Acute Care Services Committee Agency Report Adjusted Need Petition for Outpatient Dialysis Stations in Orange County Proposed 2020 State Medical Facilities Plan

Petitioner: UNC Hospitals 101 Manning Drive Chapel Hill, NC 27514

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Request:

UNC Hospitals (UNCH) requests an adjusted need determination for four outpatient dialysis stations in an acute care setting for Orange County in the *North Carolina 2020 State Medical Facilities Plan (SMFP)*.

Background Information:

Chapter Two of the *Proposed 2020 State Medical Facilities Plan (SMFP)* allows for "[a]nyone who finds that the North Carolina State Medical Facilities Plan policies or methodologies, or the results of their application, are inappropriate may petition for changes or revisions. Such petitions are of two general types: those requesting changes in basic policies and methodologies, and those requesting adjustments to the need projections." The *SMFP* annual planning process and timeline allow for submission of petitions for changes to policies and methodologies in the spring and petitions requesting adjustments to need projections in the summer. It should be noted that any person might submit a certificate of need (CON) application for a county need determination in the Plan. The CON review could be competitive and there is no guarantee that the petitioner would be the approved applicant.

The original county need methodology was established in 1993. Beginning with the Proposed 2020 SMFP, the methodology is fully incorporated in to the annual healthcare planning process. This component is based on all residents of North Carolina, regardless of where they are currently receiving services. Future patient counts are projected 12 months into the future based on a five-year trend line. Need is based on 80% utilization of existing certified stations, at 3.2 patients per station. The methodology assesses individual county need for each of North Carolina's 100 counties. The methodology states that "if a county's…projected station deficit is 10 or greater and

the SMFP shows that utilization of each dialysis facility in the county is 80% or greater, the ...county station need determination is the same as the projected...station deficit rounded to the nearest whole number." However, if "...the projected station deficit is less than 10 or if the utilization of any dialysis facility in the county is less than 80%, the county has no need for additional stations."

The threshold of 10 stations is taken from the "Basic Principles," which states, "[n]ew facilities must have a projected need for at least 10 stations to be cost effective and to assure quality of care." This basic principle was created to assure that new facilities would have enough patients to assure quality services and to be financially viable.

Application of the dialysis county need determination methodology in the *Proposed 2020 SMFP* generated no county need determinations for a new dialysis facility anywhere in the state.

UNCH submitted a petition to adjust the outpatient dialysis station need determination in Orange County for the following reasons: 1) county need determinations are rare; 2) less than 10 stations are needed; and 3) an opportunity to request reimbursement for services for all patients who qualify for Medicare and Medicaid is needed.

Analysis/Implications:

County Need Determinations

The Petitioner asserts that county need determinations are "fairly uncommon." The Agency agrees on the basis of data published in the *Semiannual Dialysis Reports (SDR)* from July 2009 through July 2019, only eight county need determinations were generated as seen in Table 1. below.

| SDR | County | Number of New Dialysis Stations Needed |
|--------------|-------------|--|
| January 2016 | Catawba | 10 |
| July 2013 | Nash | 19 |
| | Scotland | 11 |
| July 2011 | Harnett | 11 |
| | Northampton | 10 |
| July 2011 | Cabarrus | 23 |
| | Randolph | 10 |
| July 2009 | Alexander | 10 |

 Table 1. Ten-Year Overview of County Need Determinations

Source: SDRs July 2009-July 2019

During this same time period (2009-2019), North Carolina experienced significant growth in both dialysis stations and facilities as shown in Table 2. below.

| SDR | July 2009 | July 2019 | Percent of Growth |
|---|--------------|--------------|----------------------|
| Total Number of Certified Dialysis Stations | 3,895 | 5,321 | 37% |
| Total Number of Dialysis Facilities Certified | | | |
| and Operating | 161 | 226 | 40% |

Table 2. Ten-Year Overview of Dialysis Station and Facility Growth in N.C.

Source: SDRs July 2009-July 2019

The Agency notes 104 dialysis stations were generated by the county need methodology and 12 stations were granted as adjusted need determinations by the State Health Coordinating Council (SHCC). This accounts for a total of 116 dialysis stations, while the actual increase reported in the SDRs was 1,419. As a percentage of this total, the number of dialysis stations generated by the county need methodology and "adjustments" was only 11 percent. This means the other 89% (1,303 dialysis stations) were developed pursuant to the facility need methodology at the initiative of the providers. Based on this data, and the fact Orange County currently shows a projected deficit of 1 dialysis station in Table 9C: ESRD Dialysis Station Need Determinations by Planning Area from the *Proposed 2020 Plan*, it is unlikely a county need determination for Orange County will occur anytime in the near future.

10-Station Threshold

Although the Basic Principles in Chapter 9 specify a 10-station minimum, the SHCC has previously made exceptions to the minimum facility size in response to petitions (4 stations in Dare County; 5 stations in Macon County; and 5 stations in Graham County).

The Petition indicated that UNC does [not] want to develop an outpatient dialysis facility designed to serve patients on a long-term basis. Rather, they wish to continue to serve patients' emergent medical needs and later refer them to a dialysis facility in their community.

Over the past two years. the Petitioner has experienced an increase in the number of patients needing outpatient dialysis treatments. The reason for each patient's dialysis treatment is not always available, making it difficult for the Petitioner to collect data on the number of dialysis stations needed to meet the growing outpatient demand. Dialysis unit staff at UNC indicate that they typically serve one to two adult patients and one to two pediatric patients at any given time. The Petitioner believes four outpatient dialysis stations would meet current needs and provide enough flexibility for high demand periods.

Opportunity to Request Reimbursement

The Petitioner is unable to receive reimbursement for outpatient dialysis treatments provided using its inpatient dialysis program. Thus, the Petitioner must develop Medicare-certified outpatient dialysis stations for patients to potentially qualify to receive Medicare or Medicaid coverage. A county need determination for four outpatient dialysis stations in Orange County is required for the Petitioner to have an opportunity to submit a certificate of need application for the stations.

Agency Recommendation:

The Agency supports the standard methodology for determining need for new dialysis stations as presented in the *Proposed 2020 SMFP*. Given the available information submitted by the August 8, 2019 deadline and in consideration of the factors discussed above, the Agency recommends approval of the request for an adjusted need determination for four outpatient dialysis stations located on the campus of an acute care hospital in Orange County. Certificate of Need shall impose a condition requiring the approved applicant to document that it has applied for Medicare certification no later than three (3) years from the effective date on the certificate of need.