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Ms. Martha Frisone, Chief, Health Planning and Certificate of Need
Ms. Amy Craddock, Assistant Chief, Health Planning
Health Planning and Certificate of Need Section
Division of Health Service Regulation
NC Department of Health and Human Services
DHSR.SMFP.Petitions-Comments@dhhs.nc.gov

Re: Comments on North Carolina Division of Health Service Regulation ("DHSR") State Medical Facilities Plan Methodologies.

Dear Ms. Frisone and Ms. Craddock:

On behalf of PDA, Inc. ("PDA"), thank you for providing an opportunity to comment on adjustments to methodologies in the proposed 2022 State Medical Facilities Plan ("SMFP") as they relate to the effects of COVID on FY2020 planning data. We understand that any changes to the SMFP methodologies will not go into effect until January 1, 2022.

The Agency communication dated December 4, 2020, indicates five methodologies are under consideration for adjustment: acute care hospital beds, operating rooms, magnetic resonance imaging ("MRI") scanners, linear accelerators ("LinAc"); and positron emission tomography ("PET") scanners. After reviewing the methodologies and our knowledge of COVID impact, PDA suggests no change in methodology for acute care beds, LinAc, and PET, and a wait and see for operating rooms. However, *adjustments should be considered for MRI need planning*. The paragraphs that follow briefly explain our reasoning.

No Change in Certain Need Methodologies

It is clear that COVID-19 changed utilization of all health services; moratoriums reduced access, and the disease increased demand for some services. On average, utilization for most services may be down 10 to 20 percent for the 2020 fiscal year. In most services, use in the pre-COVID-19 first quarter of FFY 2020 appeared to be higher than the similar period for FFY 2019. The biggest COVID-19 reductions occurred between March and May 2020 (Q2 and Q3), when the Governor imposed moratoriums on non-essential services. Most services began to recover during Q3 and Q4. The net effect will likely reflect in lower reported annual use in FFY 2020 than would have occurred without the pandemic. Alone, this would support an upward planning adjustment to account for the unusual pandemic effect. However, the pandemic accelerated other changes in health care delivery that are likely to remain. Specifically, emergency visits and related technology use may be down permanently. Telehealth accelerated and increased home care options.

COVID 19 impacts are still occurring in FFY 2021. One-year of data is not adequate to show the full effects on healthcare planning. It is too early to tell if the FFY 2020 decline in service use is a trend, or a pandemic-associated outlier. If the SHCC makes no change in need methodologies for acute care beds, LinAcs, and PET scanners, there will likely be little adverse effect on statewide access to these services.

- Acute care beds – early data provided by the Agency show that, with the exception of a severe decline in April 2020, the rest of acute care days in CY2020 – both before and after April – were relatively on par with CY2018 and CY2019. Furthermore, a need determination is calculated when the projected deficit of beds is at least 20 beds or 10 percent of the inventory of the single hospital with the fewest acute care beds in its planning inventory. In the 2021 SMFP, five service areas showed a need. Of the remaining 79 service areas, only Craven and Orange showed a deficit that did not produce a bed need.[1] Allowing utilization to recover fully from COVID-19-related volume declines should not cause access issues. Orange has received bed allocations in recent years.[2] Craven could make a special need request, if its residents perceive a need.
- PET scanners – the 2021 SMFP shows need for four additional PET scanners, one each in four of the six service areas. Only one provider in each of the four had enough scans to create a need determination (at least 80% utilization).[3] No provider in any other service area in the state came close to that utilization level in FY2019. This suggests ample PET capacity across the state. COVID changes would not materially affect the methodology.
- LinAc – NC has 28 multi-county LinAc service areas. A need determination occurs when the total number of ESTVs (simple treatment equivalents) divided by 6,750 ESTVs, minus the number of LinAcs is greater than or equal to 0.25. In FY2019, only Service Area 19 (New Hanover, Brunswick, Columbus, Pender) met the threshold. Only two others showed positive calculations, 0.16 and 0.04 in Service Areas 7 (Anson, Mecklenburg, Union) and 17(Hoke, Lee, Montgomery, Moore, Richmond, and Scotland).[4] Although, FFY 2020 data will likely show depressed utilization, the data are not likely to have a material impact on need calculations.

Operating Rooms: Wait and See

So many factors affect the Operating Room methodology that we are unwilling to make a recommendation before seeing the data. The moratoriums reduced operating room use in March-April 2020 and again in January 2021.[5] The OR need methodology is retrospective and based on historic hours of use and future populations. Licensure renewal information for FY 2020 should pick up the longer turnover times associated with CDC recommendations for intubation and air evacuation for infection control.[6] These should automatically adjust standard hours per room in the group types. This could offset declines in use. However, Step 2 should be evaluated against the FFY 2020 data.

[1] Table 5A, 2021 SMFP, pages 37-45
[2] Table 5A, Column E, page 42; "Orange County; Adjustments for CONs/Previous Need; 114 beds"
[3] Table 17F-1, 2021 SMFP, page 369
[4] Table 17C-5, 2021 SMFP, page 335
[5] https://files.nc.gov/covid/documents/guidance/healthcare/COVID-19-Elective-Surgeries-Final.pdf
[6] https://www.cdc.gov/infectioncontrol/guidelines/environmental/appendix/air.html#tableb1

The pandemic accelerated the shift to freestanding settings. National strategic planners expect more surgery to shift to outpatient settings.[7] For example, prior to 2021, CMS was encouraging site-neutral payments to reduce the price difference between hospital-based and freestanding surgery centers.[8] The current methodology is designed to increase surgery options in more populated areas; and, for the last three years, the SMFP's have generated substantial new opportunities. It would be helpful if staff could show need with and without Step 2 adjustments.

Adjust MRI Methodology

The MRI methodology has had a longstanding flaw, even without the effects of COVID-19. This methodology is not population based. It is based only on reported utilization of existing equipment. Once equipment in a service area is operating at capacity, the methodology allocates only one more MRI per year to the service area, regardless of the size of its population. At a certain point, existing equipment cannot absorb any more demand and patients are forced to seek service elsewhere. MRI supply is unevenly distributed across the state; and the methodology *reinforces the uneven distribution. The result is inequitable access to this standard diagnostic imaging tool*. A simple MRI per capita calculation illustrates the disparity.

For example, the Durham/Caswell service area has 5.0 MRIs per 100,000 residents. By contrast, the Wake County service area has 2.3 MRIs per 100,000 people. Durham/Caswell has more than two times the Wake access. Similar disparities occur in other high population counties like Guilford and Mecklenburg; Table 1 below illustrates the access disparity, comparing four of the highest and four of the lowest MRI per capita service areas. It is for illustration. The list is not exhaustive.

Table 1 –Comparison of Fixed Equivalent MRIs in Selected High and Low Access Service Areas

Service Area	2021 Estimated Population	Fixed Equivalent MRIs Per 100K Pop
High Access		
Orange	150,125	6.9
New Hanover	242,987	3.7
Durham / Caswell	348,566	5.0
Forsyth	386,583	5.2
Low Access		
Cumberland	333,751	2.1
Guilford	551,354	2.8
Wake	1,130,815	2.3
Mecklenburg	1,156,107	2.7

Sources and Notes: NC Office of State Budget and Management, county population estimates by age and sex, 2000-2039; accessed 02.01.21; Column F, Table 17E-1, 2021 SMFP, pages 347-364; Total service area fixed equivalent MRIs / Total service area population x 100,000

[7] https://www.modernhealthcare.com/providers/hospitals-see-opportunity-risk-ambulatory-surgery-centers
[8] https://www.healthcarefinancenews.com/news/cms-finalizes-site-neutral-payment-rule

The disparity has its origins in the early days of MRI and the academic medical center exemption (Policy AC-3). MRI is now a standard diagnostic tool, but, unlike linear accelerators, the methodology has no adjustment for population. Hence, the methodology continues to support the disparity by generating a need for only one or no MRI units per service area per year. This perpetuates a cycle of placing easily accessible new MRI units in high availability service areas and restricting competition in other low access areas. Because only one entity can receive a CON, the methodology encourages multiple rounds of expensive CON applications and appeals. Unfortunately, it means that residents of low availability markets are forced find service in high availability markets– and the cycle begins again, making it appear that demand is lower in the low access service areas.

This is similar to the problems that occurred when every NC county received the same number of COVID vaccines. In that instance, there was a reverse migration from urban to rural areas, because the rural counties had more supply than they could quickly absorb.

Pausing need determinations for MRI or applying FFY 2020 data to the existing methodology would only extend the disparities for clearly underserved service areas like Wake and Mecklenburg counties.

We encourage the Agency and the State Health Coordinating Council to take advantage of the rare opportunity the 2022 planning cycle has presented to focus on the MRI methodology's long-standing flaws.

Thank you for your time and attention. These proposed considerations are important for North Carolina and we believe they merit serious consideration by the State Health Coordinating Council. Please do not hesitate to contact me at nlane@pda-inc.net if you have any questions.

Sincerely,

Nancy Lane
President
PDA, Inc.