



**Petition for an Adjusted Need Determination
For One Additional Mobile MRI Scanner in HSA III**

PETITIONER

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STATEMENT OF REQUESTED ADJUSTMENT

Carolina Neurosurgery & Spine Associates (CNSA) respectfully petitions the State Health Coordinating Council (SHCC) to create an adjusted need determination in the *2023 State Medical Facilities Plan (2023 SMFP)* for one additional mobile MRI scanner to serve Health Service Area (HSA) III.

BACKGROUND

CNSA is a medical and surgical physician practice, specializing in neurosurgery physical medicine & rehabilitation (physiatry), orthopaedic spine surgery, neurology and pain management. Established in 1940, CNSA is one of the oldest neurosurgical practices and is 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 be trained by its surgeons in these 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 provider 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 one fixed multi-position MRI and one mobile MRI. In addition, due to its high volume of imaging referrals, CNSA currently hosts a vendor-owned mobile MRI. However, due to the high demand

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for MRI services, particularly in HSA III, CNSA is unable to contract for additional vendor-owned mobile MRI services because of a lack of vendor capacity to provide another mobile MRI scanner to CNSA, as discussed in more detail below. The majority of CNSA's surgical patients require at least one MRI scan, as do many of its non-surgical patients. The need for timely, high quality MRI studies for these patients, many of whom are in pain or in need of surgery to resolve life-threatening illness or injury, creates an ongoing need for MRI scanners with sufficient capacity, operated by skilled technologists specially trained in performing brain, spine and other neurological studies. While vendor-provided mobile MRI service can address some of the need when volume or provider experience fall short of requiring full-time service, CNSA has fully utilized a vendor-owned mobile MRI scanner for many years and has successfully operated its own mobile MRI scanner for nearly two decades, along with the only fixed multi-position MRI scanner in the state. As detailed below, CNSA believes that another mobile MRI scanner is needed to serve residents of HSA III, demonstrated by the experience of CNSA, one of the largest independent physician providers of MRI service in the region. As the Agency is aware, there is no defined service areas for mobile MRI scanners. In the past, need determinations have been made for larger areas of the state, including multiple Health Service Areas, and CNSA does have offices in multiple HSAs. However, given the specific attributes of HSA III, described herein, CNSA believes that the requested adjustment is most needed in HSA III. While a need determination could be limited to a single county, such as Mecklenburg, CNSA also believes that a broader service area will ensure that the equipment can be well-utilized, while also preventing unnecessary duplication. As such, CNSA is requesting the mobile MRI scanner be designated to serve HSA III.

REASONS FOR THE REQUESTED ADJUSTMENT

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. A summer petition is required to place a need in the upcoming *SMFP*.” CNSA believes that a brief discussion of the recent 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 and the particular need for an additional mobile MRI scanner to serve HSA III.

As the SHCC is well aware, a workgroup convened starting in November 2021 to evaluate the current MRI methodology that 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 and appreciates the time and effort put forth by the members of the workgroup in developing its recommendation for revisions to the current MRI methodology, it continues to believe that there are times in which a need for an additional mobile MRI exists, particularly 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, detailed further below, at the end of its final meeting that convened on February 15, 2022, which was approved by the SHCC on April 6, 2022. Even though the SHCC has already approved the MRI workgroup's recommendation for revision of the current methodology, the workgroup's revised MRI Methodology 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. Notwithstanding the revision of the current methodology in the *Proposed 2023 SMFP*, which must receive final approval from the SHCC and the Governor before any changes to the current

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methodology are published in the *SMFP*, CNSA believes there remain issues with the current MRI methodology, specifically as it relates to mobile MRI scanners. While this petition does not propose to address those issues, the following discussion is provided as background to this petition for a special need adjustment.

Notably, in response to petitions from CNSA 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, apparently at least in part based on opposing comments from the largest statewide provider of MRI services using “grandfathered” scanners. In spring 2022, CNSA once again submitted a petition to the SHCC to include a new policy that would provide a pathway for a provider with a well-utilized mobile MRI to obtain another mobile MRI, and once more CNSA’s petition was denied, leaving no clear pathway for providers like CNSA with well-utilized mobile MRI scanners to apply to supplement their capacity, except through a need determination for a fixed MRI scanner in the *Proposed 2023 SMFP*. 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. Thus, following the SHCC’s recommendation made in conjunction with the denial of CNSA’s spring petition, namely that anyone wishing to apply for a mobile scanner should avail themselves of the existing summer petition process, CNSA is submitting this petition for an adjusted need determination for an additional mobile MRI scanner in HSA III in the *Proposed 2023 SMFP*. An adjusted need determination for an additional mobile MRI scanner in HSA III would enable CNSA or other potential mobile providers in the area to pursue CON approval for a provider-owned mobile MRI scanner. As discussed in detail below, the proposed mobile MRI scanner will enhance CNSA’s ability to ensure sufficient access and operate at a lower cost than if it were to continue relying on vendor-owned mobile MRI services or an additional fixed MRI that is unable to service the multiple CNSA sites through the service area.

Much like the current MRI methodology, the MRI workgroup’s recommendation for the MRI Methodology in the *Proposed 2023 SMFP* includes need thresholds arranged in tiers based on the number of fixed equivalent MRIs present in the service area. While the current (*2022 SMFP*) methodology states that annual maximum capacity of a single fixed MRI is 6,864 adjusted procedures annually (66 hours per week x 52 weeks per year x 1.8 procedures per hour) the MRI workgroup’s recommendation involves adjusting the annual maximum capacity of a single fixed MRI to 6,240 adjusted procedures annually (66 hours per week x 52 weeks per year x 1.8 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 for the MRI workgroup’s recommended MRI Methodology are included in the table below.

<i>Service Area Fixed Scanners</i>	<i>Adjusted Thresholds</i>	<i>Planning Threshold</i>
2+	4,992	80.0%
1	4,368	70.0%
0	1,872	30.0%

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What is not included in the table above is a planning threshold for mobile MRIs. Chapter 17 of the *Proposed 2023 SMFP* does not define capacity for mobile MRI scanners. However, according to 10A NCAC 14C .2703(b)(8), 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 by its third year of operation. 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 without an adjusted need determination. In addition, as the population and MRI volume in HSA III continue to grow, so too will the demand for the convenient, cost-effective, high quality MRI services provided by CNSA at each of its locations. The proposed adjusted need determination is the most reasonable alternative currently available for CNSA to supplement its mobile MRI capacity without relying on vendor-owned mobile MRI services or an additional fixed MRI scanner that cannot serve multiple sites.

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, as it is unable to provide service at any other sites due to capacity constraints. MRI services at CNSA's locations in Cabarrus and Guilford counties are provided through a vendor-owned mobile MRI service, Alliance HealthCare Radiology (Alliance). In addition, since Federal Fiscal Year (FFY) 2017, CNSA has contracted with Alliance to provide additional capacity at its Charlotte location as demand has increased. Further, CNSA is currently building new offices in Huntersville (opening in mid-2023) and Mt. Holly/Belmont (opening in 2024). Both of these new offices will open with a mobile pad in place, ready to serve patients locally, but without access to mobile MRI capacity, either through a vendor or a CNSA-owned scanner, as described in further detail below.

As shown in the table below, according to the Registration and Inventory of Medical Equipment forms, since FFY 2018, the vendor-owned mobile MRI has well exceeded the planning threshold of 3,328 weighted scans. In addition, since FFY 2016, the mobile MRI owned by CNSA has provided significantly more than the planning threshold, even doubling the planning threshold since FFY 2019. Further, CNSA's multi-position MRI has consistently exceeded 80 percent of its planning threshold of 3,364 scans¹.

¹ The CON regulations found at 10A NCAC 14C .2703(a)(7)(A) 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 projected at 3,364 or more adjusted MRI procedures.

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	FFY 2021
Cabarrus	Vendor-Owned Mobile	1,228	1,169	1,194	1,381	1,117	1,323
Guilford	Vendor-Owned Mobile	2,094	1,830	1,822	1,789	1,598	1,904
Mecklenburg – Charlotte	Vendor-Owned Mobile	-	245	786	1,404	1,294	1,400
Vendor-Owned Subtotal		3,322	3,244	3,801	4,575	4,009	4,627
Mecklenburg – Charlotte	CNSA-Owned Mobile	4,367	5,064	4,980	5,136	5,991	6,263
Mecklenburg – Ballantyne	CNSA-Owned Mobile	1,423	1,501	1,520	1,684	1,511	1,602
CNSA-Owned Mobile Subtotal		5,790	6,565	6,500	6,819	7,502	7,865
Mecklenburg – Charlotte	CNSA-Owned Fixed*	4,293	4,505	4,379	4,395	3,937	4,164
CNSA-Owned Mobile/Fixed Subtotal		10,082	11,070	10,879	11,215	11,439	12,029
CNSA/Vendor-Owned Grand Total		13,404	14,314	14,680	15,789	15,448	16,656

Source: LRAs.

*Fixed multi-position MRI scanner.

**Weighted scans were adjusted to match the *Proposed 2023 SMFP* need methodology weighting of 40/33 (1.21) for complex outpatients for all years that are shown above.

As shown above, CNSA’s fixed and mobile scanners along with the vendor-owned mobile MRI serving CNSA provided a combined total of over 16,000 total adjusted scans in FFY 2021. Based on the fixed MRI procedure thresholds discussed above, these three scanners operated at 89.0 percent of the total capacity of 6,240 adjusted procedures in FFY 2021 and have exceeded the 80 percent threshold (4,992 adjusted procedures per scanner in the aggregate) since FFY 2019, despite the pandemic-driven one-year decrease in FFY 2020. While this standard is not used to generate need for additional mobile scanners, it is further validation that CNSA has the volume to support this request. Of particular note, since FFY 2017, the volume performed on the vendor-owned mobile scanner has exceeded 100 percent of the CON rule standard for mobile MRI scanners.

While the SHCC may be aware of the number of legacy or “grandfathered” mobile MRI scanners present in the state, what should also be noted is the challenge faced by providers like CNSA in obtaining the necessary capacity for its patients. In order to remain compliant with federal and state regulations regarding physician referrals to ancillary services, a mobile MRI scanner used by CNSA must meet the “in-office exemption,” which includes the requirement that it is available full-time for the practice. In other words, unlike other providers, a practice like CNSA cannot benefit from a vendor with a single day available, or even multiple days, but must contract with the vendor to have the scanner available full-time. As can be confirmed using information provided on its Registration and Inventory Reports, Alliance reported using the same mobile MRI to serve CNSA’s locations in Cabarrus, Guilford, and Mecklenburg

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counties². In addition, Alliance reported that its mobile MRI only served CNSA locations, whereas most other mobile MRIs serve multiple providers. This information demonstrates the challenge CNSA faces in obtaining additional capacity from existing mobile MRI providers. In fact, over the past few years, CNSA has reached out to multiple mobile MRI vendors requesting the use of a scanner on a full-time basis, as required by regulations, but has been repeatedly told that capacity to provide the capacity of an entire scanner is unavailable. As recently as June 2022, CNSA received an email from Kristin Edwards, Alliance's Territory Director for North Carolina, who wrote in part,

"I've spent time working with our internal team to determine if we are able to fulfill your request for a second MRI unit. Unfortunately, at this time we do not have a CON available to provide additional time for you and your team. We are continuously evaluating the units and the routing and you are certainly a priority for us, so we will be sure to keep you informed with timelines for when we anticipate an additional unit will become available."

Even though Alliance owns more mobile MRI scanners than any other provider in the state, particularly "grandfathered" units, it is unable to meet the need for additional capacity to serve CNSA patients.

Alliance has also had issues maintaining the existing full-time schedule on the scanners that currently serve CNSA. As recent as the week this petition was submitted, Alliance had to cancel one day of service, the second such recent occurrence, due to staffing issues. While CNSA understands the incredible challenges all healthcare providers face given the ongoing labor shortage, it believes that owning another mobile MRI scanner, rather than relying on a vendor, would allow it to better ensure uninterrupted service for its patients. In particular, CNSA would not have to balance the schedules of other providers for its MRI technologists, as Alliance must. Of note, to date CNSA has not experienced similar issues with staffing the fixed and mobile MRI scanners it owns.

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. 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 petitions in 2020 and 2022, driven by its own financial interests. However, the sheer volume of scans provided by CNSA using the vendor-owned mobile MRI, along with the inability of Alliance and other mobile MRI vendors to provide additional capacity is evidence that CNSA needs the ability to apply for a CON for a second mobile MRI.

Not only does CNSA demonstrate that it can support a second CNSA-owned mobile MRI today, but there are also 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. Approval of this petition will allow CNSA to apply for a CON for another mobile MRI, which, if

² 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.

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approved, would provide a more cost-effective solution to expanding access to MRI services for its patients compared to contracting with a mobile vendor, even if a vendor could provide another scanner.

MRI Volume Growth in Mecklenburg County

The previous discussion highlights the particular issues that have driven CNSA's efforts to allow it to apply for another mobile MRI scanner. CNSA recognizes, however, that approval of the petition would allow anyone to apply for a mobile MRI scanner to serve sites in HSA III. While there is no methodology for mobile MRI scanners, as noted above, the growth in overall MRI volume in HSA III and in Mecklenburg County in particular indicate that the allocation of another mobile MRI scanner would not result in unnecessary duplication; rather, the approval of the petition would provide additional capacity to meet the growing MRI volume in the region, which is not addressed by the current methodology.

From the *2016 SMFP* to the *2022 SMFP*, there have been a total of 23 MRI need determinations across the state, and counties within HSA III have accounted for eight of the 23, or 35 percent. While HSA III is more highly populated than most of the other HSAs, according to the North Carolina Office of State Budget and Management (OSBM), in 2023, HSA III has a population of 2,406,414 of the state's total population of 10,743,629, or 22 percent³. Thus, HSA III includes just 22 percent of the state's population but has accounted for 35 percent of the MRI need determinations over the past several years.

Within HSA III, Mecklenburg County is overwhelmingly the most populous county, accounting for nearly one-half (49 percent) of the HSA's population, and patients from each of the HSA counties and beyond receive MRI services in the county. Since the *2016 SMFP*, there has been a need determination for at least one additional fixed MRI scanner in HSA III each year, and in all but 2018, Mecklenburg County has had a need for one of those scanners⁴. Of the 23 total statewide need determinations since 2016, Mecklenburg County accounts for eight of those, or 26 percent. The second highest number of need determinations was three in Wake County over the same period. While a portion of this need has been driven by the strong population growth in the area, the growth in MRI scans has been even higher. From the *2016 SMFP* to the *2022 SMFP*, unadjusted MRI scans in the Mecklenburg County service area have grown from 101,680 to 127,152, or 3.8 percent, compared to the population growth of 1.5 percent, per OSBM.

CNSA understands that there are numerous reasons for the growth in MRI volume in HSA III and Mecklenburg County, and that the need methodology for fixed MRI scanners is designed to address much of this growth. However, CNSA believes it is clear that the approval of this petition and the allocation of an additional mobile MRI scanner in the region is appropriate, given the long-term trend of MRI volume growth in HSA III, particularly Mecklenburg County.

³ Source: North Carolina OSBM, Standard Population Estimates, Vintage 2020 and Population Projections, Vintage 2021, updated January 27, 2022

⁴ CNSA notes that the *Proposed 2023 SMFP* does not include a need determination for Mecklenburg County. However, during the development of this petition, it discovered that an internal staffing change had led to an inadvertent delay in submitting its Registration and Inventory of Medical Equipment forms for 2023. That omission has been corrected, which will increase the adjusted scans per MRI scanner in the service area.

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 Doshier 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

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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. The proposed adjusted need determination for one additional mobile MRI scanner in HSA III in the *Proposed 2023 SMFP* would offer CNSA an opportunity to apply for a CON to develop an additional provider-owned mobile MRI scanner to serve the greater Charlotte region, for many of the same reasons expressed by these other providers.

Adverse Effects on Patients If the Petition Is not Approved

Without the approval of this petition, CNSA will not be able to obtain its own additional mobile MRI scanner 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 technologists 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 by acquiring a provider-owned mobile MRI through an adjusted need determination for one additional mobile MRI scanner in HSA III in the *Proposed 2023 SMFP*. 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 and the other existing and newly-developed locations.

In addition, as noted above, the ability of CNSA or any physician practice to contract with a mobile vendor for MRI service to Medicare and Medicaid patients is limited by law to scanners for which the practice has 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 only find any mobile MRI scanner with available capacity, it must also 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 establish an adjusted need determination for an additional mobile MRI scanner in HSA III may result in 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

Recommend Changes to the MRI Methodology/New MRI Policy

As the SHCC is aware, CNSA filed a petition in 2020 and 2022 in the spring cycle requesting the addition of a new *SMFP* policy that would enable it to apply for another mobile MRI scanner. Both petitions were denied, and the Policy TE-4 that was drafted for the *Proposed 2021 SMFP* was ultimately removed before the final *2021 SMFP* was adopted. While CNSA is appreciative of the SHCC and Healthcare Planning staff for forming a workgroup to evaluate and update the MRI need methodology in the *Proposed 2023 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 new MRI methodology does not include or address any new alternative pathway through which a provider can develop a mobile MRI scanner. Moreover, in its response to CNSA's 2022 spring petition, the SHCC recommended that CNSA consider a summer special need adjustment petition given the somewhat limited and unique need that it described in its previous petitions. Therefore, CNSA believes that another petition to change the methodology or develop a new policy is not the best alternative at present.

File for a Fixed MRI Scanner Need Determination

CNSA also 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. Although volume at its mobile MRI sites is increasing, the only location where CNSA could likely support an additional fixed MRI at present 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. Moreover, the Healthcare Planning and Certificate of Need Section has recently determined that applications for a fixed MRI to replace an existing vendor-owned MRI scanner (as CNSA would be proposing to do in this instance) are less effective than providers proposing a new fixed MRI scanner that would not replace a vendor-owned MRI scanner. Please see pages 81 and 82 of the Agency Findings for the 2021 Wake County MRI review for this determination⁵. Thus, even if it were to apply for a fixed MRI scanner to "replace" the vendor-owned capacity, the Healthcare Planning and Certificate of Need Section itself has deemed that application to be a less effective alternative in a CON review, thereby diminishing CNSA's likelihood of success if it pursued this alternative. As such, the better alternative is to request a special need determination for a mobile MRI scanner for which CNSA could apply.

EVIDENCE THAT THE PROPOSED CHANGE WOULD NOT RESULT IN UNNECESSARY DUPLICATION

CNSA believes that the proposed additional mobile MRI scanner avoids unnecessary duplication in HSA III. Today, many of the mobile MRIs serving North Carolina sites are legacy or "grandfathered"; thus, they are not beholden to any CON conditions or limitations. Of note, mobile MRIs with "grandfathered" status are

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<https://info.ncdhhs.gov/dhsr/coneed/decisions/2021/sept/findings/2021%20Wake%20MRI%20Review%20Findings.pdf>

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able to relocate anywhere across the state or out of the state without CON approval. Further, as noted above, other mobile MRI vendors have indicated that they do not have sufficient capacity to provide CNSA with a full-time scanner, which indicates that while some capacity may exist in areas of the state, providers serving HSA III have limited MRI capacity. In addition, the analysis presented above demonstrates that MRI volume in HSA III, and Mecklenburg County in particular, is growing, and the approval of a mobile MRI scanner in the region will not substantially impact existing providers, create underutilized scanners, or result in unnecessary duplication.

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.

Safety and Quality

By acquiring its own mobile MRI, CNSA will have more control and oversight of the staff and technologist(s) that operate the scanner. Currently, the vendor-owned mobile MRI service provides its own staff and technologists, for 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 technologists 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 technologists 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. As stated above, CNSA has recently had issues with Alliance being able to maintain a full-time schedule on its mobile MRI scanner due to staffing issues; CNSA believes these challenges can be better managed through ownership of its own additional mobile MRI scanner rather than contracting with a vendor for another full-time mobile scanner, even if one were available.

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 some of this potential access issue by acquiring a provider-owned mobile MRI through an adjusted need determination for one additional mobile MRI scanner in HSA III in the *Proposed 2023 SMFP*. As shown above, CNSA clearly demonstrates that it can support a second provider-owned mobile MRI; thus, approval of this petition would provide a pathway through which providers in HSA III that can fully utilize

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additional mobile MRI services – such as CNSA – can 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 additional mobile MRI scanner 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, 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 additional mobile MRI, CNSA will be able to reduce expenses that would be incurred if it contracted with a vendor for another full-time mobile scanner, even if one were available, 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.