concludes they are reasonable.

PSKC provide a copy of the executed Purchase and Sale Agreement for the site to demonstrate the site is currently owned by PSKC. Therefore, no lease or rent costs are included in the statement.

PSKC provided a copy of the draft Medical Director Agreement that substantiates the costs identified in the pro form revenue and expense statement.

PSKC provided a detailed description of the assumptions used for projecting revenue, expenses, and net income of Richmond Beach Kidney Center with 19 stations. The department concludes they are reasonable.

For PSKC's project, the department concludes this sub-criterion is met.

DaVita, Inc.

For DaVita's project, sub-sections (a) and (c) of WAC 246-310-815(1) apply. DaVita provided the following information related to this sub-criterion. [source: Application, p20, p27 & Appendix 9 and July 31, 2018, screening response, pdf7-8]

DaVita's three closest facilities to 8901 Greenwood Ave N., Seattle WA, 98103 are:

- DaVita Olympic View Dialysis Center
- DaVita Bellevue Dialysis Center
- DaVita Westwood Dialysis Center

First Full Year: 2021, based on a first patient date in September, 2020.

Total Stations: CON Approved stations.

Total Chronic Capacity: 6 shift capacity is assumed to be 100% utilization.

Patient Census Projections: Census projections are based on a 5-year projection of planning area patients using a regression of 5 years historical data and DaVita's own experience and expertise.

Total Treatments: Total Treatment Volume is assumed to be based on average yearly census, a 5% missed treatment rate consistent with DaVita's own experience and expertise, and three treatments weekly for 52 weeks per year.

Revenue per treatment: No inflation is applied to revenue per treatment, which is based on the last full year of operation, 2017 and its payor mix, for comparable facilities.

Cost inflation: DaVita's experience and expertise leads to an assumption that non-medical director or lease costs (which are previously contracted) are likely to inflate at \sim 2% per year, and each category is assumed as such.

Medical Director Expense: based on contracted, known expenses in latest medical director agreements that run through the extent of the three year projection window. This includes post-certification ICHD, PD, and HHD compensation, despite no plans to open PD or HHD programs at this time, yielding the most conservative possible interpretation.

Lease Expense: base rent is directly pulled from the lease contract for each calendar year, with the payment term projected to start in June 2019. Tax and CAM are calculated based on the first year estimate of \$9.00 per square foot annually estimated in the lease contract, inflated at 2% annually.

Labor Assumptions: Based on safe, fair, and efficient staffing ratios for projected census and required staff type. Benefits are assumed at a rate of 60% of wages based on historical precedent. Salaries and wages are projected to inflate at 2% annually.

'Other purchased services' include: (1) pre-employment screening and time keeping services and (2) employment advertising. 'Other direct expenses' include: (1) telephone, (2) travel, (3) freight & postage, (4) dues & subscriptions, and (5) insurance.

In order to determine the G&A allocation, DaVita first identifies each comparable facility per WAC 246-310-815 (listed in response to question #9, above). G&A is allocated on a per-treatment basis, so DaVita then takes each comparable facility's G&A allocation for the last full year of data available (1/1/2017-12/31/2017) and divides it by its total treatments for the same period. This produces three G&A allocations per treatment. The average of these three G&A allocations is used for the projection, with 2% per year inflation estimated.

Table 11 provides expected payor mix for the DaVita Green Lake Dialysis Center, projected using DaVita's comparable facilities and aligned with the pro forma operating statement. Due to DaVita Olympic View Dialysis Center's use as a comparable facility, the "Commercial, HMO, Other Government, and Other" category is higher than normally seen at a DaVita dialysis facility in the vicinity due to its treatment of Kaiser Permanente of Washington patients. If only DaVita Westwood Dialysis and DaVita Bellevue Dialysis are included, DaVita projects Table 11a (for pro forma purposes in Appendix 9, all comparables are used).

Applicant's Table

Table 11 DaVita Green Lake Dialysis Center Projected Payor Mix	Percentage by Revenue	Percentage by Patient
Medicare	17.67%	34.69%
Medicaid	0.94%	2.09%
Commercial, HMO, Other Government, and Other	81.39%	63.22%
Total	100.00%	100.00%

Table 11a DaVita Green Lake Dialysis Center Projected Payor Mix	Percentage by Revenue	Percentage by Patient
Medicare	22.84%	43.02%
Medicaid	1.57%	3.39%
Commercial, HMO, Other Government, and Other	75.59%	53.59%
Total	100.00%	100.00%

Using the assumptions stated above, DaVita projected the end-of-year number of in-center dialyses and patients for fiscal years 2020 through 2023, which are shown in Table 10.¹⁸ [source: July 31, 2019, screening response, Appendix 9A]

Department's Table 10 DaVita Green Lake Dialysis Center Projected Patients and Dialyses for Fiscal Years 2020 – 2023

	FY 2020	FY 2021	FY 2022	FY 2023
Number of Stations	19	19	19	19
Total In center Patients	3	23	63	95
Total In center Treatments	87	1,865	6,333	11,678

DaVita also projected the revenue, expenses, and net income for fiscal years 2020 through 2023, which are shown in the table below. [source: July 31, 2019, screening response, Appendix 9A]

Department's Table 11
DaVita Green Lake Dialysis Center
Projected Revenue and Expenses for Fiscal Years 2020 - 2023

	FY 2020	FY 2021	FY 2022	FY 2023
Net Revenue	\$35,830	\$768,793	\$2,610,598	\$4,813,738
Total Expenses	\$416,925	\$1,748,858	\$2,862,639	\$4,393,123
Net Profit / (Loss)	(\$381,095)	(\$980,065)	(\$252,041)	\$420,615

The 'Net Revenue' line item is gross in-center revenue, minus deductions for bad debt and charity care.

The 'Total Expenses' line item includes all expenses related to the operation of the projected 19-station facility in fiscal years 2020 through 2023. The expenses also include allocated costs consistent with

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¹⁸ DaVita's fiscal years begins January 1 and ends December 31. [source: Application, Appendix 10]

historical DaVita percentages. Medical director costs are \$100,000 annual and consistent with the draft agreement in the application.

Public Comment

In public comment, NKC stated that DaVita's revenue and expense statements contains errors and questionable assumptions, therefore the application's conformance with WAC 246-310-220 and WAC 246-310-815 cannot be confirmed. NKC's public comments are restated below. [source: NKC September 5, 2018, public comment, pp5-6]

"In its original application, DaVita submitted a pro forma financial statement, Appendix 9, based on its three closest facilities (Olympic View, Westwood and Bellevue). In its application, DaVita acknowledges that the combined payer mix of the three facilities likely has a slightly higher commercial mix due to its inclusion of Olympic View as the 3rd facility.

In its June 29, 2018 request for supplemental information, the Program questioned DaVita's inclusion of Olympic View due to its expected high percentage of HMO patients. DaVita's response was to provide yet a 3rd example of payer mix. This example excluded Olympic View and added Mill Creek. DaVita went on to state that it was including a new pro forma financial statement that based the underlying assumptions (revenue and expenses) on the Mill Creek, Bellevue and Westwood facilities. This pro forma, identified as Appendix 23, was included in the submittal. Appendix 23 (including Mill Creek as the 3rd comparable) results in an average revenue per treatment that is \$63.11 higher than the pro forma based on Olympic View as the 3rd comparable facility even though the Mill Creek included payer mix has a lower percentage of commercial patients. DaVita offers no explanation for these inconsistencies.

Regardless of which DaVita proforma the CN Program elect to evaluate, NKC points out the following problems:

- A. Inclusion of Inflation: Inflation is included in DaVita's pro formas despite specific instructions in the new ESRD CN application form published by the Program in March 2018. Specifically, page 2 of the guidelines state:
 - Use non-inflated dollars for all cost projections
 - **Do not** include a general inflation rate for these dollar amounts.

DaVita's pro forma assumptions, included in Appendix 9 and Appendix 23, specifically state:

- i. Cost Inflation: DaVita's experience and expertise leads it to an assumption that non-medical director or lease costs (which are previously contracted) are likely to inflate at ~2% per year, and each category is assumed as such.
- ii. Labor Assumptions: Based on safe, fair, and efficient staffing ratios for projected census and required staff type. Benefits are assumed at a rate of 60% of wages based on historical precedent. Salaries and wages are projected to inflate at 2% annually.
- B. Benefit Rate is Likely an Error: As noted above, DaVita notes that benefits are assumed at rate of 60% of wages. NKC questions DaVita's assumption that benefits are assumed to be 60% of wages. The average benefit rate of all non-DaVita Non-Special Circumstance CN applications was about 26%. DaVita offers no explanation as to why its benefit rate is so high.

C. Calculation of Average Net Revenue and Expense/Treatment: In its screening response, DaVita states that it calculated its average net revenue per treatment and expense per treatment by taking the average of these line items for the three closest facilities. This simple average has the potential to skew an average as it does not take into consideration variances due to size of a facility. A more accurate average would be to calculate a weighted average. For example, by summing total revenues for the three closest facilities and dividing by the sum of the treatments for the three closest facilities."

Rebuttal Comment

DaVita provided the following rebuttal comments for the issues raised by NKC. [source: DaVita October 5, 2018, rebuttal pp10-13]

Inflation is permitted in cost projections, and if inflation is omitted DaVita's projected financial performance improves.

The Department's regulations require an applicant to project costs. They say nothing about whether inflation should be included or not included.

As NKC notes, the Program's application form contains guidance stating that an applicant should not include inflation in cost projections. But omitting inflation makes the cost projections less accurate. Therefore, DaVita asked the Program whether it would be permissible to include inflation, and the Program confirmed that it would be permissible if it were a reasonable estimate. DaVita accordingly included it.

If the Program tells DaVita in a future application cycle that it is forbidden to include inflation in cost projections, even though it makes those projections more accurate, DaVita of course will abide by the Program's instructions. However, the Program told DaVita during this application cycle that adjusting cost projections for inflation was permissible. It would be deeply unfair if the Program were to penalize DaVita for using a more accurate methodology to project costs than is required, a methodology that the Program told DaVita was acceptable.

In any event, if inflation is removed from the cost projections, it improves the financial feasibility of DaVita's facility. This is shown in the following table:

Department Note: A demonstrative statement was provided in DaVita's rebuttal comments but the statement was not recreated for this evaluation.

Therefore, DaVita's proposed facility is financially feasible whether or not inflation is included in the cost projections.

DaVita's projected staffing costs are accurate.

NKC argues that DaVita's staff benefits are unreasonably high. 27 NKC is making another apples-vs.-oranges comparison, as it did with respect to payor mix.

The starting point is to recognize that although staffing costs in facilities may vary due to geography, size, and other factors, and staffing costs for specific employees may vary due to experience and other factors, DaVita's staffing costs and NKC's staffing costs generally are within the same range. This should hardly be a surprise. DaVita and NKC are both experienced operators of dialysis facilities, and therefore can be expected to staff their facilities at an appropriate level, to run their facilities efficiently, and to pay market rates. This can be confirmed by the staffing costs identified by DaVita and NKC in their respective applications.

DaVita's pro forma contains two lines relating to staff expenses: "Salaries & Wages" and "Employee Benefits & Taxes." For the third full year of operation (2023), the \$848,685 salaries & wages and the \$512,979 employee benefits & taxes total \$1,361,664. During that year, the facility is projected to have an average of 79 patients (i.e., between the 63 year-end census for 2022 and the 95 year-end census for 2023) and 11,678 in-center treatments.

Like DaVita, NKC breaks down staff expenses into two lines in its proforma, which NKC calls "Salaries & Wages" and "Benefits." For comparison to DaVita's third full year of operation, the closest year in NKC's historic financials, in terms of patient census, is 2016, during which NKC had between 72 and 75 patients on average (i.e., based on the year-end census figures for 2015 and 2016) and 10,485 incenter treatments. Adding the \$1,185,451 salaries & wages and the \$286,335 benefits for 2016 totals \$1,471,786.

Although one cannot expect that two different dialysis facilities' staffing costs will match exactly, it is notable that NKC's staffing costs during a year in which it had between 72 and 75 in —center patients (\$1,471,786) are very close to DaVita's projected staffing costs for a year in which it expects to have about 79 patients (\$1,361,664). NKC's staffing costs are about 8% higher, but this appears to be almost entirely due to the fact that Lake City operates a home program that served 26 patients during the year in question, and additional staffing is required to operate a home program. Indeed, NKC's application indicates that it paid approximately \$100,000 in staff wages, excluding benefits, for the home training program in 2016, which would account for virtually the entire difference between NKC's staffing costs and DaVita's staffing costs.

NKC only can create a discrepancy by ignoring the fact that Davita's total staffing costs are very similar to NKC's and focusing instead on the breakdown between the two line items that are added together to show total staffing costs.

For DaVita's projected third full year of operation (2023), 62.3% (\$848,685/\$1,361,664) of total staffing costs are in the 11Salaries & Wages" line and the remaining 37.7% (\$512,979/\$1,359,109) of total staffing costs are in the "Employee Benefits & Taxes" line. To stay with the NKC historical figures reference above, because they are for a year with a comparable patient census, 80.5% (\$1,185,451/\$1,471,786) of NKC's total staffing costs are in the "Salaries & Wages" line and the remaining 19.5% (\$286,335/\$1,471,786) of NKC's total staffing costs are in the "Benefits" line.

Therefore, DaVita and NKC have very similar total staffing costs, but the breakdown between the two line-items is significantly different. This is because DaVita and NKC apparently defined 11benefits" differently when preparing their pro formas. One likely difference is that NKC may have included overtime pay and shift-differential pay (i.e., additional pay for less desirable shifts, such as Saturday evenings) in wages, whereas DaVita included these in benefits. Another possible difference is that NKC may have included PTO in wages, whereas DaVita included PTO in benefits. These types of decisions about what to include in each category would account for why DaVita's line-item breakdown is weighted more heavily towards benefits whereas NKC's line-item break down is weighed more heavily towards wages.

In the case of DaVita Everett, an existing facility whose expansion is the subject of a contemporaneous Certificate of Need application and for which existing data is readily available at the individual facility level, shift differential, overtime, and PTO comprise a combined 38% of the total taxes and benefits category, or well over one-third of the total (the remainder being medical insurance, taxes, and various other benefits).

NKC is making an apples-vs.-oranges comparison by comparing what NKC defined as benefits in NKC's proforma with what DaVita defined as benefits in DaVita's proforma. Because NKC and DaVita apparently allocated certain things, likely including overtime pay and shift-differential pay and possibly also including PTO, to different line items, the 11benefits" line-items look quite different. But if the Program compares total staffing costs, the definitional differences become irrelevant. And, as expected, the total staffing costs are quite similar.

The Department's regulation requires an "average," not a "weighted average," of the comparables' net revenue per treatment rates.

NKC argues that DaVita should have used a "weighted average" of statistics from comparable facilities, rather than a simple average. But the Department's rules do not require applicants to use a weighted average. And to the contrary, in the superiority criteria the Department expressly" [d]etermine[s] the individual measure scores for each application by taking the simple average of the comparable scores for each measure." WAC 246-310-827(8)(b) (emphasis added).

If the Program directs DaVita to use a weighted average in future application cycles, DaVita of course will follow the Program's directions. However, it would be improper for the Program to apply a "weighted average" requirement, which appears nowhere in the regulations, during this application cycle. NKC appears to have created this purported standard out of thin air.

Department Evaluation

DaVita proposes a new 19 station dialysis center in King County planning area #1. DaVita based its projected utilization of the new Green Lake Dialysis Center consistent with WAC 246-310-815(1)(a) and (c). Based on a review of the assumptions used for projecting utilization of the 19 station dialysis center, the department concludes they are reasonable.

DaVita provide a copy of the executed Lease Agreement for the site to demonstrate site control. Since DaVita will be leasing the site, rent/lease costs must be included in pro forma revenue and expense statement. DaVita's provided a 'crosswalk' of the costs as listed in the lease agreement to substantiate the costs listed in the pro forma revenue and expense statement.

DaVita also provided a copy of the executed Medical Director Agreement that substantiates the costs identified in the pro form revenue and expense statement.

DaVita provided a detailed description of the assumptions used for projecting revenue, expenses, and net income of Green Lake Dialysis Center with 19 stations. NKC provided concerns about DaVita including inflation in its pro forma revenue and expense statements. Specifically, DaVita provides an assumption description called "cost inflation" and includes the following description:

"Cost inflation: DaVita's experience and expertise leads to an assumption that non-medical director or lease costs (which are previously contracted) are likely to inflate at ~2% per year, and each category is assumed as such."

DaVita refers to a 2% as "inflation," but this does not accurately capture what DaVita is doing and is not consistent with the type of inflation that the department precludes in CN applications. DaVita's application states that 2% is based on past experience in those categories.

The application form specifies that non-inflated **dollars** should be used. If a general inflation rate had been applied to all dollars in all line items (including revenues, deductions and contracted costs), this

would be problematic and contrary to application instructions. However, DaVita is not applying a general inflation rate to their pro forma. Rather, they are using their past experience operating dialysis centers to predict that expenses not tied to agreements/contracts have historically increased at approximately that rate.

The department regularly provides technical assistance to applicants and advises that when known, known expenses should be included. Again, consistent with WAC 246-310-815, DaVita based its revenue and expense projections on performance at their closest three facilities. Because this 2% is consistent with DaVita's experience operating dialysis facilities, this is a reasonable approach. The department concludes that DaVita's revenue and expense statement assumptions are reasonable.

For DaVita's project, the department concludes this sub-criterion is met.

(2) <u>The costs of the project, including any construction costs, will probably not result in an unreasonable impact on the costs and charges for health services.</u>

WAC 246-310-815 outlines the financial feasibility review requirements for dialysis projects. For this project, each applicant must demonstrate compliance with the following sub-sections of WAC 246-310-815(2).

WAC 246-310-815(2)

An applicant proposing to construct a finished treatment floor area square footage that exceeds the maximum treatment floor area square footage defined in WAC <u>246-310-800(11)</u> will be determined to have an unreasonable impact on costs and charges and the application will be denied. This does not preclude an applicant from constructing shelled space.

Northwest Kidney Centers

NKC provided the following information under this sub-criterion. [source: Application, p19]

"This project will have no impact on the costs and charges for services. NKC's charges for services are not determined by capital expenditures. The pro forma operating assumptions and statement, which include the impact of the depreciation expense on operations, is included in Exhibit 9."

NKC provided a copy of its current and proposed line drawings for Lake City Kidney Center which shows where the existing and new stations will be located. [source: Application, Exhibit 5]

Consistent with WAC 246-310-800(11), NKC's Lake City Kidney Center's maximum treatment floor area square footage for 37 stations and one isolation station is 10,325. NKC's project will use 5,970 square feet. [source: Application, p8]

Public Comment

None

Rebuttal Comment

None

Department Evaluation

The estimated costs for this project is \$11,238,608, which includes \$5,000 for relocation of administrative services to a new site. The costs are comparable to those reviewed in past applications for similar type projects and similar sized facilities. The department does not consider the capital expenditure to be excessive for this project.

NKC Lake City Kidney Center's current Medicare and Medicaid reimbursements is 67.4% of revenue and commercial/other is 32.6%. The addition of stations is not expected to change the reimbursement percentages. Given that majority of dialysis, payments are by Medicare and Medicaid reimbursement, the percentages are reasonable.

Regardless of the number of patients projected, under the new ESRD PPS payment system, Medicare pays dialysis facilities a bundled rate per treatment and that rate is not the same for each facility. Each facility, within a given geographic area, may receive the same base rate. However, there are a number of adjustments both at the facility and at patient-specific level that affects the final reimbursement rate each facility will receive. What a dialysis facility receives from its commercial payors will also vary.

Even if two different dialysis providers billed the same commercial payer the same amount, the actual payment to each facility will depend on the negotiated discount rate obtained by the commercial payer from each individual provider. The department does not have an adopted standard on what constitutes an unreasonable impact on charges for health services. Based on the department's understanding of how dialysis patients may qualify for Medicare payments, the department concludes that the information provided by NKC indicates that this project would not have an unreasonable impact on charges for Medicare and Medicaid, since that revenue is dependent upon cost based reimbursement.

To be compliant with WAC 246-310-800(11), Lake City Kidney Center's maximum floor space for a 33 station facility is 10,325. NKC projects the actual floor space will be 5,970. NKC's project does not exceed the maximum treatment floor area square footage allowable.

Based on the above information provided in the application, the department concludes that NKC's projected costs associated with the this project would not have an unreasonable impact on the costs and charges for healthcare services in King County planning area #1. **This sub-criterion is met.**

Puget Sound Kidney Centers

PSKC provided the following information under this sub-criterion. [source: Application, pdf22] "As noted in response to Question #8, PSKC's charges are not determined by capital costs for new facilities. PSKC's charges are the same at each of its facilities. The development of PSKC Richmond Beach will not result in an unreasonable impact on the costs and charges for health services in King 1."

PSKC provided a copy of its proposed line drawings for PSKC Richmond Beach. [source: Application, Exhibit 3]

Consistent with WAC 246-310-800(11), PSKC Richmond Beach Kidney Center's maximum allowable square footage for 19 stations and one isolation station is 5,950. PSKC's project will use 5,121 square feet. [source: Application, pdf10]

Public Comment None

Rebuttal Comment

None

Department Evaluation

The estimated costs for this project is \$8,538,099, which includes all costs associated with the establishment of the dialysis center, including \$3,110,000 to purchase the site. The costs are comparable to those reviewed in past applications for similar type projects and similar sized facilities. The department does not consider the capital expenditure to be excessive for this project.

PSKC Richmond Beach Kidney Center's projected Medicare and Medicaid reimbursements is 71.0% of revenue and commercial/other is 29.0%. Given that majority of dialysis, payments are by Medicare and Medicaid reimbursement, the percentages are reasonable.

Regardless of the number of patients projected, under the new ESRD PPS payment system, Medicare pays dialysis facilities a bundled rate per treatment and that rate is not the same for each facility. Each facility, within a given geographic area, may receive the same base rate. However, there are a number of adjustments both at the facility and at patient-specific level that affects the final reimbursement rate each facility will receive. What a dialysis facility receives from its commercial payors will also vary.

Even if two different dialysis providers billed the same commercial payer the same amount, the actual payment to each facility will depend on the negotiated discount rate obtained by the commercial payer from each individual provider. The department does not have an adopted standard on what constitutes an unreasonable impact on charges for health services. Based on the department's understanding of how dialysis patients may qualify for Medicare payments, the department concludes that the information provided by PSKC indicates that this project would not have an unreasonable impact on charges for Medicare and Medicaid, since that revenue is dependent upon cost based reimbursement.

To be compliant with WAC 246-310-800(11), Richmond Beach Kidney Center's maximum floor space for a 19 station facility is 5,950. PSKC projects the actual floor space will be 5,121. PSKC's project does not exceed the maximum treatment floor area square footage allowable.

Based on the above information provided in the application, the department concludes that PSKC's projected costs associated with the this project would not have an unreasonable impact on the costs and charges for healthcare services in King County planning area #1. **This sub-criterion is met.**

DaVita, Inc.

DaVita provided the following information under this sub-criterion. [source: Application, pp19-20]

"WAC 246-310-815(2) requires that applicants limit the costs of facility projects by creating a test of reasonableness in the construction of finished treatment floor area square footage. The treatment floor area must not exceed the maximum treatment floor area square footage defined in WAC 246-310-800(11). As outlined in response to Question Eleven under the Project Description, DaVita does not propose to construct treatment floor space in excess of the maximum treatment floor area square footage, and thus, under the WAC 246-310-815(2) test, this project does not have an unreasonable impact on costs and charges."

DaVita provided a copy of its proposed line drawings for the new dialysis center. [source: Application, Appendix 16]

Consistent with WAC 246-310-800(11), DaVita Green Lake Dialysis Center's maximum allowable square footage for 19 stations and one isolation station is 5,950. DaVita's project will use 4,844 square feet. [source: Application, pp11-12]

Specific to the costs and charges for health services, DaVita provided the statements below. [source: Application, pp19-20]

"Additionally, as noted in response to question seven, reimbursements for dialysis services are not subject to or affected by capital improvements and expenditures by providers; the proposed project will have no impact on increases in charges for services within the ESRD planning area."

Public Comment

None

Rebuttal Comment

None

Department Evaluation

The estimated costs for this project is \$3,252,405, which includes all costs associated with the establishment of the dialysis center, including \$1,916,333 for building out the space in an existing building. The costs are comparable to those reviewed in past applications for similar type projects and similar sized facilities. The department does not consider the capital expenditure to be excessive for this project.

DaVita Green Lake Dialysis Center's projected Medicare and Medicaid reimbursements is 18.61% of revenue and commercial/other is 81.39%. Given that majority of dialysis, payments are by Medicare and Medicaid reimbursement, the percentages above appear to be unusual.

Regardless of the number of patients projected, under the new ESRD PPS payment system, Medicare pays dialysis facilities a bundled rate per treatment and that rate is not the same for each facility. Each facility, within a given geographic area, may receive the same base rate. However, there are a number of adjustments both at the facility and at patient-specific level that affects the final reimbursement rate each facility will receive. What a dialysis facility receives from its commercial payors will also vary.

Even if two different dialysis providers billed the same commercial payer the same amount, the actual payment to each facility will depend on the negotiated discount rate obtained by the commercial payer from each individual provider. The department does not have an adopted standard on what constitutes an unreasonable impact on charges for health services. Based on the department's understanding of how dialysis patients may qualify for Medicare payments, the department concludes that the information provided by DaVita indicates that this project would not have an unreasonable impact on charges for Medicare and Medicaid, since that revenue is dependent upon cost based reimbursement.

To be compliant with WAC 246-310-800(11), Green Lake Dialysis Center's maximum floor space for a 19 station facility is 5,950. DaVita calculated that its actual floor space will be 4,844. DaVita's project does not exceed the maximum treatment floor area square footage allowable. However, the department notes above that DaVita did not take into consideration the one isolation station that is not counted at the center. Pather DaVita calculated its floor plans using 17 in-center stations instead of 18. When recalculated, DaVita's floor space does not exceed the 5,950 maximum space.

¹⁹ Consistent with WAC 246-310-809, if a new dialysis center will be established and it will provide isolation services, the isolation is not counted in the numeric need methodology, but is counted in the floor plan space for calculations.

Based on the above information provided in the application, the department concludes that DaVita's projected costs associated with the this project would not have an unreasonable impact on the costs and charges for healthcare services in King County planning area #1. **This sub-criterion is met.**

(3) The project can be appropriately financed.

WAC 246-310 does not contain specific source of financing criteria as identified in WAC 246-310-200(2)(a)(i). There are also no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that directs how a project of this type and size should be financed. Therefore, using its experience and expertise the department compared each applicant's projected source of financing to those previously considered by the department.

Northwest Kidney Centers

NKC provided the following information about financing the \$11,238,608 costs for this project. [source: Application, p16 and p18]

"At the current time, NKC anticipates undertaking a tax-exempt bond financing through the Washington Health Care Facilities Authority (WHCFA) for approximately \$9.3 million of the \$11,000,000+ required for this project. The remaining funding will come from NKC reserves. Our proforma financial assumes an interest rate of 3.8%.

As the CN Program is aware, the WHCFA will not approve a financing, nor confirm an interest rate until all CN obligations are met. The rate we used in the pro forma is slightly higher than current rates. We anticipate filing an application with WHCFA in early 2020. In the event that the tax-exempt financing is delayed for some reason, our audited financials included in Appendix 1 demonstrate that we have adequate reserves to undertake and complete 100% of the project without external financing. We are electing to disclose the potential for tax-exempt bonds at this time, so that the CN Program has the ability to analyze the impact of the interest expense (versus no interest expense) associated with this method.

Department's Table 12 Capital Expenditure Breakdown

Capital Expenditure Breakdown	
Item	Amount
Utilities Inspection Fee / Insurance	\$75,000
Building Construction/ Engineering Fees	\$8,371,467
Fixed Equipment (not in construction contract)	\$270,816
Moveable Equipment	\$498,994
Architect Fees	\$554,640
Consulting Fees	\$65,000
Permit Fees	\$55,000
Supervision & Project Management	\$350,000
Washington State Sales Tax	\$997,691
Total Capital Expenditure	\$11,238,608

Public Comment

None

Rebuttal Comment

None

Department Evaluation

NKC intends to finance approximately 83%, or \$9,300,000 of the \$11,238,608, the project using taxexempt bond financing through the Washington Health Care Facilities Authority (WHCFA). The remaining funding of \$1,938,608 or 17% will come from NKC reserves.

WHCFA Funding

NKC is correct that WHCFA will not approve financing or confirm an interest rate until all CN obligations are met. This means that while NKC's project assumes a specific interest rate, that rate is not necessarily confirmed by WHCFA. However, NKC used a rate in the pro forma that is slightly higher than current rates. This approach is conservative and acceptable.

NKC Reserve Funding

NKC provided documentation that the funds are available.

If this project is approved, the department would attach a condition requiring NKC to finance the project consistent with the financing description provided in the application. With a financing condition, the department concludes the NKC project **meets this sub-criterion**.

Puget Sound Kidney Centers

PSKC provided the following information about financing the \$8,538,099 costs for this project. [source: Application, pdf19-22]

"PSKC will debt-finance this project (\$8.5 million). Included in Exhibit 5 is a letter from Banner Bank outlining the terms of the financing. In addition, the remainder of the capital expenditure (less than \$50,000) will be funded using PSKC reserves. Also included in Exhibit 5 is a letter from Mr. Ken Kouchi, CFO, confirming the use of reserves for the remaining project cost.

PSKC entered into a purchase and sales agreement for an existing medical/office building that will be remodeled into the dialysis center. The agreement was finalized and signed in March 2018. Included in Exhibit 8 is a copy of the purchase and sales agreement for the site. Exhibit 9 includes documentation from the King County Assessor's office related to the ownership of the selected site which demonstrates that Richmond Building, LLC (the listed seller on the purchase and sales agreement) is the owner.

The proposed site is zoned neighborhood business. Operating a kidney center at this location is an authorized use. Included in Exhibit 10 is documentation from the City of Shoreline confirming the zoning, and that operating a dialysis center is a permissible use."

Department's Table 13 Capital Expenditure Breakdown

Item	Amount
Building Purchase	\$3,110,000
Building Construction	\$3,193,750
Fixed Equipment (not in construction contract)	\$426,690
Moveable Equipment	\$634,379
Architect / Engineering Fees	\$505,000
Other-City permits, meters, sidewalks, PUD	\$272,190
Washington State Sales Tax	\$396,090
Total Capital Expenditure	\$8,538,099

Public Comment

During the review of these projects, both NKC and DaVita expressed concerns about whether PSKC would be able to fund the project. Comments submitted on this topic are below. [

Northwest Kidney Center Public Comments

[source: September 5, 2018, public comment, p7-8]

"We acknowledge that PSKC has excellent quality and is a patient-centric nonprofit dialysis provider deeply rooted in the community. Given the CON superiority system now in place, PSKC is in an excellent position to win in superiority in any region in which they apply this year. Also, as context for our comments, we are aware that the PSKC approved Lakewood clinic project and 5 PSKC applications this cycle would double the capacity of PSKC from 110 stations to 219 stations in 37 months (between today and October 2021.) Total capital costs of the six projects is \$43 Million. This kind of growth for this organization is of concern and warrants a closer look at what is being proposed:

- A. Financials used in the King 1 application: PSKC included a letter from Banner Bank (page 52 of their application) that states: "Based on the financial information through December 2017, we fully expect that PSKC will qualify for secured long term financing (up to a 10 year maturity with a 25 year amortization) of up to \$8.5 million for purposes of developing a new dialysis center in Shoreline, King County (PSKC Richmond Beach)". As an applicant in the King 1 planning area, we find the application incomplete as the bank references financial performance that the public does not have access to for review. The submitted financials are from 2014, 2015 and 2016. Please ask PSKC to provide 2017 financial statements which are referenced in the bank letter.
- B. Financing: NKC noticed that Banner Bank was proposing financing the King 1 project at a rate of 99.6% of the overall project's value. NKC believes this to be unrealistic, and that a bank would generally loan no more than 80% of a project possibly up to 90% with certain secured collateral or obligations. As well, cash reserves will be required to demonstrate liquidity for loan covenants. How does PSKC plan to maintain reserves to meet this probable expectation of the bank? We ask this because we recognize PSKC is currently constructing a \$10.8M Lakewood clinic and has applied this cycle for 5 CONs totaling \$32 M in capital expenditures with borrowing as the key source of cash. PSKC states they have no affiliates for this project, in Lakewood or referenced in its other five applications so are only using PSKC financials for these projects. As a result, we question the financial capability of PSKC to meet WAC 246-310-220 and be successful achieving this King One project (and four other concurrent CON projects and Lakewood) if approved and spending \$43 million.
- C. Growth: PSKC has been very successful in its steady growth over the past many years and has served the community well. However, PSKC is proposing to double in size by expanding from 110 stations to 219 stations in 37 months (between today and October 2021) throughout different counties around Washington State. Logistically, financially and operationally that would be a stretch for any organization which needs to be recognized.

DaVita, Inc. Public Comments

[source: September 5, 2018, public comment, p4-5]

"An applicant must show that it can satisfy the ability to fund its application, thus the Department's question in its application that requires the applicant to identify the source(s) of financing (loan, grant, gifts, etc.) [for the project] and provide supporting documentation from the source.

PSKC has not successfully demonstrated that it can finance the projects it has proposed. PSKC has, in total, proposed simultaneous projects that require commercial debt financing for \$25.5 million (see the below table, presuming PSKC is actually proposing \$3.5 million in financing for Arlington).

DaVita, Inc.'s Table

Planning Area	PSKC Project	Proposed Fir	nancing Amount
Snohomish 1	Arlington	\$	3,500,000
King 1	Richmond Beach	\$	8,500,000
Kitsap	Silverdale	\$	-
Thurston	Lacey	\$	6,500,000
Clark	Vancouver	\$	7,000,000
Total		\$	25,500,000

While the year-end financial statements in its Application for 2016 show \$7,837,464 in cash reserves, essentially all of those are committed to an existing project. As condition #3 of CN #1598 for its 29-station Lakewood facility, PSKC is committed to \$8,957,745 in capital expenditure solely from its capital reserves, more than it had extant on December 31, 2016. Assuming PSKC even has \$8,957,745 in capital reserves, this means that PSKC is essentially solely reliant on debt financing for any of the above projects.

PSKC has provided a letter in Exhibit 5 from Banner Bank to demonstrate its ability to qualify for a loan to fund this project. This is letter is inadequate to demonstrate that PSKC will obtain the loan, and is not conditionable. As an analogy, if you were to purchase a home, you would obtain a pre-approval letter for at least the amount in question, then when entering contract on the home, would almost certainly have a financing contingency. That contingency protects you from having to proceed on the contract if you are not actually approved. The same is true, at a larger scale, in this case. PSKC provides a letter from Banner Bank that amounts to a pre-approval letter. While it contains general terms, without having gone through underwriting, there is absolutely no guarantee those terms will remain consistent or the funding will even be granted and PSKC has no control over that outcome.

Furthermore, as outlined above, PSKC is not attempting to finance this project in a vacuum. Not only are all of PSKC's existing cash reserves committed to another project, but it is proposing financing a further four projects at a total of \$25.5 million (and build another one with cash reserves). Although the bank letter suggests, in a footnote, that Banner Bank will lend to PSKC on multiple projects, Banner Bank does not commit to doing so. It notes that each project "would be considered and underwritten on its own merits," and for good reason. Its client, PSKC, is proposing not just this project, but five (four of which require financing). Its language in the footnote about not anticipating multiple projects materially affecting its willingness to fund those projects is simply not reliable nor credible.

Based on current commercial lending standards, the upper limit on borrowing for PSKC would be Net Debt of roughly 3-4 times annual EBITDA. EBITDA stands for Earnings Before Interest, Taxes, Depreciation and Amortization. In essence, it is calculated by adding back the income taxes, debt-service interest, and depreciation & amortization to earnings. Net Debt is a company's current cash reserves plus its outstanding debt.

In its 2016 financial statements, PSKC had \$2,823,804 in revenues over expenses, including unrealized gains on investments (Application, 2016 Financial Statements, p.4). As a non-profit, PSKC does not pay income taxes of note, and its financial statements do not indicate material debt service payments. It had depreciation and amortization of \$1,474,096. This yields an estimate of 2016 EBITDA of \$4,297,900.

As PSKC's cash reserves are more than 100% spoken for as an obligation to fulfilling the Department's condition for financing of its Lakewood facility (essentially, a debt PSKC owes to itself and is required

to spend over a certain time period), but its outstanding debt in 2016 was \$0, DaVita charitably assumes that PSKC's Net Debt is \$0. As PSKC has indicated it will also cash-finance its proposed Silverdale facility in Kitsap County with cash it does not appear to have, this is more than generous.

If this is the case, given a generous assumed upper limit of four times Net Debt to EBITDA for PSKC to borrow, this gives \$17,191,600 as a limit to PSKC's borrowing (EBITDA of \$4,297,000 * 4). PSKC proposes to finance \$25,500,000 worth of projects. There is no way that PSKC can claim security in its financing for those projects, nor is that financing reliable for Certificate of Need purposes. Moreover, the closer PSKC were to come to its borrowing limit, the less likely it would be that it could obtain financing terms as generous as those identified in its application—and in this application cycle, PSKC unrealistically proposes to blow through the ceiling on its potential borrowing under current commercial lending standards.

CON applications often involve a large healthcare provider such as DaVita or a hospital system which easily can pay for the proposed project, often with cash. PSKC does not fall into this category, and PSKC's ability to pay for this project is a real concern. If the Department were to approve PSKC's application and then PSKC could not move forward due to lack of financing, planning-area patients would be denied needed dialysis station capacity that another applicant, such as DaVita, could provide. This is one reason why the financial feasibility criteria exist and are enforced. Additionally, if the Department were not to deny PSKC's applications based on PSKC's violation of 827(3)(c), discussed above, or on other grounds, PSKC theoretically could win under the superiority criteria everywhere it has applied. Because PSKC cannot finance all of the projects it has applied for, it would then have to determine where to move forward and where not to move forward. The need would remain unmet where PSKC chooses not to move forward, which very well could be this planning area. Here, the terms Banner Bank outlines are simply unreliable in PSKC's multi-application environment, and thus not only should PSKC be denied under WAC 246-310-220(1), but it should also be denied as its financial projections are unreliable. PSKC's application should be denied under the financial feasibility standards."

Rebuttal Comment

In response to the concerns raised by both NKC and DaVita, PSKC provided the following rebuttal comments. [source: PSKC October 5, 2018, rebuttal comments, pp6-10]

PSKC's Financing Is Reliable and Meets All Certificate of Need Requirements

DaVita states, and PSKC agrees, that CN guidelines require an applicant to identify the source of financing for a project and provide supporting documentation. Years of prior CN approvals demonstrate that a letter from a lender meets these requirements. PSKC has done exactly this.

Additionally, DaVita questions PSKC's ability to finance projects in the manner demonstrated in its CN applications and questions whether we meet the overall financial feasibility standards. We agree that the PSKC King 1 application needs to be considered in light of the other projects that PSKC is proposing. In fact, our analysis demonstrates that we fit comfortably within all financial parameters and we are highly confident in our ability to meet all applicable financial feasibility requirements.

DaVita's public comment cites a total of \$25.5 million in proposed financing for PSKC projects in Cycle 1, and another nearly \$9 million for PSKC's currently under development (and already funded) Pierce 5 project. The nearly \$9 million for Pierce 5 is already committed and, as noted below, the correct dollar amount for the remaining three applications in Cycle 1 is less than \$25 million. Each of the Cycle 1 applications include a letter of preliminary commitment from our long-standing banking partner, Banner Bank, thus meeting CN requirements.

Understanding the financial support that Banner Bank is willing to provide PSKC is critical to understanding the overall financial feasibility of our CN applications. We provided separate letters from Banner Bank in connection with each of our application filings. The amount of financing that Banner Bank is willing to provide for each project is as follows:

PSKC Recreated Table

Richmond Beach	\$8,500,000
Arlington	\$4,000,000
Lacey	\$6,500,000
Total	\$19,000,000

Our application materials fully support the financial feasibility of this project in the context of PSKC's overall operations. To refute DaVita's comments fully and transparently, PSKC undertook an additional proforma financial ratio analysis of the impact of the entirety of the projects currently under development and the three new projects we have remaining in Cycle 1. To do so, we evaluated PSKC's ratios from today until 2024 (the third full year of operation of the last of three projects being proposed in Cycle 1). We evaluated ourselves against the exact same financial ratios that the CN Program employs with hospital projects. These ratios are identified in Table 1, and our ratios, following project completion are included in Attachment 1.

PSKC Rebuttal Table
Table 1

CN Program Financial Ratios

Ratio	Formula	DOH Target (Above/Below)	2017 Statewide Ratio
Long Term Debt to Equity	Long Term Debt/Equity	Below	0.446
Current Assets/Current Liabilities	Current Assets/Current Liabilities	Above	3.396
Assets Funded by Liabilities ²	Current Liabilities + Long term Debt/Assets	Below	.501
Operating Expense/Operating Revenue	Operating expenses / operating revenue	Below	0.978
Debt Service Coverage	Net Profit+Depreciation and Interest Expense/Current Mat. Long Term Debit and Interest Exp	Above	4.906

Source: Financial ratios based on the CN Program's August 2018 evaluation of RCCH/Capella's Acquisition of

Lourdes Medical Center, p. 30

Over the last several years, PSKC has demonstrated its ability to operate at the highest levels with outstanding quality, low cost, and fiscal conservatism. PSKC has made significant investments in all of its facilities while incurring virtually no long-term debt- a condition unachieved by most other dialysis providers. We operate safe, aesthetically pleasing facilities that are unencumbered by any indebtedness-and we own, not rent, dialysis space, in contrast with most providers. As a result, PSKC has been able to keep its costs and rates lower than other providers in the marketplace.

Due to the current opportunities that are available in key markets, PSKC management has made the decision to utilize its current debt capacity and take advantage of financing that has always been available. Because of our very strong financial position, we are able to use our substantial unencumbered asset base that we own to finance a significant portion of proposed projects and use

cash reserves to fund projects as committed in prior CN applications. Leased facilities would not provide that lendable asset base. PSKC Management can demonstrate that cash reserves were used to fund all projects committed in that manner, and that proposed projects can be funded through debt proceeds in the manner and to the extent confirmed by Banner Bank, our financial partner.

Further, DaVita has attempted to define and place a borrowing capacity on PSKC based upon its own interpretation of commercial lending practices - utilizing a simplified multiplier of EBIDTA. DaVita provides no foundation for its assumption that 3-4X EBIDTA is an industry standard for asset-poor companies like itself, much less that such a standard is applicable to PSKC's asset-rich circumstances. Whatever the source of DaVita's formula, it does not take into consideration the strength of PSKC's balance sheet that has accumulated due to its financial discipline and decision to defer the use of debt financing in the past and the willingness of its current lender to provide the necessary financing for proposed projects. After factoring in all proposed debt, PSKC falls comfortably within its lender's parameters and the statewide standards utilized by the department for assessing financial feasibility. PSKC clearly and unequivocally meets the financial feasibility standards.

PSKC's ability to fund this project and our other Cycle 1 projects is not in question. DaVita raises this only in another desperate attempt to have PSKC not reach superiority. As DaVita admits, "PSKC could theoretically win under the superiority criteria everywhere it has applied." PSKC agrees. PSKC is proud of its quality, access, cost performance, and is highly confident that we meet and exceed all criteria in WAC 246-310-220. As stated in our public comments, our applications are unassailable. PSKC's leadership team literally spent months developing the applications and reviewing data for correctness, and our assumptions for reasonableness are accurate. We also engaged in numerous conversations with CN Program staff to ensure 100% understanding and clarification of the new CN guidelines.

Further, and most importantly, PSKC demanded of itself to know that patients would be well-served by these applications, that the collective growth represented in the applications was planned and orderly, and that access, quality, cost-effectiveness, and the financial position of PSKC was not unreasonably affected during the growth. Under its decades-long-standing leadership, PSKC has put into place a leadership team, and the infrastructure, to support the growth and continue to ensure "top box" quality. We have also partnered with a lender to ensure the funding PSKC needs to develop these projects is available.

PSKC is honored to grow to ensure that more patients, doctors, communities, and payers statewide have access to our exceptional quality and reasonable rates. DaVita's comments are simply an effort to beg that we do not reach superiority.

<u>Information Already In The Record Regarding Financing Is Complete And Meets All Applicable</u> Criteria In WAC 246-310-220

At the time of submittal of Cycle 1 CN applications, PSKC's latest audited financials were from 2016. Our 2017 audited financials were not published until late June 2018. The letter we submitted in the CN application from Banner Bank related to the Richmond Beach project stated that it had reviewed our financial information through December 2017 in indicating that we would qualify for secured long term financing (up to a 10-year maturity with a 25-year amortization) of up to \$8.5 million.

NKC asked the CN Program to request that we provide our audited 2017 statements, since they were neither included in the application (not finalized), nor requested by the CN Program in screening. While PSKC would gladly submit these Statements further demonstrating our financial wherewithal, we have been advised by the CN Program that the record is complete and no new information can be provided.

PSKC is confident that our proposed financing information already in the record is complete and sufficient.

The Financing of King 1, And In Fact Each Of Our Cycle 1 Applications Is Reasonable And Safeguards The Financial Position Of PSKC

NKC suggests that Banner Bank is proposing to finance the King 1 project at a rate of 99.6% of the overall project's value. NKC then goes on to state that they believe "this to be unrealistic." Banner Bank provided us with a "maximum" amount of financing that they would provide on a project to project basis, and that was the basis for our assumptions for the proformas submitted with our applications. As we described above in our response to the concerns raised by DaVita, Banner Bank is taking into consideration PSKC's strong balance sheet and our very low current debt levels, and feels very comfortable financing our proposed projects at the levels indicated in our applications. The most recent letter, along with the previous letters that we've received from Banner and provided to the CN Program, demonstrate this.

PSKC's Proposed Growth Is Purposeful, Planned And Orderly

PSKC wants to thank NKC for acknowledging that PSKC has been "very successful in [our] steady growth over the past many years." NKC knows PSKC's leader quite well, and knows that PSKC would not jeopardize its patient-centric, quality, efficient practices. The growth we outlined in Cycle 1 has been fully vetted. Under our decades-long-standing leadership, PSKC has put into place a leadership team, and the infrastructure, to support our proposed growth and continue to ensure "top box" quality. We have also partnered with a lender to ensure the funding PSKC needs to develop these projects is available. Our proposed projects and superior services will benefit the dialysis residents in the State. PSKC has planned, and is positioned and prepared to operationalize our new facilities with the same quality and standards we have done with other projects."

Department Evaluation

Both NKC and DaVita raised concerns that PSKC may financially overextend with the applications it has submitted during the 2018 cycle 1 reviews. However, PSKC provided information in its rebuttal comment to assure that it was not financially overextended now, nor would PSKC take that risk in the future. Further, PSKC withdrew two of its five applications submitted during this review cycle and was refunded for portions of the review fee. The department concludes that the concerns raised are not grounds for denial.

PSKC intends to debt finance the project approximately \$8,500,000, approximately 99%, with Banner Bank and provided documentation from the banking institution that the funds are available to PSKC. The remaining \$538,099 is to be funded through PSKC reserves and PSKC provided a letter from its chief financial officer confirming the use for reserves for the remaining amount.

If this project is approved, the department would attach a condition requiring PSKC to finance the project consistent with the financing description provided in the application. With a financing condition, the department concludes the PSKC's project **meets this sub-criterion**.

DaVita, Inc.

DaVita provided the following information about financing the \$3,252,405 costs for this project. [source: Application, pp18-19]

"DaVita, Inc, via its subsidiary Total Renal Care, Inc., is solely responsible for the capital costs identified above.

The DaVita Green Lake Dialysis Center executed lease, with a term extending at least five years beyond project completion, is included in Appendix 15. Zoning & county assessor documentation for the proposed DaVita Green Lake Dialysis Center is provided in Appendix 15.

Construction cost is estimated based on the non-binding contractor estimate presented in response to Question 6. Construction cost number includes sales tax. Sales tax is assumed at the Seattle, King County rate of 10.1% for all fixtures, furnishings, and equipment, and where else applicable."

Department's Table 14 Capital Expenditure Breakdown

Custom Expenditure Breakdown				
Item	Amount			
Utilities to Lot Line	\$101,950			
Building Construction (includes sales tax)	\$1,916,333			
Fixed Equipment (not in construction contract)	\$234,672			
Moveable Equipment	\$616,710			
Architect / Engineering Fees	\$180,750			
Supervision & Inspection of Site	\$116,000			
Washington State Sales Tax	\$85,990			
Total Capital Expenditure	\$3,252,405			

Public Comment

None

Rebuttal Comment

None

Department Evaluation

DaVita intends to finance the project with reserves and demonstrated the funds are available. If this project is approved, the department would attach a condition requiring DaVita to finance the project consistent with the financing description provided in the application. With a financing condition, the department concludes the DaVita project **meets this sub-criterion**.

C. Structure and Process (Quality) of Care (WAC 246-310-230)

Northwest Kidney Centers

Based on the source information reviewed the department concludes that Northwest Kidney Centers has met the structure and process of care criteria in WAC 246-310-230.

Puget Sound Kidney Centers

Based on the source information reviewed the department concludes that Puget Sound Kidney Centers has met the structure and process of care criteria in WAC 246-310-230.

DaVita, Inc.

Based on the source information reviewed the department concludes that DaVita, Inc. has met the structure and process of care criteria in WAC 246-310-230.

(1) A sufficient supply of qualified staff for the project, including both health personnel and management personnel, are available or can be recruited.

WAC 246-310 does not contain specific WAC 246-310-230(1) criteria as identified in WAC 246-310-200(2)(a)(i). There are also no known recognized standards as identified in WAC 246-310-200(2)(a)(ii)

and (b) that directs what specific staffing patterns or numbers of full time equivalents (FTEs) that should be employed for projects of this type or size. Therefore, using its experience and expertise the department determined whether the proposed staffing would allow for the required coverage.

Northwest Kidney Centers

NKC provided the following staffing table showing current and projected staff for the expanded Lake City Kidney Center. [source: Application, p22]

Department's Table 14
Lake City Kidney Center Current and Proposed Staff

Lake City Kluncy Center Current and Proposed Starr					
	FYE 2018	FYE 2019	FYE 2020	FYE 2021	FYE 2021
FTEs	Annualized	Projected	Projected	Projected	Totals
Clinical Director	0.20	0.00	0.00	0.00	0.20
Nurse Manager / Care Manager	1.00	0.00	0.00	0.00	1.00
Tech	11.66	1.26	0.00	0.10	13.02
RN In center	6.96	0.00	0.00	0.04	7.00
RN Home Training	1.00	0.00	0.00	0.00	1.00
Facility System Specialist	0.50	0.00	0.00	0.50	1.00
MSW	1.00	0.00	0.00	0.15	1.15
Dietician	0.91	0.00	0.00	0.14	1.05
Receptionist	1.00	0.00	0.00	0.00	1.00
FTE Totals	24.23	1.26	0.00	0.93	26.42

	FYE 2021	FYE 2022	FYE 2023	FYE 2024	FYE 2024
FTEs	Totals	Year 1	Year 2	Year 3	TOTAL
Clinical Director	0.20	0.00	0.00	0.00	0.20
Nurse Manager / Care Manager	1.00	0.00	0.00	0.00	1.00
Tech	13.02	3.86	3.26	2.96	23.10
RN In center	7.00	2.09	1.75	1.60	12.44
RN Home Training	1.00	0.50	0.00	0.00	1.50
Facility System Specialist	1.00	0.00	0.00	0.00	1.00
MSW	1.15	0.29	0.21	0.24	1.89
Dietician	1.05	0.27	0.19	0.22	1.73
Receptionist	1.00	0.00	0.00	0.00	1.00
FTE Totals	26.42	7.01	5.41	5.02	43.86

NKC provided the following clarification regarding the staffing table above. [source: Application, p23]

Focusing on recruitment and retention of necessary staff, NKC provided the following information. [source: Application, p23 and July 31, 2018, screening responses, pp4-5]

[&]quot;The staffing in Table 11 is based on current staff to patient ratios and actual average salaries at NKC Lake City. WAC 246-310-815(c)(iii) states that known expenses must be used in the pro forma income statement. Given that NKC knows both staffing ratios and average salaries, this information is included in both Table 11 and the pro forma financials."

[&]quot;Given that NKC's current average length of service is 10.3 years and further given our competitive wages and benefits, we do not anticipate any difficulty in recruiting any additional staff needed for this expansion.

NKC is proactive in its efforts to assure quality staffing at all time. NKC offers a competitive wage and benefit package as well as numerous other recruitment and retention strategies. Specific strategies include:

- NKC offers competitive wage and benefit packages. To ensure that its wages and benefits remain competitive, NKC conducts an annual market survey to benchmark its compensation package.
- NKC remains active on various job board including but not limited to indeed.com, nursing association, Health e-careers, and other local resources.
- NKC also has contacts with colleges and universities throughout the Puget Sound area to both recruit staff as well as to serve as a clinical rotation site.
- *NKC* staff participate, at least monthly, in job fairs in and around the Puget Sound area.
- NKC also offers a substantial tuition reimbursement program for existing staff. Typically, in an average year, 15-20 employees take advantage of this program. Primarily, dialysis technician staff use this program to become registered nurses.
- NKC human resources staff are active in various boards and councils that focus on sharing of recruitment and retention strategies.
- NKC human resources staff also work with agency personnel as needed for the use of temporary filling of staff positions.
- NKC has a highly successful employee referral program that incentivizes current employees to refer colleagues from outside the organization for open positions
- NKC will, as needed, work with outside recruiters if a position has been challenging to fill.

Recent history demonstrates that NKC has been successful in staffing our new facilities. The most recent examples include the Federal Way East and Federal Way West Campus facilities. These new units were staffed with a combination of individuals that chose to transfer from other locations and new hires to the organization. In the case of Lake City, because NKC is proposing an expansion, NKC is already in the planning area as a provider of services. In addition, NKC likely has part time staff that would be willing to expand their work hours.

The record will further demonstrate that in those rare circumstances in which we have faced staffing shortages (due to extended leave of absences or other issues), we have successfully used our roster of per diem staff or staff from other facilities nearby to supplement. The proximity of NKC Lake City to NKC Scribner and NKC Kirkland also allows for sharing with those facilities in the event we have a situation that requires additional staffing."

Public Comment

None

Rebuttal Comment

None

Department Evaluation

Information provided in the application demonstrates that NKC is a well-established provider of dialysis services in Washington State and in King County planning area #1. Its Lake City Kidney Center has been operational since approximately 2002.

With an additional 19 stations, NKC expects Lake City Kidney Center's staff to increase by another 20 FTEs—from approximately 23 to 43—by the end of year 2024. NKC intends to rely on its recruitment and retention strategies used in the past for this project. This approach is reasonable.

Based on the above information, the department concludes that NKC has the ability and expertise to recruit and retain qualified staff for this project. **This sub-criterion is met**.

Puget Sound Kidney Centers

PSKC provided the following staffing table showing projected staff for the new dialysis center. [source: Application, pdf26]

Department's Table 15 Puget Sound Kidney Centers Proposed Staff

	FYE 2020	FYE 2021	FYE 2022	FYE 2023	FYE 2023
FTEs	Partial Yr	Increase	Increase	Increase	Totals
Direct Care Manager	0.60	0.00	0.40	0.00	1.00
Home RN	0.20	0.00	0.10	0.20	0.50
RN	1.00	2.00	1.00	1.00	5.00
Care Coordinator	0.00	0.00	0.75	0.25	1.00
Dialysis Techs	3.00	3.75	3.00	2.25	12.00
BioMed Tech	0.60	0.00	0.40	0.00	1.00
Stock Tech	0.00	0.60	0.40	0.00	1.00
Computer Tech	0.10	0.00	0.00	0.00	0.10
MSW	0.30	0.30	0.20	0.20	1.00
Dietitian	0.30	0.30	0.20	0.20	1.00
Administrative Assistant	0.60	0.00	0.40	0.00	1.00
FTE Totals	6.70	6.95	6.85	4.10	24.60

PSKC provided the following clarification regarding the staffing table above. [source: Application, p23]

"PSKC's fiscal year is January 1, through December 31. The staffing was based on PSKC's actual experience. PSKC schedules direct patientcare staff to maintain a safe and efficient level of care.

- General patient staffing ratios are:
- Dialysis Technician 4:1 (Isolation 1:1)
- Registered Nurse 16-20:1
- Social Worker 100:1
- Renal Dietitian 100:1
- Home Registered Nurse 18-22:1
- Care Coordinator 80-100:1

All other personnel are determined by days and hours in operation.

The average wage/FTE identified is based on PSKC's known average labor cost and the years of employment/step at which the majority of staff work. Consistent with WAC 246-310-815(c), which states that new facilities should use known expenses, PSKC based its staffing on empirical experience. We believe this accurately identifies labor cost. If the CN Program wishes further clarification, please request in screening."

Focusing on recruitment and retention of necessary staff, PSKC provided the following information. [source: Application, pdf28 and July 31, 2018, screening responses, pdf3-4]

"In addition to providing exceptional patient care, PSKC offers a competitive wage and benefit package, a positive and supportive work environment, and a philosophy that encourages existing staff to receive training and additional education. For each of these reasons, PSKC has not experienced

difficulty recruiting and retaining qualified staff in any facility. PSKC's goal is to "grow" its own, and PSKC's training, education and flexible human resource policies have allowed PSKC to excel with this strategy. Based on our historical record and performance, we do not anticipate any significant difficulties recruiting the staff needed for this new facility.

While we are aware of a staffing shortage across the state and nation, it has not been a deterrent to PSKC being able to staff our facilities with patient safety as our top priority. PSKC is an excellent place to work with competitive wages or salaries, and a generous benefit plan.

Beyond the strategies for attracting and retaining employees that were identified in the CN application, PSKC's commitment to, and involvement with, the communities we serve has resulted in many long standing and collaborative relationships with various educational health care programs. This has also opened opportunities for promoting dialysis to new graduates and health care professionals in other specialty areas who might be looking to change specialties. For example, phlebotomists apply for dialysis technician positions, and dialysis technicians looking to advance their careers desire to finish RN curriculum. PSKC helps with some scholarship support.

Further, PSKC's Education Department provides training and education to various patients, university, and community college health care student populations, and also actively promotes positions that are open. This active promotion occurs at community events such as health/job fairs and also with college nursing program presentations. The King 1 planning area will be included in these types of outreach; similar to the outreach PSKC produces in other areas it serves.

PSKC has also benefited greatly from "word of mouth" by current employees and use of social media networking sites to attract potential candidates using a more informal or individual approach. Given that PSKC has a facility in an adjacent planning area, and its corporate office is less than 20 miles away, PSKC anticipates it will be able to implement these strategies in the King 1 planning area.

Lastly, it is common for nurses and technicians to compare employers, especially when the job market is as strong as it is currently in Western Washington, and using this information, nurses and techs continue to choose PSKC as their employer. Knowing that past success is the best predictor for the future, we have no reason to doubt that this will continue."

Public Comment

None

Rebuttal Comment

None

Department Evaluation

Information provided in the application demonstrates that PSKC is a well-established provider of dialysis services in Washington State and in Snohomish County. PSKC does not have a presence in King County at this time, however, many of its Snohomish County dialysis centers have been operational for many years.

With an establishment of a 19-station dialysis center in Richmond Beach, PSKC expects to need approximately 25 FTEs by the end of year three (2021). PSKC intends to rely on its recruitment and retention strategies used in the past for this project. This approach is reasonable.

Based on the above information, the department concludes that PSKC has the ability and expertise to recruit and retain qualified staff for this project. **This sub-criterion is met**.

DaVita, Inc.

DaVita provided the following staffing table showing projected staff for the new dialysis center. [source: July 31, 2018 screening response, pdf5]

Department's Table 16 DaVita, Inc. Proposed Staff

	FYE 2020	FYE 2021	FYE 2022	FYE 2023	FYE 2023
FTEs	Partial Yr	Increase	Increase	Increase	Totals
Administrator	1.00	0.00	0.00	0.00	1.00
Admin Assistant	1.00	0.00	0.00	0.00	1.00
MSW	0.01	0.09	0.26	0.30	0.66
Dietician	0.01	0.09	0.26	0.30	0.66
RN-InCenter/PD/HHD	0.76	3.80	0.19	4.01	8.76
BioMed Tech	0.50	0.00	0.00	0.00	0.50
Other	0.02	0.14	0.37	0.45	0.98
FTE Totals	3.30	4.12	1.08	5.06	13.56

DaVita provided the following clarification regarding the staffing table above. [source: Application, p23 and July 31, 2018, screening response, pdf4-5]

"DaVita notes that, as the facility is expected to be operational during September 2020, four months of information are relevant to fiscal year 2020.DaVita projects FTEs based on staffing ratios for patients per shift, combined with clinical expertise. Standard ratios are noted in Table 18. Overall census estimates are based on the assumptions describing the pro forma in Appendix 9. Aggregated salary, wage, and benefit rates for each FTE category are noted in Table 18, based on actual rates from 2017 comparable facilities. Benefits are calculated at 60% of gross salaries and wages. "Other" includes, among other miscellaneous categories, patient education and inventory management roles, as well as staff training."

Focusing on recruitment and retention of necessary staff, DaVita provided the following information. [source: Application, p23 pdf28 and July 31, 2018, screening responses, pdf3-4]

"DaVita anticipates no difficulty in recruiting the necessary personnel to continue to staff DaVita Green Lake Dialysis Center. Based on our experience operating facilities in the Seattle area, DaVita anticipates that staff from geographically adjacent facilities will serve patients at the new DaVita Green Lake Dialysis Center, and some new staff may also be required. DaVita has been repeatedly recognized as a Top Employer and a Military Friendly Employer (DaVita.com/about/awards) and offers a competitive wage and benefit package to employees. DaVita posts openings nationally both internally and external to DaVita."

DaVita does not expect any significant barriers to recruiting staff for Green Lake Dialysis Center. As outlined in its application, DaVita has been repeatedly recognized as a Top Employer and a Military Friendly Employer and offers a competitive wage and benefit package to employees, and posts openings nationally. However, in the unlikely event Green Lake Dialysis Center faces any barriers to recruiting staff, DaVita would take a multi-faceted approach, utilizing those methods necessary to ensure timely patient care. These methods may include, but are not limited to, selective use of signing bonuses and

incentives for select staff recruitments, cross-staffing with nearby DaVita facilities where possible, and if absolutely essential, limited use of agency temporary staff, with a continued focus on recruitment and retention of permanent teammates as soon as possible. As mentioned, however, DaVita does not expect any significant barriers to recruiting staff, especially given its existing expertise with operating dialysis facilities in the Seattle area."

Public Comment

None

Rebuttal Comment

None

Department Evaluation

Information provided in the application demonstrates that DaVita is a well-established provider of dialysis services in Washington State and in King County. DaVita does not operate any dialysis facilities in King County planning area #1.

With an establishment of a 19-station dialysis center in the Green Lake area, DaVita expects to need approximately 13 FTEs by the end of year three (2021). DaVita intends to rely on its recruitment and retention strategies used in the past for this project. This approach is reasonable.

Based on the above information, the department concludes that DaVita has the ability and expertise to recruit and retain qualified staff for this project. **This sub-criterion is met**.

(2) <u>The proposed service(s)</u> will have an appropriate relationship, including organizational relationship, to ancillary and support services, and ancillary and support services will be sufficient to support any health services included in the proposed project.

WAC 246-310 does not contain specific WAC 246-310-230(2) as identified in WAC 246-310-200(2)(a)(i). There are also no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that directs what relationships, ancillary and support services should be for a project of this type and size. Therefore, using its experience and expertise the department assessed the materials contained in the application.

Northwest Kidney Centers

NKC provided the following statements under this sub-criterion,. [source: Application, pp25-26]

"Table 12 details the existing ancillary and support service vendors already in place at NKC Lake City.

Applicant's Table
Table 12
NKC Lake City
Ancillary and Support Services

Service	Vendor
IT/Network Engineering	GCI Northpoint
Copier leases and support	Copiers NW
Janitorial Services	Citywide
Lab Services	Ascend

Source: Applicant

At the time the first Phase of the renovated Lake City is operational, NKC will be operating three Support Centers in Burien/SeaTac, SeaTac, and Seattle that provide ancillary and support services to each dialysis facility. These Support Centers are staffed with our own NKC employees and are not outside contractors. Table 13 details which services are provided on site and which ones are administered via the Support Centers (Off-site).

Applicant's Table
Table 13
Ancillary and Support Services for NKC Lake City

Service	Offered Onsite/Offsite
Administration	Off site
Community Relations	Off site
Human Resources	Off site
Informatics Nurses	Off site
Information Systems	Off site
Material Management	Off site
Medical Staff Credentialing	Off site
Nutrition Services	On site
Patient Education	On site
Patient Financial Counseling	On site
Pharmacy	On and Offsite
Plant Operations	On site
Public Relations	Off site
Technical Services	On site
Visitor Dialysis	On site
Water Purification Specialists	On site

Source: Applicant

Table 14 details the health care entities that NKC has working relationships with. No changes to existing ancillary or support agreements are anticipated as a result of this project."

Applicant's Table

Table 14 NKC's Working Relationships with Healthcare Facilities

NKC's Working Relationships with Healthcare Facilities		
Category	Examples/Providers	
Clinics/Nephrology Groups (Sample)	Examples/Providers MHS Auburn Regional Medical Center CHI / Highline Medical Center CHI / St. Francis Hospital Evergreen Hospital Medical Center MultiCare Tacoma General Northwest Hospital Overlake Hospital Medical Center Swedish Edmonds Swedish Edmonds Swedish Issaquah Swedish Medical Center University of Washington Valley Medical Center Virginia Mason Medical Center Cascade Kidney Specialists CHI Franciscan Nephrology Associates Eastside Nephrology Harborview Medical Center MultiCare Nephrology Polyclinic, The (and The Polyclinic Madison Center) Rainier Nephrology Seattle Nephrology South Seattle Nephrology Associates Transplant and Nephrology NW University of Washington Medical Center Valley Medical Center Nephrology Services Virginia Mason Federal Way	
Community partners working to cure kidney disease, slow the onset of kidney disease, which collaborate to help educate and support our patients or help support our system Other not for profit dialysis providers	American Diabetes Association – Washington Chapter Kidney Research Institute National Kidney Foundation – Washington Chapter Navos Washington Dental Society / Access to Dental Northwest Health Response Network (King / Pierce County Healthcare Emergency Services Coalition) Puget Sound Kidney Centers Olympic Peninsula Kidney Centers Skagit Valley Kidney Centers Seattle Children's Hospital	

Source: Applicant

NKC also provided a copy of NKC Lake City Kidney Center's existing patient transfer agreement with Swedish Medical Center. [source: Application, Exhibit 19]

NKC also provided a copy of the executed Medical Director Agreement with nephrologist Jung Joh, MD. The agreement was executed in July 2003 and has been updated periodically since that time. The most recent update was September 2017. The executed agreement identifies roles and responsibilities for both NKC and Dr. Joh. Additionally, all costs are identified in the agreement. [source: Application, Exhibit 10]

Public Comment

None

Rebuttal Comment

None

Department Evaluation

As previously stated, Lake City Kidney Center has been operating in King County planning area #1 since approximately 2002. All ancillary and support services have been established for the dialysis center since that time. NKC states that no new agreements or revisions to existing agreements are necessary for this project.

The Medical Director Agreement is executed and is not expected to change with the addition of 19 dialysis stations.

The Patient Transfer Agreement is also executed and not expected to change with the addition of 19 dialysis stations.

The department also concludes that all other required ancillary and support agreements and relationships are already in place.

Based on the information above, the department concludes that NKC demonstrated that it would have the necessary ancillary and support services at its existing Lake City Kidney Center. **This sub-criterion** is met.

Puget Sound Kidney Centers

PSKC provided the following information for this sub-criterion. [source: Application, pdf28-29]

"Table 13 provides a listing of the proposed ancillary and support services required for PSKC Richmond Beach. While vendor(s) are identified for several of these services (current PSKC vendors), no specific agreements have been entered into at this time.

Applicant's Table

Table 13

Proposed Ancillary and Support Service Agreements Agreement Type Vendor(s) Electronic Medical Records Health Informatics (Infian) Anemia Management PhySoft, Inc. Laboratory Services Spectra Laboratory Required CMS Data Reporting National Healthcare Safety Network (NHSN). CROWNWeb Equipment/Materials Cardinal, Baxter, Henry Schein, NxStage, Fresenius, Praxair Management Transportation Services TBD Biohazard/Waste Management TBD Janitorial Services TBD

Source: Applicant

PSKC Richmond Beach will provide the full range of Medicare required ancillary and support services including:

Administration	Patient Financial Counseling
Information Systems	Plant Operations
Material Management	Social Services
Nursing Services	Staff Education
Nutrition Services	Technical Services
Patient Education	

Table 14 details the ancillary and support services and indicates which would be provided onsite and which would be provided offsite through PSKC Corporate.

Applicant's Table

Table 14
Proposed Ancillary and Support Services for PSKC Richmond Beach

Service	Offered Onsite/Offsite
Administration	Off site
Human Resources	Off site
Information Systems	Off site
Material Management	Off site
Nursing Services	On site
Nutrition Services	On site
Patient Education	On site
Patient Financial	Off site
Counseling	
Plant Operations	On site
Social Services	On site
Staff Education	Off site
Technical Services	On site

Source: Applicant

PSKC provided the following information about a Patient Transfer Agreement for the new dialysis center. [source: Application, pdf31 and Exhibit 14]

"Upon CN approval, PSKC will expand its current transfer agreement with Providence- Everett to include PSKC Richmond Beach. A copy of the current transfer agreement is included as Exhibit 14. Also, to improve patient choice, we will most likely add Northwest Hospital in Northgate."

PSKC also provided a copy of a draft Medical Director Agreement with nephrologist Win Kyaw, MD. The draft agreements identifies roles and responsibilities for both PSKC and Dr. Kyaw. Additionally, all costs are identified in the agreement. [source: Application, Exhibit 7]

Public Comment

DaVita provided public comments on PSKC's Draft Medical Director Agreement asserting that it is unreliable. [source: DaVita September 5, 2018, public comment, p3]

"The Department requires a Medical Director Agreement ("MDA") that, if in draft form, may be conditioned for signature by time of facility opening, in keeping with CMS regulation. That is, the MDA must have been fully negotiated by the parties, and be ready for signature at time of submission to the Department. In the case of PSKC's proposed Richmond Beach facility, PSKC has not provided the Department with a draft MDA that is fully negotiated by the parties (or that PSKC intends to honor).

PSKC provides a draft MDA for its Richmond Beach facility that bears some remarkable similarities to all of its other proposed draft medical director agreements filed for 2018 Non-Special Circumstances Cycle 1. It has the same term, through 12/31/2024. It has the same 2-year auto-renewal provision. It has the same non-compete length (the life of the contract). And crucially, it has the same non-compete clause. PSKC's five outstanding applications all have the same non-compete clause, which names Snohomish, Skagit, and Island counties, simply changing the name of the physician.

What rational dialysis provider, believing its quality improvement programs and intellectual property were valuable and worth protecting, would sign an agreement it intended to honor with a physician to provide medical director services in its facility that allowed that physician to take those programs and intellectual property to a competitor that was literally located next door? There is not one.

Yet this is what PSKC has done. It has proposed an MDA for its Richmond Beach facility in King County that would allow any other dialysis provider to relocate to the building next door and contract with Dr. Kyaw for medical director services. The Department may be confident that PSKC has not negotiated the noncompete clause in its proposed draft contract with Dr. Kyaw, as this is not even an agreement that PSKC itself would ultimately execute. PSKC plainly has provided a "template" MDA here, that it would tailor to this project (including, most obviously, adding the proposed Richmond Beach facility to the non-compete area) after it is approved. This is insufficient for CON purposes.

If PSKC does not intend to honor the draft agreement's non-compete terms, why would it submit a draft agreement with Dr. Kyaw and those terms at all? The answer is either that PSKC is using Dr. Kyaw as a placeholder in lieu of another provider it intends to substitute later, or that PSKC intends to revise this agreement's key terms, including non-compete language, prior to signing, due to its accidental submission of terms it had included in other agreements.

It logically continues that if the medical director named in the draft agreement is one whom the ESRD provider has no intent of using as its medical director in the facility, or the agreement contains terms that no rational provider would have negotiated and would need to renegotiate prior to signing, that the agreement cannot have been fully negotiated with the actual intended medical director, and is unreliable for Certificate of Need purposes."

Rebuttal Comment

PSKC's rebuttal comments on the Medical Director Agreement is below. [source: PSKC October 5, 2018, rebuttal comments, pp2-3]

"PSKC concurs with DaVita that the CN Program requires a draft Medical Director Agreement. DaVita goes on to state that the Agreement "must have been fully negotiated and ready for signature" at the time of CN submittal, and it argues that ours is not, because of how we handled a non-compete clause with the proposed Medical Director.

DaVita's statement is not supported by the four requirements identified in the CN guidelines related to draft agreements. These guidelines, included on page 2 of the CN application packet for dialysis applications states:

If any of the documents provided in the application are in draft form, a draft is only acceptable if it includes the following elements:

- a. identifies all entities associated with the agreement,
- b. outlines all roles and responsibilities of all entities,
- c. identifies all costs associated with the agreement, and
- d. includes all exhibits that are referenced in the agreement.

The draft Agreement PSKC submitted met all four of these required elements. It is PSKC's business decision when and how to negotiate a non-compete clause in its agreements. The fact that PSKC has chosen not to enforce further non-compete requirements on Dr. Kyaw is PSKC's choice, and is not open for debate. DaVita suggests that our proposed non-compete is somehow generic, and thus questions the sincerity of PSKC's plan to contract with Dr. Kyaw as its Medical Director at its new Richmond Beach facility. PSKC is fully prepared to enter into a Medical Director agreement with Dr. Kyaw and have Dr. Kyaw sign the agreement as drafted. DaVita's speculations to the contrary are without merit.

Moreover, DaVita's suggestion that no "rational" provider would permit its medical directors to serve patients at competing facilities in the same county is not only mistaken but willfully misleading. PSKC supports its clinicians as they advance in their careers, and is also sensitive to the difficulty some providers face in locating or attracting physicians with the required expertise to oversee kidney dialysis facilities. We thus avoid the sort of ruthless hoarding of medical talent that DaVita apparently takes as given.

Notwithstanding its argument to the Program, DaVita is well aware of PSKC's less jealous philosophy toward its physicians' outside commitments; **DaVita has in fact benefited from PSKC's largesse** by allowing two of our other existing PSKC medical directors to serve as medical directors in their nearby facilities (Mount Baker and Burlington).

In any event, nonessential changes to a draft agreement (that is, changes to terms other than the roles and responsibilities, costs, and exhibits) are permitted; the CN rules and prior CN Program decisions require only that the final signed agreement be consistent with the draft, not that it be identical. Even were the final agreement between PSKC and Dr. Kyaw to include amendments to minor details from the draft, such as the geographical extent of the non-compete clause as raised by DaVita, it would not change the essential terms of the agreement as contemplated by the draft. Da Vita's concerns, even if valid, would thus be fully addressed by a condition on PSKC's CN that the final Medical Director Agreement be submitted prior to opening, and that the final signed document be consistent with the draft submitted with our application."

Department Evaluation

As previously stated, PSKC has been operating in Snohomish County for many years, but does not operate a dialysis center in King County. PSKC has established ancillary and support agreements in place for its Snohomish County facilities, and would use the same strategies to establish ancillary and support agreements for its Richmond Beach facility in King County.

PSKC provided a draft Medical Director Agreement between itself and with nephrologist Win Kyaw, MD. The draft agreements identifies all roles and responsibilities for both entities and includes all costs associated with the agreement. DaVita expressed concerns with the non-compete clause in the draft agreement. DaVita implies that PSKC provided the same draft agreement in each of its applications submitted during this review cycle and suggests that the agreement is merely a 'place-holder' by PSKC to obtain the CN approval. DaVita further implies that PSKC may not even implement the medical Director Agreement w/ Dr. Kyaw. After reviewing the agreement, staff does not come to the same conclusion as DaVita. The agreement is valid and typical of agreements that are conditioned if the project is approved.

The department is compelled to clarify information provided in PSKC's rebuttal. PSKC provided the following response to DaVita's public comment.

"In any event, nonessential changes to a draft agreement (that is, changes to terms other than the roles and responsibilities, costs, and exhibits) are permitted;..."

PSKC appears to consider the identification of the medical director to be 'nonessential.' The department does not. While there are unforeseen circumstances where a medical director may change after the project is approved, this action is not considered to be 'standard.' None of the Washington State dialysis providers, including PSKC, have a history of changing the medical director on a regular basis after approval. If this project is approved the department would attach a condition to the approval requiring PSKC to provide a copy of the executed Medical Director Agreement consistent with the draft agreement.

PSKC's existing Patient Transfer Agreement is with Providence Regional Medical Center in Everett. If this project is approved, PSKC intends to expand the current agreement to include its Richmond Beach facility. Since there are no costs associated with Patient Transfer Agreements, applicants are not required to identify the hospital in the draft agreement. This approach by PSKC is acceptable. If this project is approved, the department would attach a condition to the approval requiring PSKC to provide a copy of the executed Patient Transfer Agreement with the new facility included.

The department also concludes that all other required ancillary and support agreements and relationships are already in place. **This sub-criterion is met.**

DaVita, Inc.

DaVita provided the following information for this sub-criterion. [source: Application, p24, pdf28-29] "Ancillary services such as social services, nutrition services, financial counseling, pharmacy access, patient education, staff education, information services, material management, administration and biomedical technical services will be provided on site. Additional services are coordinated through DaVita's main office in Denver, Colorado, and support offices in Federal Way and Tacoma, Washington, and elsewhere. These ancillary and support services provided centrally include the Guest Services Program that provides assistance in locating other dialysis facilities for patients wishing to travel or relocate. In addition, DaVita offers centralized revenue cycle, management services, quality improvement services, biomedical equipment maintenance and a number of other high-value off-site programs.

DaVita anticipates establishing working relationships with local hospitals, both for emergency patient transfer as well as coordinated discharge and acceptance of patients. DaVita also anticipates continuing its relationships with area physician practices to ensure the highest quality coordinated care for patients. Finally, DaVita anticipates establishing relationships with local nursing homes to provide care for their resident ESRD patients, many of which it already collaborates with in other area dialysis facilities.

DaVita provided a draft Patient Transfer Agreement for the new dialysis center. [source: Application, Appendix 12]

DaVita also provided a copy of the executed Medical Director Agreement with a physician associated with The Everett Clinic known as Noemie C. Juaire, MD. The agreement identifies roles and responsibilities for both DaVita and Dr. Juaire. Additionally, all costs are identified in the agreement. [source: Application, Appendix 3]

Public Comment

None

None

Department Evaluation

While DaVita's Green Lake Dialysis Center will be a new center in King County planning area #1, it is not DaVita's only center in King County or in Washington State. Consistent with the approached used in applications where a new dialysis center would be established, the department accepts either draft agreements or listing of ancillary and support services. For this project, DaVita provided a listing of ancillary and support services expected to be use for the new dialysis center. This approach is acceptable.

DaVita provided a copy of the executed for the 19 station dialysis center. The agreement is between Total Renal Care (a subsidiary of DaVita) and The Everett clinic. The agreement outlines all roles and responsibilities for each entity, includes all costs associated with the agreement, and has an initial term of five years. At the end of five years, the agreement automatically renews annually unless either entity notifies the other of an intent to terminate the agreement. This agreement is acceptable.

DaVita provided a draft Patient Transfer Agreement between itself and an undisclosed hospital. While the department generally requires draft agreements to identify both entities, since there are no costs associated with Patient Transfer Agreements, applicants are not required to identify the hospital in the draft agreement. If this project is approved, the department would attach a condition to the approval requiring DaVita to provide a copy of an executed Patient Transfer Agreement for the new facility.

The department also concludes that all other required ancillary and support agreements and relationships can be established.

Based on the information above, the department concludes that DaVita demonstrated that it would have the necessary ancillary and support services at its Green Lake Dialysis Center. **This sub-criterion is met.**

(3) <u>There is reasonable assurance that the project will be in conformance with applicable state licensing requirements and, if the applicant is or plans to be certified under the Medicaid or Medicare program, with the applicable conditions of participation related to those programs.</u>

WAC 246-310 does not contain specific WAC 246-310-230(3) criteria as identified in WAC 246-310-200(2)(a)(i). There are no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that a facility must meet when it is to be Medicare certified and Medicaid eligible. Therefore, using its experience and expertise the department assessed the applicant's history in meeting these standards at other facilities owned or operated by the applicant.

The evaluation of WAC 246-310-230(5) is also evaluated under this sub-criterion, as it relates to facility compliance history. Compliance history is factored into the department's determination that an applicant's project would be operated in compliance with WAC 246-310-230(3).

Northwest Kidney Centers

NKC provided the following statements related to this sub-criterion. [source: Application, p27 &p29]

"NKC has no history with respect to the actions noted in CN regulation WAC 246-310-230(5) (a). NKC operates all existing programs in conformance with applicable federal and state laws, rules and regulations."

Public Comment

None

Rebuttal Comment

None

Department Evaluation

The department reviews two different areas when evaluating this sub-criterion. One is the conformance with Medicare and Medicaid standards and the other is conformance with state standards. To accomplish this task for these projects, the department first reviewed the quality of care compliance history for all healthcare facilities operated outside of Washington State using the 'star rating' assigned by Centers for Medicare & Medicaid Services (CMS). Then the department focused on the CMS 'star ratings' for Washington State facilities.

Centers for Medicare & Medicaid Services (CMS) Star Ratings

CMS provides the following overview regarding its star rating for dialysis centers.

"The star ratings are part of Medicare's efforts to make data on dialysis centers easier to understand and use. The star ratings show whether your dialysis center provides quality dialysis care - that is, care known to get the best results for most dialysis patients. The rating ranges from 1 to 5 stars. A facility with a 5-star rating has quality of care that is considered 'much above average' compared to other dialysis facilities. A 1- or 2- star rating does not mean that you will receive poor care from a facility. It only indicates that measured outcomes were below average compared to those for other facilities. Star ratings on Dialysis Facility Compare are updated annually to align with the annual updates of the standardized measures."

[source: CMS website]

CMS Star Rating for Out-of-State Centers

NKC does not operate any out of state facilities.

CMS Star Rating for Washington State Centers

NKC owns, operates, or manages 17 facilities, and of those, 16 are currently operational. Of the 16 facilities reporting to CMS by NKC, one facility does not have the necessary amount of data to compile a star rating. For the remaining 15 facilities with a star rating, the average rating is 4.47.

The department also focused on its own state survey data performed by the Department of Health's Office of Health Systems Oversight.

Washington State Survey Data

While 16 of the 17 NKC facilities are operational, in the most recent three years, ten facilities have been surveyed. All surveys resulted in no significant non-compliance issues. [source: DOH OHSO survey data]

In this application, NKC identified its current medical director, Jung Joh, MD, and current staff at NKC Auburn Kidney Center. Using data from the Medical Quality Assurance Commission, the department found that the medical director and all current are compliant with state licensure and have no enforcement actions on their license.

In review of this sub-criterion, the department considered the total compliance history of the dialysis facilities owned and operated by NKC. The department also considered the compliance history of the medical director associated with the facility. The department concludes that NKC's Auburn Kidney

Center has been operating in compliance with applicable state and federal licensing and certification requirements. The department also conclude there is reasonable assurance that the addition of stations to Auburn Kidney Center would not cause a negative effect on the facility's compliance history. The department concludes that NKC's project **meets this sub-criterion.**

Puget Sound Kidney Centers

PSKC provided the following statements related to this sub-criterion. [source: Application, pdf 32 & p33]

"PSKC has no history with respect to the actions noted in CN regulation WAC 246-310-230(5) (a). In fact, and as detailed in the cost containment section, PSKC has documented high quality per the CN Program's new superiority indicators (WAC 246-310-827).

In its most recent CN approval for PSKC, the Program reviewed PSKC's quality and compliance with state and federal requirements. As part this review, the CN Program considered the CMS star ratings for each of PSKC's six operational facilities. In that review, the CN Program found that each of the facilities had a 3 star or better rating. PSKC has updated the CMS Star Ratings and as noted in Table 16, all facilities now rate as a 4 or 5."

Public Comment

None

Rebuttal Comment

None

Department Evaluation

The department reviews two different areas when evaluating this sub-criterion. One is the conformance with Medicare and Medicaid standards and the other is conformance with state standards. To accomplish this task for these projects, the department first reviewed the quality of care compliance history for all healthcare facilities operated outside of Washington State using the 'star rating' assigned by Centers for Medicare & Medicaid Services (CMS). Then the department focused on the CMS 'star ratings' for Washington State facilities.

CMS Star Rating for Out-of-State Centers

PSKC does not operate any out of state facilities.

CMS Star Rating for Washington State Centers

PSKC owns, operates, or manages 7 facilities, and of those, 6 are currently operational. For the 6 facilities with a star rating, the average rating is 4.33.

The department also focused on its own state survey data performed by the Department of Health's Office of Health Systems Oversight.

Washington State Survey Data

While 6 of the 7 NKC facilities are operational, in the most recent three years, three facilities have been surveyed. All surveys resulted in no significant non-compliance issues. [source: DOH OHSO survey data]

In this application, PSKC identified its current medical director, Win Kyaw, MD. Using data from the Medical Quality Assurance Commission, the department found that the medical director is compliant

with state licensure and has no enforcement actions on the license. Given that PSKC proposes a new facility, staff have not been identified.

In review of this sub-criterion, the department considered the total compliance history of the dialysis facilities owned and operated by PSKC. The department also considered the compliance history of the medical director associated with the facility. The department concludes that PSKC has been operating in compliance with applicable state and federal licensing and certification requirements. The department also conclude there is reasonable assurance that the addition of a new dialysis center would not cause a negative effect on PSKC's compliance history. The department concludes that PSKC's project **meets this sub-criterion.**

DaVita, Inc.

DaVita provided the following statements related to this sub-criterion. [source: Application, p25-26]

"DaVita and the United States Department of Health and Human Services, Office of Inspector General entered into a Corporate Integrity Agreement ("CIA") to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs and, in particular, included the appointment of an Independent Monitor to prospectively review DaVita's arrangements with nephrologists and other health care providers for compliance with the Anti-Kickback Statute (collectively, "Federal Health Care Programs and Laws"). That Independent Monitor completed the prospective review process in the fall of 2017. Each arrangement is now reviewed by the Risk Rating team to ensure that it is compliant with these Federal Health Care Programs and Laws. A full copy of the Corporate Integrity Agreement is included with this application in Appendix 20.

The applicant has no adverse history of license revocation or decertification in Washington State. DaVita has no criminal convictions related to DaVita's competency to exercise responsibility for the ownership or operation of its facilities. As previously reported, a DaVita facility in Tennessee was decertified and closed ten years ago (2007) and DaVita voluntarily temporarily shut down a facility in Texas nine years ago (2008). DaVita has also supplied, in Appendix 13, a list of all state regulatory agencies with which it interacts."

Public Comment

None

Rebuttal Comment

None

Department Evaluation

The department reviews two different areas when evaluating this sub-criterion. One is the conformance with Medicare and Medicaid standards and the other is conformance with state standards. To accomplish this task for these projects, the department first reviewed the quality of care compliance history for all healthcare facilities operated outside of Washington State using the 'star rating' assigned by Centers for Medicare & Medicaid Services (CMS). Then the department focused on the CMS 'star ratings' for Washington State facilities.

CMS Star Rating for Out-of-State Centers

In the application, DaVita states that it provides outpatient dialysis centers and services approximately 185,000 patients in 45 states and the District of Columbia. DaVita reports dialysis services to CMS for approximately 2,728 facilities in 46 states and the District of Columbia. Of the 2,728 facilities reporting

to CMS by DaVita, 371 do not have the necessary amount of data to compile a star rating. For the remaining 2,357 facilities with a star rating, the national average rating is 3.71.

CMS Star Rating for Washington State Centers

For Washington State, DaVita owns, operates, or manages 42 facilities in 19 separate counties. All of the 42 centers are operational, however, three do not have the necessary amount of data to compile a star rating.²⁰ For the remaining 39 centers with a star rating, the Washington State average rating is 4.08

The department also focused on its own state survey data performed by the Department of Health's Office of Health Systems Oversight.

Washington State Survey Data

While all 42 of DaVita facilities are operational, in the most recent three years, 24 facilities have been surveyed. All surveys resulted in no significant non-compliance issues. [source: DOH OHSO survey data]

In this application, DaVita provided its medical Director Agreement with The Everett Clinic. The agreement identifies Noemie Juaire, MD as the medical director and Katrina Carli as ta pre-approved physician for medical director services. Using data from the Medical Quality Assurance Commission, the department found that both physicians are compliant with state licensure and have no enforcement actions on the license. Given that DaVita proposes a new facility, staff have not been identified.

In review of this sub-criterion, the department considered the total compliance history of the dialysis facilities owned and operated by DaVita. The department also considered the compliance history of the two physicians that would be associated with the facility. The department concludes that DaVita has been operating in compliance with applicable state and federal licensing and certification requirements. The department also conclude there is reasonable assurance that the addition of a new dialysis center would not cause a negative effect on DaVita's compliance history. The department concludes that DaVita's project meets this sub-criterion.

(4) The proposed project will promote continuity in the provision of health care, not result in an unwarranted fragmentation of services, and have an appropriate relationship to the service area's existing health care system.

WAC 246-310 does not contain specific WAC 246-310-230(4) criteria as identified in WAC 246-310-200(2)(a)(i). There are also no known recognized standards as identified in WAC 246-310-200(2)(a)(ii) and (b) that directs how to measure unwarranted fragmentation of services or what types of relationships with a services area's existing health care system should be for a project of this type and size. Therefore, using its experience and expertise the department assessed the materials in the application.

Northwest Kidney Centers

NKC provided the following information for this sub-criterion. [source: Application, p27 and July 31, 2018, screening response, p6]

"NKC Lake City has been providing outpatient dialysis services in the King 1 Dialysis Planning Area since 2001, despite several expansions (last one in 2015), growth has continued and today exceeds the projections contained in our prior CN application. NKC Lake City's current occupancy means that its patients have difficulty receiving timely access to services. The additional stations will assure that our commitment to the community to provide timely access and high quality remains.

²⁰ The three centers are: Belfair Dialysis Center in Mason County, Cooks Hill Dialysis Center in Lewis County, and Renton Dialysis Center in King County.

NKC Lake City has all of the ancillary and support agreements and a comprehensive array of in-house services already in place that help to assure that continuity of care is in place for patients. Even the approach we are taking to the NKC Lake City remodel—replacing the existing stations in vacated space first, so as not to displacing or disrupt current patients reflect NKC's values regarding continuity.

NKC has operated outpatient dialysis services since 1962; growing from 9 patients to over 1,700 today. NKC has, and continues to be, committed to providing optimal health, quality of life and independence for people with kidney disease. Further, NKC has experienced firsthand, and to the direct benefit of our patients that fragmentation is reduced or eliminated, when services are highly coordinated.

NKC strives to provide services that deliver dialysis care that is coordinated via multiple entities including, but not limited to, physicians, other health care providers (nursing homes, assisted living facilities), home health care, hospitals, etc. as dialysis patients frequently have multiple providers and entities from which they receive services. For example, for nursing home or assisted living patients, NKC will report any care needs or issues identified during dialysis (as well as inform the patient's physician, if appropriate). In addition, as patients are admitted and discharged from the hospital, NKC staff follow their care needs to ensure that the facility is prepared to provide dialysis to these patients upon discharge from the hospital.

In addition, NKC filed an application and secured a Comprehensive ESRD Care (CEC) accountable care organization designation from CMS. This entity, known as the Northwest Kidney Care Alliance is designed to identify, test, and evaluate new ways to improve care for Medicare beneficiaries with End-Stage Renal Disease (ESRD). The premise is that a new payment and service delivery model that provides Medicare beneficiaries with person-centered, high-quality and non-fragmented care that reduces costs and improves outcomes is better for patients. This is the only such entity in Washington State.

NKC opened the very first out of hospital dialysis center in the Country. As noted on page 27 of the application, NKC Lake City has been providing dialysis services in the King 1 planning area since 2001. Because of our longevity and our commitment to patient centered care, NKC enjoys long-standing established relationships with area health care providers, including but not limited to hospitals, physicians, nursing homes, assisted living facilities and adult family homes. In addition, NKC has mechanisms in place to assure that coordination of services are in place and fragmentation is avoided. In fact, as the only existing provider in the planning area, NKC is well positioned to assure that fragmentation does not occur. It is more likely that fragmentation would occur as a new provider enters the planning area as they would need to establish relationships.

NKC Lake City through its Nurse Manager, Care Manager, Social Worker and support through Admitting and Patient Services staff, routinely coordinate and communicate with the patients' physicians, families or other relevant care providers for any changes that might impact their care."

Public Comment

None

Rebuttal Comment

None

Department Evaluation

NKC has been a provider of dialysis services in Washington State for many years. NKC also has a history of establishing relationships with existing healthcare networks in King County. Additionally, NKC's project would promote continuity in the provision of healthcare services in the planning area by adding stations in a planning area where additional dialysis stations are needed.

NKC provided documentation in the application to demonstrate that the project would promote continuity in the provision of health care services in the community and not result in unwarranted fragmentation. Based on the information above, the department concludes that NKC's project **meets** this sub-criterion.

Puget Sound Kidney Centers

PSKC provided the following information for this sub-criterion. [source: Application, pdf32]

"As with all PSKC facilities, PSKC Richmond Beach will provide a collaborative, comprehensive, and patient-centered approach to the provision of dialysis services. In addition, PSKC's unrelenting focus on high-quality, compassionate care, coupled with respect for the patients, staff, and other providers has served the community well. Without dispute, PSKC's quality is outstanding as evidenced by publicly available metrics and the CN Program's own superiority indicators. Prior to establishing this new facility, PSKC will actively seek out and establish working relationships that support care in King 1."

Public Comment

None

Rebuttal Comment

None

Department Evaluation

PSKC has been a provider of dialysis services in Washington State for many years. While PSKC does not currently operate any dialysis centers in King County, PSKC has a history of establishing relationships with existing healthcare networks in King and Clallam counties. Additionally, PSKC's project would promote continuity in the provision of healthcare services in the planning area by establishing a new facility in a planning area where additional dialysis stations are needed.

PSKC provided documentation in the application to demonstrate that the project would promote continuity in the provision of health care services in the community and not result in unwarranted fragmentation. Based on the information above, the department concludes that PSKC's project **meets this sub-criterion**.

DaVita, Inc.

DaVita provided the following information for this sub-criterion. [source: Application, p24 & p26]

"Appendix 17 provides a summary of quality and continuity of care indicators used in DaVita's quality improvement program. The DaVita Continuous Quality Improvement (CQI) program incorporates all areas of the dialysis program. The program monitors and evaluates all activities related to clinical outcomes, operations management, and process flow. Dialysis-specific statistical tools (developed by DaVita) are used for measurement, analysis, communication, and feedback. Continuing employee and patient education are integral parts of this program. Appendix 17 includes an example of DaVita Quality Index (DQI) data.

Appendix 18 includes an example of DaVita's Physician, Community and Patient Services offered through DaVita's Kidney Smart Education Program. Appendix 12 includes a copy of a draft transfer agreement between DaVita Green Lake Dialysis Center and an area care hospital partner. DaVita has been honored as one of the World's Most Admired Companies® by FORTUNE® magazine since 2006, confirming its excellence in working effectively with the communities it serves (DaVita.com/about/awards).

The proposed DaVita Green Lake Dialysis Center will have an appropriate relationship to the service area's existing health care system. DaVita Green Lake Dialysis will be a key component of the expanded health care system in the service area, and the project will enable enhanced patient access in the King I planning area with highly utilized facilities, all currently with a census of more than 5.0 patients per station. Furthermore, DaVita has a long track record of working with area providers and collaborating with them to provide the highest quality care for patients."

Public Comment

None

Rebuttal Comment

None

Department Evaluation

DaVita has been a provider of dialysis services in Washington State for many years. DaVita also has a history of establishing relationships with existing healthcare networks in King County. Additionally, DaVita's project would promote continuity in the provision of healthcare services in the planning area by establishing a new facility in a planning area where additional dialysis stations are needed.

DaVita provided documentation in the application to demonstrate that the project would promote continuity in the provision of health care services in the community and not result in unwarranted fragmentation. Based on the information above, the department concludes that DaVita's project **meets** this sub-criterion.

(5) There is reasonable assurance that the services to be provided through the proposed project will be provided in a manner that ensures safe and adequate care to the public to be served and in accord with applicable federal and state laws, rules, and regulations.

Department Evaluation for Northwest Kidney Centers

This sub-criterion was evaluated in conjunction with WAC 246-310-230(3) above and is considered met.

Department Evaluation for Puget Sound Kidney Centers

This sub-criterion was evaluated in conjunction with WAC 246-310-230(3) above and is considered met.

Department Evaluation for DaVita, Inc.

This sub-criterion was evaluated in conjunction with WAC 246-310-230(3) above and is considered met.

D. Cost Containment (WAC 246-310-240)

Based on the source information reviewed, the department concludes that the Northwest Kidney Centers project did not meet the cost containment criteria in WAC 246-310-240.

Based on the source information reviewed and agreement to the conditions identified in the conclusion section of this evaluation, the department concludes that the Puget Sound Kidney Centers project has met the cost containment criteria in WAC 246-310-240.

Based on the source information reviewed, the department concludes that the DaVita, Inc. project did not meet the cost containment criteria in WAC 246-310-240.

(1) <u>Superior alternatives, in terms of cost, efficiency, or effectiveness, are not available or practicable</u>. To determine if a proposed project is the best alternative, the department takes a multi-step approach. <u>Step one</u> determines if the application has met the other criteria of WAC 246-310-210 thru 230. If it has failed to meet one or more of these criteria, then the project is determined not to be the best alternative, and would fail this sub-criterion.

If the project has met the applicable criteria in WAC 246-310-210 through 230 criteria, in <u>step two</u>, the department assesses the other options considered by the applicant. If the department determines the proposed project is better or equal to other options considered by the applicant and the department has not identified any other better options this criterion is determined to be met unless there are multiple applications.

If there are multiple applications, the department's assessment is to apply any service or facility superiority criteria contained throughout WAC 246-310 related to the specific project type in <u>Step three</u>. The department completes step three under WAC 246-310-827.

Step One

Northwest Kidney Centers

For this project, NKC met the applicable review criteria under WAC 246-310-210, 220, and 230.

Puget Sound Kidney Centers

For this project, PSKC met the applicable review criteria under WAC 246-310-210, 220, and 230.

DaVita, Inc.

For this project, DaVita met the applicable review criteria under WAC 246-310-210, 220, and 230.

Public Comment

None

Rebuttal Comment

None

Department Evaluation

All three applicant's met the review criteria under WAC 246-310-210, 220, and 230. The department will review all three applications under step two below.

Step Two

Northwest Kidney Centers

NKC identified the following options before submitting this application. [source: Application, p31 and July 31, 2018, screening response, p10]

"NKC spent the past year evaluating the following options:

- 1) Develop a new facility
- 2) Remodel and expand an existing facility to add 19 stations
- 3) Remodel and expand an existing facility to add something less than 19 stations
- 4) Forego any expansion

Land is in short supply in North King and given the natural expansion capacity at NKC Lake City, NKC ultimately determined that it would be better for patient care to expend dollars not on high cost land or real estate, but rather to make investments in the existing, highly accessible, NKC Lake City location. The existing NKC Lake City location is now more than 15 years old, and while it has been fully maintained, some systems are reaching the end of their useful lives, and the patient care spaces are not the same patient environment of care standard that NKC is building new stations to today. NKC's architects have determined that with the relocation of the non-patient care spaces from the Blagg Pavilion that the existing space is more than sufficient to house 19 additional stations. In addition to housing the new stations, the remodel of the existing space will enhance the care environment, and make the space more operationally efficient and easier for staff to provide care. In addition, we are able to provide a better home training environment, expand our ability to serve Hep B isolation patients and continue our CKD education programs. Because NKC Scribner has no room for expansion, because of the costs of land and real estate, because of the improvements to the care environment that can be realized for current patients as well as proposed by the remodel, because of the operational efficiencies expected and because our patients have requested that NKC expand in North King, the application in front of the CN Program seeks a 19 station addition.

As discussed in the CN application, NKC's existing two dialysis centers in King 1 are operating at or near capacity. Since the applications were filed in June, the Northwest Renal Network has released O1 2018 data that confirms our two facilities continue to be at high occupancy (NKC Lake City at 87% and NKC Scribner at 98%, respectively). NKC determined that access would be negatively impacted for patients that choose to receive their dialysis and related care from NKC if we do not secure additional dialysis capacity in King 1. As such, NKC made the decision to move forward and request CN approval to add stations. Given that there are limited land and/or buildings available, NKC evaluated the feasibility of adding additional stations at NKC Lake City (NKC Scribner has no capacity for expansion). NKC further evaluated establishing a 3rd facility in the planning area but was unable to find a suitable building to purchase or lease or land upon which to build a new facility (as noted on page 31 of the application, NKC Scribner has no space for additional capacity). Given that the existing NKC Lake City could accommodate a 19 station expansion, NKC concluded from a capital cost and operational perspective, this was the most cost effective and efficient option. In addition, NKC owns NKC Lake City (land and building) so there were no legal restrictions to this option. In terms of staffing, NKC Lake City, with an expansion, expects to realize some staffing efficiencies. Finally, both NKC Lake City and NKC Scribner both provide very good quality of care and 'doing nothing' (not submitting an application) was determined to be detrimental to patients. Table 2 provides additional detail regarding the alternatives considered."

Applicant's Table Table 2 NKC Lake City Options Considered

	Develop a new facility	Remodel and Expand NKC Lake City with 19 Stations	Remodel and Expand NKC Lake City with Less than 19 Stations	Forego Any expansion
Access to Care	Promotes Access to Care by meeting total station need	Promotes Access to Care by meeting total station need	Promotes access to care but could limit access in short term.	Reduces patient access
Capital Cost	Requires capital investment; would be more costly than expanding NKC Lake City	Requires capital investment however at a lower cost by sharing resources from the existing treatment center	Would not be significantly less costly than adding 19 stations due to capital cost of construction	No capital expenditure
Legal Restrictions	Requires CN approval and any legal issues for new site	Requires CN approval; no other legal issues NKC owns NKC Lake City property.	Requires CN approval no other legal issues NKC owns NKC Lake City property	None
Staffing Impacts	Potentially requires more staffing than NKC Lake City expansion. Opportunity to create additional jobs	Requires additional staff for expansion; opportunity to realize staffing efficiencies.	Requires additional staff for expansion; opportunity to realize staffing efficiencies. Opportunity to create additional jobs	None

Source: Applicant

During the review of this project, the department asked NKC to provide a detailed discussion of the option of adding all 19 stations in one phase rather than two phases. NKC provided the following clarification on the implantation of the 19 stations. [source: July 31, 2018, screening response, p11]

"As noted in response to earlier questions, NKC fully intends to build space for all 19 stations at the same time. Phase 2 is, in essence, a brief phase that provides NKC with a short window in which to make 10 new stations available prior to the remaining 10 being completed. We did this because of high census: we want to get some stations available as soon as possible. However, that said, with the proposed schedule, all stations would be operational by June 2021. The 2nd phase of this project is relatively short.

Throughout our history we have focused on improving access to care by building centers where patients live, creating a safe healthy environment where treatment can be provided in a respectable way. NKC fully intends to have all 19 approved stations available to our patients as cost efficiently and effectively as possible. As we own this property, patients throughout the community and other health service providers know that we will be at this location for many years into the future. Some key points:

- By expanding NKC Lake City we are supporting the expansion of the high quality of service already being provided to patients today.
- The capital costs for this project are an investment into our patient's future by investing into a building that is owned vs leased. NKC has no intention of leaving this property and there is no "end date" to when care can be provided.
- NKC has extensive relationships with care providers in the community, clinics, hospitals, physician groups and nursing homes that have been in place for over 15 years.
- NKC will begin recruiting early in the project to allow new staff to be trained at other units and within Lake City Kidney Center well in advance of the new stations coming on line.
- The most efficient way to create stations is through expanding the services of an existing unit. NKC is excited about the ability to create a state of the art new center for our existing patients and for the patients who need care in the community."

Public Comment

None

Rebuttal Comment

None

Department Evaluation

NKC currently operates many dialysis facilities in King County, including two centers in planning area #1. NKC provided a comprehensive discussion of alternatives considered, including not submitting an application. After reviewing the information, the department concludes that NKC appropriately rejected all other alternatives before submitting its application.

Puget Sound Kidney Centers

PSKC identified the following options before submitting this application. [source: Application, pdf35]

"PSKC evaluated three options:

- Do nothing;
- Establish a new facility with fewer than 19 stations; or
- Establish a new facility with 19 stations

Given the need for the large number of additional stations in King 1, coupled with the adjacency of the planning area to Snohomish 3 (where PSKC South operates a facility wherein 15% of patients reside in King 1 and wherein our occupancy is more than 5.26 patients per station, despite having recently added four stations), PSKC chose to establish a new facility. We expended time and resources to try and identify a location in the north end of the King 1 Planning Area so that we could improve access and provide scheduling relief for PSKC South patients and families as well as the two existing facilities in the King 1 Planning Area. Because we were able to identify a site, establishing a new facility made sense.

Once the decision was made to pursue a new facility and the site selected, the architects determined that the location would accommodate 19 stations. Therefore, PSKC chose to submit an application for the entire station need.

PSKC Richmond Beach will provide all of the access related services required by the CN Program (shift after 5:00PM, home training, a permanent bed station, and isolation capabilities). PSKC is confident in our ability to staff the facility, while maintaining operational efficiency and lower patient charges.

In addition, the new facility, PSKC Richmond Beach, will be located on a site owned by PSKC. While using an existing building, PSKC still intends to remodel, ensuring that it will consider patient comfort and amenities, quality, safety, staff efficiency and support at every decision point. PSKC is confident the dialysis community will reap the benefits of our unrelenting focus on the "three pillars" of good health care, 1) outstanding quality of care, 2) improved access to care, and 3) reduced cost of care."

Public Comment

None

Rebuttal Comment

None

Department Evaluation

PSKC does not currently operate any dialysis facilities in King County. PSKC provided a comprehensive discussion alternatives considered, including not submitting this application. After reviewing the information, the department concludes that PSKC appropriately rejected all other alternatives before submitting its application.

DaVita, Inc.

DaVita identified the following options before submitting this application. [source: Application, pp26-27]

"Alternative 1: Do nothing. That is, do not apply for additional stations in the King 1 planning area. King 1 is growing in ESRD population, with a three-year annualized in-center ESRD census growth rate of 5.87% and demonstrated need for nineteen (19) stations. NKC Lake City and NKC Scribner have little available capacity, particularly so for NKC Scribner, with census above 97% utilization. With strong demand for access to DaVita's services but no application, patients will be forced to dialyze at less convenient times, locations, or even out of the planning area entirely. This alternative was rejected.

Alternative 2: Apply for nineteen (19) stations in the King 1 planning area.

As summarized above, King 1 shows substantial need for dialysis services. DaVita will rapidly offer high-quality dialysis services to patients in the King 1 planning area, additional provider choice, and additional, centrally located access. This alternative was selected."

Public Comment

None

Rebuttal Comment

None

Department Evaluation

DaVita does not currently operate any dialysis facilities in King County planning area #1. DaVita provided a comprehensive discussion alternatives considered, including not submitting this application. After reviewing the information, the department concludes that DaVita appropriately rejected all other alternatives before submitting its application.

Step Three

Department Evaluation

WAC 246-310-827 states: For purposes of determining which of the competing applications should be approved, the criteria in this section will be used as the only means for comparing two or more

applications to each other. No other criteria or measures will be used in comparing two or more applications to each other under any of the applicable sub-criteria within WAC <u>246-310-210</u>, <u>246-310-240</u>.

WAC 246-310-827(3)-(10) outline the process for identifying a superior project if more than one application met the applicable review criteria discussed above. As stated in the introduction section of this evaluation, the data submitted under WAC 246-310-803 is collected and scores are calculated prior to the submission of any applications. Per WAC 246-310-827(5), providers had the opportunity to comment and submit corrections during the development of the scores. The dataset was final as of the first working day of April in 2018. Public comment or rebuttal to update or correct this data during the review of these projects is not accepted.

Using the superiority workbook posted April 2, 2018, the department has identified the final scoring of each applicant. The worksheet is attached in Appendix B to this evaluation. The summary is below.

Department's Superiority Table 17

Applicant	Score	
Northwest Kidney Centers	24.50	
Puget Sound Kidney Centers	26.83	
DaVita, Inc.	19.83	

As shown above, PSKC's score of 26.83 is higher than both NKC and DaVita. WAC 246-310-827(9) provides the following direction.

"The application with the highest total score will be the superior alternative for the purpose of meeting $WAC\ 246-310-240(1)$."

Based on WAC 246-310-827(9) above, PSKC is considered the best available alternative for the community and meets this sub-criterion. Both NKC and DaVita fail to meet the sub-criterion.

- (2) In the case of a project involving construction:
 - (a) The costs, scope, and methods of construction and energy conservation are reasonable;
 - (b) The project will not have an unreasonable impact on the costs and charges to the public of providing health services by other persons.

Department Evaluation for Northwest Kidney Centers

This sub-criterion was evaluated in conjunction with WAC 246-310-220 above and is considered met.

Department Evaluation for Puget Sound Kidney Centers

This sub-criterion was evaluated in conjunction with WAC 246-310-220 above and is considered met.

Department Evaluation for DaVita, Inc.

This sub-criterion was evaluated in conjunction with WAC 246-310-220 above and is considered met.

(3) The project will involve appropriate improvements or innovations in the financing and delivery of health services which foster cost containment and which promote quality assurance and cost effectiveness.

Northwest Kidney Centers

NKC provided the following information for this sub-criterion. [source: Application, p33]

"Approximately 95% of the building's interior is being remodeled along with 60% of the exterior as part of this project, and NKC is planning upgrades of the air handling systems to higher, more efficient heating and cooling. While we believe that the facility will meet LEED Silver upon project completion, NKC is not contemplating applying for certification."

Public Comment

None

Rebuttal Comment

None

Department Evaluation

NKC's project could have the potential to improve delivery of dialysis services to the residents of King County planning area #1 with the addition of 19 dialysis stations in the planning area. **This sub-criterion** is met.

Puget Sound Kidney Centers

PSKC provided the following information for this sub-criterion. [source: Application, pdf37]

"The site selected is an existing medical office building that will be remodeled to operate an outstanding dialysis facility that will meet the high standards PSKC has established for its new-build operations which include natural light for the patients, and beautiful, aesthetic amenities to make the facility more comfortable, attractive, warm and inviting for the patients and their families.

In addition, PSKC Richmond Beach will be designed to meet or exceed current energy code requirements. High efficiency systems, including water infiltration systems, with lower life-cycle operating costs will be used wherever possible. The PSKC Richmond Beach area is in a well-manicured area of Shoreline, and our facility will stand out for its attractiveness for the patients and area residents, much like all of our other facilities.

Public Comment

None

Rebuttal Comment

None

Department Evaluation

PSKC's project could have the potential to improve delivery of dialysis services to the residents of King County planning area #1 with the addition of 19 dialysis stations in the planning area. **This sub-criterion is met.**

DaVita, Inc.

DaVita provided the following information for this sub-criterion. [source: Application, p27]

"DaVita Green Lake Center will meet all current energy conservation standards required. Furthermore, DaVita design standards, reflected in the single-line drawing, are planned to promote energy efficiency, create efficient workflows, clean sightlines and a safe and welcoming environment for patients."

Public Comment

None

Rebuttal Comment

None

Department Evaluation

DaVita's project could have the potential to improve delivery of dialysis services to the residents of King County planning area #1 with the addition of 19 dialysis stations in the planning area. **This sub-criterion is met.**

APPENDIX A

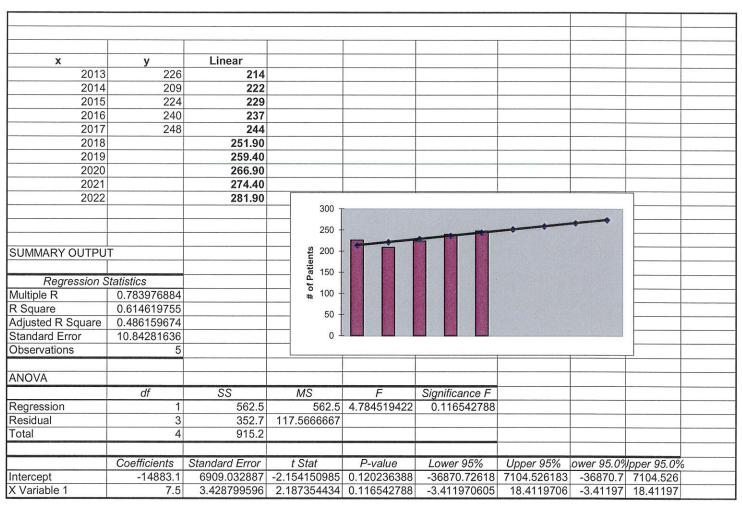


2018 King County 1 ESRD Need Projection Methodology

	Planning Area	6 Year Utiliz	zation Data	- Resident I	ncenter Pat	tients		
	King 1	2012	2013	2014	2015	2016	2017	
	98028	8	13	12	14	11	10	
	98103	16	21	20	20	19	19	
	98105	5	6	5	11	13	12	
	98107	5	10	12	10	12	12	
	98115	16	14	12	13	12	12	
	98117	12	16	12	18	21	18	
	98125	32	38	34	35	48	46	
	98133	49	54	58	57	64	67	
	98155	32	43	35	30	27	36	
	98177	12	11	9	16	13	16	
	98195	0	0	0	0	0	0	
	TOTALS	187	226	209	224	240	248	
246-310-812(4)(a)	Detect Observed		00.000/	7.50%	7.400/	7.4.40/	0.000/	
240-310-012(4)(a)	Rate of Change		20.86%	-7.52%	7.18%	7.14%	3.33%	
	6% Growth or Greater?		TRUE	FALSE	TRUE	TRUE	FALSE	
	Regression Method:	Linear						
246-310-812(4)(c)			Year 1	Year 2	Year 3	Year 4	Year 5	
			2018	2019	2020	2021	2022	
Projected Resident								
Incenter Patients	from 246-310-812(4)(b)		251.90	259.40	266.90	274.40	281.90	
Station Need for								
Patients	Divide Resident Incenter	by 4.8	52.48	54.04	55.60	57.17	58.73	
	Rounded to next whole n	umber	53	55	56	58	59	
246-310-812(4)(d)	subtract (4)(c) from approv							
Existing CN Approved S	stations	Total	40	40	40	40	40	
Results of (4)(c) above			53	55	56	58	59	
Net Station Need			-13	-15	-16	-18	-19	
Negative number indicates ne	ed for stations							
Diamaian Assa Essili	4:							
Planning Area Facili Name of Center								
	# of Stations						74	
NKC - Lake City	18							
NKC - Scribner Seattle Children's Hosp	22 9	Note: The	a ototions	oro not -	ounted in	the numer	io mothal-l	
		Note: Thes	se stations	are not c	ounted in	the numer	ic methaol	оду
Total	40							
Source: Northwest Renal	NI 1 1 1 0040 0047							



2018 King County 1 ESRD Need Projection Methodology



APPENDIX B

Data Element	NKC Kirkland	NKC Lake City	NKC Scribner	Average
Home Training	1.00	1.00	0.00	0.67
Shift after 5:00	1.00	1.00	1.00	1.00
Nursing Home Score	1.00	5.00	4.00	3.33
Comorbidity Score	3.75	3.75	5.00	4.17
SMR	2.00	2.00	4.00	2.67
SHR	2.00	2.00	2.00	2.00
Total Performance Score	6.00	8.00	8.00	7.33
Net Revenue Per Treatment	2.00	4.00	4.00	3.33
Total	1960年1月1日 - 19 2 日			24.50

Data Element	PSKC South	PSKC Everett	PSKC Monroe	Average
Home Training	1.00	1.00	1.00	1.00
Shift after 5:00	1.00	1.00	1.00	1.00
Nursing Home Score	5.00	3.00	5.00	4.33
Comorbidity Score	5.00	2.50	5.00	4.17
SMR	2.00	2.00	2.00	2.00
SHR	2.00	2.00	2.00	2.00
Total Performance Score	6.00	6.00	10.00	7.33
Net Revenue Per Treatment	5.00	5.00	5.00	5.00
Total			All and a second and the second and	26.83

Data Element	DaVita Bellevue	DaVita Olympic View	DaVita Westwood	Average
Home Training	0.00	1.00	1.00	0.67
Shift after 5:00	1.00	1.00	1.00	1.00
Nursing Home Score	4.00	2.00	2.00	2.67
Comorbidity Score	2.50	3.75	6.25	4.17
SMR	2.00	2.00	2.00	2.00
SHR	2.00	2.00	2.00	2.00
Total Performance Score	4.00	4.00	6.00	4.67
Net Revenue Per Treatment	1.00	4.00	3.00	2.67
Total		1. A. The A. C. The		19.83

Applicant	Score	
Northwest Kidney Centers	24.50	
Puget Sound Kidney Centers	26.83	
DaVita	19.83	