STATE OF WASHINGTON

DEPARTMENT OF HEALTH

Olympia, Washington 98504

June 18, 2021

Brian Gibbons, CEO
Astria Sunnyside Hospital
AH NP8—Astria Health
1016 Tacoma Avenue
P.O. Box 719
Sunnyside, WA 98944

Sent via email: Brian.Gibbons@astria.health.org

RE: CN Application #21-11 for ESRD Yakima County Planning Area

Mr. Gibbons:

The review of the Certificate of Need application submitted by AH NP8, a subsidiary of Astria Health, proposing to establish a 27-station dialysis facility center in Yakima within the Yakima County Planning Area has been completed. Attached is a written evaluation of the application.

For the reasons stated in the attached evaluation the Astria Yakima Dialysis Center application is consistent with applicable criteria of the Certificate of Need Program, provided that the applicant agrees to the following in its entirety.

Project Description:

This certificate approves the establishment of a 27-station dialysis center to be located at 209 South 12th Avenue, Suite 100, within the Yakima County Planning Area in Yakima [98902].

Services available at the proposed facility include in-center hemodialysis, home hemodialysis, peritoneal dialysis training, a dedicated isolation station, a permanent bed station, and shifts beginning after 5pm. Following is the approved station breakdown at project completion.

Station Type	CMS Certified Stations	Stations Counted for Station Use and Methodology
General Use In-Center Stations	25	25
Permanent Bed Station	1	1
Exempt Isolation Station	1	0
Isolation Station	0	0
Total Stations	**27**	**26**

Conditions:

Approval of the project description as stated above. Astria. 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.

1. Astria shall finance this project consistent with the financing described in the application.
2. Prior to providing dialysis services at Astria Yakima Dialysis Center, Astria shall provide an executed medical director agreement consistent with the agreement provided in Attachment 4 of its August 7, 2020, screening responses.
3. Prior to providing dialysis services at Astria Yakima Dialysis Center, Astria shall provide an executed lease agreement consistent with the agreement provided in Attachment 2 of its August 7, 2020, screening responses.
4. Prior to providing dialysis services at Astria Yakima Dialysis Center, Astria shall provide an executed transfer agreement consistent with the draft in Appendix 11 of its initial application.
5. Prior to providing dialysis services at Astria Yakima Dialysis Center, Astria shall provide the Certificate of Need Program with a listing of its credentialed staff for review. The listing shall include each staff person's name and professional license number.

Approved Costs:

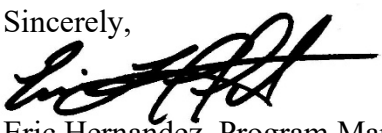
The approved capital expenditure to establish this new facility is $2,973,567, which includes the land purchase, construction, equipment, financing costs, and various fees and taxes. Costs are paid partially by Astria Health.

Notify the Department of Health within 20 days of the date of this letter whether you accept the above project description, conditions, and approved costs for this project. If you accept these in their entirety, this application will be approved, and a Certificate of Need sent to you.

If any of the above provisions are rejected, this application will be denied. The department will send you a letter denying your application and provide you information about your appeal rights.

Send your written response to the Certificate of Need Program at this e-mail address: FSLCON@doh.wa.gov. 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,



Eric Hernandez, Program Manager
Certificate of Need
Office of Community Health Systems

Attachment

YEAR 2020 CYCLE 1 NON-SPECIAL CIRCUMSTANCE EVALUATION DATED JUNE 18, 2021 FOR THREE CERTIFICATE OF NEED APPLICATIONS PROPOSING TO ADD DIALYSIS STATION CAPACITY IN THE YAKIMA COUNTY PLANNING AREA

APPLICANT DESCRIPTIONS

Astria Health

The applicant in this application is identified as "AH NP8," a 501(c)(3) non-profit corporation that is a wholly-owned subsidiary of Astria Health, a private, non-profit corporation that is headquartered in Yakima Valley in Yakima County. Astria Health is the non-profit parent organization of two hospitals, a home health agency, 14 medical clinics, and 24 specialty clinics located in towns and cities throughout Yakima County and surrounding communities. The chart below shows the name and location of the two Astria Health hospitals. [source: Astria Health website and Application, Appendix 1]

Hospital	City	State
Astria Sunnyside Hospital	Sunnyside	Washington
Astria Toppenish Hospital	Toppenish	Washington

In this evaluation this applicant will be referenced as Astria Health.

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: NKC website, Application, p2; Exhibit 3]

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 currently operates 20 kidney dialysis facilities.

Fresenius Medical Care

Renal Care Group Northwest (RCGNW) is one of three entities owned by Renal Care Group, Inc. (RCG). RCGN is responsible for the operation of facilities under three separate legal entities. These entities include Pacific Northwest Renal Services (PNRS), Renal Care Group Northwest (RCGNW), and Inland Northwest Renal Care Group (IN-RCG). In March of 2006, Fresenius Medical Care Holdings (FMC) became the sole owner of RCG. In addition to the three entities listed above, FMC also operates two other entities, including QualiCenters, Inc. and National Medical Care, Inc. As all of these subsidiaries are owned by one parent corporation-Fresenius Medical Care. This evaluation shall refer to this applicant and all subsidiaries as FMC.

FMC operates outpatient dialysis centers throughout the United States. In Washington State, FMC owns, operates, or manages several kidney dialysis facilities. [source: Application Exhibit 2, CMS Dialysis Facility Compare website]

PROJECT DESCRIPTIONS

Astria

Astria proposes to establish a new 27-station facility in Yakima (25 general dialysis stations, one permanent bed station, and one CN-exempt isolation station.). The facility would be located at 209 South 12th Avenue, in Yakima, within Yakima County. The dialysis center would provide the following services:

- In-center hemodialysis for patients who dialyze in a chronic setting,
- In center hemodialysis for patients requiring isolation and/or a dialysis in a permanent bed,
- In-center hemodialysis for patients requiring treatment shifts that begin after 5:00 PM,
- Training for Continuous Ambulatory Peritoneal Dialysis (CAPD) patients,
- Training for Continuous Cycle Peritoneal Dialysis (CCPD) patients and
- Training for Home hemodialysis patients.

Astria expects the facility would be operational by May 2022. The department notes that the delays in the review of these applications might cause delays in operational dates. [source: Applicant's screening responses, p3]

The total capital expenditure for this project is $2,973,567. This includes all costs associated with establishing the facility, including the land purchase. [source: Application p14]

Northwest Kidney Centers

NKC proposes to establish a new 27-station facility in Yakima, to be called NKC Yakima Kidney Center. The facility would be located at 14 South 5thAvenue in Yakima, within the Yakima County Planning Area. The dialysis center would 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.

NKC expects the facility would be operational by April 2022, or fifteen months after NKC has an uncontested Certificate of Need. [source: Applicant's screening responses, p1]

Though isolation services would be available, there would be no exempt isolation station meeting the definition under WAC 246-310-800(9). [source: Screening Response pdf2]

The total capital expenditure for this project is $6,798,959. This includes all costs associated with establishing the facility. [source: Application p16]

Fresenius Medical Care

FMC proposes to establish a new 17-station dialysis center at 916 North 16th Avenue, Suite 100, in Yakima, within the Yakima County planning area. The new center would be known as FKC Yakima River. 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.

If approved, FMC expects the 17-station dialysis center would be operational by February 2022. The department notes that the delays in the review of these applications might cause delays in operational dates. FMC identified that the isolation services would be offered in a station meeting the definition under WAC 246-310-800(9). The total counted stations would be 16. [source: Application, Exhibit 5]

The total capital expenditure for this project is $2,604,524, which includes construction costs, equipment, and associated fees and taxes. [source: Application, p15]

APPLICABILITY OF CERTIFICATE OF NEED LAW

Each project is 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.

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.

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

This application was received during the year 2020 concurrent review. WAC 246-310-803 requires an applicant to submit specific data elements to the Certificate of Need Program. For the 2020 concurrent review cycle, the data must be received before February 18, 2020. Of the applicants, only two are existing providers of dialysis services NKC and FMC, thus subject to this requirement. NKC and FMC submitted the data elements timely. 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 applications under the Kidney Disease Treatment Centers-Nonspecial Circumstances Concurrent Review Cycle #1 for calendar year 2020. During the course of the review, it was discovered that one of the affected parties, DaVita, had not been afforded an opportunity to provide rebuttal comments. Review was paused and recommenced once DaVita's rebuttal was received. When DaVita was afforded an opportunity to provide rebuttal comments, it was instructed only to provide rebuttal information related to information received by the department during the public comment period. The rebuttal DaVita provided, however, was exclusively addressed at rebutting the other parties' **rebuttal** submissions. As a consequence, the department concluded that DaVita's rebuttal comments were not permissible and did not consider them. Below is the chronological summary of the review timelines.

APPLICATION CHRONOLOGY

Action	NKC	Fresenius Medical Care	Astria
Letter of Intent Submitted	June 1, 2020	June 1, 2020	June 1, 2020
Application Submitted	July 1, 2020	July 1, 2020	July 1, 2020
Department's pre-review activities • DOH Screening Letter • Applicant's Responses Received	July 31, 2020 August 31, 2020	July 31, 2020 August 31, 2020	July 31, 2020 August 31, 2020
Beginning of Review	September 8, 2020		
End of Public Comment • Public comments accepted through the end of public comment • No public hearing requested or conducted	October 8, 2020		
Rebuttal Comments Submitted	November 9, 2020		
Department's Initial Anticipated Decision Date	January 21, 2021		
Review paused to allow DaVita to rebut Comment	January 29, 2021		
DaVita Rebuttal Comments Submitted	March 1, 2021		
Department's Revised Anticipated Due Date	May 17, 2021		
Department's Actual Decision Date [1]	June 18, 2021		

AFFECTED PERSONS

"Affected persons" are defined under WAC 246-310-010(2). In order to qualify as an affected person, someone must first qualify as an "interested person," defined under WAC 246-310-010(34).

[1] This decision was delayed as a result of statewide employee furloughs and the inadvertent failure to allow DaVita to provide rebuttal comments, as discussed above.

For these projects, each applicant is an affected person for the other competing application.

DaVita, Inc.
DaVita Inc. is a national and Washington State provider of dialysis services. In the Yakima County ESRD Planning Area, DaVita operates five dialysis centers.[2] On July 16, 2020, DaVita, Inc. submitted its request for interested person status. DaVita provided comments on this application and, therefore does qualify as an affected person.

SOURCE INFORMATION REVIEWED

- Astria Certificate of Need application
- Astria screening responses
- Northwest Kidney Centers Certificate of Need application
- Northwest Kidney Centers screening responses
- Fresenius Medical Care Certificate of Need application
- Fresenius Medical Care screening response
- Public comments
- Rebuttal comments
- Years 2014 through 2019 historical kidney dialysis data obtained from the Northwest Renal Network
- Department of Health's ESRD Need Projection Methodology for the Yakima County planning area posted to its website March 2020
- 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

Astria

For the reasons stated in this evaluation, the application submitted by Astria/AH NP8 proposing to establish a 27-station dialysis facility in Yakima, within the Yakima County Planning Area is consistent with applicable criteria of the Certificate of Need Program. The approval requires agreement to the project description, conditions, and approved capital expenditure identified below.

Project Description:
This certificate approves the establishment of a 27-station dialysis center to be located at 209 South 12th Avenue, Suite 100, within the Yakima County Planning Area in Yakima [98902]. The table below provides a breakdown of the total number of stations at project completion.

[2] DaVita Mt. Adams, DaVita Union Gap, DaVita Wapato, DaVita Yakima, and DaVita Zillah.

	CMS Certified Stations	Stations Counted in Methodology
General Use In-Center Stations	25	25
Permanent Bed Station	1	1
Exempt Isolation Station[3]	1	0
Total Stations	**27**	**26**

Services to be provided at the new dialysis center include:

- In-center hemodialysis for patients who dialyze in a chronic setting,
- In center hemodialysis for patients requiring isolation and/or a dialysis in a permanent bed,
- In-center hemodialysis for patients requiring treatment shifts that begin after 5:00 PM,
- Training for Continuous Ambulatory Peritoneal Dialysis (CAPD) patients,
- Training for Continuous Cycle Peritoneal Dialysis (CCPD) patients and
- Training for Home hemodialysis patients.

Conditions:

1. Approval of the project description as stated above. Astria 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. Astria shall finance this project consistent with the financing described in the application.
3. Prior to providing dialysis services at Astria Yakima Dialysis Center, Astria shall provide an executed medical director agreement consistent with the agreement provided in Attachment 4 of its August 7, 2020, screening responses.
4. Prior to providing dialysis services at Astria Yakima Dialysis Center, Astria shall provide an executed lease agreement consistent with the agreement provided in Attachment 2 of its August 7, 2020, screening responses.
5. Prior to providing dialysis services at Astria Yakima Dialysis Center, Astria shall provide an executed transfer agreement consistent with the draft in Appendix 11 of its initial application.
6. Prior to providing dialysis services at Astria Yakima Dialysis Center, Astria shall provide the Certificate of Need Program with a listing of its credentialed staff for review. The listing shall include each staff person's name and professional license number.

Approved Capital Expenditure:
The total capital expenditure for this project is $2,973,567.

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

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

[3] Defined under WAC 246-310-800(9)

CRITERIA DETERMINATIONS

A. Need (WAC 246-310-210)

Astria

Based on the source information reviewed the department concludes that Astria 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)

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).

Fresenius Medical Care

Based on the source information reviewed, the department concludes that FMC 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).[4]

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.[5]

[4] 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]

[5] WAC 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 2018.

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 in-center 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.

Astria
Astria proposes to establish a 27-station facility in Yakima. Astria submitted the numeric methodology posted to the department's website for the Yakima County planning area. The methodology projected need for 27 stations in year 2024.

Public Comment
None

Rebuttal Comment
None

Northwest Kidney Centers
NKC proposes to establish a 27-station facility in Yakima. NKC submitted the numeric methodology posted to the department's website for the Yakima County planning area. The methodology projected need for 27 stations in year 2024.

Public Comment
None

Rebuttal Comment
None

Fresenius Medical Care
FMC proposes to establish a 17-station dialysis center to be located in Yakima. FMC relied on the numeric methodology posted to the department's website for the Yakima County planning area. The methodology projected need for 27 stations in year 2024.

Public Comment
None

Rebuttal Comment
None

Department Evaluation of the Numeric Methodology for the Yakima County Planning Area
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 2020 numeric methodology was posted in March 2020 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 the Yakima County planning area. A summary of the department's numeric methodology is shown in Table 1 below.

Department's Table 1
Yakima County Planning Area Numeric Methodology Summary

	4.5 in-center patients per station		
	2024 Projected # of stations	**Minus Current # of stations**	**2024 Net Need or (Surplus)**
DOH Methodology Posted to Website	88	61	27

As shown in the table above, once the 61 existing stations are subtracted from the projected need, the result is a net need of 27 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.[6] 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 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:

(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.

[6] WAC 246-310-210(1)(b).

For the Yakima County planning area, 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.

Astria
There are five dialysis centers currently operating in the Yakima County planning area. Astria provided a table showing that all five centers were operating above the 4.5 standard. [source: Application, p7]

Public Comment
None

Rebuttal Comment
None

Northwest Kidney Centers
There are five dialysis centers currently operating in the Yakima County planning area. NKC provided a table showing that all five centers were operating above the 4.5 standard. [source: Application, p7]

Public Comment
None

Rebuttal Comment
None

Fresenius Medical Care
There are five dialysis centers currently operating in the Yakima County planning area. FMC provided a table showing that all five centers were operating above the 4.5 standard. [source: Application, p9]

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 June 1, 2020. The data available as of June 1, 2020, is March 31, 2020. The utilization of the five existing dialysis centers located in the Yakima County planning area is shown below.

Department's Table 2
June 30, 2020, Utilization Data
Yakima County Planning Area

Facility Name	# of Stations	# of Patients	Patients/Station
DaVita Mt. Adams	14	85	6.1
DaVita Union Gap	12	67	5.6
DaVita Wapato	6	29	4.8
DaVita Yakima	21	122	5.8
DaVita Zillah	8	45	5.6

As shown in the table above, all five facilities meet the utilization requirement thus this standard is met for the planning area.

(2) 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

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.[7] 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.

Astria

In response to this sub-criterion, Astria provided the following statements. [source: Application, p11]

[7] WAC 246-453-010(4).

Astria's health care facilities have a proven and documented history of providing care to low income and traditionally underserved populations. Astria Yakima will be committed to providing health care services to all individuals based on need; and we will prohibit discrimination on the basis of age, race, color, creed, ethnicity, religion, national origin, marital status, sex,, sexual orientation, gender identity or expression, disability, veteran or military status, or any other basis prohibited by federal, state or local law.

Astria also provided the following draft policies for this project. [source: Application, Exhibit 5]

- Admission Policy
- Charity Care Policy
- Patient Rights and Responsibilities Policy
- Non-Discrimination Policy

Public Comment
None

Rebuttal Comment
None

Department Evaluation
Astria provided copies of the necessary policies proposed to be used at the new dialysis center, which are acceptable for CN purposes.

Medicare and Medicaid Programs
Astria currently participates in the Medicare and Medicaid programs for its healthcare facilities but does not operate a dialysis facility. As directed WAC 246-310-815, Astria prepared estimates of its payer mix. The information is summarized below. [source: Application, p15]

Department's Table 3
Projected Payer Mix

Source	Percentage of Revenue by Payer	Percentage of Patients by Payer
Medicare	50%	41%
Medicaid	35%	35%
Commercial, HMO	10%	20%
Self Pay/Other	5%	4%
	100.0%	**100.0%**

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

Northwest Kidney Centers
In response to this sub-criterion, NKC provided the following statements. [source: Application, p12]

NKC has a long-established history of developing and providing services that meet the dialysis needs of the communities it serves. NKC Yakima, 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."

NKC also provided the following policies for this project. [source: Application, Exhibit 6]

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

Public Comment
None

Rebuttal Comment
None

Department Evaluation
NKC provided copies of the necessary policies used at all NKC dialysis centers, which are acceptable for CN purposes.

Medicare and Medicaid Programs
NKC currently participates in the Medicare and Medicaid programs for its operational dialysis centers. As directed WAC 246-310-815, NKC based its payer mix on the payer mix of their existing closest three dialysis facilities. The information is summarized below. [source: Application, p17]

Department's Table 4
Projected Payer Mix

Source	Percentage of Revenue by Payer	Percentage of Patients by Payer
Medicare	54.5%	78.2%
Medicaid	8.5%	13.3%
Other: Commercial	37.0%	8.5%
Total	**100.0%**	**100.0%**

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

Fresenius Medical Care
FMC provided the following information for this sub-criterion. [source: Application, p13]

"Patient access is critical to improving the health and quality of life of our patients. But patient access is multi-faceted and not simply represented by the aggregate number of stations available. Patients require access to the specific treatment modality and convenient hours of operation that meet their individual clinical and personal needs."

Patients with limited financial means also face additional barriers to care due to the financial burden of out-of-pocket expenses. However, RCG strives to address this issue for our patients when needed by providing charity in our Washington facilities. A copy of our charity care policy is contained in Exhibit 6.

FMC also provided the following policies for this project. [source: Application, Exhibits 6 & 7]

- Patient Admission Policy

- Patient Rights and Responsibilities Policy
- Charity Care/Indigence Policy

Public Comment
None

Rebuttal Comment
None

Department Evaluation
FMC provided copies of the necessary policies used at all FMC dialysis centers, including the proposed Yakima River facility.

Medicare and Medicaid Programs
FMC currently participates in the Medicare and Medicaid programs for its operational dialysis centers. As directed WAC 246-310-815, FMC based its payer mix on FMC's three closest facilities.

For the proposed Yakima River facility, FMC 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, p18]

Department's Table 5
FMC Projected Payer Mix

Source	Percentage of Revenue by Payer	Percentage of Patients by Payer
Medicare	67.9%	34.5%
Medicaid	18.7%	7.1%
Commercial	8.6%	42.3%
Misc insurance	2.7%	1.7%
Self pay	0.3%	0.1%
old rev accounts	0.0%	0.4%
Total	**100.00%**	**100.0%**

Based on the information above, the department concludes that **FMC'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) The special needs and circumstances of osteopathic hospitals and non-allopathic services.

(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) 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.

(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)

Astria

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

Northwest Kidney Centers

Based on the source information reviewed the department concludes that Northwest Kidney Centers has not met the financial feasibility criteria in WAC 246-310-220 and WAC 246-310-815.

Fresenius Medical Care

Based on the source information reviewed the department concludes that Fresenius Medical Care 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.

Astria

For Astria's project, sub-sections (a) and (c) of WAC 246-310-815(1) apply. Astria provided the following information related to this sub-criterion. [source: Application Appendix 9; Screening responses, pp8-9]

Applicant's Table

Financial Assumptions:

	2022	2023	2024	2025
Revenue				
Charge per treatment (incenter):	$325	$325	$325	$325
Charge per treatment (home):	$325	$325	$325	$325
Charge per treatment for home training	$450	$450	$450	$450
Deductions From Revenue				
Bad Debt	1.00%	1.00%	1.00%	1.00%
Charity Care	1.12%	1.12%	1.12%	1.12%
Expenses				
Salaries and Wages	See revised Table 11; annual expenses include staff additions throughout the year. Revised Table 11 reflects the FTE count at the end of each year.			
Benefits (% of salaries)	30%	30%	30%	30%
Medical Supplies	$29/treatment for Hemodialysis $100/treatment for home hemodialysis and $105/treatment for equivalent PD treatment			
ESA (EPO)	$25.00 per treatment			
Other Pharmacy	$6.50/treatment			
Laboratory	$5.57/treatment			
Other supplies (Housekeeping supplies, minor Equipment/office/Pat nutritional)	$2.50/treatment			
Utilities	$4.26/SF			
Maintenance and Repair	None/covered by vendor under warranty	$8.50/treatment	$8.50/treatment	$8.50/treatment
Water Treatment	$240/month			
Lease (per lease agreement; commencing April 2022)	$14,076.25/month (see monthly lease summary)			

	2022	2023	2024	2025
Building R & M	$3,750	$5,000	$5,000	$5,000
Depreciation (7-year life)	$87,186	$130,779	$130,779	$130,779
Amortization of Tenant Improvements (15 year)	$91,714	$137,571	$137,571	$137,571
Medical Director (per medical director agreement)	$62,500	$75,000	$78,750	$82,688
Overhead Allocation	(9% of net revenue)			
Other Purchased Services (housekeeping, pest control, freight, medical waste disposal)-	$5.50/treatment			

"The assumptions were developed using:

1) *Astria's knowledge of the Yakima County market for health care services, resident health status and patient unmet needs;*
2) *Our review of recent certificate of need approved dialysis facilities in rural Washington State, including Yakima County;*
3) *The experience of our local nephrologist who is commencing the recruitment of an additional nephrologist to the community; and*
4) *Data and experience from our international dialysis consulting firm that works predominantly with independent and hospital-based dialysis providers.*

Using the assumptions stated above, Astria projected the end-of-year number of in-center dialyses and patients for fiscal years 2022 through 2025. They are shown in the table below.[8] [source: Application, Exhibit 8]

[8] NKC's fiscal years begins July 1 and ends June 30. [source: Application, Appendix 8]

Department's Table 6
Astria Yakima
Projected Patients and Dialyses for Fiscal Years 2022 – 2025

	FY2022 (partial year)	FY2023	FY2024	FY2025
Number of Stations	27	27	27	27
Total In center Patients	34	64	96	130
Total In center Treatments	1815	6935	11422	16210
Total Home/Peritoneal Patients	6	8	17	20
Total Home/Peritoneal Treatments				

Astria also projected the revenue, expenses, and net income for the same years, shown in the table below. [source: Application, Screening Responses, Attachment 4]

Department's Table 7
Astria Yakima Kidney Center
Projected Revenue and Expenses for Fiscal Years 2022 - 2025

	FY2022 (partial year)	FY2023	FY2024	FY2025
Net Revenue	$684,155	$2,478,996	$4,178,341	$5,967,682
Total Expenses	$1,130,602	$2,573,840	$3,696,113	$4,917,023
Net Profit / (Loss)	($446,447)	($94,844)	$482,228	$1,050,659

The 'Net Revenue' line item is gross in-center and training revenue, minus deductions for bad debt and charity care. Contractual allowances were not separately identified.

The 'Total Expenses' line item includes all expenses related to the operation of the facility in fiscal years 2022 through 2025. The expenses also include allocated costs consistent with historical percentages. Medical director costs amount to $65,000 annually

Public Comment
NKC provided the following comments related to Astria's financial information:

Estimated Capital Expenditure*: Astria has provided a very aggressive budget to establish a 27-station clinic, and it appears to be missing details within the Estimated Capital Expenditure provided in Table 9. By omitting the "Fixed Equipment" (line g) costs, they are stating that the fixed equipment is included in the "Building Construction" (line f) costs. This means that items like the water filtration equipment, dialysate mixing, and IT network are all built into the same costs associated with construction. We are requesting that this be confirmed. We believe this line item was likely omitted in error in the Astria application since the cost per foot is below industry standards for this kind of construction before these costs are added.*

Source of Financial Capital – during Bankruptcy*: While NKC has only reviewed the Astria application submitted we have concerns over the viability of an applicant to successfully create a new center when they are under Chapter 11 Bankruptcy Protection. We certainly understand protections*

that exist and the limitations on any discrimination provided, though we doubt that those laws are intended to be applied to opening a new business line with capital investment. We fully respect Astria's decision to apply but are concerned the bankruptcy impacts their ability to demonstrate financial feasibility per WAC 246-310 220 and potentially to comply with other sections of the state rules. Astria stated in question 14 of their application "they would emerge from bankruptcy in the summer of 2020". We question whether the department will appropriately be able to confirm this fact or whether Astria will be able to convey the outcome of this process to the department while both still follow guidelines for an application that is under review.

The Astria proposal lacks sufficient detail on the underlying Payor Mix and Financial Assumptions. Without this detail, the Department will be unable to ascertain the projects conformance to WAC 246-310-220: *Table 10, page 15 of the Astria application identifies the projected payor mix for the proposed location. The table seems to contain errors – specifically the "Percentage by Revenue" column and the impact of an error in commercial insurance on the overall financials. If the assumptions for the Proforma are based on the assumptions outlined in the payor mix table, the projections are not accurate and cannot be validated. In addition – the application submitted failed to identify key details needed for assessment of the costs within the Proforma associated with the project making the application incomplete and not able to be measured against the criteria outlined in the ESRD Rules of 2018.*

Operational Date was modified: *As noted in the Astria response to screening question 7, Astria has changed its projected Operational date to May of 2022. The reason for the change was not defined and as noted between the two tables (shown below) – all of the key milestones have been modified – design, construction start and stop and operational date. The impact of this modification to the Proforma and projected financial performance of the clinic has not been clearly defined, calling into question the viability of the proposed clinic See both tables below:*

FMC provided the following comment related to this criterion:

1. Astria lacks necessary bankruptcy disclosures for the AH NP8 Yakima project.
The AH NP8 CN request does not meet the following Financial Feasibility criterion in WAC 246-310-220:
(1) The immediate and long-range capital and operating costs of the project can be met.
(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.
(3) The project can be appropriately financed.

Astria Health ("Astria") is currently in Chapter 11 bankruptcy reorganization.2 Under Chapter 11, Astria is required to submit a disclosure statement for the purpose of soliciting acceptance of a plan of reorganization. Pursuant to section 1125 of the Bankruptcy Code, a disclosure statement must contain "adequate information" for a creditor to make an informed decision about whether or not to accept terms of a plan of reorganization. 11 U.S.C. § 1125(a)(1). Although a court's determination of "adequate information" is made on a case-by-case basis, courts have held that a disclosure statement must contain all pertinent information bearing on the success or failure of the proposals in the plan of reorganization. Specifically, a disclosure statement should contain all material information relating to the risks posed to creditors and equity interest holders under the proposed plan of reorganization. Information that should be disclosed includes but is not limited to:

• the anticipated future of the company;
• the Chapter 11 plan;

• financial information, data, valuations or projections relevant to the creditors' decision to accept or reject the Chapter 11 plan;
• information relevant to the risks posed to creditors under the plan; and
• the actual or projected realizable value from recovery of preferential or otherwise voidable transfers. See In re Metrocraft Publ'g Servs., Inc., 39 B.R. 567, 568 (Bankr. N.D. Ga. 1984).

On July 7, 2020, Astria filed a Disclosure Statement with the Bankruptcy Court. The statement does not contain a single disclosure with respect to Astria's intent for AH NP8 to apply for a certificate of need and use Astria's funding to finance the project. Furthermore, Astria's Disclosure Statement made to the creditors and the Court is contrary to the representations made in the AH NP8 CN application and screening response.

The AH NP8 CN Application, submitted on July 1, 2020, predates the Astria Disclosure Statement. In its CN Application, AH NP8 asserts that "Astria Yakima is owned by AH NP8."4However, a footnote in the Astria Disclosure Statement provides that "[e]ach of the Debtor's nondebtor affiliates (including AH NP8) have no assets and do not file tax returns." 5 Although Astria Yakima is not yet approved or operational, the fact that this proposed dialysis facility could have value is relevant information for creditors. Therefore, this information should have been included in the Astria Disclosure Statement.

In its screening response, AH NP8 represents that Astria Yakima will lease the Astria Regional Medical Center ("ARMC") from debtor SHC Medical Center – Yakima for the dialysis facility.6 Astria, however, made no disclosures related to the leasing of ARMC to the creditors or Bankruptcy Court. If Astria is removing an asset from liquidation at the expense of funds available to pay general unsecured creditors, this fact must be disclosed to creditors.

Significantly, Astria made no disclosures related to its financing commitment of $2,973,567 to fund AH NP8 for the dialysis facility.7 It is unclear whether Astria's secured creditors who have blanket security interests in the Astria accounts and cash are required to consent to this kind of use. Nevertheless, the use of approximately $3,000,000 in funds that would otherwise be used to pay creditor claims is a fact that should be disclosed to creditors. Moreover, if the AH NP8 dialysis facility project is approved and begins construction while Astria remains in bankruptcy, this use of funds requires Bankruptcy Court approval.

Astria's failure to provide adequate information in its bankruptcy disclosures renders its financials unreliable, and on this basis, the Department should deny this application.

2. Astria's salary projections do not match its stated wage and FTE staffing assumptions, resulting in unreliable financial projections.
The salary calculations within Astria's pro forma conflicts with its staffing and wage assumptions. Over Astria's forecast period, correction of the salary and benefit calculations for consistency with its staffing and wage assumptions results in about $837,000 additional salary costs and $250,000 additional staff benefits costs. The staffing and benefits costs within the Astria Pro Forma financials are thus unreliable, and Astria has not demonstrated that the immediate and long-rage capital costs of the project can be met.

Astria's staffing and wage assumptions are presented in Table 1, along with the implied salary and benefit costs in Table 2. The differences between salary costs calculated using Astria's staffing and wage assumptions and those presented within its Pro Forma financial are given in Table 3.

Applicant's Table

Table 1: Astria Staffing and Wage Assumptions

Staffing (Table 11, pg. 47)		FTEs			
Position	Wage	2022	2023	2024	2025
Administrator	$ 45	1	1	1	1
Social Worker	$ 31	0.3	0.7	1	1.4
RNs	$ 40	2.7	4.18	6.3	7.98
Patient Care Tech	$ 21	4.25	7.95	12	16.2
Dietician	$ 33	0.3	0.7	1	1.4
Reception/Clerical	$ 20	1	1.5	1.5	2
Equipment Tech	$ 30	0.5	1	1	1
Total		**10.05**	**17.03**	**23.8**	**30.98**

Source: Astria Yakima Screening, p. 47

Table 2: Astria Salary Calculations Based on Staffing and Wage Assumptions

Implied Salaries		FTEs			
Position	Hours/ Year	2022	2023	2024	2025
Administrator	2080	$ 93,600	$ 93,600	$ 93,600	$ 93,600
Social Worker	2080	$ 19,344	$ 45,136	$ 64,480	$ 90,272
RNs	2080	$ 224,640	$ 347,776	$ 524,160	$ 663,936
Patient Care Tech	2080	$ 185,640	$ 347,256	$ 524,160	$ 707,616
Dietician	2080	$ 20,592	$ 48,048	$ 68,640	$ 96,096
Reception/Clerical	2080	$ 41,600	$ 62,400	$ 62,400	$ 83,200
Equipment Tech	2080	$ 31,200	$ 62,400	$ 62,400	$ 62,400
Salaries, Total		**$ 616,616**	**$ 1,006,616**	**$ 1,399,840**	**$ 1,797,120**
Benefits (30%)		**$ 184,985**	**$ 301,985**	**$ 419,952**	**$ 539,136**

Source: Fresenius calculations; Astria Yakima Screening, p. 47

Table 3: Comparison of Astria Salary Assumptions and Stated Salary Amounts

Table 11 Salary Calculations	2022	2023	2024	2025	
Salaries, Total	$ 616,616	$ 1,006,616	$ 1,399,840	$ 1,797,120	
Benefits, Total	$ 184,985	$ 301,985	$ 419,952	$ 539,136	
Astria Pro Forma	2022	2023	2024	2025	
Salaries	$ 367,484	$ 829,858	$ 1,188,862	$ 1,596,820	
Benefits	$ 110,245	$ 248,957	$ 356,659	$ 479,046	
Difference	2022	2023	2024	2025	Period Total
Salaries	**$ 249,132**	**$ 176,758**	**$ 210,978**	**$ 200,300**	**$837,168**
Benefits	**$ 74,740**	**$ 53,028**	**$ 63,293**	**$ 60,090**	**$251,151**

Source: Fresenius calculations; Astria Yakima Screening, pp. 42 & 47

The salary and benefits calculations presented in Table 2 are consistently hundreds of thousands more than the salary and benefit figures presented within its pro forma financials and given in Table 3. The salary and benefit calculations present within the Astria pro forma thus do not correspond to the staffing and wage rate assumptions provided in Astria's application and screening response. Over the entire forecast period, correction of the salary and benefit calculations for consistency with its staffing and wage assumptions leads to about $837,000 additional salary costs, and $250,000 additional staff benefits costs.

The conflicting information and calculations of facility staffing costs undermines the reliability of Astria's financial projections and questions the financial feasibility of its proposed project. As such, Astria has not demonstrated that the immediate and long-range capital and operating costs of the project can be met, and its application should be rejected.

3. ***There are several additional errors, inconsistencies, and/or ambiguous assumptions within Astria Health's financial projections.***

Astria's pro forma revenue and expense statement and supporting documents contain multiple mistakes and/or instances in which the stated assumptions are not sufficiently clear to reproduce the stated projections.

Startup costs not calculated across a consistent time period

Expenses for 2022 are not calculated over a consistent period. In some cases, they are calculated over an 8 month period (depreciation, amortization of tenant improvements), while in other cases they are calculated over a 9-month period (lease costs, utilities, water treatment, building R&M), and in still other cases, they are calculated over a 10-month period (Medical Director).10 No explanation or justification is given for why these different line items have different timelines in the startup period. Furthermore, while some of these differences may be reasonable, some are not. For example, the amortization of tenant improvements should be on the same timeline of tenant rent, indicating that Astria has omitted one month of tenant improvement costs within its 2022 costs. For another example, the Astria hiring timeline suggests at least some staffing costs beginning in January 2022,11 four months before they are projected to begin within the Astria pro forma financials.

More generally, utilization of Astria's proposed facility in 2022 is over an 8-month period, so these differences indicate varying expectations of timing between when Astria plans to begin treating patients and when they must begin covering certain expenses. Astria has not provided sufficient justification for why these timelines should differ, which undermines the reliability of its financial projections.

Depreciation

Astria has provided no information regarding its depreciation of project expenses and how the project will be financed other than stating that "The project will be funded from Astria Health." 12 However, within the provided pro forma and associated assumptions, Astria lists expenses related to both "Depreciation" and "Amortization of Tenant Improvements." "Depreciation" is assumed over a 7-year period, while "Amortization of Tenant Improvements" is labeled with a 15-year period. We present these numbers in Table 4.

Applicant's Table

Table 4: Astria Pro Forma Depreciation Amounts

Year	2022	2023	2024	2025
Months	8	12	12	12
Depreciation (7-year life)	$87,186	$130,779	$130,779	$130,779
Amortization of Tenant Improvements (15 year)	$91,714	$137,571	$137,571	$137,571

Source: Astria Yakima Screening p. 45

These amounts reflect about $10,898.25 per month in "Depreciation" and $11,464.25 per month in "Tenant Improvements." Taken over the length of the stated periods imply a total of $915,453 of value depreciated, and $2,063,565 in Tenant Improvements. These amounts combined equal $2,979,018, which is close, but does not equal, the $2,973,567 in stated project expenses.

Charity Care miscalculated for 2025
Astria presents charity care in 2025 equal to $73,223 and revenue equal to $6,101,924.14 Thus, for 2025, charity care is equal to 1.2% of revenue, not 1.12% of revenue as stated in the assumptions and reflected in all prior years.

DaVita provided the following comments related to this criterion:

1. The application identifies an incorrect number of stations. The planning area shows need for 27 stations, however in Table 3, Astria proposes a facility with 28 stations + 1 exempt ISO station. Table 3 in the application shows 27 general use and 1 permanent bed, which would be 28 total stations. The square footage calculation in the table confirms that there are 28 distinct stations + 1 exempt ISO. Because the number of stations is not properly identified, the calculations and forecasts in the pro forma are not reliable and the application does not meet the standard for financial feasibility 246-310-815. For convenience, the table is passed below

Applicant's Table

Table 3
Maximum treatment floor area square footage: WAC 246-310-800(11)

Area Type	Number of Stations	Sq. Ft Per Station	Total Square Feet
(a) General Use	27	150	4,050
(b) Permanent Bed	1	200	200
(b) Exempt Isolation	1	200	200
(c) Future Expansion	0	150	0
Other Treatment Floor Space	*75% * sum of (a), (b) and (c)*		3,337.50
Total			**7,787.50**

2. No lease is provided. The application does not demonstrate site control because no lease is provided. One wonders if the active bankruptcy case involving Astria, discussed in more detail below, precludes Astria from entering a financial commitment, such as a lease, at this time.
.....

4. The pro forma does not make sense. Referring to #2 above, without a lease there is no way to confirm the lease expense forecasted in the pro forma. It also does not make sense that the lease amount for partial year 2022 is $337,830; exactly the same as the lease amount for each of the full years. If there are any increases in the lease in future years, they are not reflected in the pro forma; however that is impossible to verify because, again referencing #2, no lease was attached.

It also does not make sense that utilities are estimated at $48,000 for every year. Again, it makes no sense the partial year 2022 would be the same as the subsequent full years. It is also unreasonable that utilities do not go up over time as census increases. Certain utilities may stay the same regardless of census, but some utilities must be higher with more patients. It will take more water to treat the 132 estimate patients in 2025 than the 50 estimated patients in 2022, yet the utility estimate is constant. It will take more electricity to run the machines needed to treat the higher patient volumes, and indeed things like water used for washing hands or flushing toilets will be higher.

For these reasons, the estimates provided in the pro forma are unreliable and do not meet the criteria set forth for financial feasibility 246-310-815.

.....

7. Astria Health is listed as debtor in the bankruptcy petition #19-01189-WLH11, and the application does not clarify whether they can commit to the financial obligations in the applications without bankruptcy court approval.

Current activity on the bankruptcy petition includes activity through 9/30/2020 (the date this letter is being prepared), and does not indicate that it has been discharged or resolved. According to the proceedings, Astria must receive court approval for financial transactions. The application does not include any affidavit from the bankruptcy court authorizing Astria to commit to the project proposed in their application.

Rebuttal Comment
Astria rebutted the above claims:

1. The Competitors' Bankruptcy Based Comments Are Without Merit
In their public comments, Fresenius, DaVita and Northwest Kidney Centers (referred to the "Competitors"), raise issues related to a certain Disclosure Statement (a copy of which is publicly available on the website www.kccllc.com/astria) filed on July 7, 2020 (since amended) in the jointly-administered Chapter 11 Bankruptcy Case of Astria Health and certain affiliates in the United States Bankruptcy Court for the Eastern District of Washington (the "Bankruptcy Court") under lead case number 19-01189-11 (the "Bankruptcy Case"), as well as the status of the Bankruptcy Case and its impact on the Application. Principally, the Competitors assert that the Disclosure Statement does not mention the Applicants' pending application for the Certificate of Need ("CON") or, that if the CON is granted, that Astria will lease property to Applicant and that the Astria entities are able to provide financial assistance to the Applicant of approximately $3 million as needed over time to February 2022. These assertions are of no consequence for several reasons:

First and foremost, as the Competitors recognize, the Applicant is not a Debtor in the Bankruptcy Case or any other case. This distinction is critical because Bankruptcy law does not require a disclosure statement to discuss activities of non-debtor affiliates, including actions that are in a nascent stage such, as the pending CON application or subsequent actions that are contingent thereon. By its plain terms, § 1125 of title 11 of the United States Code (the "Bankruptcy Code"), to which Fresenius cites, governs disclosure statements of debtors, which the Applicant indisputably is not. In fact, the applicant is even further removed from the Bankruptcy Case as it was formed for the purpose of submitting the Application by another non-Debtor, AH NP 8.

Similarly misplaced is the Competitors' suggestion that the Debtors' status and financial prospects remain unclear. To the contrary, the Disclosure Statement was approved by the Bankruptcy Court as legally sufficient during a hearing on November 6, 2020. At that hearing, the Bankruptcy Court also scheduled a confirmation hearing on the Debtors' Plan of Reorganization (or "Plan") for December 18, 2020. Plan confirmation will allow the Debtors to reorganize and otherwise promptly emerge from Bankruptcy. No material objections to the Plan are expected from creditors as it is supported by the Debtors' primary secured creditors, who are co-proponents of the Plan, as well as the Official Committee of Unsecured Creditors, which represents the interests of unsecured creditors. These facts indicate that the Debtors will successfully reorganize and emerge from Bankruptcy prior to the projected CON approval date of February 2021, and well before the anticipated operational date of February 2022.

Even if the Applicant were a debtor in bankruptcy -- which it is not -- the CON application would not require disclosure because it constitutes an ordinary course of business transaction. Under § 363 of the Bankruptcy Code, Bankruptcy Court approval is necessary only for non-ordinary course transactions. 11 U.S.C. § 363(b)(1). The ordinary course nature of the CON application is further evidenced by the fact that Debtor Sunnyside Hospital already provides inpatient dialysis services through a third party in Sunnyside, Washington. Thus, if the Applicant were a Debtor, the requested CON would merely constitute ordinary course expansion of existing dialysis services to Yakima.

Additionally, post-confirmation, contingent, ordinary course actions need not be described in a Disclosure Statement, especially if their impact is not material to the financial recovery of creditors. This is because the purpose of a disclosure statement is to provide creditors with sufficient information about the proposed plan of reorganization to make an informed decision on whether to vote in favor of or against the plan. A disclosure statement need only contain "adequate information," meaning "information of a kind, and in sufficient detail, as far as is reasonably practicable in light of the nature and history of the debtor and the condition of the debtor's books and records, that would enable a hypothetical reasonable investor typical of holders of claims or interests of the relevant class to make an informed judgment about the plan." In re Bellows, 554 B.R. 219, 225 (Bankr. D. Ak. 2016) (quoting In re Indian Nat'l Finals Rodeo, Inc., 453 B.R. 387, 399 (Bankr. D. Mont. 2011)). Therefore, nonmaterial, and ordinary course disclosures that would not contribute to a hypothetical reasonable investor's ability to make an informed judgment about the plan need not be included.

The fact that the Debtors will be able to provide rental space and financial assistance (in the form of the capital expenditure and start-up) to the Applicant if the CON application is approved is not required to be discussed in the Disclosure Statement because the actions are de minimus to the Debtors' go forward operations. As noted in the Applicant's August 27, 2020 submission, Astria's positive cash position was $31.3 million as of July 31, 2020. Moreover, the Disclosure Statement evidences that the Debtors' annual gross revenues are approximately $140 million. Disclosure Statement, IV.A. ("The Astria Health system, ... is the largest non-profit healthcare system based in Eastern Washington, with annual revenues of approximately $140 million."). In light of these facts, a lease of already owned but currently unoccupied property, and a contingent obligation to provide up to $3 million in assistance over time (which are both contingent on CON approval), are not sufficiently material to necessitate disclosure.

Fresenius also contends that either the Application or the Disclosure Statement is incorrect because the Application provides in a footnote that "[e]ach of the Debtor's nondebtor affiliates have no assets and do not file tax returns" and that the nondebtor affiliates includes AH NP8. This is a red herring. AH NP8 has no assets as a practical matter because ownership of a subsidiary which also has no assets does not change whether AH NP8 has assets; zero plus zero equals zero. And, obviously, AH NP8 has

not filed taxes because it has no taxable income. If the Application is approved, the CON would become an asset which would be disclosed when required.
As such, one must recognize the Competitor's actions here for what they are; an attempt to stifle competition.

Astria Yakima's Financial Assumptions are Reasonable and Realistic and Our Various Agreements Meet or Exceed All CN Requirements.

AH NP8 reminds the Program that it retained an international dialysis consulting service company with specific expertise in independent and hospital-based dialysis providers. They provided data and support related to reimbursement, clinical and technical operations, outpatient dialysis management, industry standards, business planning, cost reporting, staffing, staff training, and development and implementation of quality and compliance programs. The support and expertise provided by this firm has provided us great insight and support. They reviewed the public comment of the Competitors, found nothing of merit and participated in development of the following responses:

A. Staffing:
In its public comment, Fresenius claims that Astria's salary projections do not match our stated wages and that our FTE assumptions are understated. Fresenius has misinterpreted our staffing assumptions. As noted in Appendix 1 of the August 2020 Screening Response, (monthly census) was expected to increase each month. The staffing expenses were then 'right fit' to the projected patient census BY MONTH.

The assumptions included in Appendix 4 (financial assumptions) state that the total FTEs noted in revised Table 11 were year-end FTEs. In other words, the salary and wages expense line item is based on the monthly salary and wages determined by the FTE count in each month. The annual total in Table 11 was provided to note the total FTEs expected at the end of each year. As an example, for year 2023 (year 2), Fresenius has assumed (or as their table states "implied") RN FTE's at 4.18 which is Astria Yakima's month 12 number of FTE's.

Fresenius then incorrectly assumed 4.18 FTE's X 2080 hours X the average wage to calculate $347,776. Again, in our proforma, we do not reach 4.18 FTE's until month 12. In month 1, we only need 2.7 RN FTE's, and each month, the FTE's are adjusted up to match the increase in patient census, until, by month 12, we reach 4.18.

In other words, because staff are added throughout the year, using the year end FTE count would overstate expected annual salaries and wages. Fresenius' tables include this overstatement, and their arguments are incorrect.

B. Underlying Assumptions and Start Up Costs are Consistent with the Pro Forma Financials:

Our Competitors questioned the some of the underlying financial assumptions related to expenses during the start-up period and the projection horizon, alleging that they are somehow inaccurate or unreliable. This is not the case. As noted in the screening response, Astria revised its operational timeline to May 2022 and all the financial assumptions reflect this change. To meet this timeframe, Astria assumed that it will incur some costs over an 8-10 month initial operating period, partial Year 1. Table 1 summarizes the comments raised and restates our underlying assumptions.

Applicant's Table

Table 1
Financial Assumption Clarification

Line Item (s)	Assumption
Start up/initial operating period related to Lease/Building Repair and Maintenance/Water Treatment, Medical Director line items	Related to lease, building repair, maintenance, water treatment and medical director, Fresenius suggests that our start-up period is not consistent between the various line items. Our experts worked with us to develop a start-up/initial operating period that reflects the reality of when staff and medical director will be added and when the building will be equipped, stocked and occupied. For example, patients will be treated in the unit for 8 months of the initial operating year (May 2022 opening); but the medical director will be in place for 10 months and the building will be occupied by staff for (training, equipping, etc.) for 9 months (one month prior to patients receiving treatment).
Depreciation/Amortization of Tenant Improvements	Fresenius also commented on depreciation and amortization. Consistent with GAAP, these costs commence with the facility opening in May 2022.
Utility expenses	Related to utilities, DaVita suggested that our utility costs were flat across the projection horizon. This is correct, Astria Yakima conservatively assumed full occupancy each year in estimating utilities. Astria's familiarity with utility costs in Yakima County and specifically with the utility costs of this building give us very high confidence that $48,000/year is "spot on". We also assumed a full year of utility costs in the start-up period.
Charity care	Fresenius notes that we "overstated" charity care in 2025 (by $4,881). That is accurate, but it has no impact on the pro formas, and we are glad to be held to that higher level in 2025.
Payer Mix	The information provided in Table 3 of the application was an estimate, and Astria Yakima did reverse the commercial line item (such that percentage of patients and revenue were reversed.). However, all dialysis applicants appear to calculate revenues the same way Astria did such that **no applicant's proposed payer mix can be confirmed with the data included in the actual pro forma.** Importantly and most relevant, the revenue impact from contracted commercial payor rates are factored into the gross revenues (charges). And, in fact, Astria's overall net revenue per treatment assumption is consistent with the national average net revenue per treatment for independent dialysis facilities.

D. The Lease Meets all CN Requirements .
Both NKC and DaVita noted that there was no lease agreement provided in the application, neither commented on the lease agreement in the screening response. Also, the record should reflect that DaVita's comments on the lease expense (#4 of their public comments) are irrelevant as they reference the pro forma financial in the original application which was revised in screening.

Astria notes for the record that the lease agreement is consistent with CN requirements. This lease agreement, provided in Attachment 2 of the screening response, includes a commitment to execute upon CN approval. The lease agreement contains the required commitment for a site for CN purposes (the initial term is for 10 years and there are three options to renew).

E. The Medical Director Agreement Meets all CN Requirements
Contrary to statements made by DaVita, Astria submitted a medical director agreement that is consistent with CN requirements. This agreement, included in Attachment 4 of the screening response, contains the required commitment to execute the agreement upon CN approval.

Further, both the fees included in the pro forma financials and the term is consistent with CN requirements.

…..

A. The Capital Expenditure Includes all Related Costs
As requested by NKC, Astria confirms that no line item was omitted in the capital expenditure and the fixed equipment costs are included in the building construction line item.

Further, included in Attachment 1 is a letter from Astria's architect indicating that even if during final design, Astria Yakima opted to make minor changes to the space (changing location of stations and/or other spaces), these changes can be done well within the estimated capital expenditure and square footage. In fact, we understand this to be a standard practice because single line drawings are defacto, not final.

Department Evaluation
Astria proposes a new 27-station dialysis center in the Yakima County Planning Area. Astria based its projected utilization of the facility consistent with WAC 246-310-815(1)(a) and (c). Based on a review of the assumptions used for projecting utilization of the dialysis center, the department concludes they are reasonable.

Astria provided a detailed description of the assumptions used for projecting revenue, expenses, and net income of proposed dialysis center.

Fresenius identified issues pertaining to Astria's recent reorganization under bankruptcy protection, apparent inconsistencies between Astria's wage and staffing assumptions and Astria's pro forma income statmements, issues with lease, start-up costs, and depreciation.

Northwest Kidney Centers identified similar issues – Astria's bankruptcy proceedings, the estimated capital expenditure of the proposed project, Astria's lease agreement, and is proposed payer mix.

DaVita cited issues with Astria's financial assumptions, and the bankruptcy as well.

In rebuttal, Astria provided a detailed description of is position in the bankruptcy process. The department notes that Astria's final reorganization plan was approved by the court in December 2020. Astria provided financial records demonstrating that it had sufficient cash on hand to fund this project and provide for its ongoing financial obligations until the center reaches profitability in the third year of operation. The department concludes that Astria has made a credible demonstration that it is able to fund the project.

Astria also provided rebuttal of the criticism of its medical director agreement, lease agreement, staffing and depreciation costs. The department notes that the medical director and lease agreements are drafts, however appropriate costs are identified and consistent with the financial projections. As is the practice

of the department, were this project to be approved, it would be conditioned upon Astria providing executed copies of both agreements prior to completion of the project.

The department also reviewed Astria's rebuttal discussion of staffing and other expenses and concludes that Astria's has demonstrated that its projected financial statements are consistent with its stated assumptions.

Based on the above information, the department concludes that the immediate and long-range operating costs of the new facility can be substantiated. **This sub-criterion is met.**

Northwest Kidney Centers

For NKC's project, sub-sections (a) and (c) of WAC 246-310-815(1) apply. NKC provided the following information related to this sub-criterion. [source: Application Exhibit 8]

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, 2022.*
2. *Volumes*
    a. *Patient In-Center Census: In-Center Census is expected to reach 130 by June 30, 2025 with the center supporting 18 home patients. Yakima county has continued to grow beyond the capacity of the current units. All units are currently operated by a for-profit dialysis provider and Northwest Kidney Centers will be able to provide a choice for patients and physicians in the area..*
    b. *Treatments are calculated based on 13 treatments per month and a 5% no-show rate.*
3. *Gross Revenue*
    a. *a. Medicare: The modeled weighted average charge per treatment for all billable services is reflective of the actual average amount for the 3 closest existing facilities for the first 8 months of fiscal year 2020.*
    b. *b. Medicaid: The modeled weighted average charge per treatment for all billable services is reflective of the actual average amount for the 3 closest existing facilities for the first 8 months of fiscal year 2020.*
    c. *c. Medicaid: The modeled weighted average charge per treatment for all billable services is reflective of the actual average amount for the 3 closest existing facilities for the first 8 months of fiscal year 2020.*
    d. *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 3 closest existing facilities for the first 8 months of fiscal 2020.*
4. *Deductions from Gross Revenue*
    a. *a. Total Contractual Deductions is the weighted average reflective of the actual average payer mix for the 3 closest existing facilities for the first 8 months of fiscal year 2020.*
    b. *b. Bad Debt is reflective of the actual average bad debt write-off for the 3 closest existing facilities per treatment for the first 8 months of fiscal year 2020.*
    c. *c. Charity is reflective of the actual average bad debt write-off for the 3 closest existing facilities per treatment for the first 8 months of fiscal year 2020.*
5. *Direct Expenses: All direct expenses are modeled based on the actual average amount per treatment for the existing 3 closest facilities for the 12 months of fiscal year 2020.*
    a. *No inflation has been assumed in the forecast period*
    b. *Medical Director is based on contracted amount*
    c. *Depreciation is based construction of a new facility with applicable depreciation rates for Land Improvements, Shell and Core, Equipment fixed and movable.*

d. *Other Supplies refers to office supplies, janitorial supplies, building and plant supplies. Other Purchased Services refers to language interpretation services, freight, landscaping, window washing and pest control.*

6. *Overhead is based on the facilities allocation of overhead for the 3 closest facilities as filed fiscal year 2019 cost reports. Overhead included administrative, support services and the labor and supplies related to home program*

"NKC Yakima's current proposed payer mix is detailed in Table 10."

Applicant's Table 10

Payer Mix	Percentage by Revenue	Percentage by Patient
Medicare	54.5%	78.2%
Medicaid	8.5%	13.3%
Commercial	37.0%	8.5%
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 2022 through 2025. They are shown in the table below.[9] [source: Application, Exhibit 8]

Department's Table 7
NKC Yakima
Projected Patients and Dialyses for Fiscal Years 2022 – 2025

	FY2022 (partial year)	FY2023	FY2024	FY2025
Number of Stations	27	27	27	27
Total In center Patients	5	45	90	130
Total In center Treatments	62	3,705	10.004	16,302

NKC also projected the revenue, expenses, and net income for the same years, shown in the table below. [source: Application, Appendix 8]

Department's Table 8
NKC Yakima Kidney Center
Projected Revenue and Expenses for Fiscal Years 2022 - 2025

	FY2022 (partial year)	FY2023	FY2024	FY2025
Net Revenue	$28,456	$1,621,998	$4,382,240	$7,142,483
Total Expenses	$366,985	$2,156,218	$4,554,855	$6,953,576
Net Profit / (Loss)	($338,529)	($534,220)	($172,615)	$188,907

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

[9] NKC's fiscal years begins July 1 and ends June 30. [source: Application, Appendix 8]

The 'Total Expenses' line item includes all expenses related to the operation of the facility in fiscal years 2022 through 2025. The expenses also include allocated costs consistent with historical percentages. Medical director costs amount to $65,000 annually.

Public Comment

FMC provided the following comment related to NKC's financial projections:

1. Northwest Kidney Centers' salary projections conflict with its stated wage and FTE staffing assumptions, resulting in significant financial discrepancies.

There are two components to the Department's determination of whether an application satisfies Subcriterion 1. First, the pro forma financial statements and supporting information provided by an applicant must be reliable and, as such, demonstrate the proposed project is financially feasible. Second, even if the statements and supporting information appear to be reliable, the Department must also evaluate the overall reliability of both the applicant and the organizations with which the applicant is affiliated. If there are questions or concerns about the reliability of the applicant or its affiliated organizations, this in turn raises questions and concerns about (1) whether the "capital and operating costs of the project can be met" and (2) the financial feasibility of the proposal in general.

With regards to staffing, the salary calculations within the NKC pro forma are in sharp conflict with its staffing and wage assumptions. NKC's method of calculating salary and benefit costs affects both the timing of these expenses, as well as their overall amounts. Correcting the salary and benefit calculations for consistency with the NKC staffing and wage assumptions leads to about $350,000 additional salary costs, and $81,000 additional staff benefits costs over the forecast period May 2022 to June 2025. Furthermore, these costs should have been distributed towards the beginning of the forecast period, rather than the end as they were. The timing of salary costs must be consistent with the NKC timeline and affects expected capital requirements across the different years. As such, correction of the salary and benefit calculations results in much greater capital requirements over the first two forecast years.

We present NKC's staffing and wage assumptions in Table 1, along with the implied salary and benefit costs in Table 2. The differences between salary costs calculated using NKC Yakima's staffing and wage assumptions and those presented within its pro forma financials are given in Table 3.

Applicant's Table

Table 1: NKC Staffing and Wage Assumptions

Staffing (Table 11, pg. 47)		FTEs			
Position	Wage	2022	2023	2024	2025
Clinical Director	$ 74.34	0.28	0.28	0.28	0.28
Nurse Manager/ Care Manager	$ 55.80	1	1	1	1
Tech	$ 20.75	1	6.92	12	16.52
RN-In Center	$ 47.96	1	2.7	5.4	5.4
RN-Home Training (PD and HD)	$ 48.28	0.25	0.5	0.5	0.75
Facility System Specialist	$ 27.61	0.25	0.5	0.75	1
Technical Services	$ 35.06	0.5	0.68	0.68	0.68
MSW	$ 36.44	0.05	0.41	0.82	1.18
Dietician	$ 36.77	0.05	0.41	0.82	1.18
Receptionist	$ 19.81	1	1	1	1
Total		**5.38**	**14.4**	**23.25**	**28.99**

Source: NKC Yakima Screening, p. 13.

Table 2: NKC Salary Calculations Based on Staffing and Wage Assumptions

Implied Salaries		Salaries			
Position	Hours/ Year	2022	2023	2024	2025
Clinical Director	2080	$ 43,296	$ 43,296	$ 43,296	$ 43,296
Nurse Manager/ Care Manager	2080	$ 116,064	$ 116,064	$ 116,064	$ 116,064
Tech	2080	$ 43,160	$ 298,667	$ 517,920	$ 713,003
RN-In Cneter	2080	$ 99,757	$ 269,343	$ 538,687	$ 538,687
RN-Home Training (PD and HD)	2080	$ 25,106	$ 50,211	$ 50,211	$ 75,317
Facility System Specialist	2080	$ 14,357	$ 28,714	$ 43,072	$ 57,429
Technical Services	2080	$ 36,462	$ 49,589	$ 49,589	$ 49,589
MSW	2080	$ 3,790	$ 31,076	$ 62,152	$ 89,438
Dietician	2080	$ 3,824	$ 31,357	$ 62,715	$ 90,248
Receptionist	2080	$ 41,205	$ 41,205	$ 41,205	$ 41,205
Salaries, Total		**$ 427,020**	**$ 959,523**	**$ 1,524,910**	**$ 1,814,275**
Benefits (25.1%)		**$107,182**	**$240,840**	**$382,752**	**$455,383**

Source: Fresenius calculations; NKC Yakima Screening, p. 13

The salary calculations presented in Table 2 are greater than and change differently over time than the salary and benefit figures presented within the pro forma. We present these two different sets of salary calculations in Table 3.

Table 3: Comparison of NKC Salary Assumptions and Stated Salary Amounts

Table 11 Salary Calculations	2022	2023	2024	2025	
Salaries, Total	$ 427,020	$ 959,523	$ 1,524,910	$ 1,814,275	
Benefits, Total	$107,182	$240,840	$382,752	$455,383	
NKC Pro Forma	2022	2023	2024	2025	
Salaries	$ 9,491	$ 540,968	$ 1,461,563	$ 2,362,158	
Benefits	$ 2,326	$ 136,014	$ 367,478	$ 598,941	
Difference	2022	2023	2024	2025	Period Total
Salaries	**$ 417,529**	**$ 418,555**	**$ 63,347**	**$ (547,883)**	**$351,548**
Benefits	**$104,856**	**$104,826**	**$15,274**	**$(143,558)**	**$81,399**

Source: Fresenius calculations; NKC Yakima Screening, p. 5, 13.

The salary and benefit calculations present within the NKC pro forma thus do not correspond to the staffing and wage rate assumptions provided in NKC's application and screening response. Adjusting the pro forma for NKC's stated staffing and wage assumptions results in significantly higher salary and benefit expenditures over the period 2022 to 2024, and lower salary and benefit expenditures in 2025.

This discrepancy stems from NKC calculating salary and benefit costs as a fixed cost per treatment, a method which is not consistent with the NKC staffing schedule, or with the realities of hiring. Over the entire forecast period, correction of the salary and benefit calculations leads to about $350,000 additional salary costs, and $81,000 additional staff benefits costs.

The conflicting information and calculations of facility staffing costs raises significant concerns and uncertainty regarding the financial feasibility of NKC's proposed project. NKC has thus not demonstrated that the immediate and long-range capital and operating costs of the project can be met, and its application should be rejected.

2. Depreciation method / useful life for leasehold improvements and equipment not disclosed, rendering NKC's depreciation calculations unreliable.
Depreciation expenses identified in NKC's pro forma equal $435,139 per year.4 Calculated over a 15-year period, these costs reflect a capital expenditure of $6,527,085, a figure below the NKC stated project costs of $6,798,959.5 Thus, either NKC Yakima has planned an amortization period of 15 years, 7 months, and 2 weeks, it has chosen not to amortize $271,874 of its project costs, or it has calculated depreciation incorrectly within either its financial pro forma or its application. Under any interpretation, NKC has not provided sufficient detail regarding the useful life assumptions driving a straight-line depreciation method for the leasehold improvements and equipment, and has not provided the Department with enough information to verify or validate the depreciation calculations or the reasonableness of the assumptions.

Furthermore, NKC Yakima holds a 10-year lease. As such, project depreciation costs should be depreciated over a 10-year period, the term of the lease. Crucially, shortening the depreciation period to anything less than 11 years causes annual depreciated project costs to increase such that net profit becomes negative every year of the forecast period.7 Thus, NKC Yakima has provided financial projections which, when corrected for an appropriate depreciation period, fail to show positive net income in any year of the forecast period. The sensitivity of the NKC financial projections to a shorter depreciation period raises uncertainty regarding these projections. As a result, NKC Yakima has not demonstrated that the immediate and long-range capital costs of the project can be met, and its application should be denied.

3. Landlord Work not disclosed or included in capital expenditures despite being listed in WAC 246-310-800(3)(e).
Financial feasibility questions #4-5 in the application form states:
4. Complete the table below with the estimated capital expenditure associated with this project. Capital expenditure for the purposes of dialysis applications is defined under WAC 246-310-800(3). If you have other line items not listed below, include the definition of the line item. Include all assumptions used to create the capital expenditure estimate.
5. Identify the entity responsible for the estimated capital costs identified above. If more than one entity is responsible, provide breakdown of percentages and amounts for all.
4
Subsection (d) of WAC 246-310-800(3) specifically identifies "Building owner tenant improvements". Yet, NKC's response to #5 suggests that it is the sole entity responsible for the capital costs and makes no mention of landlord expenditures that would fall under the WAC 246-310-800(3) definition. Exhibit B in the building lease, titled "LANDLORD'S WORK" lists numerous activities expected to be undertaken by the Landlord (Osprey Financial, LLC). The expenses presented in building lease Exhibit B are consistent with those defined under "Building owner tenant improvements" in WAC 246-310-800(3)(d). Therefore, NKC failed to accurately or sufficiently identify all applicable capital expenditures and the entities responsible in its application or subsequent screening response. Without full disclosure of the total costs associated with the proposed project, the Department is unable to evaluate NKC Yakima's conformance to WAC 246- 310-220(1)-(2).

DaVita provided the following comment:

WAC 246-310-815 requires that a proposed kidney dialysis facility demonstrate positive net income by its third full year of operation. Establishing profitability requires that the applicant submit a reliable pro forma for this time period. The pro forma provided in NKC's Yakima application is inaccurate, so much so that an independent reviewer cannot reliably determine the financial feasibility of the project. The application must therefore be denied.

The first issue with the reliability of NKC's Yakima financial projections is found in the pro forma's revenue line item. Table 10 (below) shares that the proposed facility will derive 37% of its revenues from the 8.5% of patients it will serve who have commercial health insurance. However, in the pro forma, the total commercial revenues projected by NKC for this facility never exceeds 8% of Total Gross Revenues. Further, no additional information is provided on commercial gross revenues in the Pro Forma Assumptions section of the application, nor is there any information provided about how commercial revenue interacts with Total Contractual Deductions.

Rebuttal Comment
NKC rebutted FMC's claims:

"1. That the NKC application has a salary and wage/staffing conflict:
This statement is false – NKC's application and related content to salary, wages and staffing is sound and appropriate. The financial projections are based on the average costs of the three closest facilities as prescribed by the application instructions and the Department of Health. NKC averages the three closest facilities on a per treatment basis and applies those costs to the projected treatments of the proposed facility. The staffing schedule is representative staffing model that NKC deploys based on the number of stations and expected occupancy of a facility. The two would not necessarily agree as actual staffing levels of the three closest facilities may vary to the standard staffing models. NKC complied with the application instructions regarding costs accumulation in the proforma and the department will find the results acceptable.

2. That NKC used incorrect application of depreciation period:
This statement is false – NKC's application has used appropriate Generally Accepted Accounting Principles (GAAP) withing our application. Generally Accepted Accounting Principles prescribe that the cost of tenant improvements be depreciated over the lesser of lease term or useful life of an asset. GAAP further proscribes that when determining the length of lease management must factor in the likelihood of exercising lease extension options. The initial lease term is in fact 10 years, however the lease includes three 5- year renewal options. At this point in time, management sees no reason why they would not remain in the community for the entirety of the available renewal options which would indicate that the tenant improvements would be depreciated over 25 years, however, the average blended useful life of the tenant improvements is more reasonably set at 15 years.

NKC's application has applied reasonable and appropriate assumptions and is the superior application.

3. FMC states that NKC failed to identify relevant landlord capital costs ("Building owner tenant improvements"):
This statement is also false and is holding NKC to an unfair standard to work that has nothing to do with our lease and decided well before we located this property. NKC has not failed to identify TI improvements, and in contrast, has clearly defined them within our application. NKC is not responsible for, nor required to identify, improvements in the building that are not connected to our lease and are not specific to NKC as a tenant. At the point we contacted Osprey Financial LLC (landlord) to inquire about the proposed property, Osprey Financial' s representative informed NKC that they were in

process of making improvements to the building for a future retail tenant as part of their investment in the property. This work was decided, designed and intended to be completed well before our lease could be acted upon

.

WAC 246-310-800(3)(d) states:
"Building owner tenant improvements including, but not limited to: Asbestos removal, paving, concrete, contractor's general conditions, contractor's overhead and profit, electrical, heating, ventilation and air conditioning systems (HVAC), plumbing, flooring, rough and finish carpentry and millwork and associated labor and materials, and utility fees." (italics added).

The building improvements are outside of our lease and are not improvements that we have negotiated or asked for as they were already in process and planned for by the owner prior to NKC approaching them to secure a lease. These are not "tenant improvements" but rather investment by the owner. This would be as if we were holding FMC accountable in their application financials for past improvements that were done to their leased building – it is not within the scope of WAC 246-310-800(3)(d).

In summary:
NKC's application and related projections on salary, wages and staffing are appropriate. Our use of Generally Accepted Accounting Principles (GAAP) withing our application exceeds standards and are how the Department would expect NKC to show and is not in question. Finally, NKC has fully disclosed all costs in relation to the building improvements that are connected to our project. As the applications are reviewed it will be clear that NKC's application is superior.

NKC also rebutted DaVita's comments:

"That NKC does not meet WAC 246-310-815 and does not demonstrate positive net income by its third full year of operation:
This statement is false – NKC's application, as presented, clearly shows that we meet all aspects defined in WAC 246-310-815.

"Thus, it is accurate that 8.5% of the patient treatments from the three closest facilities represents a corresponding 8.0% of gross revenue. Both the proforma and the table are an accurate representation of the revenue and associated contractual deductions of the three closest facilities.

That NKC's proforma does not take into account safe facility staffing levels and labor costs:
This statement is also false – NKC's staffing levels are safe, meet CMS standards and are correctly accounted in our proforma.

DaVita's second argument implies that the number of registered nurses is completely variable when in fact both Registered Nurses and Dialysis Technicians are only semi-variable. NKC staff's units to the number of operating stations. There is a minimum of one registered nurse for each 12 stations for all hours of operations which requires 2.7 registered nurses to cover all shifts 6 days per week. Twelve stations running 3 shifts can accommodate up to 72 patients. Table 8 within our application shows that less than 72 patients are projected for the first full year of operations. In the second year, the patient count exceeds 72 patients thus a second registered nurse is added. It takes 5.4 registered nurses to cover up to 24 stations at full occupancy of 144 patients. The projections show patient counts growing to only 130 patients. It is anticipated that in years beyond the projection period that the additional 3 stations would be needed, and a third registered nurse would be added at that time. Similar to registered nurses, dialysis technicians are staffed based on operating stations only at a ratio of one dialysis tech to four

stations, which is why the dialysis technician staffing grows at a disproportionate rate to the registered nurse staffing.

Department Evaluation

NKC proposes a new 27-station dialysis center in the Yakima County planning Area. NKC based its projected utilization of the facility consistent with WAC 246-310-815(1)(a) and (c). Based on a review of the assumptions used for projecting utilization of the dialysis center, the department concludes they are reasonable.

FMC provided comment regarding apparent inconsistencies between NKC's FTE projections and staffing costs. NKC rebutted that this was not an error and that the costs are fully accounted for. NKC states, *". The two would not necessarily agree as actual staffing levels of the three closest facilities may vary to the standard staffing models."* The department finds this argument reasonable, particularly when observing that the FTE counts provided in the projections may be end-of-year totals and would not necessarily correlate exactly to a multiplication of the end-of-year FTEs and average wage for any given position if the total FTEs for that job classification varied at all during the year.

FMC's arguments about the depreciation schedule used by NKC and its assertion that NKC did not adequately capture capital costs expended by the landlord are sufficiently rebutted by NKC. With its descriptions of how it allocates depreciation, and the fact that landlord improvements of communal space are a typical element of commercial leases and are not generally considered part of the capital cost for a CN project.

DaVita identified inconsistencies between NKC's stated payer mix and the values provided in its projected income statements. NKC states that commercial payers represent 37% of the facility's gross revenue and that 8.5% of its patients are covered by commercial payers in the application narrative, however the projected income statements provided in screening show a very different payer mix. Each year of the projected income statement shows approximately 8.1% of gross revenue attributed to "Commercial Plans." NKC's rebuttal attributes DaVita's observation to an erroneous assumption that *"DaVita's first argument assumes that the average revenue per patient is identical across payors when in fact is can be substantially different depending on what services and drugs are bundled into the contracted rate*" fails to explain the difference between the gross revenue amounts in its pro-forma for commercial payers (~8.1%) and the amount stated in its payer mix table (37.5%). The department concludes that 8.5% of NKC's patients may indeed be covered by commercial insurance, however the pro-forma amounts indicate that it is NKC, not DaVita that appears to be conflating percentage of patients with percentage of revenue. Because these two assumptions cannot be reconciled, the department finds NKC's revenue projections to be unreliable.

The cost of medical director services is outlined in NKC's draft medical director agreement. The costs are substantiated in the pro forma, and the terms are consistent with other similar agreements accepted by the department. Were this project to be approved, the department would require an executed copy prior to completion of the project.

Based on the above information provided by the applicant and comment, the department is unable to conclude if NKC's projected revenue and expense statements are reasonable. **This sub-criterion is not met.**

Fresenius Medical Care

For FMC's project, sub-sections (a) and (c) of WAC 246-310-815(1) apply. FMC provided the following information related to this sub-criterion. [source: Application, p12; screening responses, Exhibit 8]

Utilization Forecast Methodology

Please see below a description of the methodology used to construct the in-center and home patient projections. It is assumed the number of treatments per patient is 144 treatments per year.

In-Center Patients

In-center patients are projected based on the incremental patient demand projections from step (b) of the Department's need methodology. Please note that FKC Yakima River is assumed to only capture part of the incremental patient demand growth beginning in 2024 as its 16 stations are projected to be over 5 patients per station. It is assumed the number of treatments per patient is 146.7 treatments per year.

Home Patients

The three closest clinics to the proposed FKC Yakima River project are Leah Layne, Moses Lake, and Columbia Basin. Of these three facilities, Moses Lake and Columbia Basin reported home patients in the 1Q2020 NWRN modality report---representing a 23.4% ratio with those facilities' in-center patient census. The 23.4% home percentage was applied to FKC Yakima River's projected in-center patient projections discussed above to forecast home patients. It is assumed the number of treatments per patient is 168.9 treatments per year.

Information and assumptions used to prepare Table 12 include:

• The wage and salary figures are based on three closest facilities' 2019 data. They are held constant over the forecast period.

• It is assumed a FTE ("full time equivalent") employee works 2,080 hours per year.

• Non-productive hours are estimated at 10% of productive hours, based on FMC experience.

• Benefits are calculated at 30.2% of wages and salaries based on the three facilities' 2019 data.

• The staff to patient ratio matrix below was used to construct minimum FTE counts for the projection years based on future patient counts presented in Table 7.

Revenues

Revenues and payer mix are based on CY2019 data from the three closest facilities ("actuals"). Revenues are calculated by payer and treatment. Bad debt and charity care are subtracted from revenues to yield net revenue figures.

Charity Care

Calculated at 0.88% of revenue based on the experience of Fresenius' facilities in Washington State.

Bad Debt

Calculated on a per treatment basis from actuals.

Expenses

- *Unless otherwise noted, expenses have been calculated based on CY2019 per treatment actuals from three closest facilities multiplied by projected number of treatments*

- *Personnel expenses are based on identified patient to staff ratios and incorporates a 10% non-productive factor. Wage figures have been compiled from actuals.*
- *(New) Rent Expense : see Section 3.1 in the lease agreement. Rent commence is anticipated to be March 2021 per Section 2.1.*
- *Other Property: other property expenses (property tax, CAM) is assumed to be 10.8% of base rent based on CY2019 actuals from the three closest facilities.*
- *Tenant Improvement Allowance: see Section 7.3 in the lease agreement. TIA is $40/sf. There is 7,987 rentable square feet. Therefore, the TIA is $319,480 (i.e. $40 * 4,7987).*
- *Leased Dialysis Machine and Other Interest: calculated based on CY2019 per treatment actuals from three closest facilities multiplied by projected number of treatments*
- *Project-related Depreciation is straight-line; assumes 10 years on leaseholds and 8 years on equipment.*
- *Physician Compensation: commencement is anticipated to be at 1st patient treated (February 2022), consistent with MDA Section 3.01.1. Annual compensation initially is $60,000 (Section 3.01.1). Further, a 2.50% fee escalator is applied at the each anniversary (Section 3.01.2)*

Using the assumptions stated above, FMC projected the end-of-year number of in-center dialyses and patients for partial year 2022 and full years 2023 through 2024, which are shown in the table below. [source: Screening responses, p4]

Department's Table 9
FMC Yakima River Dialysis Center
Projected Patients and Dialyses for Fiscal Years 2022 – 20245

	Partial Year 2022	2023	2024	2025
Number of Stations	16	16	16	16
Total In center Patients	56	73	81	85
Total In center Treatments	7,528	10,706	11,879	12,465
Total Home Patients	13	17	19	20
Total Home Treatments	2,013	2,871	3,209	3,378

FMC also projected the revenue, expenses, and net income for fiscal years 2022 through 2025, which are shown in the table below. [source: Screening responses, Exhibit 8]

Department's Table 10
FMC Yakima River Dialysis Center
Projected Revenue and Expenses for Fiscal Years 2022 – 2025

	Partial Year 2022	2023	2024	2025
Net Revenue	$5,034,169	$7,163,752	$7,961,029	$8,359,667
Total Expenses	$2,747,307	$3,762,514	$4,129,219	$4,314,760
Net Profit / (Loss)	**$2,286,862**	**$3,401,238**	**$3,831,810**	**$4,044,907**

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 facility in years 2022 through 2025. The expenses also include allocated costs consistent with historical FMC percentages. Medical director costs are consistent with the executed agreement in the application.

Public Comment
NKC provided the following comments related to the reliability of the pro forma:

"Related to FMC's pro forma financials, we raise the following concerns and/or questions:
▪ The Certificate of Need rules (see WAC 246-210-815) require an applicant with existing facilities to base all assumptions (except known expenses) on the three closest facilities. As noted in the assumptions included on page 17 of the Screening Response PDF, FMC based nearly all assumptions except charity care on its three closest facilities. For charity care, it based the percentage on its Statewide average. Why? It is likely that charity care is higher at its three closest facilities than it is statewide. It should be noted that bad debt was based on the three closest facilities.

▪ FMC stated that it based its other property expense on the 2019 information for the three closest facilities. Given that FMC has a lease agreement for space, an estimate for these costs should be available for the selected site; not based on unrelated site costs. The landlord should have provided a current estimate.

▪ The staffing information contained in Exhibit 8 (both in the application and the screening response) fails to provide individual salary information, as required by application guidelines. These guidelines require applicants to provide salaries by FTE category. Without this information, it is not possible to determine if there is an error in the calculation of the total salaries and wages line item.

▪ FMC proposes to lease its 16 dialysis machines but has not provided a copy of the lease. In its assumptions on page 17 of its screening response, FMC states that the lease cost is based on the number of treatments. FMC has not identified a phased project, so we must assume that all dialysis machines will be in place and set-up on day 1 of operations. FMC's lease expense line item does increase every year: an increase of 42% between years 1 and 2, another 11% between years 2 and 3 and another 5% between years 3 and 4, but the annual increase in the lease costs do not match the increases in in-center treatments. Lease arrangements most typically establish a monthly lease rate per machine, and are not tied to volume or treatments. How does a lease with such unknown variability (treatments) reconcile to the cost and age of the equipment with a residual value, etc.? Who is taking the risk if treatments fall significantly lower than estimates, or in the worst case if patients do not dialyze there (i.e. what if treatment volume is zero)? Without a copy of the lease, it is impossible to determine how the costs are assigned, and how reasonable the costs are. The Department does not have the information it needs to determine financial feasibility.

DaVita provided the following comment regarding FMC's projected utilization and lease agreement:

2. WAC 246-310-815 requires that a proposed kidney dialysis facility demonstrate positive net income by its third full year of operation. Establishing profitability requires that the applicant submit a reliable pro forma for this time period. The pro forma provided in FKC's Yakima application is inaccurate, so much so that an independent reviewer cannot reliably determine the financial feasibility of the project. The application must therefore be denied.

The basis for the large inaccuracy in FKC's application comes from its entirely unreasonable assumption that the clinic will serve 56 in-center hemodialysis patients by the end of 2022, which is just 10 months into the facility's projected operations (see: Table 7 on Page 12 of FKC's application). This utilization assumption has been invalidated by the history of all dialysis providers opening new clinics, even when a new provider came to a similarly large planning area and started to serve patients. For example, there were 302 in-center hemodialysis patients served in the Pierce 5 Planning Area as of 6/30/2020, which is within 10% of the 325 in-center hemodialysis patients served in the Yakima Planning Area as of 6/30/2020 (source: Northwest Renal Network). There, Puget Sound Kidney Centers has been operating a new, 29-station facility for approximately 6 months and serves just seven in-center hemodialysis patients as of 6/30/2020.

In its application, FKC gives the following rationale for assuming a facility census of 56 in-center patients by the end of 2022:

> In-Center Patients
> In-center patients are projected based on the incremental patient demand projections from step (b) of the Department's need methodology. Please note that FKC Yakima River is assumed to only capture part of the incremental patient demand growth beginning in 2024 as its 16 stations are projected to be over 5 patients per station. It is assumed the number of treatments per patient is 146.7 treatments per year.

But in step (b) of its application, FKC shares a total projection of 370 patients in Yakima County by 2021 and 386 patients by 2022:

Table 4. Yakima County Dialysis Planning Area Projected Year-End Resident In-Center Hemodialysis Patients. Linear Projection.

Year	2020	2021	2022	2023	2024
Number of Patients	353	370	386	403	420

Source: Applicant. Please see also
https://www.doh.wa.gov/Portals/1/Documents/pubs/KDYakima.pdf

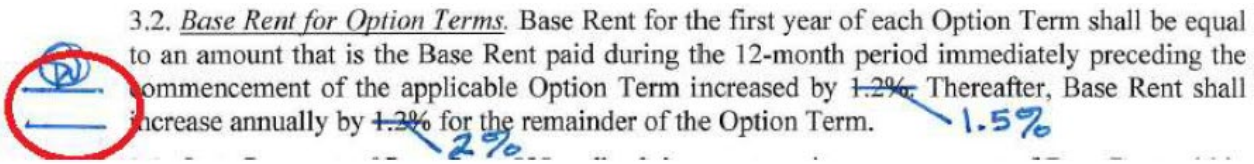
By assumptions that FKC itself has provided, the accurate patient census that FKC should have provided for end of 2022 is 16 in-center patients, the difference between Year-End Patients in 2022 and 2021. Indeed, serving 16 patients at the end of 10 months of operation would be a far more reasonable assumption. The Puget Sound Kidney Centers experience with its Lakewood facility in Pierce 5 confirms this. Their error in assuming three and a half times the number of patients at the clinic during this time period renders the entire resulting pro forma wholly unreliable, both in terms of revenues and expenses, and the entire application should be disqualified on this basis alone.

…

4. The Lease Agreement attached as Appendix 10A does not meet the standard for site control required by the Financial Feasibility requirements of WAC 246-310-220, namely, that the Department cannot rely on the lease terms as provided being legally binding to both parties.

a. Page 3 of the lease, section 3.2 includes a manual adjustment to the agreement, with a place for each part to initial confirming the change – this is unusual in a negotiated agreement of this type. Typically, the final agreement would reflect these changes in the actual text, in order to avoid the issue that now

presents itself – an invalid change to the escalation in rent. In reality, only one party initialed the change; the initial from Renal Care Group is missing. For convenience, the section is pasted below, with the missing initial circled in red:


3.2. Base Rent for Option Terms. Base Rent for the first year of each Option Term shall be equal to an amount that is the Base Rent paid during the 12-month period immediately preceding the commencement of the applicable Option Term increased by ~~1.2%~~ 1.5% Thereafter, Base Rent shall increase annually by ~~1.3%~~ 2% for the remainder of the Option Term.

b. The signature block on p. 30 of the agreement includes only the signature from the landlord, and not the tenant, Renal Care Group Northwest – thus the tenant, Renal Care Group Northwest (the Applicant), has not signed the lease. While it is possible that the agreement was signed in counterparts (i.e., there are two copies of the agreement, one signed by the landlord, and one by the tenant), a second copy was not provided to the Department.

c. An agreement signed by only one party, and with a change initiated and only signed by one party, is not a valid contract – a contract requires the consent of both parties. Therefore, this lease is not legally in effect and does not meet the standard of site control required by WAC 246-310-220.

Rebuttal Comment

FMC provided the following rebuttal comments for the issues raised by NKC.

Financial Feasibility (WAC 246-310-220 & 246-310-815)

1. FKC Yakima River's charity care projections are appropriately calculated and accepted by the Department.

NKC questions why FKC applies financial assumptions from the three closest facilities for all of its expense and revenue assumptions, except for Charity Care where it is calculated based on the statewide average. As stated in the FKC application, FKC Yakima River projects charity care to equal 0.88 percent of total revenue. This projection is based on the experience of Fresenius' facilities in Washington State, and has been consistently applied and consistently approved in FMC's CN applications.

2. FKC Yakima River's "Other Property Expenses" projections are accurate and appropriately calculated.

NKC questions why the FKC Pro Forma reflects expenses related to "Other property expenses" based on three closest facilities and asserts that this should have been calculated from information from landlord specific to the site. As explained within the FKC application, "Other Property Expenses" were calculated based on the corresponding proportions of base rent at the kidney dialysis facilities FKC Leah Layne, FKC Moses Lake, and FKC Columbia Basin.3 Note the "Other Property Expenses" for FKC Yakima River is based on the average percentage (%) of base rent from the three closest clinics, not the average dollar ($) amount. Thus, the FKC Yakima River "Other Property Expenses" are reliable, as they are based on the actual operating history of regional kidney dialysis clinic operations yet still proportionate to the specific proposed project. This reflects a valid and reasonable approach to estimating expenses, which the Department has previously accepted.

3. NKC's assertion that it is not possible to determine if there is an error in the calculation of salaries and wages is unsubstantiated. FMC provided all necessary salaries and wage data necessary for the Department's review.

In Revised Exhibit 8 included in FMC's Screening Response, FMC provided the number of FTEs and Total Salaries by FTE category, as required. 4 From this information, it is a straightforward calculation

to determine salaries by FTE category. For example, for Outpatient RNs in 2023, FKC Yakima River projects $324,834 in salary costs to 3.65 productive FTEs (4.02 productive + non-productive FTEs). The annual salary costs per FTE for Outpatient RNs are then $324,834/4.02 = $80,905. For an hourly wage, it is possible to further adjust by the number of work hours per year, commonly assumed equal to 2,080 (40 hours per week, 52 weeks per year). The assumed hourly wage for Outpatient RNs is thus about $38.90. We note that the FTE table presents numbers which are rounded to the nearest tenth of a decimal, so there is marginal variation in the numbers.

As demonstrated above, NKC's assertion that it is not possible to determine if there is an error in the calculation of salaries and wages is unsubstantiated. With elementary arithmetic one can easily calculate the annual / hourly salaries and wage rates by FTE category.

4. FKC Yakima River's dialysis machine expenses are reasonable and reliable projections, and it is consistent with the long-standing and well-established methodology approved by the Department in its approvals of prior Fresenius projects..

As explained in the FKC Yakima River screening responses, costs associated with leased dialysis machines have been calculated on a per treatment basis, using per treatment costs from the three closest facilities. These per treatment costs are calculated using total treatments, which include both in-center treatments and home treatments. NKC expressed essentially two criticisms regarding this method, which we address in turn.

First, NKC implies in its public comments that, based on FKC Yakima River estimating costs on a per treatment basis, only in-center treatments should have been used to calculate expenses related to leased dialysis machines. However, the three closest facilities used to calculate per treatment costs were also used to calculate the distribution of in-center treatments to in-home treatments (about 79% incenter to 21% in-home). Thus, it does not matter whether this amount is calculated for total treatments for each of the three closest facilities and then applied to projected total treatments for FKC Yakima, or calculated for in-center treatments for each of the three closest facilities and then applied to projected in-center treatments for FKC Yakima. Both methods will arrive at the same number. NKC's comment would thus only be relevant if FKC Yakima River had applied a different distribution of in-center versus in-home treatments than existed at the facilities used to calculate the per treatment costs.

Second, NKC criticizes the connection between dialysis lease costs and projected treatments, stating that "Lease arrangements most typically establish a monthly lease rate per machine, and are not tied to volume or treatments," and poses a series of rhetorical questions regarding machine residual value and lower-than-anticipated patient utilization. As stated in the FKC Yakima River screening responses, the methodology by FKC to estimate lease costs has been shown to provide reasonable and reliable projections, as this has been a long-standing and well-established methodology approved by the Department in its approvals of prior Fresenius projects. Furthermore, as in FMC's screening response, the patient utilization projections for FKC Yakima River reflect Department projections of excess demand and are far less aggressive and optimistic than those by NKC Yakima. Thus, FKC Yakima River's proposed project is much better situated than NKC Yakima's to weather a situation where patient demand is lower than expected."

FMC Provided the following Rebuttal to DaVita's comments:
1. FKC's Yakima River utilization projections for 2022 is fully consistent with the Department's methodology quantifying unmet patient demand.

In its public comments, DaVita argues that a more reasonable utilization projection method is to use the "difference between Year-End Patients in 2022 and 2021." 2 However, based on its argument, DaVita appears to not understand the difference between a "level" and a "change."

In 2019, a total of 330 patients were treated by Yakima kidney dialysis providers. Given the current number of dialysis stations within Yakima is equal to 61, this reflects a patient-to-station ratio equal to 5.4, above the 4.8 standard used by the Department. This is indicative of planning area providers operating at capacity. Thus, it is reasonable to expect that existing planning area providers will continue to treat 330 dialysis patients, but no more. Given a projected demand of about 386 patients in 2022, excess demand in the Yakima planning area is expected to equal about 56 patients. The FKC Yakima River utilization methodology assumes this excess demand will be absorbed by its proposed Yakima facility, and that these patients do not outmigrate to other planning areas. See Table 1 below.

Table 1: Projected In-Center Patients and Excess Demand Served by FKC Yakima River, 2022

Projected In-Center Patients	**2022**
FKC Yakima River	56
Excess Demand Calculations	**2022**
Projected Yakima County In-Center Patient Demand	386
2019 In-Center Patients (Yakima)	330
Projected Yakima County Excess Demand	56
Proportion of Excess Demand Served	**2022**
FKC Yakima River	100%

Conversely, the utilization methodology proposed by DaVita in its public comments necessarily assumes that in 2022, of the 56 patients projected to need dialysis in excess of existing planning area capacity, FKC Yakima River will treat 16 and the remaining 40 will outmigrate to other areas. As support for this position, DaVita cites the recent experience of Puget Sound Kidney Centers' Lakewood facility. However, Yakima and Pierce 5 are different planning areas, with different population centers, population densities, and geography. Thus, while the DaVita assumption of patient outmigration may be reasonable and match the experience in the Pierce 5 planning area, it is less applicable for the Yakima planning area.

The FKC Yakima River utilization methodology derives directly from the excess demand calculated in the Department of Health's Yakima County ESRD Need Projection Methodology and assumes that, given sufficient capacity, Yakima County residents will obtain kidney dialysis services from Yakima County providers. This methodology is more reasonable and less arbitrary than that proposed by DaVita in its public comments.

4. DaVita failed to recognize that FKC Yakima River updated its fully executed lease agreement in screening. Therefore, DaVita's criticisms of the lease agreement are inaccurate

DaVita claims that the FKC Yakima River lease agreement includes draft changes only signed by the landlord. However, this fails to recognize that within the FKC Screening Response, FKC Yakima River provided a fully executed lease agreement, signed by both parties, including acknowledgement and initial of both parties of the specific lease section 3.2 raised by DaVita. Thus, DaVita's statement that the lease is a draft agreement is not correct, and its criticism is without merit.

Department Evaluation

FMC proposes a new 16-station dialysis center in Yakima. FMC based its projected utilization of the new FKC Yakima River 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 dialysis center, the department concludes they are reasonable.

Despite DaVita's assertions that FMC's lease document was inadequate, in its screening responses FMC provided a copy of the executed Lease Agreement for the site to demonstrate site control. Since FMC will be leasing the site, rent/lease costs must be included in pro forma revenue and expense statement. FMC'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. The department also observes that the draft lease agreement provided in FMC's initial application would also likely have been found acceptable,

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

FMC provided a detailed description of the assumptions used for projecting revenue, expenses, and net income of Yakima Dialysis Center. NKC voiced concerns about lease expenses, salaries, and dialysis machine lease costs. FMC appropriately rebutted these arguments by identifying the bases for each of these costs and the department concludes that FMC's explanations are appropriate and credible. DaVita stated objections to FMC's projected utilization and questioned the adequacy of FMC's lease agreement. As noted above, DaVita's attack on the lease agreement is not on point. Similarly, the department concluded above that FMC's utilization projections are appropriate given the projected need for additional stations in the planning area.

Based on the above information, the department concludes that the immediate and long-range operating costs of the new facility can be substantiated. **This sub-criterion is met.**

(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.

AC 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 246-310-800(11) 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.

Astria

Astria provided the following information under this sub-criterion. [source: Application, p15]

"Reimbursements for dialysis services are not subject to or affected by capital improvements and expenditures by providers; and therefore, the proposed project will have no impact on increases in charges for services within the Planning Area. In fact, the addition of choice, for patients and payers, may actually cause price competition and reduce charges.

"The capital costs of capital projects are "monitored" in the State by virtue of WAC requirements regarding the construction of finished treatment floor area square footage as defined in WAC 246-310-800(11). Astria Yakima's project is well within the maximum treatment floor area square footage. As

such, and per the WAC 246-310-815(2) test, this project does not have an unreasonable impact on costs and charges."

Astria provided a copy of its proposed line drawings for Yakima Kidney Center which shows the square footage. [source: Application, Appendix 4]

Consistent with WAC 246-310-800(11), Astria Yakima's maximum treatment floor area square footage for 27 stations is 7,788. Astria's project will use 4,559 square feet. [source: Application, pp6-7]

Public Comment

DaVita provided the following comment regarding Astria's proposed square footage:

"The application identifies an incorrect number of stations. The planning area shows need for 27 stations, however in Table 3, Astria proposes a facility with 28 stations + 1 exempt ISO station. Table 3 in the application shows 27 general use and 1 permanent bed, which would be 28 total stations. The square footage calculation in the table confirms that there are 28 distinct stations + 1 exempt ISO. Because the number of stations is not properly identified, the calculations and forecasts in the pro forma are not reliable and the application does not meet the standard for financial feasibility 246-310-815. For convenience, the table is passed below.[source: DaVita Comment on Astria project, p2}

DaVita's Table

Table 3
Maximum treatment floor area square footage: WAC 246-310-800(11)

Area Type	Number of Stations	Sq. Ft Per Station	Total Square Feet
(a) General Use	27	150	4,050
(b) Permanent Bed	1	200	200
(b) Exempt Isolation	1	200	200
(c) Future Expansion	0	150	0
Other Treatment Floor Space	*75% * sum of (a), (b) and (c)*		3,337.50
Total			**7,787.50**

NKC provided comment regarding Astria's projected capital costs:

"Estimated Capital Expenditure: Astria has provided a very aggressive budget to establish a 27-station clinic, and it appears to be missing details within the Estimated Capital Expenditure provided in Table 9. By omitting the "Fixed Equipment" (line g) costs, they are stating that the fixed equipment is included in the "Building Construction" (line f) costs. This means that items like the water filtration equipment, dialysate mixing, and IT network are all built into the same costs associated with construction. We are requesting that this be confirmed. We believe this line item was likely omitted in error in the Astria application since the cost per foot is below industry standards for this kind of construction before these costs are added."

"The Astria proposal lacks sufficient detail on the underlying Payor Mix and Financial Assumptions. Without this detail, the Department will be unable to ascertain the projects conformance to WAC 246-310-220: Table 10, page 15 of the Astria application identifies the projected payor mix for the proposed location. The table seems to contain errors – specifically the "Percentage by Revenue" column and the impact of an error in commercial insurance on the overall financials. If the assumptions for the Proforma are based on the assumptions outlined in the payor mix table, the projections are not accurate and cannot be validated. [source: NKC Comments, pp 1-2]

Rebuttal Comment
Astria provided the following rebuttal:

*"**The Capital Expenditure Includes all Related Cost**s*
As requested by NKC, Astria confirms that no line item was omitted in the capital expenditure and the fixed equipment costs are included in the building construction line item.

"Further, included in Attachment 1 is a letter from Astria's architect indicating that even if during final design, Astria Yakima opted to make minor changes to the space (changing location of stations and/or other spaces), these changes can be done well within the estimated capital expenditure and square footage. In fact, we understand this to be a standard practice because single line drawings are defacto, not final.

*"**Maximum Floor Treatment Space is Well Below Maximum for 27 Stations***
Astria is proposing a 27- station dialysis facility that will include one isolation station and one permanent bed station. Both of these stations are depicted on the single line drawings contained in Appendix 4 of the application (stations 23 and 14, respectively). Table 3 of the application estimates the maximum floor treatment space. In our calculation, we conservatively assumed that all 27 stations were general stations, and then added one for isolation and one for a permanent bed. Even with this conservative approach, Astria is well under the maximum."

Payer Mix
The information provided in Table 3[10] of the application was an estimate, and Astria Yakima did reverse the commercial line item (such that percentage of patients and revenue were reversed.). However, all dialysis applicants appear to calculate revenues the same way Astria did such that no applicant's proposed payer mix can be confirmed with the data included in the actual pro forma. Importantly and most relevant, the revenue impact from contracted commercial payor rates are factored into the gross revenues (charges). And, in fact, Astria's overall net revenue per treatment assumption is consistent with the national average net revenue per treatment for independent dialysis facilities.

Department Evaluation
The estimated cost for this project is $2,973,567. 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.

As noted above, Astria did mis-name the columns in its payer mix table in the application; however, the department concludes that Astria's explanation of the error is credible and the payer mix is reasonable with this correction. Astria's projected Medicare and Medicaid reimbursements is 76% of revenue and commercial/other is 24%. 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.

[10] This information is found in Table 10 of the application, not Table 3

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 Astria 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), Astria's maximum floor space for a 27-station facility is 7,788. Astria projects the actual floor space will be 4,559. Astria's project does not exceed the maximum treatment floor area square footage allowable.

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

Northwest Kidney Centers

NKC provided the following information under this sub-criterion. [source: Application, p17]

"This project will have no impact on the costs and charges for services. The capital costs for this project will not negatively impact payers or patients. 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 8.

"In addition, WAC 246-310-815 (Financial Feasibility) provides a 'test' on the impact of costs and charges for health care services by limiting the cost of the project to less than the maximum floor treatment space. As noted in Table 2, NKC's project expansion is less than the maximum floor treatment space and therefore, the project does not have an unreasonable impact on the costs and charges of health care services."

NKC provided a copy of its proposed line drawings for Yakima Kidney Center which shows the square footage. [source: Application, Exhibit 5]

Consistent with WAC 246-310-800(11), NKC's Yakima Kidney Center's maximum treatment floor area square footage for 27 stations is 7,788. NKC's project will use 5,711 square feet. [source: Application, p7]

Public Comment

FMC provided comment regarding the capital expenditure for the project that is discussed earlier in this evaluation at page 36, therefore it will not be restated here.:

Rebuttal Comment

NKC provided rebuttal information regarding FMC's concerns about this project's capital costs. As with FMC's comment, this is discussed earlier in this evaluation at page 36

Department Evaluation

The estimated cost for this project is $6,798,959. 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 Yakima Kidney Center's projected Medicare and Medicaid reimbursements is 63% of revenue and commercial/other is 37%. Given that majority of dialysis payments are by Medicare and Medicaid reimbursement, the percentages are reasonable. However, as noted on page 36 of this evaluation, there is a conflict between this stated payer mix and the revenue projections provided in the pro forma financial statements.

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), Yakima Kidney Center's maximum floor space for a 27-station facility is 7,788. NKC projects the actual floor space will be 4,711. 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 this project would not have an unreasonable impact on the costs and charges for healthcare services in the Yakima County planning area. **This sub-criterion is met.**

Fresenius Medical Care

FMC provided the following information under this sub-criterion. [source: Application, pp16-17]

"This project has no impact on either charges or payment, as reimbursement for kidney dialysis services is based on a prospective composite per diem rate. In the case of government payers, reimbursement is based on CMS (Center for Medicaid and Medicare) fee schedules which have nothing to do with capital expenditures by providers such as Fresenius. In the case of private sector payers, Fresenius negotiates national, state, and regional contracts with payers. These negotiated agreements include consideration/negotiation over a number of variables, including number of covered lives being negotiated; the provider's accessibility, including hours of operation; quality of care; the provider's patient education and outreach; its performance measures such as morbidity and/or mortality rates; and increasingly, consideration of more broad performance/quality measures, such as the CMS Quality Incentive Program ("QIP") Total Performance Score ("TPS").

Fresenius does not negotiate any of its contracts at the facility-level, thus, the capital costs associated with the proposed FKC Yakima River facility would have no impact on payer negotiations or levels of reimbursement. In this regard, facility-level activities, such as number of FTEs, operating expenses or capital expenditures have no effect on negotiated rates, since such negotiations do not consider facility-level operations. As such, the proposed FKC Yakima River facility will have no effect on rates Fresenius would receive in the Yakima Dialysis Planning Area."

FMC provided a copy of its proposed line drawings for the new dialysis center. [source: Application, Exhibit 5]

Consistent with WAC 246-310-800(11), FKC Yakima River Dialysis Center's maximum allowable square footage for 16 stations and one isolation station is 5,163. FMC's project will use 2,882 square feet. [source: Application, Exhibit 5]

Public Comment
None

Rebuttal Comment
None

Department Evaluation
The estimated cost for this project is $2,604,524, which includes all costs associated with the establishment of the dialysis center. 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.

FMC Yakima River Dialysis Center's projected Medicare and Medicaid reimbursements is 86.6% of revenue and commercial/other is 13.4%. 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 FMC 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), Yakima River Dialysis Center's maximum floor space for a 17-station facility is 5,163. FMC calculated that its actual floor space will be 2,882. FMC'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 FMC's projected costs associated with this project would not have an unreasonable impact on the costs and charges for healthcare services in Yakima County. **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.

Astria
Astria provided the following information about financing the $2,973,567 costs for this project. [source: Application, p14 and p16]

"The project will be funded from Astria Health. A letter committing to the funding will be provided with screening."

With its screening responses, Astria provided a letter from John Gallagher, President and CEO, demonstrating its commitment to allocating the necessary funds to the project. [Source: Screening responses, Attachment 3]

Public Comment
None

Rebuttal Comment
None

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

Northwest Kidney Centers
NKC provided the following information about financing the $6,798,959 costs for this project. [source: Application, p14 and p18]

"As discussed earlier in this section, NKC will use reserves to fund this project. Included in Exhibit 7 is a letter from Carrie McCabe, CFO documenting the intent of NKC to use reserves for the project."

Public Comment
None

Rebuttal Comment
None

Department Evaluation
NKC intends to finance the entire project from reserves. A review of the audited financial statements provided with the application confirms that adequate resources exist to meet this need.

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**.

Fresenius Medical Care
FMC provided the following information about financing the $2,889,395 costs for this project. [source: Application, p18]

"RCG will use existing reserves from its parent company, Fresenius, to fund this project. Exhibit 13 includes a letter from Mr. Mark Fawcett, Senior Vice President and Treasurer, attesting to the availability of funds and a commitment to this project."

Public Comment
None

Rebuttal Comment
None

Department Evaluation
FMC 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 FMC to finance the project consistent with the financing description provided in the application. With a financing condition, the department concludes the FMC project **meets this sub-criterion**.

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

Astria
Based on the source information reviewed the department concludes that Astria has met the structure and process of care criteria in 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.

Fresenius Medical Care
Based on the source information reviewed the department concludes that Fresenius Medical Care 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.

Astria
Astria provided the following staffing table showing projected staff for the Yakima Kidney Center. [source: Screening responses, Attachment 4]

Applicant's Table
Revised Staffing Table, 2022-2025 (Year End Staffing by FTE)

	Hourly Rate	FYE 2022	FYE 2023	FYE 2024	FYE 2025
Administrator	$45.00	1	1	1	1
Social Worker	$31.00	0.3	0.7	1	1.4
RN's	$40.00	2.7	4.18	6.3	7.98
Patient Care Technician	$21.00	4.25	7.95	12	16.2
Dietician	$33.00	0.3	0.7	1	1.4
Receptionist\Clerical Support	$20.00	1	1.5	1.5	2
Equipment Technician	$30.00	0.5	1	1	1
Total		**10.05**	**17.03**	**23.8**	**30.98**

Astria provided the following clarification regarding the staffing table above. [source: Application, p19]

Astria Health is one of the largest health care employers in Yakima County. We offer competitive wage and benefit packages to employees, and in fact, have a number of employees with clinical training, experience and high interest in dialysis that have expressed an interest in being reassigned to the dialysis center. Other recruitment and retention activities include posting on various job boards, including but not limited to indeed.com, nursing associations, Health e-careers, and other local resources; participating in job fairs and serving as a clinical rotation site for a number of colleges and universities.

Public Comment
None

Rebuttal Comment
None

Department Evaluation
With the establishment of a 27-station dialysis center, Astria expects to need approximately 31 FTEs by the end of year three. Astria intends to rely on its recruitment and retention strategies used in the past for this project. This approach is reasonable. Astria is a well-established provider of healthcare services in Yakima County. Information provided in the application demonstrates that Astria has the infrastructure in place to recruit necessary staff.

Based on the above information, the department concludes that Astria provided sufficient information to demonstrate compliance with this sub-criterion. **This sub-criterion is met.**

Northwest Kidney Centers
NKC provided the following staffing table showing projected staff for the Yakima Kidney Center. [source: Screening responses, p4]

Applicant's Table

		Projected			
	Avg. Hourly Rate	**FYE June 30 2022**	**FYE June 30 2023**	**FYE June 30 2024**	**FYE June 30 2025**
Clinical Director	74.34	.28	.28	.28	.28
Nurse Manager/Care Manager	55.80	1.00	1.00	1.00	1.00
Tech	20.75	1.00	6.92	12.00	16.52
RN –In Center	47.96	1.00	2.70	5.40	5.40
RN-Home Training (PD and HD)	48.28	.25	.50	.50	.75
Facility System Specialist	27.61	.25	.50	0.75	1.00
Technical Services	35.06	.50	.68	.68	.68
MSW	36.44	.05	.41	.82	1.18
Dietician	36.77	.05	.41	.82	1.18
Receptionist	19.81	1.00	1.00	1.00	1.00
Total		**5.38**	**14.40**	**23.25**	**28.99**

NKC provided the following clarification regarding the staffing table above. [source: Application, p19]

The staffing in Table 11 is based on the current staff to patient ratios and actual average salaries of NKC's three closest facilities. 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 the pro forma financials.

Focusing on recruitment and retention of necessary staff, NKC provided the following information. [source: Application, pp20-21]

"NKC is proactive in its efforts to assure quality staffing. 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 associations, Health e-careers, and other local resources.*
- *NKC also has contacts with colleges and universities throughout the state to both recruit staff as well as to serve as a clinical rotation site.*
- *NKC staff participate (when COVID-19 rules allow), in job fairs in and around the Puget Sound area and we would expand this in Yakima as well.*
- *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.*

- *NKC has been successful in recruiting in new markets and we know we will be successful in Yakima as well*

Recent history demonstrates that NKC has been successful in staffing our new facilities. The most recent examples include NKC Federal Way East (located in King 11), NKC Federal Way West Campus (located in King 5) and NKC Fife Kidney Center (Pierce 4) and NKC Rainier Beach Kidney Center (King 2). These new units were staffed with a combination of individuals that chose to transfer from other locations and new hires to the organization. NKC has been successful in recruiting for centers outside of our typical market – specifically in Port Angeles – more than 3 hours (and a ferry ride) north of Seattle and we expect to be successful in Yakima as well.

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 to supplement."

Public Comment
None

Rebuttal Comment
None

Department Evaluation
With the establishment of a 27-station dialysis center, NKC expects to need approximately 29 FTEs by the end of year three. NKC intends to rely on its recruitment and retention strategies used in the past for this project. This approach is reasonable. NKC is a well-established provider of dialysis services in Washington State. Information provided in the application demonstrates that NKC has the infrastructure in place to recruit necessary staff.

Based on the above information, the department concludes that NKC provided sufficient information to demonstrate compliance with this sub-criterion. **This sub-criterion is met.**

Fresenius Medical Care
FMC provided the following staffing table showing projected staff for the new dialysis center. [source: Screening response, p8]

Applicant's Table

Productive FTEs, by Type	Feb-Dec 2022	2023	2024	2025
In-Center FTE's				
Facility Administrator	1.00	1.00	1.00	1.00
Outpatient RN	2.80	3.65	4.05	4.25
Patient Care Technician	7.00	9.13	10.13	10.63
Equipment Technician	0.45	0.58	0.65	0.68
Social Worker	0.45	0.58	0.65	0.68
Dietitian	0.45	0.58	0.65	0.68
Secretary	0.45	0.58	0.65	0.68
Subtotal	12.59	16.11	17.77	18.60
Home FTE's				
Home RN	0.65	0.85	0.95	1.00
Subtotal	0.65	0.85	0.95	1.00
Total	13.24	16.96	18.72	19.60

FMC provided the following clarification regarding the staffing table above. [source: Application, pp19-20]

"The staff to patient ratio matrix below was used to construct minimum FTE counts for the projection years based on future patient counts…:

Applicant's Table

	Staff to Patient Ratios (FTE Staff)
PCT (1)	1:8
RN (2)	1:20
Equipment Technician (3)	1:125
Social Worker (3)	1:125
Dietician (3)	1:125
Secretary (3)	1:125
Nurse Manager (4)	1
Home RN (2)	1:20

(1) A PCT works two shifts of patients each day, with 4 patients per shift.
(2) A RN works two shifts of patients per day, with 10 patients per shift.
(3) These FTEs are staffed based on staff-to-patient ratios identified in the table.
(4) The Center for Medicare and Medicaid ("CMS") requires that a dialysis facility be staffed with one FTE manager, irrespective of size of the facility or number of patients.

Focusing on recruitment and retention of necessary staff, FMC provided the following information. [source: Application, p21]

By virtue of the proposed geographic location, we anticipate recruiting staff from Yakima County as well as from neighboring counties. To be effective in staff recruitment and retention, RCG offers competitive wage and benefit packages. Further, to ensure that we have adequate staff across all our facilities in Washington, we have built a local float pool of WA Licensed Patient Care Techs and RN's to ensure we have coverage for patient care. Fresenius also has an internal staffing agency, Fresenius Travel, in which we can request assistance. We also have the capability of using outside staffing agencies to fill critical needs.

Public Comment
None

Rebuttal Comment
None

Department Evaluation
With the establishment of a 17-station dialysis center, FMC expects to need 19.6 FTEs by the end of year three. FMC intends to rely on its recruitment and retention strategies used in the past for this project. This approach is reasonable. FMC is a well-established provider of dialysis services in Washington State and in central Washington. Information provided in the application demonstrates that FMC has the infrastructure in place to recruit necessary staff.

Based on the above information, the department concludes that FMC provided sufficient information to demonstrate compliance with this sub-criterion. **This sub-criterion is met.**

(2) The proposed service(s) 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.

Astria

Astria provided the following statements under this sub-criterion, [source: Application, p19; Screening responses, p4]

"Ancillary and support services will generally be provided by our parent or one of our exiting (sic) sister organizations. These services include human resources, materials management, IT, medical staff credentialing, patient financial counseling, pharmacy, and plant management. We will also select a water purification vendor.

Other services such as social services, nutrition, patient education, staff education, administration and biomedical services will be on-site, but coordinated closely with Astria Health.

Applicant's Table

Service	Direct On-Site	Off Site by:
Human Resources		Astria Sunnyside Hospital
Materials Management		Astria Sunnyside Hospital
IT		Astria Sunnyside Hospital
Medical Staff Credentialing		Astria Sunnyside Hospital
Patient Financial Counseling		Astria Sunnyside Hospital
Pharmacy		Astria Sunnyside Hospital
Plant Management		Astria Sunnyside Hospital
Water Purification		Vendor, to be contracted
Social Services	X	
Nutrition	X	
Patient education	X	
Staff education	X	
Administration	X	
Biomedical/Equipment maintenance	X	

Astria also provided a copy of the draft Medical Director Agreement with Mid-Valley Nephrology Associates. No medical director was identified in the agreement provided with Astria's screening responses, but Vamsi Kanneganti, MD was identified in the initial application. The draft agreement identifies roles and responsibilities for both Astria and Mid-Valley Nephrology. Additionally, all costs are identified in the agreement. [source: Application, p19; Screening responses, Attachment 4]

Astria provided a draft transfer agreement between the proposed dialysis center and Astria Sunnyside Hospital. The agreement identifies the roles and responsibilities of each party and is intended to continue in effect indefinitely unless terminated by either party or either party has its license or Medicare certification revoked.

Public Comment

None

Rebuttal Comment
None

Department Evaluation
As previously stated, Astria has been operating in Yakima County for many years, with two hospitals and several other healthcare facilities. Most ancillary and support services will be provided by Astria's Sunnyside hospital.

Astria also provided a copy of an executed Medical Director Agreement for the dialysis center. The agreement outlines all roles and responsibilities for each entity, includes all costs associated with the agreement, and has an initial term of three year, with automatic renewal unless either party terminates the agreement. This agreement is acceptable.

Similarly, Astria's draft transfer agreement is acceptable and were this project to be approved, it would be conditional upon the applicant providing an executed transfer agreement prior to completion of the project.

Based on the information above, Astria demonstrated that it would have the necessary ancillary and support services at the proposed Yakima facility. The department concludes that **this sub-criterion is met.**

Northwest Kidney Centers
NKC provided the following statements under this sub-criterion, [source: Application, pp21-22]

"Ancillary and support services proposesd for NKC Yakima are detailed in Table 12

Applicant's Table

Service	Vendor
IT/Network Engineering	GCI Northpoint
Copier leases and support	Copiers NW/local office
Janitorial Services	Citywide (local affiliate)
Lab Services	Ascend

NKC currently operates three Support Centers. The Support Centers provide ancillary and support services to our dialysis facilities. These Support Centers are staffed with our own NKC employees and are not outside contractors. Table 13 details which services are to be provided on site and which ones are administered via the Support Centers (Off-site).

Applicant's Table

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

NKC also provided a copy of the draft Medical Director Agreement with nephrologist Suzanne Watnick, MD. The draft agreement identifies roles and responsibilities for both NKC and Dr. Watnick. Additionally, all costs are identified in the agreement. [source: Application, Exhibit 9]

In addition, NKC provided a copy of a draft transfer agreement with Yakima Valley Memorial Hospital, The agreement identifies the roles and responsibilities of each party and has an initial term of one year but is intended to continue in effect indefinitely unless terminated by either party or either party has its license or Medicare certification revoked.

Public Comment
None

Rebuttal Comment
None

Department Evaluation
As previously stated, NKC has been operating in Washington State for many years. NKC has established ancillary and support agreements in place for its existing facilities and would use the same strategies to establish ancillary and support agreements for this proposed facility.

NKC also provided a copy of an executed Medical Director Agreement for the dialysis center. The agreement outlines all roles and responsibilities for each entity, includes all costs associated with the agreement, and has an initial term of ten years. This agreement is acceptable.

Similarly, NKC's draft transfer agreement is acceptable and were this project to be approved, it would be conditional upon the applicant providing an executed transfer agreement prior to completion of the project.

Based on the information above, NKC demonstrated that it would have the necessary ancillary and support services at the proposed Yakima facility. The department concludes that **this sub-criterion is met.**

Fresenius Medical Care
FMC provided the following table outlining their ancillary and support vendors:

Applicant's Table

Clinic Vendor List	Service
Access Information Holdings	record storage
AllFix, LLC	TV Install, etc.
ASD	Meds
Basin Refrigeration, Heating, Plumbing	hvac repair
Cintas	Linens
Dell Marketing	computers, etc.
Dura Shine	Janitorial Services
Fenwal, Inc	repair & maintenance
First Choice Services	Coffee/Bev service
Hamilton Price	food catering/meetings etc.
Health Trends	Consulting
Henry Schein	meds/supplies
Holiday Inn Express	lodging/travel
J & R Drain Cleaning, LLC	drain cleaning
J&M Electric	electrician
Jims Lock Service LLC	lock repair, rekey, etc.
Joes Tree & Landscape Service	landscape maintenance
Liberty Park florist	florist
Lightning M Investments	Rent unit 104, storage
Mercy Medical Center	parking
metro Medical	meds/supplies
Moon Security Services	OCTV monitor and camera install
Mountain West Polymers, INC	Floor epoxy for water room
Ogrady Peyton	travel staff agency
Oxarc	fire extinguishers
Patriot Backflow and Gas	backflow testing
People for People	contract for Pt transport
Ramada Moses Lake	travel/lodging
Red Door	Food/Beverage
Service Master	Janitorial
Susan Hickok	Janitorial Services
The Inn at Moses Lake	lodging/travel
U Haul Co of Washington	
UPS	delivery service
VWR International, LLC	shelving system install
Water Pro	Water filter/cooler rental

FMC also provided a copy of the executed Medical Director Agreement with Dr Rubin Chandran. The agreement identifies roles and responsibilities for both FMC and Dr. Chandran. Additionally, all costs are identified in the agreement. [source: Screening Responses, Exhibit 9]

In addition, FMC provided a copy of a draft transfer agreement with Yakima Valley Memorial Hospital (identified by its prior name of Virginia Mason Memorial Hospital) The agreement identifies the roles and responsibilities of each party and has an initial term of one year, but is intended to continue in effect indefinitely unless terminated by either party.

Public Comment
None

Rebuttal Comment
None

Department Evaluation
As previously stated, FMC has been operating in Washington State and in central Washington for many years. FMC has established ancillary and support agreements in place for its existing facilities and would use the same strategies to establish ancillary and support agreements for this facility.

FMC also provided a copy of an executed Medical Director Agreement for the dialysis center. 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. This agreement is acceptable.

Similarly, FMC's draft transfer agreement is acceptable and were this project to be approved, it would be conditional upon the applicant providing an executed transfer agreement prior to completion of the project.

Based on the information above, FMC demonstrated that it would have the necessary ancillary and support services at the proposed facility. The department concludes that **this sub-criterion is met.**

(3) 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.
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).

Astria
Astria provided the following statements related to this sub-criterion. [source: Application, pp21]

"Neither Astria Yakima nor Astria Health have any history related to the actions noted in WAC 246-310-230 (5) (a)."

Public Comment
DaVita provided the following comment on Astria's project:
The Single Line Drawings provided in Appendix 4 do not meet the standard for Structure and Process of Care 246-310-230. There are many elements of the site design that simply do not meet the standard for safe patient care:
- Biomed office is in the basement, but there is no way to get a "dirty" machine from the treatment floor to the repair area without going through a "clean" area. It appears the path must go through both the lobby and an elevator, which would be "clean" areas.

- Stations 13, 14, 20 & 21 have line-of-sight issues
- No isolation station is shown in the drawings, even though it is indicated in the application. Referencing #1 above, Table 3 shows 28 + 1 ISO stations, however the drawings show 27 + 0 ISO. Note that this is a violation of CMS code and would mean the facility could not be certified for treatment of Medicare and Medicaid patients.
- Patient prep is in the middle of the treatment floor and stations 20 & 21 are impaired by it

NKC Also commented on Astria's project:
Concerns over design and infection control: NKC has concerns over a design feature of the plans Astria proposed in its application. As shown on Attachment 1, Astria designed the "patient prep" area on the far side of the clinic which implies that all patients must walk deep into the clinic in order to prepare for treatment. During a pandemic and with a vulnerable population present, a care provider will want to minimize exposure risks of patients, and as such – not require all patients to be entering and exiting the treatment area any more than is medically necessary to do so.

Rebuttal Comment
Astria provided the following table in response to comments about its facility design:

Applicant's Table

Table 2
Facility Design Clarification

Comment	Offered by:	Astria Yakima Response
Astria designed the "patient prep" area on the far side/middle of the clinic which implies that all patients must walk deep into the clinic in order to prepare for treatment.	NKC/DaVita	The patient prep area noted in the drawings is not the main area. Astria will have a privacy-partitioned prep area in the large entrance/waiting area. The patient prep needs to be where patients enter as all patients are weighed at entry and exit so that accurate weights can be determined pre and post dialysis.
Biomed office is in the basement, but there is no way to get a "dirty" machine from the treatment floor to the repair area without going through a "clean" area. It appears the path must go through both the lobby and an elevator, which would be "clean" areas.	DaVita	Astria will place disposable covers on the machines then transport them to the Biomed office. This is a recognized practice.
Stations 13, 14, 20 & 21 have line-of-sight issues	DaVita	The patient prep area in front of stations 20 & 21 is not designed to obstruct line of sight from the nurses' station (note dotted lines). At this time, Astria intends to use stations 13 & 14 for patients with behavior issues, patients new to dialysis etc. that require constant 1:1 staff to patient ratio. Line of sight is not an issue with 1:1 staffing.
No isolation station is shown in the drawings, even though it is indicated in the application. Referencing #1 above, Table 3 shows 28 + 1 ISO stations, however the drawings show 27 + 0 ISO.	DaVita	Chair #23 has been designed as a private room, which will be used exclusively for isolation. This meets CMS requirements. Astria does not intend to request nor operate an exempt isolation station as allowed per WAC 246-310-800(9).

Department Evaluation

The department reviews three different areas when evaluating this sub-criterion. One is a review of the Centers for Medicare and Medicaid Services (CMS) "*Terminated Provider Counts Report*" covering years 2018 through 2021. The department uses this report to identify dialysis facilities that were involuntarily terminated from participation in Medicare reimbursement.

The department also reviews a dialysis provider's conformance with Medicare and Medicaid standards, with a focus on Washington State facilities. The department uses the CMS "*Survey Activity Report*" to identify Washington State facilities with a history of condition level findings. For CMS surveys, there are two levels of deficiencies: standard and condition.[11]

- Standard Level

[11] Definitions of standard and condition level surveys: https://www.compass-clinical.com/deciphering-tjc-condition-level-findings/

A deficiency is at the Standard level when there is noncompliance with any single requirement (or several requirements) within a particular standard that is not of such character as to substantially limit a facility's capacity to furnish adequate care, or which would not jeopardize or adversely affect the health or safety of patients if the deficient practice recurred.

- Condition Level
  Deficiency at the Condition level may be due to noncompliance with requirements in a single standard that, collectively, represent a severe or critical health or safety breach, or it may be the result of noncompliance with several standards within the condition. Even a seemingly small breach in critical actions, or at critical times, can kill or severely injure a patient, and such breaches would represent a serious or severe health or safety threat.

The department also reviews the CMS star ratings for Washington State facilities. CMS provides the following overview regarding its star rating for dialysis centers.

"*The star rating shows how well a dialysis center delivers care compared to the national average, based on Medicare data. Each dialysis center receives a rating between 1 and 5 stars, with 3 stars representing the national average. A five-star rating means a center has quality of care that is considered 'much above average' compared to other dialysis facilities. A one or two-star rating means that measured health outcomes for that center were below average. The star rating is part of Medicare's work to make data on the quality of patient care easier to understand and use. Patient survey results aren't included in the star rating.*" [Source: CMS website]

Below is a summary of the three areas reviewed for Astria:

Terminated Provider Counts Report
Focusing on years 2018 through current, no facility operated by Astria has been involuntarily terminated from CMS participation. [Source: CMS Quality, Certification, and Oversight Reports]

Conformance with Medicare and Medicaid Standards for Washington State Centers
Astria does not operate any dialysis facilities, however, Astria's parent organization owns and operates two hospitals and one home health agency in Yakima County: Astria Toppenish Hospital and Astria Sunnyside Hospital. Each hospital has been surveyed twice since 2018 with standard citations issued and no follow-up visits. Sunnyside Home Health has been surveyed once since 2018 with no citations issued. [Source: Department of Health OHSO records]

CMS Star Rating for Washington State Centers
Astria does not operate any other dialysis facilities. As a result, there is no star rating information available.

Astria also provided a copy of a draft Medical Director Agreement between itself and Mid-Valley Nephrology Associates, PLLC, and identified Vamsi Kanneganti, MD, as the designated medical director for the facility. [Source: Application, p 19 and Appendix 6] Using data from the Medical Quality Assurance Commission, the department found that Vamsi Kanneganti, MD associated with this agreement is compliant with state licensure and has no enforcement actions on his license.

Since this application proposes a new facility Astria has not yet identified its credentialed staff. If this project is approved the department would attach a condition requiring Astria provide a listing of credentialed staff prior to providing dialysis services.

In review of this sub-criterion, the department typically considers the total compliance history of the dialysis facilities owned and operated by the applicant nationally, however, Astria operates no other dialysis facilities. As a result, no such examination was performed.

The department also considers the compliance history of the proposed Medical Director and credentialed persons associated with the applicant and the proposed dialysis center. Based on the information reviewed, the department concludes that Astria's existing healthcare facilities have been operating in compliance with applicable state and federal licensing and certification requirements. The department also concludes there is reasonable assurance that the establishment of the new dialysis center would not have a negative impact on Astria's compliance.

The department also reviewed Astria's rebuttal to the comments questioning its facility design and concludes that Astria's rebuttal is sufficient.

Based on the information here, Astria demonstrated that the proposed dialysis center could be established and operated in conformance with the applicable state licensing requirements; and that it would likely meet conditions of participation required by Medicaid and Medicare. With a condition to disclose its proposed staff, the department concludes that **this sub-criterion is met.**

Northwest Kidney Centers
NKC provided the following statements related to this sub-criterion. [source: Application, pp24-25]

"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 three different areas when evaluating this sub-criterion. One is a review of the Centers for Medicare and Medicaid Services (CMS) "*Terminated Provider Counts Report*" covering years 2018 through 2021. The department uses this report to identify dialysis facilities that were involuntarily terminated from participation in Medicare reimbursement.

The department also reviews a dialysis provider's conformance with Medicare and Medicaid standards, with a focus on Washington State facilities. The department uses the CMS "*Survey Activity Report*" to identify Washington State facilities with a history of condition level findings. For CMS surveys, there are two levels of deficiencies: standard and condition.[12]

- Standard Level
  A deficiency is at the Standard level when there is noncompliance with any single requirement (or several requirements) within a particular standard that is not of such character as to

[12] Definitions of standard and condition level surveys: https://www.compass-clinical.com/deciphering-tjc-condition-level-findings/

substantially limit a facility's capacity to furnish adequate care, or which would not jeopardize or adversely affect the health or safety of patients if the deficient practice recurred.

- Condition Level
  Deficiency at the Condition level may be due to noncompliance with requirements in a single standard that, collectively, represent a severe or critical health or safety breach, or it may be the result of noncompliance with several standards within the condition. Even a seemingly small breach in critical actions, or at critical times, can kill or severely injure a patient, and such breaches would represent a serious or severe health or safety threat.

The department also reviews the CMS star ratings for Washington State facilities. CMS provides the following overview regarding its star rating for dialysis centers.

"*The star rating shows how well a dialysis center delivers care compared to the national average, based on Medicare data. Each dialysis center receives a rating between 1 and 5 stars, with 3 stars representing the national average. A five-star rating means a center has quality of care that is considered 'much above average' compared to other dialysis facilities. A one or two-star rating means that measured health outcomes for that center were below average. The star rating is part of Medicare's work to make data on the quality of patient care easier to understand and use. Patient survey results aren't included in the star rating.*" [Source: CMS website]

Below is a summary of the three areas reviewed for NKC.

Terminated Provider Counts Report
Focusing on years 2018 through current, none of NKC's dialysis centers were involuntarily terminated from participation in Medicare reimbursement. [Source: CMS Quality, Certification, and Oversight Reports]

Conformance with Medicare and Medicaid Standards for Washington State Centers
Focusing on years 2018 through current, of NKC's 20 Washington State dialysis centers eight were surveyed at least once. Of the eight facilities, one center had condition level findings which required follow up visits. This facility is currently in compliance with CMS standards. [Source: CMS Quality, Certification, and Oversight Reports]

CMS Star Rating for Washington State Centers
NKC is approved to own and operate a total of 20 dialysis centers all in Washington State. The 20 facilities are located in King, Clallam, Snohomish, and Pierce counties. Of the 20 facilities, CMS provided star ratings for 17 facilities.[13] The average star rating for the 17 facilities is 4.35 out of 5.00 stars. Since NKC Yakima, the facility proposed with this application would be a new facility it does not have a star rating. [Source: CMS Dialysis Facility – Listing by Facility Report]

NKC also provided a copy of a draft Medical Director Agreement for NKC Yakima between itself, and Suzanne Watnick, MD. [Source: Application, Exhibit 9] Using data from the Medical Quality Assurance Commission, the department found that Suzanne Watnick, MD associated with this agreement is compliant with state licensure and has no enforcement actions on her license.

[13] One facility Rainier Beach, CCN 502601 has not been operational long enough to supply sufficient measure data. Another facility, NKC Fife, CCN 502597 did not have enough quality measure data to calculate a star rating. The last facility is was recently approved and just received its CCN, NKC Everett, CCN 502603

Since this application proposes a new facility NKC has not yet identified its credentialed staff. If this project is approved the department would attach a condition requiring NKC provide a listing of credentialed staff prior to providing dialysis services.

As mentioned earlier, there are many within the larger NKC organization with oversight and decision-making responsibilities that likely impact day to day operations of all of its facilities. The department reviewed these persons listed as having a medical credential. Of the ten physicians, five registered nurses, one dietician, and three social workers; only one had an expired Washington State credential. The applicant provided a nationally recognized credential. If this projected is approved, it will be stipulated with a condition that the one dietician renew her Washington State credential.

In review of this sub-criterion, the department typically considers the total compliance history of the dialysis facilities owned and operated by the applicant nationally, however, NKC only owns and operates dialysis facilities in Washington State. In Washington State, since 2018, 40% of NKC's facilities have had at least one survey, and one out of nine surveys conducted in the timeframe had condition-level findings. None of NKC's Washington State facilities are currently out of compliance with CMS, which includes the one center with condition level findings. NKC's average star rating is 4.35, whereas the average star rating for all Washington State providers' facilities is 4.26. The national average star rating for all providers' facilities is 3.76. NKC's Washington State facilities are above the average of all Washington State providers, as well as all providers' facilities nationally.

The department also considers the compliance history of the proposed Medical Director and credentialed persons associated with the applicant and the proposed dialysis center. Based on the information reviewed, the department concludes that NKC's existing facilities have been operating in compliance with applicable state and federal licensing and certification requirements. The department also concludes there is reasonable assurance that the establishment of the new dialysis center would not have a negative impact on NKC's compliance.

Based on the information here, NKC demonstrated that NKC Yakima could be established and operated in conformance with the applicable state licensing requirements; and that it would likely meet conditions of participation required by Medicaid and Medicare. With a condition to disclose its proposed staff, the department concludes that **this sub-criterion is met.**

Fresenius Medical Care

FMC provided the following statements related to this sub-criterion. [source: Application, p23]

"Fresenius is committed to conduct its business activities in compliance with applicable law. The company has long maintained a corporate compliance program which includes a Code of Ethics and Business Conduct, ongoing compliance related education and training for employees, a Compliance Department to support the company and its employees with compliance concerns, including a compliance line for anonymous reporting, and monitoring and auditing of business activities.

Fresenius, as one of the largest dialysis providers in the country, is routinely involved in claims, lawsuits, regulatory matters and investigations in the ordinary course of business. As for matters responsive to the application questions, Fresenius has no history of criminal convictions relating to the ownership or operation of a health care facility within the United States within the past 10 years. Fresenius also has no history of license revocations or decertifications for facilities in Washington State. In the past 10 years, a dialysis facility located in New York (Lindenhurst Dialysis Center), for which Fresenius provided management services, and a Fresenius facility located in San Francisco (RAI – Cesar Chavez), were decertified"

Public Comment

DaVita provided the following comment about FMC's facility design:

The Single Line Drawing included in Exhibit 5 does not meet the standard for patient safety and violates WAC 246-310-020 (3) and (5): Criteria for Structure and Process for Care.

WAC 246-310-020 (3): 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. WAC 246-310-020 (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

a. The medical waste disposal areas shown in Exhibit 5 are located where someone would need to cross "clean" areas in order to dispose of medical waste. This does not meet the standard for medical building construction.
b. The biomed areas are situated so that technicians would have to cross "clean" areas to service or repair machines. This would render the "clean" areas no longer clean.

Both of these elements violate CMS requirements for ESRD treatment facilities and do not meet the standard of "safe and adequate care to the public to be served". Thus, both would compromise the facility's ability to be certified by CMS and to serve patients in Yakima.

Rebuttal Comment

FMC provided the following information to rebut DaVita's comment on its facility plans:

FKC Yakima River's floor plan and operations will be consistent with CMS regulations and do not suffer from the criticisms that DaVita levied against it.

In its public comments, DaVita criticized FKC Yakima River floor plan for the following reasons:

• Medical waste disposal areas are located where someone would need to cross "clean" areas in order to dispose of medical waste. This does not meet the standard for medical building construction.
• The Biomed areas are situated so that technicians would have to cross "clean" areas to service or repair machines. This would render the "clean" areas no longer clean.

As described below, DaVita's assertions of CMS violations with the FKC Yakima River floor plan are inaccurate and unsubstantiated.

Under the CMS regulations, ESRD facilities are required to maintain procedures in accordance with State and local laws for the "[h]andling, storage, and disposal of potentially infectious waste; and [c]leaning and disinfection of contaminated surfaces, medical devices, and equipment." Further, "[t]he space for treating each patient must be sufficient to provide needed care and services, prevent cross contamination,and to accommodate medical emergency equipment and staff."

CMS has interpreted these regulations to mean that "[p]otentially-infectious waste and soiled laundry should be removed from the patient treatment area throughout the day as the containers are filled in order to maintain an environment that enhances safe patient care. All disposable items should be placed in bags thick enough to prevent leakage." Furthermore, there are no are no specific square footage requirements for dialysis treatment areas unless specified by state or local regulations. "Sufficient space" to prevent cross-contamination would allow space to:

• Prevent blood or body fluid spatters from one patient or station to another;
• Prevent contact between machines, chairs and other equipment;
• Reasonably accommodate patient belongings;
• Provide privacy and aseptic care of catheters including dressing changes;
• Safely dispose of bodily wastes/fluids and hazardous waste; and
• Readily access hazardous waste receptacles.

The FKC Yakima River floor plan is designed so medical waste is disposed of in the appropriate medical waste containers, transported from the clinical areas on carts and stored in the medical waste room until the disposal vendor comes to remove it. The pathway does include a corridor, which has sheet vinyl flooring the same as the clinical areas, and proper infection control measures will be followed. Merely "crossing" a clean area, therefore, does not violate the CMS requirements as long as proper infection control measures are followed. FKC Yakima River will be operated with the proper "preparation, handling, and storage" of unused material, "cleaning and disinfection" procedures, and implement other infection control measures. Therefore, FMC's proposed Yakima facility meets the CMS requirements, satisfies the CN criteria, and DaVita's criticisms are without merit.

Department Evaluation

The department reviews three different areas when evaluating this sub-criterion. One is a review of the Centers for Medicare and Medicaid Services (CMS) "Terminated Provider Counts Report" covering years 2018 through 2021. The department uses this report to identify dialysis facilities that were involuntarily terminated from participation in Medicare reimbursement.

The department also reviews a dialysis provider's conformance with Medicare and Medicaid standards, with a focus on Washington State facilities. The department uses the CMS "Survey Activity Report" to identify Washington State facilities with a history of condition level findings. For CMS surveys, there are two levels of deficiencies: standard and condition.

- Standard Level

A deficiency is at the Standard level when there is noncompliance with any single requirement (or several requirements) within a particular standard that is not of such character as to substantially limit a facility's capacity to furnish adequate care, or which would not jeopardize or adversely affect the health or safety of patients if the deficient practice recurred.

- Condition Level

Deficiency at the Condition level may be due to noncompliance with requirements in a single standard that, collectively, represent a severe or critical health or safety breach, or it may be the result of noncompliance with several standards within the condition. Even a seemingly small breach in critical actions, or at critical times, can kill or severely injure a patient, and such breaches would represent a serious or severe health or safety threat.

The department also reviews the CMS star ratings for Washington State facilities. CMS provides the following overview regarding its star rating for dialysis centers.

"*The star rating shows how well a dialysis center delivers care compared to the national average, based on Medicare data. Each dialysis center receives a rating between 1 and 5 stars, with 3 stars representing the national average. A five-star rating means a center has quality of care that is considered 'much above average' compared to other dialysis facilities. A one or two-star rating means that measured health outcomes for that center were below average. The star rating is part of Medicare's work to make*

data on the quality of patient care easier to understand and use. Patient survey results aren't included in the star rating." [Source: CMS website]

Below is a summary of the three areas reviewed for FMC.

Terminated Provider Counts Report
Focusing on years 2018 through 2021, none of FMC's United States dialysis centers were involuntarily terminated from participation in Medicare reimbursement. [Source: CMS Quality, Certification, and Oversight Reports]

Conformance with Medicare and Medicaid Standards for Washington State Centers
Focusing on years 2018 through 2021, of FMC's 26 operational Washington State dialysis centers 11 were surveyed at least once. Of the 11 facilities, two centers had condition level findings both of which required a follow up visit. Both of these facilities are in currently in compliance with CMS standards. [Source: CMS Quality, Certification, and Oversight Reports]

CMS Star Rating for Washington State Centers
FMC is approved to own and operate a total of 26 dialysis centers in Washington State. The 26 facilities are located in Adams, Benton, Clark, Cowlitz, Grant, Grays Harbor, Lewis, Mason, Okanogan, Pierce, Skagit, Spokane, Stevens, Thurston, and Walla Walla counties. Of the 26 facilities, CMS provided star ratings for 25 facilities. The average star rating for the 25 facilities is 3.79. [Source: CMS Dialysis Facility – Listing by Facility Report]

FMC provided an executed Medical Director Agreement with Renasolve, Inc. The agreement identifies Rubin Chandran, MD, as the medical director for the proposed facility. Using data from the Medical Quality Assurance Commission, the department found that all Rubin Chandran, MD, associated with this agreement is compliant with state licensure and has no enforcement actions on his license.

Since this application proposes a new facility FMC has not yet identified its credentialed staff. If this project is approved the department would attach a condition requiring FMC provide a listing of credentialed staff prior to providing dialysis services.

In review of this sub-criterion, the department additionally considered the total compliance history of the dialysis facilities owned and operated by FMC nationally, while more scrutiny was given to FMC's Washington State facilities.

Nationally, two facilities affiliated with FMC had in the past 10 years, lost certification which is a minority of the over two thousand facilities owned and managed by FMC. Since 2018 none of FMC United States facilities have be involuntarily decertified.

In Washington State, since 2018, 42% of FMC's facilities have had at least one survey, and two out of 13 surveys had condition-level findings. None of FMC's Washington State facilities are currently out of compliance with CMS, which includes the two centers with condition level findings. FMC's average star rating for its Washington State facilities is 3.79, whereas the average star rating for all Washington State providers' facilities is 4.26. The national average star rating for all providers' facilities is 3.76. Although FMC's Washington State facilities are below the average of all Washington State providers, it is on pace with providers nationally.

The department also reviewed DaVita's assertions that FMC's facility design is not compliant with applicable standards. The department concludes that FMC's rebuttal is convincing.

The department also considered the compliance history of the Member Physicians that can act as medical director and current staff of the dialysis center. Based on the information reviewed, the department concludes that FMC has been operating in compliance with applicable state and federal licensing and certification requirements. The department also concludes there is reasonable assurance that the establishment of this dialysis center would not have a negative effect on FMC's compliance.

Based on the information here, FMC demonstrated that FKC Yakima River could be established and operated in conformance with the applicable state licensing requirements; and that it would likely meet conditions of participation required by Medicaid and Medicare. With a condition to disclose its proposed staff, the department concludes that **this sub-criterion is met.**

(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.

Astria

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

"Astria Health will establish a Quality Improvement Program to monitor and evaluate clinical outcomes. We will also utilize employee, provider and patient satisfaction surveys to continually improve quality. An interdisciplinary team consisting of the social work, dietary clinical nurse manager, medical director, and the patient's nephrologist and primary care provider, as well as the patient's primary caregiver (spouse, adult child, AFH, nursing home etc.) will regularly communicate and coordinate regarding transportation needs, medication management and other dialysis-related concerns..

"The proposed Astria Yakima will have an appropriate relationship to Yakima County's existing health care system. Astria Yakima will be a key component of the health care system in the service area, and the project will enable enhanced patient access to much needed dialysis services in Yakima County. In addition, Astria Yakima will provide a choice for patients and payers."

Astria also provided a list of local healthcare providers with which it intends to establish working relationships [Source: Screening responses, p4]

Applicant's Table

Type	Organizations/Scope
Hospital	▪ Astria Sunnyside Hospital ▪ Astria Toppenish Hospital ▪ Virginia Mason Memorial Hospital
Tribal Health	▪ Yakima Indian Nation
Public Health	▪ Yakima Health District for supportive health services for patients
Emergency Planning	▪ Yakima Valley Emergency Management
Clinicians	▪ Yakima Valley Farmworkers Clinics: Yakima, Granger, Prosser, Sunnyside, and Toppenish ▪ Swofford & Halma Clinic: Sunnyside ▪ Astria Health Centers: Yakima, Selah, Zillah, Union Gap, Grandview, Sunnyside, and Prosser ▪ Virginia Mason Memorial Medical Groups: Yakima, Selah, Sunnyside
Transportation	▪ Yakima Valley Transportation ▪ Yakima Transit ▪ People for People
Long-Term Care	▪ Prestige Care & Rehabilitation -Sunnyside ▪ Toppenish Nursing & Rehab Center ▪ Prestige Care & Rehabilitation -Parkside, Union Gap ▪ Emerald Care, Wapato ▪ Crescent Healthcare, Inc., Yakima ▪ Garden Village, Yakima ▪ Good Samaritan Health Care Center, Yakima ▪ Landmark Care and Rehabilitation, Yakima ▪ Summitview Healthcare Center, Yakima ▪ Willow Springs Care and Rehabilitation, Yakima ▪ Assisted living facilities and adult family homes
Higher Education	▪ Yakima Valley College ▪ Pacific Northwest University of Health Sciences ▪ Central Washington University-Yakima ▪ Eastern Washington University-Yakima

Public Comment
None

Rebuttal Comment
None

Department Evaluation
Astria has been a provider of healthcare services in the Yakima area for many years. Additionally, Astria'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.

Astria provided a draft transfer agreement with Astria Sunnyside Hospital.

Astria 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 Astria's project **meets this sub-criterion**.

Northwest Kidney Centers

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

"NKC has operated outpatient dialysis services since 1962 (the very first in the Country); growing from 9 patients to over 1,800 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.

"While our relationship with Yakima Memorial Valley Hospital is new, our relationship with Virginia Mason Medical Center has been in place for many years through their physicians and leaders – some serving on our NKC Board of Trustees. With the linkage between these two organizations forming Virginia Mason Memorial we see a strong collaborative environment with NKC entering the market to support patients. Historically NKC has maintained very strong linkages to the communities that we serve, and we see the work we could provide in Yakima County as no different.

"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). 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.

NKC has all of the ancillary and support services in place that help to assure that continuity of care is in place for patients."

NKC also provided the following table to illustrate its working relationships with other healthcare facilities:

Table 14
NKC's Working Relationships with Healthcare Facilities

Category	Examples/Providers	Status of Existing Relationship	How existing relationship will be expanded to support continuity
Hospitals	▪MHS Auburn Regional Medical Center ▪CHI / Highline Medical Center ▪CHI / St. Francis Hospital ▪Evergreen Hospital Medical Center ▪Harborview Medical Center ▪MultiCare Tacoma General ▪Northwest Hospital ▪Overlake Hospital Medical Center ▪Swedish Edmonds ▪Swedish Issaquah ▪Swedish Cherry Hill ▪Swedish Medical Center ▪University of Washington ▪Valley Medical Center ▪Virginia Mason Medical Center ▪Virginia Mason Memorial (Yakima Valley Memorial)	NKC has existing referral relationships with all of the hospitals listed and is starting a new relationship with the local leadership of Virginia Mason Memorial.	NKC's existing relationships will be expanded for the proposed facility.
Clinics/Nephrology Groups (Sample)	▪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	NKC has existing relationships with all of the physician groups listed as well as other groups located in King, Clallam and Snohomish Counties.	NKC's existing relationships will be expanded for the proposed facility and expand to include the local practices throughout the Yakima community.

Category	Examples/Providers	Status of Existing Relationship	How existing relationship will be expanded to support continuity
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	▪American Diabetes Association – Washington Chapter ▪Kidney Research Institute ▪National Kidney Foundation – Washington Chapter ▪Navos – consultation and training for NKC staff on behavioral health. ▪Seattle King County Dental Society and Project Access Northwest / Access to Dental Program ▪Northwest Healthcare Response Network (15 counties in Western Washington Healthcare Emergency Services Coalition) ▪Arcora Foundation – Partnership to improve oral health. ▪AARTH – Diabetes education. ▪Washington State Hospital Association. ▪Northwest Kidney Care Alliance – CMS Demonstration program to coordinate care for ESRD beneficiaries ▪Lifecenters NW – organ procurement program	NKC has existing relationships the entities listed to collaborate and education patients, staff and clinicians.	NKC's existing relationships will be expanded for the proposed facility.
Other not for profit dialysis providers including a mutual aid plan (in the event of a disaster). A copy of the agreement is included in Exhibit 14.	▪ Puget Sound Kidney Centers ▪ Olympic Peninsula Kidney Centers ▪ Seattle Children's Hospital	NKC has existing relationships with the other not for profit dialysis providers.	NKC's existing relationships will be continued for the proposed facility.

Source: Applicant

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 the state. 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 a copy of a draft transfer agreement with Yakima Valley Memorial Hospital.

NKC provided documentation in the application in an attempt to demonstrate that the project would promote continuity in the provision of health care services in the community by establishing a new facility in the planning area. However, because the financial feasibility of the project was not demonstrated, the department cannot conclude this project would not result in an unwarranted

fragmentation of services. Based on the information above, the department concludes that NKC's project **does not meet this sub-criterion**.

Fresenius Medical Care
FMC provided the following information for this sub-criterion. [source: Application, p23-24

"The establishment of a new facility in the Yakima Dialysis Planning Area in Camas (sic), owned and operated by RCG, will not only ensure timely access to dialysis services, but it will also realize efficiency, coordination and continuity of care through shared System-level staff, administration and other functions..

Further, there is net need in the planning area that requires an increase in capacity to be able to accommodate planning area demand and prevent unnecessary and burdensome out-migration. Therefore, the development of the FKC Yakima River will not lead to fragmentation of care, but rather prevent it by reducing out-migration and ensure care is accessible in the community."

Public Comment
None

Rebuttal Comment
None

Department Evaluation
FMC has been a provider of dialysis services in Washington State for many years. FMC also has a history of establishing relationships with existing healthcare networks in Central Washington. Additionally, FMC'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.

FMC provided a draft transfer agreement with Virginia Mason Memorial[14].

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

Department Evaluation for Northwest Kidney Centers
This sub-criterion was evaluated in conjunction with WAC 246-310-230(3) above and is considered met.

[14] During the course of the review, the hospital changed its name to Yakima Valley Memorial Hospital

Department Evaluation for Fresenius Medical Care
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 Astria project met the cost containment criteria in 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, the department concludes that the Fresenius Medical Care project did not meet the cost containment criteria in WAC 246-310-240.

(1) *Superior alternatives, in terms of cost, efficiency, or effectiveness, are not available or practicable*.
To determine if a proposed project is the best alternative, the department takes a multi-step approach. Step one 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 step two, 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 Step three. The department completes step three under WAC 246-310-827.

Step One

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

Northwest Kidney Centers
For this project, NKC did not met the applicable review criteria under WAC 246-310-230.

Fresenius Medical Care
For this project, FMC met the applicable review criteria under WAC 246-310-210, 220, and 230.

Public Comment
None

Rebuttal Comment
None

Department Evaluation

Because only Astria and FMC met the review criteria under WAC 246-310-210, 220, and 230, the department will review only those two applications under step two below.

Step Two

Astria

Astria identified the following options before submitting this application. [source: Application, p23]

"Astria Health considered several options before electing to proceed with its own certificate of need application. These options included: 1) doing nothing (foregoing the opportunity to establish a locally owned/operated not-for-profit dialysis option; 2) submitting a CN application for a lesser number of stations; and 3) submitting a CN application for all 27 stations.

Option 1 was rejected after considerable review. Data demonstrates that Yakima County has experienced strong growth in its dialysis patient population, due in large part to the demographics and socioeconomics of the County. There are higher rates of diabetes and other underlying conditions in the Hispanic community, which is rapidly growing in the County. Currently, one provider operates all 5 dialysis centers, and choice for patients and payers was a determining factor that led Astria to reject this option.

Both options 2 and 3 require Astria to "get into the business" of operating an outpatient dialysis center at the time when the Washington dialysis market is dominated by large dialysis organizations "LDOs". After analysis we concluded that we could, in fact, offer a locally based real and meaningful choice, and operate a high quality, lower net revenue per treatment option that is attractive to both payers and patients. Astria also explored pursuing a smaller new facility (in the range of 12-15 stations), but ultimately elected to pursue all 27 stations needed because of the efficiencies that will be realized. Further, Astria has medical office space that lends itself, at a relatively low capital cost, to be converted to a patient-friendly dialysis environment at a relatively low cost and within a short time frame. A shorter time frame is important to deal with the very high occupancy rates being experienced in the existing centers. For these reasons, option 3 was the preferred option."

Astria expanded on this discussion in its screening responses:
It appears that the Program intended to provide us with a listing of other alternatives, but it failed to do so. We did review the Cost Containment question posed to one of the of the other competing applicants, and we note that they were asked a similar question and given specific alternatives to respond to. The list provided to this applicant included: 1) partnering with another provider to create a new surgery center (verbatim from screening letter); and 2) any other options.

In terms of partnering with another provider:

- *Advantages include sharing of initial capital and ongoing overhead. Further, assuming that the provider is a strong quality "brand" and has a history of dialysis operations, a potentially accelerated start-up period could be realized.*
- *Disadvantages include delaying development as potential partners were vetted, a new entity created, board established, tax status secured, agreements for purchased services, etc. are developed.*

While a partner may have been a viable option, neither AH NP 8 nor Astria were able to identify a partner interested in such a partnership. Given that this will be our first dialysis unit we have commissioned an international dialysis consulting service company dedicated to independent and hospital-based dialysis providers. To date, they have provided data and support related to reimbursement, clinical and technical operations, outpatient dialysis management, industry standards,

business planning, cost reporting, staffing, staff training, and development and implementation of quality and compliance programs. The support and expertise provided by this firm has provided us great insight and support. Further, we engaged an architectural firm with prior experience in dialysis, and have been able to "re-purpose", with their guidance and expertise, an existing medical office building at a cost significantly lower than new construction.

Beyond various physical locations, AH NP 8 did not consider any other options

Public Comment
None

Rebuttal Comment
None

Department Evaluation
Astria is a well-established provider of healthcare services in Yakima County and currently operates several health care facilities. Astria provided a comprehensive discussion of alternatives considered, including not submitting an application. After reviewing the information, the department concludes that Astria appropriately rejected all other alternatives before submitting its application. This sub-criterion is met.

Fresenius Medical Care
FMC identified the following options before submitting this application. [source: Application, pp24-26]
"The following three options were evaluated in the alternatives analysis:
• Option One: Establish new 16-station facility—The Project
• Option Two: Postponing the request—Do Nothing
• Option Three: Establish new 27-station facility

FMC provided the tables below to evaluate these options:

Applicant's Table

Table 15. Alternatives Analysis: Promoting Access to Healthcare Services.

Option:	Advantages/Disadvantages:
Option One Establish new 16-station facility—The Project	• Adds additional dialysis stations to the Planning Area, as warranted by WAC 246-310-812. (Advantage ("A")) • Residents of the Planning Area will be better able to access needed facility dialysis services--improves access. (A)
Option Two Do nothing	• Would do nothing to improve access (Disadvantage ("D")).
Option Three Establish new 27-station facility	• Fully addresses station need per the numeric need methodology. (A)

Table 16. Alternatives Analysis: Promoting Quality of Care.

Option:	Advantages/Disadvantages:
Option One Establish new 16-station facility—The Project	• Adds additional dialysis station capacity. This promotes access, reduces fragmentation, thus, promotes quality (A). • Residents of the Planning Area would have increased dialysis station capacity--this improves quality of care inasmuch as it improves continuity of care (A).
Option Two Do nothing	• Planning Area residents will need to out-migrate to receive care and do so in increasing numbers without added capacity. As such, patient care will be fragmented, which harms access and quality of care (D)
Option Three Establish new 27-station facility	• Similar advantages to Option One. (A)

Table 15. Alternatives Analysis: Promoting Access to Healthcare Services.

Option:	Advantages/Disadvantages:
Option One Establish new 16-station facility—The Project	• Adds additional dialysis stations to the Planning Area, as warranted by WAC 246-310-812. (Advantage ("A")) • Residents of the Planning Area will be better able to access needed facility dialysis services--improves access. (A)
Option Two Do nothing	• Would do nothing to improve access (Disadvantage ("D")).
Option Three Establish new 27-station facility	• Fully addresses station need per the numeric need methodology. (A)

Table 16. Alternatives Analysis: Promoting Quality of Care.

Option:	Advantages/Disadvantages:
Option One Establish new 16-station facility—The Project	• Adds additional dialysis station capacity. This promotes access, reduces fragmentation, thus, promotes quality (A). • Residents of the Planning Area would have increased dialysis station capacity--this improves quality of care inasmuch as it improves continuity of care (A).
Option Two Do nothing	• Planning Area residents will need to out-migrate to receive care and do so in increasing numbers without added capacity. As such, patient care will be fragmented, which harms access and quality of care (D)
Option Three Establish new 27-station facility	• Similar advantages to Option One. (A)

Public Comment
None

Rebuttal Comment
None

Department Evaluation
FMC is a well-established provider of healthcare services in Washington and currently operates numerous dialysis facilities. FMC provided a comprehensive discussion of alternatives considered; however, the department notes that option one – establish a 16-station facility, and option three – establish a 27-station facility both have the same advantages and disadvantages. FMC does not provide a rationale for deciding between the two – in fact, it notes in its Table 15 that the 27-station facility would fully address station need, while no such claim is made for the 16-station option.

Without any identified reasons for choosing the 16-station project over a 27-station project that would better meet the forecast need in the planning area, the department cannot conclude that FMC's proposal is the best choice among the options it considered. Without such reasons, the department must conclude that FMC has not chosen the best available option, this sub-criterion is **not met.**

Step Three
Because only Astria's proposal meets Step Two, above, the department need not complete Step Three.

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

Department Evaluation for Northwest Kidney Centers
This sub-criterion was evaluated in conjunction with WAC 246-310-220 above and is not considered met.

Department Evaluation for Fresenius Medical Care
This sub-criterion was evaluated in conjunction with WAC 246-310-220 above and is not 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.

Astria
Astria provided the following information for this sub-criterion [source: Application, p24]
"The project proposes to renovate an existing building (not build new), and so the energy systems are already in place. Operational efficiency will be maximized with workflows, sightlines, and easy access/egress for patients. Most importantly, the design provides for a safe and welcoming care environment for patients and staff.

Public Comment
None

Rebuttal Comment
None

Department Evaluation
Astria's project could have the potential to improve delivery of dialysis services to the residents of Yakima County with the addition of dialysis stations in the planning area. This project met the criteria under WAC 246-310-210, WAC 246-310-220, WAC 246-310-230, and applicable portions of WAC 246-310-800 through WAC 246-310-827. **As a result, this sub-criterion is met.**

Northwest Kidney Centers
NKC provided the following information for this sub-criterion. [source: Application, pdf40]

NKC Yakima will be a treatment facility that will have the latest integrated design features that we have developed in building over the past few years. Some of these features include:

- *Controlled light infusion into the center to be sure that we reduce or eliminate glare on the patient's TV or allow direct sun to enter too far into the center.*
- *Extensive study on patient and staff flow within the center to shorten the number of steps needed to reach the patient station or respond to the needs of our patients.*

We have also integrated the following enhancements to enable long term cost reductions:

- *Use of the Braun AquaBoss heat disinfect water purification system that reduces water consumption by up to 40% and power use by 10% when compared to common chemical disinfect systems.*
- *We are changing how we approach Supply Chain and how we support our centers. NKC Yakima will be fully integrated into a cart exchange system with "kits" that are pre-packaged for use on our patients that will allow our clinical staff to spend more time providing care and less time assembling medical supplies. This moves us closer to a "best practice" of care for our patients.*

Public Comment
None

Rebuttal Comment
None

Department Evaluation
Were it compliant with all other applicable criteria, NKC's project could have the potential to improve delivery of dialysis services to the residents of Yakima County with the addition of dialysis stations in the planning area; however, this project was denied under an earlier criterion in this evaluation: WAC 246-310-230. **As a result, this sub-criterion is not met.**

Fresenius Medical Care
FMC provided the following information for this sub-criterion. [source: Application, p27]

"FKC Yakima River will meet RCG and Fresenius internal standards which have been engineered and tested to ensure that they support our high quality, efficient and patient focused standards. Our standards also meet and or exceed all applicable state and local codes, including compliance with the State Energy Code, latest edition"

Public Comment
None

Rebuttal Comment
None

Department Evaluation
Were it compliant with all other review criteria, FMC's project could have the potential to improve delivery of dialysis services to the residents of Yakima County with the addition of dialysis stations in the planning area; however, this project was denied under earlier criteria in this evaluation, WAC 246-310-220 and WAC 246-310-230. **As a result, this sub-criterion is not met.**

APPENDIX A

2020
Yakima County
ESRD Need Projection Methodology

	Planning Area	**6 Year Utilization Data - Resident Incenter Patients**					
	Yakima	**2014**	**2015**	**2016**	**2017**	**2018**	**2019**
	Yakima County	**247**	**262**	**291**	**313**	**321**	**330**
	TOTALS	**247**	**262**	**291**	**313**	**321**	**330**
246-310-812(4)(a)	**Rate of Change**		**6.07%**	**11.07%**	**7.56%**	**2.56%**	**2.80%**
	6% Growth or Greater?		**TRUE**	**TRUE**	**TRUE**	**FALSE**	**FALSE**
	Regression Method:	**Linear**					
246-310-812(4)(c)			Year 1	Year 2	Year 3	Year 4	**Year 5**
			2020	2021	2022	2023	**2024**
Projected Resident Incenter Patients	from 246-310-812(4)(b)		353.20	369.80	386.40	403.00	**419.60**
Station Need for Patients	**Divide Resident Incenter by 4.8**		73.58	77.04	80.50	83.96	**87.42**
	Rounded to next whole number		**74**	**78**	**81**	**84**	**88**
246-310-812(4)(d)	subtract (4)(c) from approved stations						
Existing CN Approved Stations		Total	61	61	61	61	**61**
Results of (4)(c) above			74	78	81	84	**88**
Net Station Need			-13	-17	-20	-23	**-27**
Negative number indicates need for stations							

Planning Area Facilities

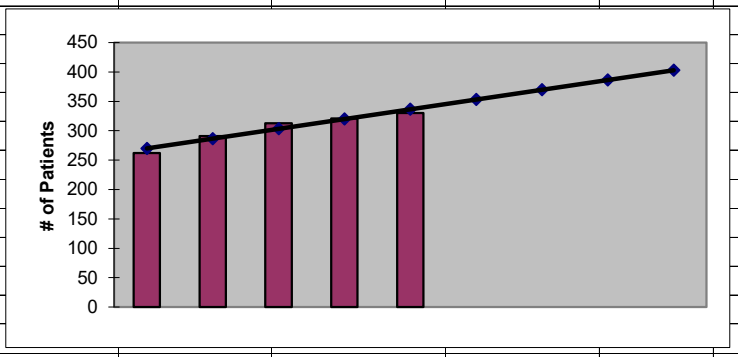
Name of Center	**# of Stations**
DaVita Mt. Adams	**14**
DaVita Union Gap	**12**
DaVita Wapato	**6**
DaVita Yakima	**21**
DaVita Zillah	**8**
Total	**61**

Source: Northwest Renal Network data 2014-2019

Most recent year-end data: 2019 posted 02/18/2020

2020
Yakima County
ESRD Need Projection Methodology

x	y	Linear
2015	262	**270**
2016	291	**287**
2017	313	**303**
2018	321	**320**
2019	330	**337**
2020		**353.20**
2021		**369.80**
2022		**386.40**
2023		**403.00**
2024		**419.60**



SUMMARY OUTPUT

Regression Statistics	
Multiple R	0.962064264
R Square	0.925567647
Adjusted R Square	0.900756863
Standard Error	8.59457193
Observations	5

ANOVA

	df	*SS*	*MS*	*F*	*Significance F*
Regression	1	2755.6	2755.6	37.30505415	0.008819009
Residual	3	221.6	73.86666667		
Total	4	2977.2			

	Coefficients	*Standard Error*	*t Stat*	*P-value*	*Lower 95%*	*Upper 95%*	*ower 95.0%*	*pper 95.0%*
Intercept	-33178.8	5481.889229	-6.05243897	0.009048252	-50624.61812	-15732.9819	-50624.6	-15733
X Variable 1	16.6	2.717842281	6.107786354	0.008819009	7.950612873	25.24938713	7.950613	25.24939