Petition for New Technology and Equipment Policy

PETITIONER

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STATEMENT OF REQUESTED ADJUSTMENT

Carolina Neurosurgery & Spine Associates (CNSA) respectfully petitions the State Health Coordinating Council (SHCC) to add a new policy to the *2023 State Medical Facilities Plan* (*2023 SMFP*). In large part, this petition is similar to the one submitted by CNSA in the spring of 2020 but has been updated to include new information. Specifically, CNSA requests that the following language be added to create Policy TE-4:

> **Policy TE-4: Substitution of Vendor-Owned Mobile MRIs with Provider-Owned Mobile MRIs**
>
> A qualified applicant is a provider who has an executed service contract with an unrelated person for mobile magnetic resonance imaging (MRI) scanner services and is unable to apply to develop a mobile MRI scanner pursuant to a need determination.
>
> The qualified applicant applying for Certificate of Need (CON) for a mobile MRI scanner pursuant to this policy shall demonstrate all the following in the CON application:
>
> 1. As reported in the most recent Registration and Inventory form or License Renewal Application (either the one submitted during the same year the CON application is submitted or the form submitted the previous year), the applicant:
>   a. contracts for mobile MRI services using a mobile MRI scanner owned by an unrelated person.

   b. performed at least 3,328 weighted MRI procedures combined for all service sites owned and operated by the applicant or a related entity.[1]
2. The proposed mobile MRI scanner will provide services at two or more sites each week and one of those sites must be an existing site where the applicant currently offers mobile MRI services using a mobile MRI owned by an unrelated person.
3. Projected utilization is consistent with the performance standards promulgated in 10A NCAC 14C .2703 and is based on reasonable and adequately supported assumptions.

Of note, this language is nearly identical to that created by the Agency in response to CNSA's petition filed in 2020. As with its original petition, CNSA has limited the scope of the proposed policy to mobile scanners only, because the recent MRI methodology workgroup limited its work to updating only the methodology for fixed MRI scanners.

BACKGROUND

CNSA is a medical practice, specializing in neurosurgery, which was established in 1940. CNSA is one of the oldest neurosurgical practices and the largest private neurosurgical practice in the country. CNSA has offices in Ballantyne, Charlotte, Concord, Gastonia, Greensboro, Huntersville, Kernersville, Matthews, and Mooresville, North Carolina and in Rock Hill, South Carolina. CNSA provides advanced surgical and non-surgical treatment for the entire spectrum of brain, spine and peripheral nerve disorders, including brain tumors, spine injuries, stroke, epilepsy, birth defects, neck and lower back pain, and pituitary tumors. As the primary provider of neurosurgical services in the Charlotte region, CNSA offers state-of-the-art treatment, participates in advanced research trials, and coordinates patient support. In the area of spinal expertise, CNSA stands on par with any private or academic group in the nation. CNSA's surgeons continue to expand the frontiers of this specialty by developing and implementing the latest techniques. Surgeons from around the world come to CNSA to train in advanced techniques.

The practice has long been a leader in bringing groundbreaking imaging technology to western North Carolina. From being the first referring physician practice to acquire a mobile MRI scanner in the Charlotte region to the first referring physician practice to acquire a multi-position MRI scanner in HSAs I, II, or III, CNSA has remained committed to ensuring its patients have access to the most advanced technology. Currently, CNSA owns and operates a fixed multi-position MRI and a mobile MRI. In addition, due to its high volume of imaging referrals, CNSA currently hosts a vendor-owned mobile MRI.

REASONS FOR THE REQUESTED ADJUSTMENT

Of the technology methodologies in the *SMFP*, most have changed multiple times since they were first developed, particularly for higher volume modalities, such as MRI. In fact, as the SHCC is well aware, a workgroup convened for the first time in November 2021 to evaluate the current MRI methodology that

[1] CNSA notes that it has deleted the underlined portion of this condition that reads "and located in the proposed service area", as published in the *Proposed 2021 SMFP*, and has done so specifically because there is no defined service area for mobile MRIs in the *SMFP,* so it is unclear if the intent is to limit the service area to any corresponding fixed MRI scanner service areas. Given the nature of mobile MRI, CNSA believes that the proposed service area should not be limited to a fixed service area, particularly for applicants seeking to replace vendor-owned mobile scanners that are currently serving more than one fixed service area.

includes the utilization and capacity of both fixed and mobile MRIs, yet only determines need for fixed MRIs. While CNSA understands that the primary goal of the MRI methodology workgroup was to examine the MRI need methodology as it relates to the need for additional fixed MRI scanners, it continues to believe that a need should be permitted for a mobile MRI when a provider has a well-utilized mobile MRI scanner and needs another mobile scanner—not a fixed scanner that cannot serve multiple sites. The workgroup concluded its recommendation for revision of the current MRI methodology at the end of its final meeting that convened on February 15, 2022. Notwithstanding the evolution of the MRI methodology, which is discussed below, and the MRI workgroup's recent recommendation for the revision of the current methodology, which must be approved by the SHCC and the Governor before any changes to the current methodology are published in the *SMFP*, CNSA believes there remain issues with the current MRI methodology, specifically as it relates to mobile MRI scanners. In particular, the lack of a methodology for mobile MRI scanners, though understandable given the number of mobile MRI scanners in the state, including numerous "grandfathered" or unregulated mobile scanners, as well as the mutable nature of mobile service, which makes capturing a reliable inventory virtually impossible, creates an issue for providers fully utilizing a vendor-owned mobile MRI scanner, in that there is no "trigger" in the methodology to allow them to obtain their own scanner nor is there a need determination that would allow a mobile scanner to serve sites in multiple counties. CNSA understands that the SHCC has discussed the fact that there is currently no methodology for "converting" a mobile MRI to a fixed scanner. While that is true, sites hosting a mobile scanner still have a pathway to apply for a fixed MRI by responding to a standard need determination. There is, however, currently no pathway in the methodology for a provider with a well-utilized mobile MRI to obtain another mobile MRI, as there is no methodology for additional mobile MRIs. As stated on page 343 of the *2022 SMFP*, "[t]*he SMFP does not have a methodology to project need for additional mobile MRI scanners.*" Rather, a summer petition is required to place a need in the upcoming *SMFP*. As such, CNSA believes that its situation is even more compelling than the issue with "converting" a mobile MRI to a fixed scanner, and that a petition filed in the spring is the appropriate time for such a petition as it provides ample opportunities for feedback from the healthcare community and its stakeholders prior to publishing the proposed Policy TE-4 in the *Proposed 2023 SMFP*, which will also be available for review and comment. Further, although there is an avenue for a provider to submit a summer petition to place a need for a mobile MRI in the upcoming *SMFP*, such an avenue allows any applicant to apply, whether it be a vendor or a provider. Moreover, CNSA believes that while this existing avenue is adequate in many situations, there should be a separate and distinct pathway for a qualified, existing mobile MRI service provider with an existing well-utilized vendor-owned mobile MRI to apply for CON approval to obtain its own mobile MRI.

As stated above, CNSA notes that in response to petitions from it and another provider in spring 2020, a new Policy was drafted for inclusion in the *Proposed 2021 SMFP*; however, that Policy was ultimately rejected by the SHCC. Even though the MRI workgroup has issued its recommendation for revision of the current methodology, the workgroup's recommendation does not consider any changes that would result in the ability for providers with well-utilized mobile MRI scanners to apply to supplement their capacity, except through a need determination for a fixed MRI scanner. In short, there is no need to delay approval of this petition as it will not impact the current MRI methodology.

While fixed MRI scanners may be the most prudent choice for many providers, CNSA believes that mobile scanners owned by a provider that can utilize them well at several of its own sites are appropriate for providing access to patients at multiple sites. The SHCC has previously appreciated the merits of mobile technology through its enactment of Policy TE-1, in which it allows providers to convert a fixed PET

scanner into a mobile PET scanner to serve multiple sites owned by the same provider or a related entity. The same principle should allow providers who own or contract for well-utilized mobile MRI scanners to apply for additional mobile MRI scanners when utilization warrants. In addition, one foundational issue that CNSA believes the SHCC must consider is that the treatment of mobile MRIs and fixed MRIs are different under the standard methodology.

Further, comments in opposition of the petition filed by CNSA in spring 2020 asserted that the proposed policy runs counter to fundamental tenets of North Carolina's health planning process by creating an opportunity to apply for a CON for a new MRI scanner without reference to any of the information relied on in the current MRI methodology; however, numerous *SMFP* policies that have been adopted by the SHCC are separate from the health planning process in the standard methodology. In fact, that is clearly one of the reasons for the creation of such a policy—to enable providers with unique circumstances to apply for services or equipment without necessitating either a special need petition for each potential applicant or a wholesale change to the methodology. Such policies include the following:

Policy AC-3: Allows academic medical center teaching hospitals to apply for beds, services, or equipment when there is no need determination, with the requirement that they meet certain criteria.

Policy AC-6: Allows open heart surgery providers to apply for a heart-lung bypass machine to be used as backup, without a need determination. While now only needed in special cases, since there is no need determination required for heart-lung bypass machines, for many years it allowed providers to apply for these units irrespective of the need determination.

Policy ESRD-2: Allows for the relocation of dialysis stations between counties, irrespective of the county need determination.

Policy ESRD-3: Allows for the development of outpatient dialysis stations in a hospital, without regard to a facility or county need.

Policy NH-2: Allows for the development of nursing beds in a CCRC, without regard to the need determination for nursing beds.

Policy NH-5 and **Policy NH-6**: Allow for the relocation of existing nursing beds from state facilities or between counties, irrespective of the county need determination.

Policy LTC-1: Allows for the development of adult care home beds in a CCRC, without regard to the need determination for those beds.

Policy LTC-2: Allows for the relocation of existing adult care home beds between counties, irrespective of the county need determination.

Policy PSY-1: Allows for the relocation of existing psychiatric inpatient beds from state facilities, irrespective of the service area need determination.

Policy TE-1: Allows for the development of new mobile PET scanners through the conversion of fixed PET scanners, without any need determination for mobile PET scanners.

Policy TE-2: Allows for the acquisition of an iMRI, without regard to a need determination in the service area for MRI scanners.

Policy TE-3: Allows for the development of fixed MRI scanners by hospitals without a fixed scanner, and regardless of the need determination for fixed MRI scanners.

Thus, at least 12 of the existing policies in the *SMFP* specifically exempt applicants from the need determination generated by the standard methodology. As such, nothing about the creation of Policy TE-4 would be novel or unique, as evidenced by the numerous policies that exist specifically to allow applications outside of the standard methodology. Furthermore, none of the CON applications developed pursuant to these policies would be considered "competitive," as the approval of one would not necessitate the denial of another.

Evolution of the MRI Methodology in the North Carolina *SMFP*

CNSA believes that a brief discussion of the development and changes to the MRI methodology is helpful in understanding the current issues created by the lack of a pathway for providers with well-utilized vendor-owned mobile MRI scanners to obtain their own mobile MRI scanner.

1999-2002

Although the North Carolina CON law has regulated MRIs since 1993, the *1999 SMFP* was the first to introduce a need methodology for MRIs. The 1999 methodology determined need for fixed MRIs based on either conversion from a mobile MRI site to a fixed or the need for an additional fixed scanner based on the volume of an existing fixed site. The methodology did not include mobile MRIs; in fact, the MRI section of the *1999 SMFP* stated, "*[i]t has not been possible to develop a feasible statewide methodology for the determination of need for a mobile provider to add another mobile unit, or for the entry of another mobile provider into the State. Some mobile units are used both in North Carolina and in an adjacent state, and mobile providers may regularly add or give up client sites. Also, it was not feasible to specify a general criterion for the initiation of service at a mobile site, because the uses of MRI are evolving rapidly*.[2]" Thus, the MRI methodology did not allocate a need for mobile MRIs or provide a pathway for a provider with a well-utilized vendor-owned mobile MRI to obtain its own provider-owned mobile MRI.

2003-2004

In response to a petition, the *2003 SMFP* included a need for two mobile MRIs in the state; one to serve HSA's I, II, and III and one to serve HSA's IV, V, and VI. These allocations set the determinative limit on mobile MRIs at two for 2003. The remainder of the MRI methodology remained unchanged in the *2003 SMFP.*

The *2004 SMFP* did not include a need determination for mobile MRIs but reverted to the pre-2004 system of not allocating mobile MRIs. The methodology for fixed MRIs remained unchanged from the previous year.

[2] *1999 SMFP*, page 98.

2005

Following the considerable effort of an MRI workgroup, the *2005 SMFP* included a major revision in the MRI methodology, which, for the first time, combined the fixed and mobile MRI tables. The new methodology also introduced the tiered planning thresholds and "weighting" of MRI procedures, two concepts that exist in the current MRI methodology. It should be noted that the MRI workgroup recognized the limitations of the revised methodology at the time, particularly the challenges of a fixed MRI methodology driven by both mobile and fixed volume; however, given the difficulties of determining the capacity and service area of mobile MRIs, the workgroup decided not to develop a need methodology for mobile MRIs.

2006-Present

Since the beginning of the MRI methodology in 1999, the focus of the methodology has been on determining need for additional fixed scanners, whether they are intended to "replace" mobile MRIs at sites with volumes that can sustain a fixed MRI, or to increase capacity in areas with well-utilized fixed MRIs. In fact, beginning with the first methodology in 1999, the *SMFP* stated, "[b]*ecause MRI technology is mobile, and apparently is financially feasible at relatively small-volume mobile sites, geographic accessibility is not a significant planning issue…Because of the availability of mobile units, MRI technology is accessible within a reasonable distance and travel time to all of the population of the state*." Thus, mobile MRIs have historically been expected to expand access in rural areas that cannot support a fixed scanner.

The current MRI methodology is based on changes made for the *2006 SMFP*, which further refined the combined inventory table to account for mobile MRIs by "fixed equivalent magnets." This methodology includes all procedures performed on mobile or fixed MRIs, and, through the "fixed equivalent" calculation for mobile sites, includes the most complete inventory of MRI capacity to date. The current MRI methodology includes need thresholds arranged in tiers based on the number of fixed equivalent MRIs present in the service area. The annual maximum capacity of a single fixed MRI is 6,864 adjusted procedures annually (66 hours per week x 52 weeks per year x 2.0 procedures per hour). Of note, the MRI workgroup's recommendation involves adjusting the annual maximum capacity of a single fixed MRI to 5,148 adjusted procedures annually (66 hours per week x 52 weeks per year x 1.5 procedures per hour). While the annual maximum capacity represents 100 percent of the procedure volume the equipment is capable of performing assuming those hours of operation, the MRI methodology relies on tiered thresholds to account for scheduling constraints, machine and room downtime, patient cancellations, and other delays that may impact the utilization of equipment, recognizing that service areas with more fixed scanners have the capacity to accommodate these delays more easily than those with fewer scanners. The tiered planning thresholds are included in the table below.

Service Area Fixed Scanners	*Inpatient and Contrast Adjusted Thresholds*	*Planning Threshold*
4 and over	4,805	70.0%
3	4,462	65.0%
2	4,118	60.0%
1	3,775	55.0%
0	1,716	25.0%

For informational purposes, the MRI workgroup's recommendation involves adjusting the planning thresholds. The table below provides the planning thresholds as recommended by the MRI workgroup.

Service Area Fixed Scanners	*Inpatient and Contrast Adjusted Thresholds*	*Planning Threshold*
4 and over	4,118	80.0%
3	4,118	80.0%
2	4,188	80.0%
1	3,604	70.0%
0	1,544	30.0%

What is not included in either of the tables above is a planning threshold for mobile MRIs. Chapter 17 of the *2022 SMFP* does not define capacity for mobile MRIs. However, CON regulation 10A NCAC 14C .2701(3) states that, "[a]*nnual capacity of a mobile MRI scanner is 4,160 weighted MRI procedures, which assumes two weighted procedures are performed per hour and the scanner is operated 40 hours per week, 52 weeks per year*." Further, according to 10A NCAC 14C .2703(a)(2), any applicant that applies for CON approval to acquire a mobile MRI must reasonably project that the mobile MRI will perform 3,328 weighted scans, or 80 percent of the annual capacity stated above, by its third year of operation. Of particular note, as demonstrated above, the MRI workgroup did not consider any adjustment of annual mobile MRI capacity, specifically as it is stated in 10A NCAC 14C .2701(3). Nonetheless, as demonstrated below, based on the standards set forth in the CON regulations, CNSA is already fully utilizing its owned mobile MRI as well as the mobile MRI provided through a vendor-owned service; still, it is unable to apply for a CON for another mobile MRI, despite demonstrating effective utilization of these mobile scanners.

Rather than proposing a new methodology for mobile scanners, which CNSA concedes would be difficult to manage and unduly burdensome to the Division of Health Service Regulation (DHSR) Planning Staff, CNSA believes that the most effective method of addressing the issue described herein is through a new Technology and Equipment policy. Each of the enumerated conditions proposed by CNSA, which closely resemble the conditions published in the *Proposed 2021 SMFP* for Policy TE-4, is intended to address these issues while minimizing the risk of unnecessary duplication and unintended consequences. The rationale for the proposed language of Policy TE-4 in the petition filed by CNSA in spring of 2020 was described in detail in CNSA's 2020 petition; however, since the language of the proposed Policy TE-4 in this petition was drafted by the Agency and initially approved for inclusion in the *Proposed 2021 SMFP*, CNSA has omitted this discussion from the current petition.

Please note that CNSA believes these conditions will provide an opportunity for applicants with a legitimate need for additional mobile MRI capacity to obtain a CON for the equipment while minimizing the number of applicants who could apply. Of note, CNSA does not believe that every mobile host site needs to own the mobile scanner, nor does it believe that most vendor-provided mobile MRI scanners should be substituted with a provider-owned mobile scanner. If the SHCC believes that more conditions are needed to achieve this goal or that the proposed conditions should be modified or deleted, CNSA supports efforts that will provide it the ability to apply for a CON for another mobile MRI scanner.

CNSA MRI Services

As mentioned above, CNSA owns and operates one fixed multi-position MRI and one mobile MRI. In addition, CNSA hosts a vendor-owned mobile MRI. CNSA's multi-position MRI is located at its Charlotte location and its mobile MRI rotates between its Charlotte and Ballantyne locations in Mecklenburg County. MRI services at CNSA's locations in Cabarrus and Guilford counties are provided through a vendor-owned mobile MRI service, Alliance Imaging (Alliance). In fact, since Federal Fiscal Year (FFY) 2017, CNSA has contracted with Alliance to provide additional capacity at its Charlotte location as demand has increased.

As shown in the table below, according to the license renewal applications (LRAs), since FFY 2016, the vendor-owned mobile MRI has well exceeded the planning threshold of 3,328 weighted scans. In addition, since FFY 2017, the mobile MRI owned by CNSA has provided more than double the planning threshold of 3,328 weighted scans. Further, CNSA's multi-position MRI has consistently exceeded 80 percent of its planning threshold of 3,774 scans[3].

[3] The CON regulations found at 10A NCAC 14C .2703(e)(1) state that an applicant proposing to acquire a fixed multi-position MRI for which the need determination in the *SMFP* was based on an approved petition for a demonstration project shall demonstrate annual utilization of the proposed multi-position MRI in the third year of operation is reasonably projected to be at least 80 percent of the capacity defined by the applicant in response to 10A NCAC 14C .2702(g)(7). The defined annual capacity in CNSA's approved multi-position MRI application (Project ID # F-8102-08), is 3,774 scans.

CNSA and Vendor-Owned Total Weighted MRI Volumes by County and Location

County-Location	*Service Type*	*Total Weighted MRI Scans*				
		FFY 2016	**FFY 2017**	**FFY 2018**	**FFY 2019**	**FFY 2020**
Cabarrus	Vendor-Owned Mobile	1,258	1,197	1,222	1,412	1,141
Guilford	Vendor-Owned Mobile	2,212	1,938	1,928	2,127	1,689
Mecklenburg – Charlotte	Vendor-Owned Mobile		253	802	1,847	1,326
Vendor-Owned Subtotal		**3,470**	**3,388**	**3,952**	**5,385**	**4,156**
Mecklenburg – Charlotte	CNSA-Owned Mobile	4,577	5,206	5,164	5,344	6,223
Mecklenburg – Ballantyne	CNSA-Owned Mobile	1,460	1,530	1,556	1,730	691
CNSA-Owned Mobile Subtotal		**6,037**	**6,736**	**6,720**	**7,075**	**6,914**
Mecklenburg – Charlotte	CNSA-Owned Fixed*	4,385	4,603	4,471	4,505	4,028
CNSA-Owned Mobile/Fixed Subtotal		**10,422**	**11,339**	**11,191**	**11,580**	**10,942**
CNSA/Vendor-Owned Grand Total		**13,892**	**14,727**	**15,143**	**16,244**	**15,098**

Source: LRAs.
*Fixed multi-position MRI scanner.

As shown above, in FFY 2019, prior to the COVID-19 pandemic, CNSA's fixed and mobile scanners along with the vendor-owned mobile MRI serving CNSA provided a combined total of over 16,000 total weighted scans. In addition, in FFY 2020, CNSA's fixed and mobile scanners along with the vendor-owned mobile MRI serving CNSA provided more total weighted scans than were performed in FFY 2016 and FFY 2017, and even during the pandemic, FFY 2020 volume was comparable to the number of total weighted scans provided in FFY 2018. Of particular note, using information provided on the LRAs, CNSA confirmed that from FFY 2016 to FFY 2020 Alliance Imaging reported using the same mobile MRI to serve CNSA's locations in Cabarrus, Guilford, and Mecklenburg counties[4]. In addition, Alliance reported that its mobile MRI only served CNSA locations, whereas most other mobile MRIs serve multiple providers. CNSA believes this is further evidence that it can support an additional CNSA-owned mobile MRI to serve the same locations currently served by Alliance. To be clear, CNSA believes that vendor-owned mobile MRI services are an important part of the healthcare continuum in the state and appreciates the availability of the service as it provides access to locations across North Carolina, particularly rural areas, that would otherwise have difficulty supporting a full-time fixed MRI or accessing MRI services in general. In particular, Alliance has provided essential capacity to CNSA as its practice has grown, and CNSA is grateful for the relationship it has had with Alliance over the years, notwithstanding the adverse position Alliance took to CNSA's similar petition in 2020. However, the sheer volume of scans provided by CNSA using the vendor-owned mobile MRI is evidence that CNSA can effectively own and operate a second mobile MRI.

[4] According to its 2017 through 2021 LRAs, Alliance reported using a GE 1.5T Signa HDxt Serial No. 1S9FA482431182635 Signa 451 mobile MRI to provide mobile MRI services to CNSA's locations in Cabarrus, Guilford, and Mecklenburg counties.

Not only does CNSA demonstrate today that it can support a second provider-owned mobile MRI, there are notable cost saving advantages associated with provider-owned equipment. As the SHCC is certainly aware, the evolution of payment models, such as the growth of Medicare Advantage and the development of North Carolina Medicaid Managed Care, are driving providers to decrease costs where possible to ensure they can continue providing high value, safe, and effective healthcare services to their patients. CNSA endeavors to capitalize on every opportunity to control and lower the cost of care for its patients. The proposed policy will allow CNSA to acquire another mobile MRI, which in turn will allow CNSA to eliminate expenses associated with the contracted mobile MRI service and give CNSA more control over cost containment associated with its MRI services. By containing costs where feasible, CNSA will have an increased ability to manage these changes in healthcare reimbursement. In addition, similar to all providers, CNSA has been dealing with the impacts of the COVID-19 pandemic. While the impact of the crisis has been severe and is ongoing, CNSA believes that the policy will help to address the impacts of COVID-19. In particular, as a practice that has experienced significant loss in volume and revenue resulting from the deferrals in elective cases, the ability to control costs by substituting a vendor-owned mobile MRI scanner with its own scanner is even more pressing than it was in early March 2020 when CNSA filed its first petition regarding proposed Policy TE-4.

Other Providers Hosting Vendor-Owned Mobile MRI Services

CNSA is not the only provider that has communicated challenges with hosting vendor-owned mobile MRI services to serve its patient population. CNSA has identified comments made by other providers in CON applications to substitute mobile MRI scanners with fixed scanners that reference the impediments experienced when operating with a third-party vendor to provide mobile MRI services. These comments are as follows:

- In the 2010 Wake County MRI Review, Wake Radiology Diagnostic Imaging indicated on page 129 of its application to acquire a fixed MRI scanner, Project ID # J-8534-10, that "*[t]he operations of the fixed MRI scanner also will be less costly than the current mobile MRI service because WRDI will reduce equipment rental costs associated with a third-party mobile equipment vendor.*"
- Page 7 of the Findings on Person Memorial Hospital's 2014 application to acquire a fixed MRI scanner, Project ID # K-10277-14, indicated that "*[a]vailability of full-time fixed MRI services will offer advantages for patients and referring physicians, overcoming the limitations of mobile MRI services, which include requiring patients to go out in the elements to access the mobile services, lack of access to MRI for emergency coverage and the complexity of keeping up with the mobile services' three day schedule.*"
- Page 10 of the Findings on J. Arthur Dosher Memorial Hospital's 2016 application to acquire a fixed MRI scanner, Project ID # O-11125-16, summarizes why maintaining the status quo was not the most effective alternative, stating that "*[r]etaining the current MRI contract ignores the need for full time MRI services at the hospital for normal and emergency MRI services. Under the existing contract, the vendor's employees leave the facility if there are no MRIs scheduled. If patients present after that, they must wait until the mobile MRI reopens, or be transported to a location with a fixed MRI. This is not in the best interest of the patients, according to the applicant. Additionally, emergency patients must be transported via ambulance to the nearest MRI, which is costly and time consuming.*"

- In the 2016 Wake County MRI Review, relative to Raleigh Radiology Cary's proposal to acquire a fixed MRI scanner, Project ID # J-11159-16, page 30 of the Findings summarizes why maintaining the status quo was not the most effective alternative, stating that "*[t]he applicant projects that the Alliance MRI scanner will not have the capacity to keep up with growth projected for its MRI services since there is no flexibility to adjust operating hours to increase capacity. In addition, the applicant states that it cannot reduce costs further under its agreement with Alliance. Furthermore, the applicant states that there is no guarantee that the Alliance contract for MRI services will continue.*"
- In the 2019 Guilford County MRI Review, relative to Wake Forest Baptist Imaging - Kernersville's proposal to acquire a fixed MRI scanner, Project ID # G-11798-19, page 31 of the Findings summarizes why maintaining the status quo was not the most effective alternative, stating that "*[t]he existing mobile MRI is expensive, experiences equipment downtime, is relatively inefficient, necessitates patients going outside the building to the mobile unit, has limited days on site, and does not provide adequate capacity*."
- In the 2019 Wake County MRI Review, Raleigh Radiology Cary (RRCary) indicated on page 44 of its application to acquire a fixed MRI scanner, Project ID # J-11825-19, that "*[b]y eliminating the current lease arrangement, and owning a newer MRI that will have more capabilities, the applicant can substantially reduce MRI operating costs, and maintain its low consumer costs. Extra overhead will disappear, and RRCary can deploy technologists from its multi-modal staff to meet patient demand, rather than vendor requirements.*" In addition, on page 78 of its application, RRCary noted "*[b]ecause the service provider continues to increase its charges without improving the equipment, RRCary is finding it exceedingly difficult to sustain the service and keep customer out-of-pocket costs low*."
- In the 2021 Wake County MRI Review, relative to Wake Radiology Garner's proposal to acquire a fixed MRI scanner, Project ID # J-12068-21, the Findings indicated on page 44 that "*[t]he proposed fixed MRI scanner will replace a leased fixed MRI scanner, which will allow Wake Radiology to guarantee long term accessibility to MRI services at WR-Garner as well as eliminating the expense of leasing the current fixed MRI scanner.*"

The comments excerpted above make clear that the matters regarding cost and access experienced by providers when hosting vendor-owned mobile MRI services are evident and consistent. Of particular note, some of these applications were proposals to replace full-time vendor-owned scanners with provider-owned scanners, which the applicants certainly believed was more effective and less costly than continuing to contract with a vendor. These and similar issues can be mitigated with the approval of Policy TE-4 as the proposed policy will result in a separate and distinct pathway for a qualified, existing mobile MRI service provider with an existing well-utilized vendor-owned mobile MRI to apply for CON approval to obtain its own mobile MRI.

Adverse Effects on Patients If the Petition Is not Approved

CNSA maintains its belief that the issues described above, particularly the fact there is no existing methodology or policy in the *SMFP* whereby an applicant with a well-utilized vendor-owned mobile MRI can apply for a CON for its own mobile MRI, are unlikely to be addressed without the approval of this petition. Providers like CNSA will continue to be unable to apply for CON approval to obtain their own mobile MRI without petitioning for a need determination in the upcoming *SMFP*, which opens the opportunity for providers and vendors alike to apply. Without the approval of this petition, CNSA will not be able to obtain its own mobile MRI and as such, will not be able to take advantage of the cost savings associated with owning its own equipment as well as benefits associated with increased oversight of mobile MRI technicians and scheduling.

Further, given the nature of a contracted mobile MRI service, CNSA cannot guarantee permanent access to the service. When its contract for the vendor-owned mobile MRI expires, the vendor may determine not to renew the contract. In the event the vendor does not renew the contract, CNSA's patients at its locations in Cabarrus and Guilford counties would not have access to mobile MRI services and access to mobile MRI services at its Charlotte location would be decreased as well. CNSA can obviate this potential access issue if there were a pathway to apply for CON approval to acquire a provider-owned mobile MRI. As shown above, CNSA clearly demonstrates that it can support an additional mobile MRI; thus, CNSA could ensure permanent access to MRI services for its patients in Cabarrus and Guilford counties as well as access to additional mobile MRI capacity at its Charlotte location.

In addition, as some members of the SHCC are no doubt aware, the ability of CNSA or any physician practice to contract with a mobile vendor for MRI service is limited by federal statutes limiting the conditions under which physicians may refer to ancillary services for which they bill. Specifically, in order to bill Medicare and Medicaid patients for an MRI performed on a scanner the physician practice does not own, the practice must have the use of that scanner on a full-time basis (the "in-office exemption"). Thus, in order to care for these medically underserved patients, CNSA must not just find any mobile MRI scanner with available capacity, it must find a vendor that is able and willing to provide a mobile scanner on a full-time basis. Not only does this limit the number of scanners available, but it also gives tremendous leverage to the vendor. Given this issue, and the fact that CNSA can fully utilize its own additional mobile MRI scanner, if allowed to pursue a CON for one, the failure to enact this policy has direct adverse effects on CNSA's ability to serve the medically underserved and to lower the cost of the care it provides to all its patients.

Alternatives Considered

File a Petition for a Special Need Adjustment

CNSA considered waiting until the summer petition cycle to file a petition for an adjusted need determination. However, as noted above, such an avenue allows any applicant to apply, whether it be a vendor or a provider. As such, this alternative may not address the need that providers like CNSA have to obtain their own mobile MRI when they can demonstrate highly utilized vendor-owned mobile MRI services. In addition, a special need adjustment would presumably only allocate a single mobile MRI scanner, which would be subject to a potential competitive review among providers in a similar situation. If the SHCC believes that providers in CNSA's condition should be able to apply for a mobile MRI scanner,

CNSA believes that a more reasonable approach is to allow providers – such as CNSA – the opportunity to apply for CON approval to obtain their own mobile MRI where they can demonstrate that they meet various conditions, without competing for a single need determination. It should be noted, however, that if the SHCC believes a special need adjustment would be a more prudent approach, CNSA would consider filing such a petition in the summer. However, given the lack of a defined service area for mobile MRIs as well as the need CNSA has to serve its locations in multiple counties and Health Service Areas, CNSA believes an adjusted need determination that addresses these issues would be challenging to define.

Recommend Changes to the MRI Methodology

CNSA also considered recommending that the current MRI methodology be changed to address some of the issues noted above; however, CNSA believes that the situation that it currently faces, while perhaps not unique to it, is rare. As such, a policy addition, rather than changes to the MRI methodology seems more appropriate and reasonable. Of note, CNSA is aware of the challenges associated with developing new methodologies, particularly the time needed to develop a workgroup, examine new approaches, and present those findings to the SHCC. Further, while CNSA is appreciative of the SHCC and Healthcare Planning Section for forming a workgroup to evaluate the existing MRI need methodology in the *SMFP* and believes that such an effort is timely and important to ensure that the MRI methodology is supportive of the need to promote reasonable access to MRI services for all North Carolina residents, the MRI workgroup's recommendation does not include or address any new alternative pathway through which a provider can develop a mobile MRI scanner. Thus, a new workgroup would need to be formed in order to deliberate and make a recommendation to the SHCC regarding development of a methodology for mobile MRI scanners. As noted previously, CNSA recognizes the particular hurdles with developing a methodology for mobile MRI scanners. As such, CNSA believes that the proposed policy will provide the pathway needed by mobile MRI providers with highly utilized vendor-owned mobile MRIs to obtain their own mobile MRI with minimal impact in the majority of the state, where the MRI methodology and special need petition avenue may be working as intended.

File for a Fixed MRI Scanner Need Determination

Lastly, CNSA considered filing a CON in response to a need determination in the *SMFP* to acquire a fixed MRI. While a fixed MRI would result in additional capacity for CNSA patients, CNSA believes a mobile MRI would be more effective at this time. As mentioned above, CNSA has locations in Cabarrus, Guilford, and Mecklenburg counties that need access to MRI services. Currently, the only location where CNSA could support an additional fixed MRI is in Mecklenburg County, which would not benefit its patients in Cabarrus and Guilford counties. In addition, CNSA would likely be disadvantaged in a competitive fixed MRI CON review given its size and relatively narrow scope of services compared to a larger health system. Instead of a fixed MRI, CNSA's patients need an additional provider-owned mobile MRI to serve the same multi-county location currently served by the Alliance mobile MRI.

EVIDENCE THAT THE PROPOSED CHANGE WOULD NOT RESULT IN UNNECESSARY DUPLICATION

CNSA believes that the proposed Policy TE-4 clearly avoids unnecessary duplication. Today, many of the mobile MRIs serving North Carolina sites are "grandfathered"; thus, they are not beholden to any CON conditions or limitations. According to Alliance's 2017 through 2021 LRAs, the mobile MRI that has been serving only CNSA locations is "grandfathered." Of note, mobile MRIs with "grandfathered" status are able to relocate anywhere across the state or out of the state without CON approval. If CNSA were able to substitute its own mobile MRI for its contracted mobile MRI service, the vendor would then have the ability to contract with another provider or providers and to relocate the mobile MRI to any other location where it is feasible to operate, in particular to rural areas or to smaller providers that cannot support their own fixed or mobile scanner. Further, as noted above, most of the existing *SMFP* policies allow providers to submit CON applications without a need determination. Clearly the SHCC does not believe, per its development of these policies, that applications outside of a need determination are unnecessary duplication. The applications are reviewed under the statutory criteria established for CON reviews, which include an examination of unnecessary duplication. In addition, applicants under Policy TE-4 would need to demonstrate that their proposals would be consistent with the Basic Principles of the *SMFP*, as described below.

EVIDENCE THAT THE PROPOSED CHANGE IS CONSISTENT WITH THE THREE BASIC PRINCIPLES

CNSA believes the petition is consistent with the three basic principles: safety and quality, access, and value.

<u>Safety and Quality</u>

By acquiring its own mobile MRI, CNSA will have more control and oversight of the staff and technician(s) that operate the scanner. Currently, the vendor-owned mobile MRI service provides its own staff and technicians, which they are responsible for training and managing. CNSA is a highly specialized neurosurgery and spine practice and the level of technical training that is required to ensure the type and quality of images necessary to make certain diagnoses are obtained consistently is above and beyond the average MRI technician training curriculum. Currently, CNSA provides supplemental training to Alliance technicians to ensure the type and quality of images required to make the proper diagnoses are obtained consistently. By acquiring its own mobile MRI, which CNSA will staff as it does its existing mobile scanner, CNSA will have direct oversight of the mobile MRI staff. Further, CNSA intends to utilize the same policies and procedures for both of its mobile MRIs which will enable CNSA to ensure and maintain consistent quality across all of its mobile MRI service locations, allow for better coordination of care, and reduce any unnecessary duplication associated with the training of its technicians in a manner that delivers consistent and effective results. Furthermore, through the acquisition of a provider-owned mobile MRI, CNSA will gain more control over the scheduling process, which will result in an improved ability to efficiently schedule MRI scans to better accommodate patients.

Access

As noted above, given the nature of a contracted mobile MRI service, CNSA cannot guarantee permanent access to the service. When its contract for the vendor-owned mobile MRI expires, the vendor may determine not to renew the contract. In the event the vendor does not renew the contract, CNSA's patients at its locations in Cabarrus and Guilford counties would be left without access to mobile MRI services and access to mobile MRI services at its Charlotte location would be decreased as well. CNSA can obviate this potential access issue if there were a pathway for qualified applicants to apply for CON approval to acquire a provider-owned mobile MRI. As shown above, CNSA clearly demonstrates that it can support a second provider-owned mobile MRI; thus, approval of the proposed Policy TE-4 would enable qualified providers – such as CNSA – with highly utilized vendor-owned mobile MRI services to obtain a provider-owned mobile MRI, thereby ensuring permanent access to MRI services for its patients.

Value

This petition also promotes value. As noted above, the proposed Policy TE-4 will provide CNSA the opportunity to control and lower the cost of care for its patients. As noted previously, the growth and evolution of reimbursement models, such as Medicare Advantage and North Carolina Medicaid Managed Care, as well as the impacts of the ongoing COVID-19 pandemic are driving providers to decrease costs where possible to ensure they are able to continue providing high value, safe, and effective healthcare services to their patients. By acquiring its own mobile MRI, CNSA will be able to eliminate expenses associated with the contracted mobile MRI service and will have more control over cost containment. By containing costs where feasible, CNSA will have an increased ability to manage these changes in healthcare reimbursement.

CNSA appreciates your careful consideration of this petition. Please let us know if we can assist the Council, its committees, and the staff during the process.

Thank you.