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March 22, 2017

Christopher G. Ullrich, M.D., Chair
NC State Health Coordinating Council
c/o Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation, NC DHHS
2704 Mail Service Center
Raleigh, NC 27699-2704

Re: Comments Regarding a Petition for Vascular Access Ambulatory Surgical Centers for ESRD Patients

Dear Dr. Ullrich:

Cone Health appreciates the opportunity to comment on the petition filed by American Access Care of NC, PLLC, Eastern Nephrology Associates, PLLC, Metrolina Nephrology Associates, PA, and North Carolina Nephrology, PA (the practices) and Fresenius Vascular Care, Inc. d/b/a Azura Vascular Care (Azura) (collectively the Petitioners) to change the need methodology for the 2019 State Medical Facilities Plan or add an Adjusted Need Determination for a Demonstration Project – Vascular Access Ambulatory Surgery Centers for ESRD Patients. Cone Health supports the standard OR need methodology as presented in the 2018 State Medical Facilities Plan (SMFP), and urges the SHCC to deny the petition.

Sincerely,

James Roskelly

James Roskelly
Executive Vice President, Strategic Development
Cone Health

Attachment

Comments on the Petition for a Change in the Need Methodology for the 2019 State Medical Facilities Plan or, in the Alternative, an Adjusted Need Determination for a Demonstration Project – Vascular Access Ambulatory Surgery Centers for ESRD Patients

Cone Health urges the NC State Health Coordinating Council (SHCC) to deny the referenced petition. The Petition provides no evidence to support the need to change the operating room need methodology in the 2019 State Medical Facilities Plan (SMFP). The petition also provides no evidence to support the need for single specialty ambulatory surgery centers (ASC) dedicated to vascular access in North Carolina.

SMFP Operating Room Need Methodology

Cone Health supports the standard operating room need methodology that was updated in 2017 and is found in Chapter 6 of the 2018 State Medical Facilities Plan (SMFP). Furthermore, since the 2018 SMFP is the first edition to utilize this updated need methodology, Cone Health does not believe any changes should be made until data are available to quantify the impact of this revised methodology. Specific to the Petition, Cone Health does not believe that the Petitioners have demonstrated the need for changes to the approved need methodology or an adjusted need determination and have based the petition on unsubstantiated claims throughout.

No Evidence to Support Need

The Petition fails to provide any clinical evidence to support the claim that vascular access procedures currently performed in office-based vascular access centers (VAC) now require a licensed operating room (OR). In fact, the Petitioners state on p. 1 that "As discussed in detail herein, physicians have long operated unlicensed vascular access centers in the physician office setting…Due to recent Medicare reimbursement changes, however, it is no longer financially feasible for many VACs to continue operation." It has not historically been the practice of the SHCC to change planning assumptions and methodologies simply to respond solely to Medicare reimbursement changes.

The Petitioners make misleading claims about delays in care in the hospital setting. On page 11, the Petition states, "[u]rgent ESRD cases are typically scheduled at the end of the day in hospital IR departments as inpatients." This statement contains false analogies and statements. First, the Petitioners indicate their policy is to see patients needing vascular access procedures on the same day or the next day. There cannot be a delay attributed to the hospital for waiting until the end of the day compared to Petitioner's ability to see the patient the following day. In some cases, the hospital could perform the procedure before the Petitioner based on their policy and based on the 24/7 nature of an acute care facility. Second, the Petitioners

indicate that the procedures are performed as inpatient procedures with no facts supporting this claim.

The Petition Does Not Support the Basic Principles of the SMFP

The SMFP contains three (3) basic principles governing the plan: safety/quality, access, and value. While the Petitioners analyze the petition from the lens of ESRD patients only, the SMFP and the SHCC are responsible for all North Carolinians.

Safety/Quality

The Petitioners fail to address concerns about patient safety. The petition contains multiple references to the complex health status of ESRD patients on pages 11-12, including the high number of co-morbidities these patients have. The Petitioners state that many existing non-ESRD focused ASCs will not accommodate patents with an ASA III score, but they do not offer any evidence as to how vascular access ASCs would overcome the anesthesia challenges that existing multi-specialty ASCs currently face with chronic co-morbid patients.

Access

The North Carolina Office of State Budget and Management estimates the current population of North Carolina is 10,155,942 as of July 2016, the most recent certified estimates available. The January 2017 North Carolina Semiannual Dialysis Report contains the number of ESRD patients receiving in-center treatment as of June 30, 2016 as 15,184. The overall percentage of North Carolinians on dialysis treatment is 0.15%. Therefore, less than two-tenths of one percent of North Carolinians might benefit from increased access to operative services proposed in this petition. If these patients were currently unable to access these services, they could benefit from increased access. However, the petitioner does not provide compelling evidence that patients cannot access these services now.

Value

The Petitioner states multiple times throughout the petition that the impetus behind the request is a reimbursement change from CMS that reduced the reimbursement under the physician fee schedule for these procedures. By the very nature of the proposal, the Petitioners are asking to move these procedures to a higher cost setting. The Petitioners acknowledge this on page 10 of the petition by stating, “the differential between physician office rates and ASC rates remains significant.” One of the key considerations for designating higher ASC and HOPD rates compared to physician offices is due to the amount of overhead necessary to operate a higher acuity facility. As stated previously in this section, only 0.15% of North Carolinians would be eligible for treatment at these new ASCs. As such, they would be most impacted by the increased costs and overhead associated with these ASCs.

In summary, the Petition fails to make a persuasive argument to justify either an operating room methodology change or an adjusted need determination for a demonstration project for vascular access ASCs for ESRD patients. Thus, Cone Health respectfully requests that the Petition be denied.