

PETITION FOR AN ADJUSTMENT TO A NEED DETERMINATION

Petition to Create an Adjusted Need Determination for Four Outpatient Dialysis Stations in Orange County in the *2020 State Medical Facilities Plan*

PETITIONER

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STATEMENT OF THE PROPOSED CHANGE

UNC Hospitals (UNCH) respectfully petitions the State Health Coordinating Council (SHCC) to include an adjusted determination for four outpatient dialysis stations in Orange County in the *2020 State Medical Facilities Plan (SMFP)*. If the proposed need determination is made, Table 9D in the *2020 SMFP* would include a need determination for four dialysis stations in Orange County, subject to the restrictions outlined below:

In response to a petition from UNC Hospitals, the State Health Coordinating Council approved an adjusted need determination for four (4) outpatient dialysis stations in Orange County. Applicants must propose to locate the dialysis stations on the campus of an acute care hospital and must demonstrate that the stations will be limited to serving patients in any of the following specific categories:

- *pediatric patients;*
- *undocumented patients;*
- *patients with no payor source;*
- *patients with behavioral health issues;*
- *patients who need to initiate dialysis treatment and receive their first few treatments in a controlled, outpatient setting in a hospital before transferring care to a community outpatient setting;*
- *patients who receive care at other existing outpatient dialysis centers but who are being discharged from inpatient care and cannot make their next scheduled outpatient dialysis appointment; and,*
- *patients who have been refused service by other outpatient dialysis providers in the county or a contiguous county for these or other reasons.*

Applicants shall be required to demonstrate that they have or will establish a relationship with an existing outpatient dialysis provider in the county or a contiguous county in order to ensure patients can be transferred once they no longer meet the criteria described above.

BACKGROUND

As the principal teaching hospital for the University of North Carolina at Chapel Hill's School of Medicine, UNCH provides a comprehensive array of healthcare services to the citizens of North Carolina. UNCH first opened in 1952 as the North Carolina Memorial Hospital and has served not only as a patient care-oriented facility, but also as a teaching, research, and community service resource for North Carolina. UNCH is recognized as one of the highest-quality healthcare institutions in the nation, winning multiple awards for its patient safety and quality of care, nursing care, research, and teaching. As North Carolina's only state-owned referral, tertiary and quaternary care center, UNCH accepts any North Carolina resident requiring treatment.

One of those services that UNCH provides, regardless of its ability to receive reimbursement, is outpatient dialysis in a hospital setting. As the only provider of hospital-based services in the county, UNCH has an excellent working relationship with Fresenius, the operator of the only outpatient end stage renal disease (ESRD) facility in Orange County. Not only does UNCH refer patients regularly to Carolina Dialysis-Carrboro, it works with the facility to manage patients awaiting kidney transplants and in need of surgery and other care associated with their disease. The medical director at Carolina Dialysis-Carrboro, Dr. Kshirsager, is faculty in the Department of Nephrology at UNC School of Medicine, and also serves as medical director for UNC Dialysis Care. UNC School of Medicine also provides medical direction for Fresenius' ESRD facilities in Pittsboro and Siler City (Chatham County) and Mebane (Alamance County). UNCH has actively worked with Fresenius throughout the development of this petition, and Fresenius supports the proposed special need determination.

UNCH recognizes that the SHCC and the ESRD working group has spent many hours revising the county and facility need methodology for ESRD. The need identified in this petition is unique and would not be addressed by either the current or proposed updated methodology. As such, UNCH believes a special need adjustment is the appropriate method for addressing this need.

REASON FOR THE REQUESTED ADJUSTMENT

Over the past several years, UNCH has provided a growing number of dialysis treatments to outpatients who have no other options for care. While it is part of UNCH's mission to serve all North Carolinians in need of care, regardless of their ability to pay, it is also important for UNCH to seek reimbursement for those services, particularly from third parties, whenever possible, in order to sustain its operations and not place an undue burden on residents of the state. Many of the patients UNCH treats have no payor source at the time of treatment but will eventually qualify for Medicaid or Medicare. In order to potentially qualify for reimbursement for some of these patients, UNCH needs to develop Medicare-certified outpatient dialysis stations, for which it requires a need determination in the *SMFP* in order to apply for a Certificate of Need.

As the SHCC is aware, even under both the current and proposed revised methodology for ESRD facilities, new outpatient dialysis stations can only be developed at existing facilities or through a county need determination, the latter of which only occurs once there is a need for 10 or more stations in the county. A county need determination is fairly uncommon; moreover, UNCH does not need 10 stations at this time, nor does it want to develop a typical outpatient dialysis facility

to serve patients on a long-term basis. As such, the most prudent approach to developing four outpatient ESRD stations is through the special need petition process.

For most providers, including UNCH, quantifying the number of patients meeting the proposed criteria who are in need of dialysis is challenging, particularly since there has historically been no billing record for these patients. In addition, some of the listed conditions are not readily identifiable as the basis for the patient’s dialysis treatment at UNCH, such as undocumented patients, patients with behavioral health issues, or patients who have been refused treatment elsewhere due to these or other conditions. However, UNCH has collected data for the last two full fiscal years for at least a portion of the outpatients who received dialysis in UNCH’s inpatient unit. Please note that for a small percentage of these patients who are outpatients but qualify for dialysis on an emergent basis, UNCH is able to receive reimbursement, if they have a payor source (which many do not). However, UNCH needs certified outpatient stations in order to ensure access and appropriate reimbursement for all its outpatient dialysis patients. The following discussion provides available data relating to the patients receiving outpatient dialysis at UNCH, although additional patients are likely not captured by the data system.

Pediatric Patients

Pediatric patients represent some of the greatest need at UNCH for outpatient dialysis treatment. If these patients were adults, they might otherwise qualify for care in an ESRD facility; however, their age adds complexity to their treatment needs and most outpatient ESRD facilities do not have the staff resources or competencies to accept pediatric patients, particularly those with medically complex conditions or who are too small or underweight for care in a community outpatient setting. UNCH always attempts to place these patients in a community dialysis facility; however, many do not qualify because of age, size or clinical condition and depend on care received at UNCH. These patients also receive more treatments at UNCH than adults; while adult patients may eventually obtain a payor, or eventually qualify for outpatient treatment at an ESRD facility, pediatric patients usually remain in the care of UNCH as long as they remain in need of dialysis (typically until they receive a kidney transplant) or until they meet the minimum age and/or weight requirements for community dialysis care. As shown in the table below, while there are not many of these patients, they do generate numerous treatments at UNCH.

Table 1: 2018 and 2019 Outpatient Pediatric Dialysis Patients and Treatments at UNCH

<i>Year</i>	<i>Pediatric Patients</i>	<i>Pediatric Treatments</i>	<i>Treatments Per Patient</i>	<i>Average Weeks of Treatment at UNCH</i>
FY 2018	10	289	29	10
FY 2019	9	294	33	11

While some patients may receive fewer treatments than others, on average, pediatric patients are dialyzed up to 11 weeks at UNCH. As part of its mission to provide “the highest quality, family-centered care to kids from all 100 counties throughout North Carolina and beyond—always regardless of a family’s ability to pay,” UNC Children’s Hospital and the inpatient dialysis unit at UNC Medical Center will continue to provide care to these patients; however, the development of outpatient dialysis stations would help it do so in a more cost effective manner.

Here are a few examples of actual pediatric patients at UNCH who would benefit from the approval of the petition:

- Patient “A” is five years old and currently receiving dialysis at UNCH due to being small for her gestational age and not meeting the minimum weight requirements for a community dialysis station.
- Patient “B” required dialysis at UNCH due to her age (also five years old) and size; she does not meet the minimum weight requirements for community dialysis, and she is not a candidate for home hemodialysis or peritoneal dialysis.
- Patient “C” is a 16-year-old male whose family had no transportation. The case managers at UNCH attempted to place him in a community facility, but he could not be accepted because he is a pediatric patient and because he only needed chronic hemodialysis for six sessions before moving out of state, making it difficult to allocate space and resources on a temporary basis. Further, without transportation, he could not travel a significant distance so attempting to find an opening at a facility farther away would have been futile. He came to UNCH for all six outpatient sessions before moving.

Without the care provided at no cost at UNCH, none of these patients would have survived. Approval of the petition will enable UNCH to continue providing this care, but with the opportunity to recover some of the costs of care with certified outpatient stations.

Adult Patients

As with pediatric patients, adult patients may also be medically complex; however, most outpatient dialysis facilities are equipped to care for adults. The issues that result in UNCH’s need to provide outpatient dialysis treatments to adult patients include the following:

- Insurance issues: patients who are in the process of obtaining a payor (Medicare or Medicaid), but need dialysis while they await being qualified often have few options in outpatient facilities during that time. For these patients, receiving outpatient care at UNCH is necessary until they have a payor and can be transferred to an outpatient facility near their home.
- Documentation issues: some patients are undocumented and therefore unable to obtain Medicare or Medicaid. While they may never obtain a payor source, having certified outpatient stations will allow this population to be treated on appropriate, certified outpatient equipment rather than using existing inpatient stations.
- Behavioral health issues: these patients often have been treated in a community outpatient facility but have been dismissed from the facility after repeated and ongoing drug use and/or behavioral issues with other patients and staff. Community ESRD facilities are not equipped or staffed to manage patients with these conditions, so the only option

available to them is the inpatient unit at UNCH. These patients often present to the Emergency Department at UNC Medical Center because they have no other option; caring for them an outpatient station on the UNC Hospitals campus would be a more appropriate use of scarce resources.

- Patients being discharged who will miss their scheduled treatment: some ESRD patients who are admitted as inpatients for a procedure, often a vascular access procedure to create an arteriovenous fistula or other access point for dialysis, are discharged at such a time that they will miss their scheduled dialysis appointment at the local facility where they receive treatment. Rather than keeping the patient admitted just to be dialyzed, it is more prudent to discharge the patient, dialyze him or her as an outpatient, then have the patient return to the facility where he or she are normally treated for their next appointment. While this is one condition under which UNCH can typically charge the patient’s payor for the service, it would be more effective to treat the patient using stations with resources to fully and appropriately care for outpatients.

As shown in the table below, these patients account for a significant number of outpatient treatments at UNCH.

Table 2: 2018 and 2019 Outpatient Adult Dialysis Patients and Treatments at UNCH

<i>Year</i>	<i>Adult Patients</i>	<i>Adult Treatments</i>	<i>Treatments Per Patient</i>	<i>Average Weeks of Treatment at UNCH</i>
FY 2018	23	370	16	5
FY 2019	29	335	12	4

In addition to these patients, UNCH also worked with Fresenius and its existing local outpatient dialysis centers which have medical coverage from the Department of Nephrology at UNC to identify patients initiating dialysis treatment who would benefit from starting dialysis in an outpatient setting in a hospital. Given potential issues for these often medically complex patients as they initiate dialysis, it is prudent to provide the first week of treatments (three) at UNCH before transferring them to an outpatient facility in the community. Since these patients are otherwise ready to be discharged from the inpatient unit, having the ability to dialyze them in the hospital, but as outpatients, is optimal from a patient care and from a cost perspective. Once they complete their first three treatments at UNCH, they will be transferred to another local provider to begin long-term treatment. According to the data gathered by Fresenius, over the past three years, there were a total of 263 patients discharged from UNCH that began treatment at a local Fresenius facility. Of these, UNCH and Fresenius estimate that 15 percent, or between 10 and 15 patients each year, would benefit from starting their treatments in an outpatient setting in a hospital. With three treatments per patient, this patient population would add another 30 to 45 treatments per year to those provided at UNCH if outpatient stations were available.

Here are a few examples of actual adult patients at UNCH who would benefit from the approval of the petition:

- Patient “D” is a peritoneal dialysis patient who came to the United States to visit family in July 2018. He had been receiving peritoneal dialysis in Mexico for three years, but he had problems with peritoneal dialysis in the US and was converted to hemodialysis during his visit. He remained on hemodialysis at UNCH for months while awaiting an emergency Medicaid determination, which would allow him to be transferred to an outpatient ESRD facility for care.
- Patient “E” had several admissions to the UNC inpatient psychiatric unit due to suicidal ideation and cocaine use; due to behavioral issues at an outpatient ESRD clinic in a nearby county, he was directed to UNCH for dialysis treatments. Once his behavior had improved, the referring ESRD facility had no available capacity to take the patient back. Further, the patient decided to participate in a drug rehabilitation program and only one such program was found that would accept Medicare-qualified dialysis patients. The patient applied for Medicare, and after several months had qualified for Medicare; however, the rehabilitation center would not agree to admit him until he had returned to an outpatient dialysis facility. The patient had ongoing transportation issues, which became the barrier to allowing him to return to an outpatient facility, and ultimately, to a drug rehabilitation facility.
- Patient “F” receives outpatient dialysis treatment at UNCH. He was involuntarily discharged from an ESRD facility in a nearby county in November 2018 after making threats of violence against the staff there and has been unable to be placed in another facility since then.

Combining the total number of pediatric and adult patients treated at UNCH in FY 2019, along with the patients receiving care at a local Fresenius facility who would benefit from initiating their treatment in an outpatient setting in a hospital results in the following potential dialysis treatments at UNCH:

Table 3: Potential Dialysis Patients and Treatments at UNCH

<i>Year</i>	<i>Patients</i>	<i>Treatments</i>	<i>Treatments Per Week</i>
FY 2019	53	674	13.0

While the potential number of patients alone would not typically justify four dialysis stations quantitatively under the standard methodology, the patients being treated are not being accepted for treatment based on available scheduling at an outpatient facility. In other words, while the average number of potential treatments per week was 13 in 2019, UNCH may provide many more treatments in a given week, and fewer in another, since these are not provided on a regularly scheduled basis. Anecdotally, UNCH’s dialysis unit staff indicate that there are typically one to two adult patients and one to two pediatric patients receiving outpatient dialysis in the inpatient unit at any given time. In addition, a total of four stations would provide sufficient flexibility for peak demand, while also allowing UNCH the possibility of locating two stations on each hospital campus in Orange County, providing maximum access for area residents. On this

basis, UNCH believes its request for four stations is reasonable, without risking approval of more stations than are needed for the foreseeable future.

ADVERSE EFFECTS IF PETITION IS NOT APPROVED

If the petition is not approved, UNCH will continue providing dialysis service to patients in need, regardless of its ability to be reimbursed for the care. However, the ability to provide the needed service is limited to the stations available in the inpatient dialysis unit. If outpatient volumes continue to increase, then UNCH will need to expand its inpatient unit to accommodate these outpatients, which is not the best use of resources for an unreimbursed service that could otherwise be reimbursed for many patients if UNCH could develop outpatient dialysis stations. Some patients, particularly those who would benefit from receiving their first few treatments in an outpatient setting in a hospital, would likely not have access to care and would need to be transferred to an ESRD facility for their first treatments if the petition is not approved.

ALTERNATIVES CONSIDERED

UNCH has discussed several possible alternatives with the Healthcare Planning and Certificate of Need Section, including applying for the stations under Policy AC-3. However, this approach is problematic. UNCH appreciates the availability of Policy AC-3 for services that merit consideration under this policy; however, the need for outpatient dialysis stations at UNCH is not based on one of the provisions of Policy AC-3 that allow approval for academic medical centers outside of the standard methodology. Ultimately, UNCH determined that the approach proposed by this petition is most effective way to provide outpatient dialysis treatment for these patients in a hospital setting.

UNNECESSARY DUPLICATION

Approval of the petition would not result in unnecessary duplication. There are currently no outpatient dialysis stations in a hospital in Orange County; UNCH must use its inpatient stations to treat outpatients. For most of these patients, UNCH will receive no reimbursement. Most importantly, many of these patients simply have no other provider to which to turn; they rely on UNCH as a safety net to provide the life-sustaining service. UNCH is not aware of any other facilities in the area that provide this care; as such, there are no similar services or providers that would be duplicated. Finally, the limitations proposed on the patients that can be treated using these stations will ensure that approval of the petition will not unnecessarily duplicate existing resources in the community.

BASIC PRINCIPLES

Safety and Quality

As noted above, UNCH is recognized as one of the highest-quality healthcare institutions in the nation, winning multiple awards for its patient safety and quality of care. Approval of the petition will allow it to continue providing high quality dialysis service to outpatients as it currently does but using certified stations that will allow it to be reimbursed for the service. This will also allow UNCH to meet all the quality requirements of an outpatient facility, which will enhance and ensure the level of quality provided to these dialysis patients.

Access

Approval of the petition will both maintain and expand access to patients in need of outpatient dialysis services in a hospital setting. Having outpatient stations at UNCH will ensure that outpatients needing dialysis have stations that are certified for such use, and that resources are available to fully and appropriately care for an outpatient population. The development of these outpatient stations will also allow UNCH to provide the service to any patients meeting the specific criteria proposed for the need determination, most of who would otherwise have no other option for accessing dialysis services.

Value

UNCH believes that approval of the petition will maximize the value of the outpatient dialysis services it provides. In particular, the development of certified outpatient dialysis stations will allow UNCH to receive reimbursement from third-party payors, particularly Medicare, which has determined that such services should be reimbursed for many of these patients. As North Carolina's only state-owned, comprehensive, full service hospital system, UNCH is committed to caring for these patients without regard to their ability to pay; however, it also has a responsibility to the citizens of the state to receive appropriate reimbursement for services provided whenever possible. As such, approval of the petition and development of outpatient stations at UNCH will return value to North Carolinians.

CONCLUSION

UNCH understands that the SHCC is in the process of revising the ESRD methodology for the *2020 SMFP*. Neither the current methodology nor the proposed methodology will address the issues identified in this petition. In order to continue providing outpatient dialysis services to these unique and underserved patients who have no other option for care, but to enable it to receive appropriate reimbursement for the service, UNCH seeks the approval of this petition to allow it to propose to develop four outpatient dialysis stations on its hospital campus.