



**Comments to the Healthcare Planning and Certificate of Need Section and
Acute Care Services Committee of the State Health Coordinating Council in Response
to Petition of EmergeOrtho/Blue Ridge Division for Buncombe/Madison/Yancey Operating Rooms**

March 21, 2019

Background

MH Hospital Manager, LLC d/b/a Mission Health (“Mission Health”) is a longstanding hospital and freestanding provider of outpatient surgery services in the Buncombe, Madison, Yancey County service area. Recently, Mission Health has become an affiliate of HCA Healthcare, Inc., a leading provider of hospital and outpatient surgery services in the United States. HCA operates more than 180 hospitals and approximately 120 freestanding ambulatory surgery centers across the United States. Mission currently operates hospital-based ORs in the Buncombe, Madison, Yancey service area. As such, both HCA and Mission Health are very familiar with the surgical needs of this community as well as state-wide and national trends in utilization, reimbursement, and cost of outpatient surgery services.

Mission Health appreciates the opportunity to provide comments in response to the petition filed by EmergeOrtho / Blue Ridge Division (“EmergeOrtho”) for a demonstration project in Buncombe, Madison, and Yancey Counties (“Service Area”) for a single-specialty orthopaedic, two-operating room, ambulatory surgery center (“ASC”). Mission Health offers the following comments.

EmergeOrtho’s Petition is Not a “Demonstration Project”

EmergeOrtho characterizes its Petition as requesting a “demonstration project.” In the past, parties have petitioned the State Health Coordinating Council (“SHCC”) to allow for inclusion of unique projects in a State Medical Facilities Plan (“SMFP”) when the applicable health planning rules and methodology did not consider or recognize distinctive features of a project and when the traditional need methodology would not allow for approval of such an unusual project. EmergeOrtho’s petition does not represent such a unique health planning situation. In fact, EmergeOrtho’s petition recognizes that the 2010 SMFP has already considered single-specialty ASC projects. (See page 3.) EmergeOrtho’s Petition fails to identify what it purports to “demonstrate” through the successful implementation of its proposed project, other than the addition of two operating rooms in an ASC facility in Buncombe County that focuses on orthopaedic procedures. That is not new. Prior demonstration projects have typically involved new or unique service offerings not regularly provided in or through existing facilities in North Carolina. Examples include but are not limited to single-specialty dental ASCs, fixed extremity MRIs, intraoperative radiation oncology MRIs, and a multi-modality prostate cancer center.

The Proposed “Demonstration Project” Already Exists

EmergeOrtho’s petition does not propose a type of healthcare facility that does not currently exist in the Service Area or multiple areas of the state and therefore its proposal does not represent a “demonstration project”. If the point of EmmergeOrtho’s demonstration project is to provide a freestanding, single specialty ASC, then these facilities exist in the Service Area and throughout the State. Orthopaedic Surgery Center of Asheville is an existing, single-specialty orthopaedic ASC operating in Buncombe County. Also, Asheville Eye Surgery Center operates as a single-specialty, freestanding ASC in the Service Area. Additionally, multiple single-specialty ASCs operate throughout the State including other orthopaedic, single-specialty ASCs in Raleigh/Wake County for example. Not only are there existing single-specialty ASCs and single-specialty orthopaedic ASCs that exist in the Service Area, but EmmergeOrtho also already operates Triangle Orthopedics Surgery Center (Wake County) and is approved for and constructing Brunswick Surgery Center.¹ Moreover, Triangle Orthopedic Surgery Center, LLC, affiliated with EmmergeOrtho, is one of the three recognized single-specialty ASC demonstration projects authorized by a prior SMFP.² EmmergeOrtho’s petition fails to include this fact in its petition. There is nothing unique proposed by EmmergeOrtho as either a single-specialty, freestanding, or freestanding ASC that warrants a “demonstration project” since these types of facilities already exist in the Service Area and throughout the State. In fact, EmmergeOrtho already has been approved for and is currently operating the exact same demonstration project in Wake County.

There are No Unique Aspects of the Project That Represent a Demonstration Project

EmergeOrtho’s petition mentions the participation of EmmergeOrtho physicians in the CMS Bundled Payment Care Initiatives (“BCPI”) as an aspect of its project but in no way does it link this participation to the demonstration project requested. There are other surgery providers that participate in bundled payment initiatives. If the bundled payment aspect of the project is unique, which EmmergeOrtho has not shown, then the demonstration project should be for ASCs participating in CMS Bundled Payment initiatives and should be open to any applicant seeking to demonstrate the potential for cost effectiveness of such a center anywhere in the State. Again, EmmergeOrtho operates one ASC in Wake County and is constructing another in Brunswick County, so to the extent EmmergeOrtho has linked the proposed demonstration project to a BCPI, EmmergeOrtho already has two locations with which to demonstrate any relevant benefits of such a linkage. It should also be noted that not just physician groups, but also hospitals, can participate in bundled payment initiatives. Mission Hospital is a participant in the BPCI Advance model.³ Again, there is nothing unique about EmmergeOrtho’s proposal that warrants a demonstration project and EmmergeOrtho already operates an identical demonstration project in Wake County.

EmmergeOrtho’s Petition Represents a Specific Project That Only it Can Develop

Typically, a recognition of a demonstration project in the SMFP allows for multiple applicants and is not so constrained as to essentially set forth a project for a sole applicant. In this instance, EmmergeOrtho sets

¹ <https://emmergeortho.com/?s=surgery+center>

² 2019 SMFP page 86.

³ <https://innovation.cms.gov/initiatives/map>

forth a very specific project, location, and applicant/entity to meet its goals of developing specifically an orthopaedic ASC in Buncombe County. The Petition does not propose a general plan for allowing review of multiple applicants proposing to address a designated unique demonstration project. In essence, EmergeOrtho sets forth a highly-limited project definition for which only it can apply. This is not the purpose of recognizing a demonstration project in the SMFP.

EmergeOrtho's Petition Demonstrates That the General CON Process is Appropriate for its Project

EmergeOrtho's petition includes and references large sections of a CON application filed by Blue Ridge Outpatient Surgery Center, LLC on May 15, 2018 in response to a recognized need in Buncombe County for additional ORs in the 2018 SMFP (CON #B-11515-18 – Petition Appendix 1). Page 10 of the application provides direct linkage of this CON application to EmergeOrtho. EmergeOrtho's application was denied. EmergeOrtho's own May 15, 2018 application demonstrates that there are no unique circumstances appropriate for a demonstration project that could not and have not appropriately been considered through the traditional CON application process. Not only was EmergeOrtho's project reasonably considered through the traditional CON process in 2018 but EmergeOrtho has also filed CON applications and been approved for a single-specialty, orthopaedic ASC through the traditional CON process for its ASC in Brunswick County. The 2018 EmergeOrtho CON application which is referenced in the Petition is currently under appeal before the Office of Administrative Hearings. So, in other words, EmergeOrtho has: i) used the traditional CON application process to seek this precise same project; ii) failed to be approved via the traditional CON review process; iii) appealed that decision which appeal is ongoing; and iv) simultaneously filed a Petition with the SHCC to obtain the same exact thing it has failed to obtain via the normal CON process. EmergeOrtho has not demonstrated in its petition that there is a unique demonstration project that cannot and should not be appropriately considered through the traditional SMFP need methodology and CON application process.

Historical SHCC Considerations and SMFPs are Irrelevant and Misrepresented in This Consideration

EmergeOrtho suggests that the Service Area has somehow been slighted by the SHCC in the planning process for the 2010 SMFP in the original recognition of single-specialty ASC demonstration projects and since. (See Petition pages 5-7.) Most importantly, EmergeOrtho fails to acknowledge that both in 2010 and currently there are two single specialty ASCs already existing in Buncombe County, including the existing Orthopaedic Surgery Center of Asheville. The continuous presence of two existing single-specialty ASCs in Buncombe County for years completely undermines EmergeOrtho's suggestion that somehow Buncombe County has not been appropriately considered for single-specialty ASC projects by the SHCC.

It is important to consider that EmergeOrtho admittedly has petitioned the SHCC for multiple years for a single-specialty, orthopaedic ASC, which has been denied each time. Nothing has changed since EmergeOrtho's last petition. The *2010 SMFP* outlined criteria for the three Demonstration Project facilities that the SMFP authorized. On page 85 of the 2010 SMFP, the following Criterion was defined for the Demonstration Project facilities, with emphasis added:

*“The Agency will evaluate each facility **after each facility has been in operation for five years.** **If** the Agency determines that the facilities are meeting or exceeding all criteria, the work group encourages the SHCC to consider allowing expansion of single specialty ambulatory surgical facilities beyond the three demonstration sites.”*

As previously found by the SHCC, the three, original single-specialty ASC demonstration projects have still not operated for a full five operating years and therefore the results of the demonstration project cannot yet be evaluated by the SHCC. In fact, University Surgery Center, LLC d/b/a Mallard Creek Surgery Center, was the last to be licensed in May 2014 and has not reported a full five years of operation.⁴ Thus, EmergeOrtho is again asking the SHCC to prematurely recognize another single-specialty ASC demonstration project when its own affiliated ASC has not reported a full five-years of operations to be evaluated.

An evaluation of Triangle Orthopedic Surgery Center’s fourth operating year (2018 Licensure Renewal Application) reveals that the entity provided 2.2% of care to self-pay/charity patients and 4.7% of care to Medicaid recipients. This level of financial accessibility is hardly convincing in terms of the success of the original demonstration project criteria. The 2010 SMFP sets forth the following criteria:

Each demonstration project facility shall provide care to the indigent population, as described below:

The percentage of the facility’s total collected revenue that is attributed to self-pay and Medicaid revenue shall be at least seven percent, which shall be calculated as follows:

The Medicare allowable amount for self-pay and Medicaid surgical cases minus all revenue collected from self-pay and Medicaid cases divided by the total collected revenues for all surgical cases performed in the facility. [Emphasis added.] (2010 SMFP Chapter 6, Table 6D.)

Total care provided by Triangle Orthopedic Surgery Center to Medicaid and charity care patients accounted for just 6.98% of total patients for year-end September 2018. It is also notable that Triangle Orthopedic Surgery Center’s Medicaid and charity care patient percentage has dropped since its early reporting years as shown below.

Triangle Orthopedic Surgery Center, LLC						
Reported Self Pay/Charity Care Patient and Medicare Patient Percentage						
	Year 1	Year 2	Year 3	Year 4	Year 5	2018 LRA
Percent Self Pay/Chairity	4.11%	2.43%	2.55%	2.62%	2.32%	2.22%
Percent Medicaid	11.08%	14.16%	4.12%	4.82%	4.88%	4.76%
Total	15.19%	16.59%	6.67%	7.44%	7.20%	6.98%

Source: Ambulatory Surgery Licensure Renewal Application 2018, Single Specialty Demonstration Project Annual Evaluations.

⁴ 2019 SMFP page 86.

By contrast, Mission Health’s hospital-based Asheville Surgery Center provided a combined 29.1% of care to self-pay/charity and Medicaid outpatient surgery cases. EmergeOrtho, through its affiliate Triangle Surgery Center, has hardly established the success of its existing demonstration project sufficient to warrant the recognition by the SHCC of another demonstration project.

Surgery Provider Access and Choice are Appropriately Considered in the Traditional Need Methodology and CON Process

EmergeOrtho suggests that the Service Area lacks access and choice of surgical care options and that the proposed demonstration project would remedy this concern. (See Petition pages 7-8.) In part, EmergeOrtho’s argument is based on the fact that Mission Health is the largest provider of surgical services in the service area. This fact is not relevant under the current OR need methodology. Again, EmergeOrtho fails to note that there is an existing single-specialty, orthopedic ASC in the Service Area that provides a choice to hospital surgery services.

The current methodology set forth in the 2018 SMFP continues to let any applicant apply for an identified need and not just those existing providers whose utilization may generate the need. This is now more true than in the past. The 2018 and 2019 SMFP need methodology groups the need calculation by health system resulting in a recognition of need within one system despite a surplus of ORs within other systems or single providers. Under the current methodology, there is no net need calculated at a service area level. This change has resulted in more need recognized within the 2018 and 2019 SMFPs, which EmergeOrtho was able to specifically take advantage of in 2018 by applying via the normal CON application process for the very project it now proposes as a “demonstration project”. In other words, under prior SMFP methodologies, a “need” determination generated by one provider’s utilization and capacity numbers could be essentially wiped out by the excess capacity of another provider in the same service area. Under the current methodology, that is no longer true and each “system” within the service area is considered independently in terms of need.

Also notably, Mission Health did not apply for the OR need recognized in the 2018 SMFP further allowing for provider choice. EmergeOrtho simply lost its bid to develop its project presented in CON #B-11515-18. That loss does not indicate a lack of choice or opportunity in Buncombe County. EmergeOrtho’s appropriate remedy is to appeal its CON denial.

Cost Effectiveness, Quality, and High-Volume Specialty Arguments are Appropriately Considered by the CON Section in CON Review

EmergeOrtho sets forth the benefits of freestanding ASC services and the volume of outpatient surgery, including orthopaedic surgery, as a basis for its demonstration project. (See Petition page 8-10.) These factors can be and have been recognized by the CON Section in its review of CON applications for new ASCs. The current OR need methodology again more than ever allows for new ASCs to be proposed and considered through the CON application process. In multiple service areas for which there was need in the 2018 SMFP, the need was generated by a hospital system. However, because there is no net need calculation for an entire service area, and any party is able to apply for an identified need, multiple ASC applications were submitted, and many were approved.

The CON Section has the ability to consider arguments of cost effectiveness, quality, and advantages of freestanding, single-specialty ASCs in these competitive reviews and they have done so in approving additional new freestanding ASCs and ORs additions in these settings. While EmergeOrtho touts its experience, cost effectiveness, and quality of care as a basis for its petition, these same arguments and factors were set forth in its 2018 CON application. Again, there is no unique circumstance in the Service Area and nothing unique about EmergeOrtho's project that cannot be reasonably and appropriately considered by the CON Section in the traditional CON review process under the current need methodology.

EmergeOrtho's Petition Would Result in Direct Duplication of Existing Services

Throughout its petition, EmergeOrtho fails to consider that there is an existing single-specialty, orthopaedic ASC in the Service Area, Orthopaedic Surgery Center of Asheville. There is an existing choice, which is a directly comparable facility in the Service Area. EmergeOrtho's project would directly duplicate this existing facility. Orthopaedic Surgery Center of Asheville was approved for two more ORs in response to the identified need in the 2018 SMFP. These ORs have not yet been developed. EmergeOrtho's proposal would directly duplicate the two new ORs to be developed by Orthopaedic Surgery Center of Asheville.

Emerge Ortho's Petition is an Inappropriate Response to a Failed CON Application

EmergeOrtho's CON application, part of which is attached to its Petition as Appendix A, was denied in a competitive CON review, in which Orthopaedic Surgery Center of Asheville prevailed. Now EmergeOrtho presents a petition for the very same project for which it was denied as a "demonstration project". As described in detail above there is nothing unique about EmergeOrtho's project or in the Service Area that would constitute or warrant a "demonstration project". Further the project described is so narrow that only the petitioner could apply. This is not the point of a demonstration project. The appropriate remedy for EmergeOrtho is for it to appeal the denial of its CON application. If the SHCC recognizes EmergeOrtho's petition, it sets a precedent that denied CON applicants can essentially seek approval or remedy through the SMFP planning process. This is not the purpose of a demonstration project. For all the reasons stated above, Mission Health requests that the SHCC deny the EmergeOrtho Petition.