Craven
HEALTH CARE
CRAVEN REGIONAL MEDICAL CENTER

Comments in Opposition to the Petition from Affordable Health Care Facilities, LLC and Jay Bradley, MD

March 18, 2009

Craven Regional Medical Center (CRMC) is hereby providing comments on the petition filed by Affordable Health Care Facilities, LLC (AHCF) and Jay Bradley, MD for a revision in the SMFP need methodology related to the development of pilot demonstration ASCs. Our comments are organized to concisely provide the background and context for review of the petition and our specific rationale for denial of the petition. As appropriate, we ask that you accept this information in the nature of comments on the AHCF petition for a revision to the SMFP methodology.

First and foremost, CRMC would like to note that AHCF's petition has not been timely filed. While AHCF's petition notes a number of concerns with the Single Specialty Ambulatory Surgery Work Group's recommendations regarding the concept of single special ambulatory surgery centers in North Carolina, CRMC maintains that such concerns are premature given that the Work Group has yet to present its final recommendations to the Acute Care Services Committee. The Work Group has until April 30, 2009 to present its recommendations to the Acute Care Services Committee and until such time as its recommendations are finalized, concerns regarding any preliminary recommendations or discussions are premature. Notwithstanding the untimely nature of AHCF's petition, CRMC opposes the petition based on reasons discussed in the comments below and recommends the petition be denied.

Background and Context for Review of the Petition

As outlined below, the current AHCF petition follows the submission of its March 5, 2008 petition and the subsequent creation of a Single Specialty Ambulatory Surgery Work Group. AHCF's petition has been filed in direct response to discussions and preliminary recommendations made by the Work Group.

AHCF's March 5, 2008 Petition

On March 5, 2008, AHCF submitted a petition requesting a change to the need methodology for ambulatory surgical operating rooms. The petition included discussion of ten key premises outlining its suggested approach for a new methodology.[1] The AHCF noted that the change was necessary to "provide more price competition, increased patient access and choice, and transparency of actual service purchase costs through a managed approach allowing for increased levels of price competition, while accounting for such factors as care for indigent populations and the fragility of rural health care delivery."

Creation of the Single Specialty Ambulatory Surgery Work Group

Subsequently thereafter on November 10, 2008, notice was issued that upon the recommendation of the Acute Care Services Committee and as approved by the North Carolina State Health Coordinating Council (SHCC), a Single Specialty Ambulatory Surgery Work Group was created consisting of the following membership: Lawrence Cutchin, MD; Sandra Greene, DrPH; and Charles Hauser, appointed by Dr. Dan Myers, SHCC Chairman. The Work Group was charged to:

- Develop a plan to evaluate and test the concept of single special ambulatory surgery centers in North Carolina;
- Formulate recommendations regarding the number of sites and potential geographic locations for pilot projects;
- Identify measures that can be used to evaluate the success of the pilot projects, to include measures of value, access to the uninsured, and quality and safety of care; and
- Recommend how the test sites will be held accountable and responsible in the event they are unsuccessful in meeting target guidelines.

The Work Group was further instructed to present its recommendations to the Acute Care Services Committee by April 30, 2009 for consideration and referral to the SHCC for inclusion in the Draft 2010 State Medical Facilities Plan.

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1 The ten premises, also discussed in ACHF's revised 2009 petition include: capital cost; indigent care and community safety net; rural counties and service areas; excessive cost counties and service areas; price ceiling limits, disclosure, and transparency for new facilities; single specialty facilities; demonstrated volume; and physician commitment to "call" coverage.

The Single Specialty Ambulatory Surgery Work Group met on November 17, 2008 and on January 26, 2009. To-date, the Work Group has yet to present any final recommendations to the Acute Care Services Committee. In fact, the Work Group is scheduled to reconvene on March 30, 2009.

ACHF's Revised March 4, 2009 Petition

The revised petition filed by AHCF and Jay Bradley, MD proposes to change the SMFP need methodology related to the development of pilot demonstration ASCs to include the following major premises from its original petition, which it maintains were ignored: price disclosure, facility charge limitations, and no limitation on the number of pilot demonstration facility sites. In particular, the ACHF cited the SMFP's core principles—quality, access, and value—as driving the need for its proposed changes.

Specific Rationale for Denial of the Petition

- CRMC opposes AHCF's petition because the Work Group upon whose preliminary recommendations AHCF bases its petition has not made its final recommendations to the Acute Care Services Committee. Until such time as the Work Group presents its final recommendations to the Acute Care Services Committee and it has an opportunity to review and act on the final recommendations, a petition to revise the methodology, which has not been finalized, is untimely. While CRMC does not dispute the fact that "[a]nyone who finds that the SMFP's policies or methodologies, or the results of their application, are inappropriate may petition for changes or revisions[,]" see page 9 of the 2009 SMFP, the fact remains that, despite AHCF's petition to revise the methodology, the need methodology related to the development of pilot demonstration ASCs cannot be revised until it exists.

- Regardless of the untimely nature of the petition filed by AHCF and Dr. Jay Bradley, MD, the petition also fails to adequately demonstrate the need to revise the SMFP need methodology related to the development of pilot demonstration ASCs. Please note that CRMC maintains that the need methodology has not been finalized, or even proposed for that matter;[2] however, for the sake of argument, CRMC considered AHCF's petition in light of the Work Group's preliminary recommendations and discussions to-date. Therefore, while CRMC

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2 Not only has the Single Specialty Ambulatory Surgery Work Group not made its final presentation and recommendation to the Acute Care Services Committee, but also, the Acute Care Services Committee has not had the opportunity to review and act upon the recommendation of the Work Group.

may refer to the Work Group's recommendations in its discussion of the petition, this is in no way meant to infer that such preliminary recommendations constitute final recommendations or methodology, as AHCF would suggest. While AHCF's petition requests changes to the need methodology, it is lacking adequate justification for such revisions, which the SHCC considered in conjunction with its original petition submitted in March of 2008. Instead, AHCF spends a large portion of its petition relaying its numerous concerns with CON regulations. CRMC believes that AHCF's strong anti-CON sentiment is improper basis and discussion for a petition requesting a change in methodology submitted to the SHCC.

- The comments made by Dr. Bradley in his presentation of the petition address issues outside of the purview of the SHCC. A vast majority of the issues cited by Dr. Bradley relate to what he represents to be the negative impact of CON regulation on:

  - Physician owned ASCs;
  - Physician recruitment;
  - Hospitals and other licensed facilities incentive to become more efficient or lower costs;
  - Reimbursement imbalance between facilities.

  CRMC maintains that presenting these issues to the SHCC in a petition requesting a change in the SMFP methodology is not the proper forum to address Dr. Bradley's concerns. Further, the resolution proposed by Dr. Bradley and AHCF does not address the very concerns (see list above for example) it raises. According to Dr. Bradley, his major concern is that hospitals are unfairly favored over physicians. However, it is unclear how the Work Group's preliminary recommendation has any impact whatsoever on the major concern voiced by Dr. Bradley. That is, Dr. Bradley fails to point to any portion of the Work Group's preliminary recommendation that could (given its charge) or even does address or impact discrepancies between hospitals and physicians. Moreover, the petition itself falls short of addressing its own concerns because the petitioning process is not the proper forum to make the type of changes necessary to address the concerns noted in the petition.

- Several complaints AHCF mentions in its petition are outside of the purview of the SHCC. The complaints include, but are not limited to the following:

- CON regulation has been ineffective at slowing the growth of health care costs in North Carolina;
- Inefficient hospital operations are shielded by CON—market place protection enables hospitals to be reimbursed on a discount off of charge basis;
- The disparate pricing environment has allowed North Carolina hospitals to make excessive earnings—evidenced by their continued expansion and building construction;
- The members of the SHCC are not held to the standards in the State Government Ethics Act.

These complaints are clear evidence of AHCF's anti-CON bias; however, none of them are appropriate for the SHCC to consider. Moreover, the complaints are unfounded, as explained below:

- Health care costs are rising in all states; however, ACHF presents no data to show that CON laws have not had an impact at lowering the growth of these costs in CON states. In contrast, costs in CON states have been shown to be lower than in non-CON states. In fact, studies conducted by the three largest US automakers indicate that CON laws are effective at lowering health care costs.[3]
- Like hospitals in other states, North Carolina hospitals also struggle to maintain a strong enough bottom line to continue to maintain their physical plant and invest in technology, while also providing care to uninsured and indigent.
- The expansion of existing hospitals and the construction of new facilities is evidence of the tremendous growth of the state and the need for adequate space to care for a growing number of patients, as well as the hospitals' commitment to reinvesting in the communities they serve.
- The Governor recently addressed the SHCC's ethical standards through an Executive Order.

AHCF cites three of the ten core tenets from its petition submitted in March 2008 that it believes the Single Specialty Ambulatory Surgery Work Group failed to address: (1) Price competition for area hospitals and other facility providers; (2) Price ceiling limits, disclosure, and transparency for CON applicant facilities; and (3) No limitation as to the number of CON applicant facilities. CRMC will address each of these tenets in turn.

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3 Available at http://www.dhss.mo.gov/con/conbenefits.pdf.

(1) Price competition for area hospitals and other facility providers

ACHF makes several claims regarding hospital-based charges compared to ASC charges. CRMC acknowledges that CMS reimbursement for hospital-based outpatient surgery is higher than that for ASCs; however, that fact is based in part on CMS' understanding that hospitals are required to care for a larger share of uninsured and charity cases for which they are not reimbursed. Enabling the development of multiple single-specialty ASCs around the state will not change CMS reimbursement for these facilities.

(2) Price ceiling limits, disclosure, and transparency for CON applicant facilities

AHCF's petition fails to properly acknowledge the reporting mechanisms that are in place. At its November 17, 2008 meeting, the Work Group discussed what to require of demonstration facilities and how to measure project effectiveness, discussion points included:

- Requiring compliance with all DHSR licensure requirements and accreditation
- Requiring cost projections comparable to or less than the costs of existing ambulatory surgery providers
- Requiring facilities to submit top 20 procedures annually to DHSR
- Requiring facilities to develop clinical guidelines and outcome measures as part of CON process

Contrary to AHCF's concerns, the Work Group did discuss measures to ensure transparency and promote the three basic principles of quality, access, and value.

(3) No limitation as to the number of CON applicant facilities

In discussing the potential locations for the facilities, the Work Group initially considered locating a pilot project in each Health Service Area (HSA); however, following input from the Agency (cautioning against such an approach, especially with regard to HSA VI), the Work Group settled on recommending fewer demonstrations (a total of three) with more operating rooms. Following its meeting on November 17, 2008, the Work Group

preliminarily recommended that one facility be located in each of the following groups of counties (for a total of three facilities):

- Mecklenburg, Cabarrus and Union counties
- Guilford and Forsyth counties
- Wake, Durham and Orange counties

The Work Group's preliminary recommendation does not limit the number of facilities that may apply; rather, it serves to limit the number of qualified applicants and places a determinative limitation on the number of facilities that can ultimately be approved. While the Work Group's preliminary recommendation does not place a limit on the number of qualified applicants that may apply to meet the demonstration project, it does limit the number of pilot projects to be developed. CRMC believes that such a limitation is necessary to ensure that the efficacy of such projects is adequately assessed prior to mass implementation. Further, as discussed by the Work Group, locating the facilities in areas where existing operating rooms are currently underutilized would not be prudent.

- Although AHCF only singles out three of the ten core tenets from its petition submitted in March 2008 that it believes the Work Group failed to address, it nonetheless restates all of the remaining tenets from its original petition in its revised 2009 petition. As such, CRMC will address those tenets that present cause for concern.

Indigent Care and Community Safety Net

AHCF suggests requiring ASCs to agree to have at least five percent of their total patient load being charity or indigent care. AHCF notes that in FY 2007 it estimated that hospital charity care plus self-pay and private-pay patient totals for ambulatory surgery cases were four percent. As discussed by the Work Group, unlike hospitals, ASCs are not required to serve the indigent. Therefore, the amount of indigent care ASCs provide on average is far less than the amount provided on average by hospitals. To further demonstrate and support the Work Group's documented concern, as evidenced in the table below, none of the existing, established single specialty ASCs in the state provide levels of charity care that would meet the standard proposed by AHCF.

Payor Mix	*Surgical Specialty*					
	Eye	*ENT*	*OB/Gyn*	*Ortho*	*Plastic*	*Podiatry*
Commercial Insurance	15.6%	80.6%	36.3%	54.3%	42.9%	60.9%
Medicare	75.5%	10.9%	1.5%	30.5%	5.7%	13.6%
Medicaid	1.9%	7.1%	41.9%	5.0%	0.9%	6.9%
Private/Self Pay	6.0%	0.2%	43.6%	0.7%	50.6%	16.7%
Other Government/All Other	0.4%	0.1%	5.2%	8.3%	0.0%	1.9%
Charity Care	0.01%	0.2%	0.1%	0.0%	0.0%	0.0%

Source: 2007 data from 2008 License Renewal Applications for single-specialty ASCs, aggregated by specialty.

Although the petition refers to several GI endoscopy ASCs that have been recently approved, the table above clearly shows that the existing single-specialty ASCs in the state do not provide any significant amount of charity care and, with the exception of OB/Gyn ASC's, provide only a minimal amount of care to Medicaid patients. Thus, the real "demonstration project" that has already existed for many years through these ASCs has shown that they do not provide any significant access to the medically underserved.

Rural Counties and Service Areas

CRMC is concerned by inconsistencies within AHCF's petition. While the petition goes to great length to fault the Work Group for its imposition of geographic limitations on the demonstration project, it goes on to impose its own that would favor rural areas. In fact, it refers to Appendix A for a list of eligible counties, which does not appear to exclude any counties in the state from being eligible for a demonstration project.

Further, while AHCF appears to define rural counties as those with a population of 85,000 or fewer, counties with more than 85,000, including Craven County, often have one or two population centers, but may also include significant rural areas.

Expansion of the Single Specialty Work Group

CRMC believes that expansion of the Work Group is neither warranted, nor proper until such time as it completes its assigned

charge. In addition, expanding the demonstration project to include virtually every area of the state defeats the purpose of a demonstration project. If the counties identified by AHCF were each approved for a two-room, single-specialty ASC, there would be no point in continuing with the demonstration project because counties with the ability to support a single specialty ASC would already have one as part of the "demonstration." CRMC favors a more reasonable, incremental approach that would allow approved facilities to provide data for further analysis before broadening the scope of the project.

In conclusion, CRMC opposes the petition for a revision in the SMFP need methodology related to the development of pilot demonstration ASCs based on our reasons outlined above. It is CRMC's observation that the recommendations reached by the Single Specialty Ambulatory Surgery Work Group at this time are merely preliminary; however, they nonetheless, contrary to AHCF's contention, adequately address the three basic principles of quality, access, and value. Further, CRMC maintains that AHCF's 2008 petition is properly before the Work Group and it has adequately considered the issues presented by AHCF in its petition and in light of the Work Group's stated charge, there is no need to require the Work Group to discuss the petition in more depth or request that AHCF formally present its petition to the Work Group.