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November 1, 2022

Eric Hernandez, Program Manager
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Certificate of Need Program
Community Health Systems
Washington Department of Health
111 Israel Road SE
Tumwater WA 98501

RE: ESRD Listening Sessions and Proposed Rulemaking

Dear Mr. Hernandez

Fresenius Medical Care North America ("FMCNA") is appreciative of the Department of Health's Certificate of Need Program hosting listening sessions and welcoming feedback regarding certificate of need rules for kidney dialysis treatment centers and end-stage renal disease. Please see attached written comments of FMCNA's proposed topics for rulemaking.

Please feel free to contact me if there are any questions. I can be reached at 503.507.4967 or casey.stowell@freseniusmedicalcare.com.

Sincerely,

Casey Stowell

Casey Stowell, RVP Pacific Northwest

Fresenius Medical Care

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Fresenius Medical Care North America ("FMCNA") is appreciative of the Department of Health's Certificate of Need ("CN") Program hosting listening sessions and welcoming feedback regarding certificate of need rules for kidney dialysis treatment centers and end-stage renal disease. FMCNA believes there is opportunity to further refine kidney dialysis rules and regulations to meet the CN program's stated goal to ensure access to needed, safe, affordable care and conduct CN activities in a transparent and effective manner. Please see the list presented below for FMCNA's proposed topics for rulemaking.

1. Streamline the special circumstance review process
2. Remove three year prohibition of +1/+2 Special Circumstance requests for relocated facilities
3. Allow a facility to be eligible for multiple +1/+2 Special Circumstance requests
4. Revise ESRD data submission requirements
5. Remove 1st treatment date and 3-year operational components in need methodology
6. Update Regular Review cycle timing
7. Timely publish CN materials
8. Revisit maximum treatment floor space requirements
9. Codify "home-only" training programs exemption

While not discussed in the written comments below, FMCNA also wishes to highlight recent efforts engaging with other dialysis providers in proposing emergency or expedited rulemaking to grant kidney dialysis treatment centers surge capacity to more effectively address emergent or otherwise extraordinary circumstances. Please see the letter to Deputy Secretary Peterson submitted on October 19th by FMCNA, Northwest Kidney Centers, Puget Sound Kidney Centers; DaVita, and the ESRD Network 16 for additional discussion of this topic, including draft language for proposed rules.

Streamline the special circumstance review process

Certificate of need applications requesting approval for a +1/+2 station expansion under the special circumstance provisions in the rules currently are required to provide essentially the same level of detail required under nonspecial circumstances. There are only minor differences between the application forms for special versus nonspecial circumstances.

The current level of detail required for special circumstances is excessive. Unlike nonspecial circumstance requests that can range from expansions of existing facilities to developing entirely new clinics, the special circumstance applications are by definition limited in the scale of the request and only applicable to existing facilities. While a request must meet all applicable CN criteria, the Need section should be the most critical component of special circumstance review. The remaining non-Need sections should be streamlined. To the extent that the review process is simplified, then there should be a proportionate decrease in the application fees required.

There should also be modifications to the special circumstance methodology for smaller facilities. The existing methodology makes it nearly impossible to qualify even if these smaller facilities are operating at full capacity under existing CN approved station counts. This is because the methodology requires that the facility six-month historical average must still be at or above the 3.2/4.5 patient per station standard when the station count includes the +1/+2 station requested. This can have a significant negative impact on smaller sized facilities, i.e., given a facility's small number of stations, an incremental one or two stations will typically cause that facility's occupancy to fall below the required minimum.

Remove three year prohibition of +1/+2 Special Circumstance requests for relocated facilities

WAC 246-310-818(4) currently prohibits newly relocated facilities from requesting +1/+2 special circumstance expansion even if it otherwise meets all of the other appropriate criteria established in the special circumstance need methodology. FMCNA recommends removing the three year prohibition. The existing prohibition unnecessarily limits planning area providers from effectively expanding capacity which leads to suboptimal access to care. If a facility has demonstrated sufficiently high occupancy to meet the numeric requirements established in WAC 246-310-818, then it has demonstrated that it is in sufficiently high demand from patients. A relocated facility that has demonstrated high occupancy ought to be able to expand to keep pace with growing demand.

Allow a facility to be eligible for multiple +1/+2 Special Circumstance requests

WAC 246-310-818(3) currently prohibits a facility approved for two special circumstance stations from further special circumstance expansions until the Department awards additional nonspecial circumstances kidney dialysis stations in the planning area. FMCNA recommends removing this barrier or modifying the rules so a facility could be eligible for multiple special circumstance approvals even if the Department has not approved additional nonspecial stations in the planning area. Similar to the reasons cited above regarding the three-year prohibition for relocated facilities, a facility that has already received a special circumstance approval that continues to report sufficiently high occupancy to meet the numeric requirements established in WAC 246-310-818, then it has demonstrated that it is in sufficiently high demand from patients. This facility should be eligible for additional expansion to keep pace with growing demand for its services.

Revise ESRD data submission requirements

The language and requirements used for the data submission requirements (WAC 246-310-803) and superiority tiebreaker analysis (WAC 246-310-827) should be reconsidered.

There is inconsistent language in the existing WAC with respect to when out-of-state clinics' data is required.

> WAC 246-310-803(1): By February 15th or the first working day thereafter of each year, each provider will electronically submit the following data elements for each of its kidney dialysis facilities in the state of Washington and **each out-of-state kidney dialysis facility that might be**

used in an application review during the next year (an out-of-state kidney dialysis facility may be used as one of the three closest facilities for a future project during the next year pursuant to WAC 246-310-827) (emphasis added)

WAC 246-310-827(3): **When available, Washington facilities must be used as comparables, as follows** (emphasis added)

Currently, the only coherent interpretation if accepting both rules as written is that out-of-state clinics could be used if a dialysis provider operates one or two Washington dialysis clinics but has out-of-state clinic(s) that could potentially be included as one of the two or three closest clinics to be used for a superiority analysis in WAC 246-310-827). This scenario does not apply to any of the existing dialysis providers in Washington State. These rules should be corrected for consistency. It is our recommendation that out-of-state clinics be entirely excluded and only use the applicant's closest Washington State clinics or default scores.

We also recommend incorporating an additional stage between the Department's draft and final superiority model to allow a provider to supplement their data and exemptions if the Department finds that it is missing or otherwise unaccounted for in the draft model. This will prevent unreasonable disqualifications from concurrent review while preserving timely and thorough data submissions necessary for the Department to conduct its tiebreaker analysis.

The Department should also consider removing the Dialysis Facility Report (DFR) and Medicare Cost Report (MCR) data components from the tiebreaker analysis. This would eliminate the need for the lengthy and time-consuming data submission process that is required under WAC 246-310-803.

Remove 1st treatment date and 3-year operational components in need methodology

A facility's 1st treatment date for its proposed project is a critical component in evaluating whether there is addressable net need in a planning area due to the provisions in WAC 246-310-812(5)(b) and (6)(b). The Department also assesses whether a facility has operated all of its stations for three years or longer under WAC 246-310-812(5)(a) and WAC 246-310-812(6)(a).

While these were well-intended rules, it has had the practical impact of significantly increasing uncertainty in planning. Relatively inaccessible documentation of appeals and historical application materials has resulted in misinterpreted operational timelines and 1st treatment dates, resulting in inefficient and costly review and appeals processes.

The Department should strongly consider removing the 1st treatment date and 3-year operational components of the need methodology. The need methodology already factors in an approved project's station counts [and corresponding future patient demand] in the need methodology, so if there is remaining net need after an approval, then an applicant should be able to apply to address that unmet need regardless of the status of the other projects.

Update Regular Review cycle timing

The Department should reevaluate the review timelines for regular review.

> WAC 246-310-806(7): The department will not accept new nonspecial circumstance applications for a planning area if there are any nonspecial circumstance applications for which the certificate of need program has not made a decision in that planning area filed under a previous concurrent review cycle. This restriction does not apply if the department has not made a decision on the pending applications within the review timelines of nine months for a concurrent review and **six months for a regular review**. This restriction also does not apply to special circumstance applications. (Emphasis added)

Six months has historically been insufficient for regular review, especially since under regular review the applicant can request a second screening. This can result in the need for an applicant to submit a potentially useless application, given the unknowns associated with a pending application as a preventative measure. We recommend that the regular review timeline be adjusted to 9-months.

Timely publish CN materials

There should be timely reporting of key CN publication materials related to ESRD activities. As discussed above, a facility's 1st treatment date for its proposed project is a critical component in evaluating whether there is addressable net need in a planning area due to the provisions in WAC 246-310-812(5)(b) and (6)(b). We appreciate the Department having its station operational reports updated in advance and during the 2022 Cycle One letter of intent and application phases. These were very helpful and timely updates, but this has not historically occurred in prior cycles.

The status and outcomes of appeals are another pertinent part of review and evaluation of net need. This has historically been very difficult to monitor. The Department's recent station operational reports have helped alleviate some of the uncertainty, as there is a column identifying if an appeal is underway, but it would be more helpful to have a similar worksheet that consolidated all current appeals in process and outcomes of recently settled/determined appeals. This should also be published and available to providers.

Finally, we have noticed a lag between when the letters and applications are submitted and eventually posted to the Department's Project Status webpage. This lag can be challenging for planning purposes when special circumstance LOIs / applications have the potential to impact net need in the planning for a nonspecial circumstance project.

Revisit maximum treatment floor space requirements

The Department's current practice of evaluating a project's conformance to maximum treatment floor space requirements, as described in WAC 246-310-800(11) and WAC 246-310-815(2), has been fair and reasonable.

While we are supportive of the Department's current practice of reviewing projects' treatment floor conformance, it may be valuable to reconsider the long-term validity of these maximum treatment floor

space requirements. To the extent that these treatment floor requirements limit the opportunity for sufficient expansion in the future, then this impacts the cost-effectiveness of expanding access to address future unmet need. For example, in high growth planning areas, a current facility may be approved for 10 stations and its existing footprint could reasonably fit as much as 15 stations within the maximum allowable space. Yet, if future need would require this clinic to expand to 20 stations to address planning area demand, then this would require either substantial construction or relocate to an entirely new location. In other words, the medium-term cost savings from limiting projects' treatment floor space may be offset by the long-term cost increases resulting from unintended consequences of these requirements.

Codify "home-only" training programs exemption

The Department should clarify the rules concerning "home-only" training programs that do not provide in-center treatment and instead are dedicated to home hemodialysis or peritoneal dialysis (together, "home dialysis").1 Home dialysis training programs provide training for home hemodialysis and peritoneal dialysis patients and related support services identified in the Conditions for Coverage under 42 C.F.R. 494.100, such as periodic home visits, care coordination, in-home monitoring, home dialysis supplies, technical support, back-up therapy coordination, and additional resources that patients need to successfully dialyze at home. Home-only programs do not operate in-center stations and are not certified by CMS as in-center outpatient dialysis facilities.

Patients report and studies show numerous clinical and lifestyle benefits associated with home dialysis when compared to conventional, three times per week, in-center hemodialysis. For example, home hemodialysis patients may receive "more frequent dialysis" (*i.e.*, dialysis more than three times per week). More frequent home hemodialysis is associated with improved 5-year survival rates (58% vs. 40%), a significantly increased likelihood to be on the Kidney Transplant List (35% vs 14.2%), more energy and vitality, and 36% less blood pressure medicine. [2] Benefits associated with peritoneal dialysis include better preservation of residual renal function, greater flexibility in their schedules, and greater quality of life overall.[3] Peritoneal dialysis has also been associated with lower costs and overall hospitalizations and home hemodialysis has demonstrated a reduction in cardiovascular hospitalizations.[4]

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1 Home hemodialysis and peritoneal dialysis are performed by a patient or a patient's care partner with the patient's dedicated, personal equipment in the patient's own home. Patients interested in home dialysis receive comprehensive, hands on training by a Medicare-certified home training provider before dialyzing independently at home.

2 See "Home Hemodialysis (HHD) & Peritoneal Dialysis (PD)" NxStage Medical, Inc., available at https://www.nxstage.com/patients/benefits-of-home-hemodialysis/.

3 Ibid.

4 Berger A, Edelsberg J, Inglese G, Bhattacharyya S, Oster G, Cost Comparison of Peritoneal Dialysis Versus Hemodialysis in End-Stage Renal Disease. Am J Manag Care. 2009;15(8):509-518, available at https://www.ajmc.com/view/ajmc_09augberger_509to518; Weinhandl ED, Nieman KM, Gilbertson DT,

Over the past two years, the Department has determined that dialysis facilities proposing to develop home-only training programs are not subject to CN review. These determinations include:

1. DOR21-02: DaVita Inc. ("DVA") peritoneal dialysis training program in Pierce County.
2. DOR21-32 and DOR22-11: DVA peritoneal dialysis and home hemodialysis training program in Yakima County.
3. DOR22-06: DVA peritoneal dialysis training program in Edmonds, within Snohomish County.
4. DOR21-30: DVA peritoneal dialysis training program in Benton County.
5. DOR21-31: DVA peritoneal dialysis training program in Smokey Point, within Snohomish County.
6. DOR21-33 and DOR21-35: FMCNA peritoneal dialysis and home hemodialysis training program in Whatcom County.
7. DOR21-34 and DOR21-36: FMCNA peritoneal dialysis and home hemodialysis training program in Yakima County.

This home-only program exemption should be codified in the CN rules. The rules should also allow flexibility for home-only programs to be consistent with evolving clinical and site of care practices. For example, there should also be clarifications that this exemption would also apply to home dialysis services provided at nursing homes / skilled nursing facilities.

Collins AJ. Hospitalization in daily home hemodialysis and matched thrice-weekly in-center hemodialysis patients. Am J Kidney Dis. 2015 Jan;65(1):98-108. doi: 10.1053/j.ajkd.2014.06.015. Epub 2014 Jul 29. PMID: 25085647, available at https://cdn.sanity.io/files/0vv8moc6/ajmc/85048b95cd4ce09d39a8f28d61eb1993493b3a3b.pdf.