Recommendations and Related Materials

from the

Quality, Access and Value Work Group

for the

October 8, 2008

State Health Coordinating Council Meeting

Agency Report

Basic Principles Revision
8.22.08

Overview
A Quality, Access and Value (QAV) work group, tasked with rewriting the Basic Principles Governing the Development of the State Medical Facilities Plan, was convened in the spring of 2008. The charge to the Work Group was as follows:

To propose a restatement of the basic principles governing the development of the State Medical Facilities Plan.

Guidelines and Considerations:

1) Changes in the health care environment require emphasis on quantification, accountability, and interrelatedness of the basic principles, with particular attention to emerging standardized quality measures. The core governing principles must be retained, but with some adjustment of emphasis: promote high quality health care services as measured by outcomes and satisfaction, promote equitable access to health care services for all North Carolina's people, and promote high value practices that will maximize the health care benefit gained for resources expended.

2) The detailed restatement of these principles should define a process in which these goals are achieved through a competitive health care market, in which successful providers prevail by offering the best balance of quality, access and value to North Carolina's health care consumers.

3) The restatement of the basic principles should be unambiguous and with sufficient clarity to enable the basic principles to reliably serve as a reference guideline for the SHCC when it considers any policy or methodology inclusion, elimination, and/or modification.

The work group, chaired by Dr. Dana Copeland, met four times and through careful and thorough consideration of each Basic Principle in relation to the many and varied changes which have occurred in the health care environment since the Basic Principles were first published, did an outstanding job of producing a draft revision of each Basic Principle.

The draft revised Basic Principles were presented to the full State Health Coordinating Council (SHCC) at the May 28, 2008 SHCC meeting. As recommended by the SHCC at that meeting, given the complexity of implementing the revised Basic Principles, their importance to the SMFP, and the need for public comment, a new QAV work group was authorized to continue to refine the revised Basic Principles. Additionally, the SHCC recommended publishing the revised Basic Principles in the Proposed 2009 North

Carolina State Medical Facilities Plan with a note requesting comments. These recommendations were made in order to continue to move forward with meeting the charge to the QAV work group.

Summary of the Comments Received During the Public Comment Period

During the public comment period, the Division of Health Service Regulation received comments from the following five commenters.

- Mike Vicario with the North Carolina Hospital Association
- Lisa Griffin with Novant Health
- Michael Freeman with Wake Forest University Baptist Medical Center
- Mary Beck with University of North Carolina Health Care
- Sue Collier with University Health Systems

Some salient points gleaned from the comments are shown below:

- Appointment a separate work group for each principle.
- Each revised Basic Principles consists of two parts: a principle and action steps.
- Action items related to the Principles must be included in policies or rules in order to be enforceable.
- Instructions and actions steps for the SHCC in development of the SMFP are different from policies and rules that can be applied in making decisions in reviewing CON applications.
- There must be consistency among the revised principles and applicable policies, rules, and criteria.
- Balancing access and cost: Providers with higher costs resulting from providing access to the underserved should not be penalized for those higher costs in a competitive CON review.
- Recognition should be given to the unique nature of rural providers and academic medical centers.
- Measures, including patient satisfaction measures, should be standardized, objective, comparable.
- Data on CON holders' compliance with measures should be publicly available.
- Not all CON applicants will have data to measure. What is the best way to compare CON applicants who are able to provide data with those CON applicants who are unable to provide data?

Agency Recommendations

The Agency appreciates the QAV work group's efforts, the support of the SHCC in this endeavor and the comments received during the public comment period. Further, the Agency looks forward to participating in continuing to move toward the goal of meeting the QAV work group charge. Based on review of the revised Basic Principles and the comments received during the public comment period, the Agency makes the following six recommendations:

1. Review and consider the comments received during the public comment period as the process of meeting the work group charge continues.
2. Separate the revised Basic Principles into two parts:
   a. For each Basic Principle, a broad principle statement, intended to guide decision making relative to formulation and implementation of the SMFP. Include these principle statements in Chapter 1 of the SMFP under "Basic Principles Governing Development of the Plan".
   b. An action plan for specific application of the Principles. This action plan will include an outline of tasks to be accomplished, entities responsible for the tasks, and anticipated completion dates. The action plan for the Principles will be combined with action plans for other initiatives of the SHCC, such as the Operating Room Work Group recommendations, in a separate document "New Initiatives and Implementation Strategies". This document, which will reflect all activities of the SHCC to be undertaken in the development of future SMFPs, will be maintained by the Planning Section and will be made available to the SHCC members and the public.

3. Add a step 5. to the "Instructions for Writing Petitions" sections in Chapter 2 of the SMFP. Suggested wording for the new step is as follows:
   5. "Evidence that the requested adjustment is consistent with the three Basic Principles Governing the Development of the SMFP: Safety and Quality, Access and Value."

4. Appoint ad hoc work groups, staffed by a Planner and assisted by a representative from the CON Section, responsible for a set of tasks in the action plan. Find and appoint to the work groups individuals with healthcare quality measurement expertise. These experts will be responsible for suggesting metrics and for designing, if needed, any systems for tracking the measures.

5. Update Policy Gen 3 to make the policy consistent with the revised Basic Principles and related tasks in the action plan. The current Policy Gen 3 was developed before the QAV work group was established and, as such, is not accordant with the revised Basic Principles and separate action plan. Updating Policy Gen 3 will ensure that the policy reflects the robust evolutionary nature of the Revised Basic Principles.

6. The Agency anticipates that completion of the tasks necessary to implement the revised Basic Principles will occur in steps over the next several years. Also, measurement of compliance with the revised Basic Principles is expected to become more robust as the indicators of Safety and Quality, Access and Value evolve. For these reasons, the Agency recommends that flexibility is built into the structure of the action plans for implementation of the revised Basic Principles, so that the SHCC may readily adapt and strengthen the implementation of the revised Basic Principles as the environment changes.

CHAPTER 1

Basic Principles Governing the Development of the North Carolina State Medical Facilities Plan

1. Safety and Quality Principle

The State of North Carolina recognizes the importance of systematic and ongoing improvement in the quality of health services. Citizens of North Carolina rightfully expect heath services to be safe and efficacious. To warrant public trust in the regulation of health services, monitoring of safety and quality using established and independently verifiable metrics will be an integral part of the formulation and application of the North Carolina State Medical Facilities Plan.

Scientific quantification of quality and safety is rapidly evolving. Emerging measures of quality address both favorable clinical outcomes and patient satisfaction, while safety measures focus on the elimination of practices that contribute to avoidable injury or death and the adoption of practices that promote and ensure safety. The SHCC recognizes that while safety, clinical outcomes, and satisfaction may be conceptually separable, they are often interconnected in practice. The North Carolina State Medical Facilities Plan should maximize all three elements. Where practicalities require balancing of these elements, priority should be given to safety, followed by clinical outcomes, followed by satisfaction.

The appropriate measures for quality and safety should be specific to the type of facility or service regulated. Clinical outcome and safety measures should be evidence-based and objective. Patient satisfaction measures should be quantifiable. In all cases, metrics should be standardized and widely reported and preference should be given to those metrics reported on a national level. The SHCC recognizes that metrics meeting these criteria are currently better established for some services than for others. Furthermore, experience and research as well as regulation at the federal level will continue to identify new measures that may be incorporated into the standards applicable to quality and safety. As experience with the application of quality and safety metrics grows, the SHCC should regularly review policies and need methodologies and revise them as needed to address any persistent and significant deficiencies of safety and quality in a particular service area.

2. Access Basic Principle

Equitable access to timely, clinically appropriate and high quality health care for all the people of North Carolina is a foundation principle for the formulation and application of the North Carolina State Medical Facilities Plan. Barriers to access include, but are not limited to: geography, low income, limited or no insurance coverage, disability, age, race, ethnicity, culture, language, education and health literacy. Individuals whose access to needed health services is impeded by any of these barriers are medically underserved. The formulation and implementation of the North Carolina State Medical Facilities Plan seeks to reduce all of these types of barriers to timely and appropriate access. The first priority is to ameliorate economic barriers and the second priority is to mitigate time and distance barriers.

The impact of economic barriers is twofold. First, individuals without insurance, with insufficient insurance, or without sufficient funds to purchase their own healthcare will often require public funding to support access to regulated services. Second, the preferential selection by providers of well-funded patients may undermine the advantages that can accrue to the public from market competition in health care. A competitive marketplace should favor providers that deliver the highest quality and best value care, but only in the circumstance that all competitors deliver like services to similar populations.

The SHCC assigns the highest priority to a methodology that favors providers delivering services to a patient population representative of all payor types in need of those services in the service area. Comparisons of value and quality are most likely to be valid when services are provided to like populations. Incentives for quality and process improvement, resource maximization, and innovation are most effective when providers deliver services to a similar and representative mixture of patients.

Access barriers of time and distance are especially critical to rural areas and small communities. However, urban populations can experience similar access barriers. The SHCC recognizes that some essential, but unprofitable, medical services may require support by revenues gained from profitable services or other sources. The SHCC also recognizes a trend to the delivery of some services in more accessible, less complex, and less costly settings. Whenever verifiable data for outcome, satisfaction, safety, and costs for the delivery of such services to representative patient populations justify, the SHCC will balance the advantages of such ambulatory facilities with the needs for financial support of medically necessary but unprofitable care.

The needs of rural and small communities that are distant from comprehensive urban medical facilities merit special consideration. In rural and small communities selective competition that disproportionately captures profitable services may threaten the viability of sole providers of comprehensive care and emergency services. For this reason methodologies that balance value, quality and access in urban and rural areas may differ quantitatively. The SHCC planning process will promote access to an appropriate spectrum of health services at a local level, whenever feasible under prevailing quality and value standards.

3. Value Principle.

The SHCC defines health care value as maximum health care benefit per dollar expended. Disparity between demand growth and funding constraints for health care services increases the need for affordability and value in health services. Maximizing the health benefit for the entire population of North Carolina that is achieved by expenditures for services regulated by the State Medical Facilities Plan will be a key principle in the formulation and implementation of SHCC recommendations for the SMFP.

Measurement of the cost component of the value equation is often easier than measurement of benefit. Cost per unit of service is an appropriate metric when comparing providers of like services for like populations. The cost basis for some providers may be inflated by disproportionate care to indigent and underfunded patients. In such cases the SHCC encourages the adjustment of cost measures to reflect such disparity, but only to the extent such expenditures can be measured according to an established, state-wide standard that is uniformly reported and verifiable. Measurement of benefit is more challenging. Standardized safety and quality measures, when available, can be important factors in achieving improved value in the provision of health services. Prevention, early detection and early intervention are important means for increasing the total population benefit for health expenditures. Development of new technology has the potential to add value by improving outcome and enhancing early detection. Capital costs of such new technology may be greater but justified by the added population benefit. At the same time overutilization of more costly and/or highly specialized, low volume services without evidence-based medical indications may contribute to escalating health costs without commensurate population-based health benefit. The SHCC favors methodologies which encourage technological advances for proven and affordable benefit and appropriate utilization for evidence-based indications when available. The SHCC also recognizes the importance of primary care and health education in promoting affordable health care and best utilization of scarce and expensive health resources. Unfortunately technologically sophisticated and costly services that benefit small numbers of patients may be more readily pursued than simple and less costly detection and prevention measures that benefit the broader population. In the pursuit of maximum population-based heath care value, the SHCC recognizes the potential adverse impact for growth of regulated services to supplant services of broad benefit to the larger population.

Long term enhancement of health care value will result from a state medical facilities plan that promotes a balance of competition and collaboration and encourages innovation in health care delivery. The SHCC encourages the development of value-driven health care by promoting collaborative efforts to create common resources such as shared health databases, purchasing cooperatives, and shared information management, and by promoting coordinated services that reduce duplicative and conflicting care. The SHCC also recognizes the importance of balanced competition and market advantage in order to encourage innovation, in so far as those innovations improve safety, quality, access, and value in health care delivery.

[Note: The activities and tasks to be undertaken by the SHCC to implement the Basic Principles are included in the "New Initiatives and Implementation Strategies" document maintained by the Planning Section.]

EXAMPLE DOCUMENT FOR DISCUSSION PURPOSES

New Initiatives and Implementation Strategies

The North Carolina State Health Coordinating Council is beginning a process to refine the methodologies used in the development and application of the North Carolina State Medical Facilities Plan to ensure a balance of the principles of quality, access and value in the formulation and implementation of the SMFP. To this end the SHCC plans to undertake the following new initiatives to accomplish its objectives over the next several years. The table below provides a general outline of the implementation schedule for the new initiatives. It should be noted, however, that the tasks and dates are subject to modification as needed to adapt to changes which may occur as progress is made in the implementation process.

TASKS	RESPONSIBLE ENTITY	ANTICIPATED COMPLETION DATE
1. Develop recommendations for standard definitions and verifiable economic measures for evaluating charity and under compensated care in planning and review process. a. Appoint persons to work group or committee b. Identify appropriate consultants to assist with research c. Complete research d. Develop draft definitions for evaluation and comment by staff e. Present draft of metrics and strategies, with staff recommendations, to SHCC committees and full SHCC for review f. Present draft product of SHCC to public for comment at public hearings g. Review public comment and develop final product h. Amend instructions for SMFP petitioners to implement use of definitions i. Develop recommendations for amendments to CON rules to assure consistency with definitions in SMFP		
2. Develop recommendations for quality and safety metrics that are facility or service specific, evidence based, objective, quantifiable, standardized and widely reported, preferably on a national level. a. Appoint persons to work group or committee b. Identify potential consultants and experts in quality assessment c. Solicit suggestions for metrics from consultants, experts and providers d. Identify and prioritize services and facilities for which measures will be developed e. Develop draft of first priority metrics for evaluation and comment by staff f. Develop strategy for incorporation of metrics into the SMFP planning process (i.e. policies and need determinations) for evaluation and comment by staff g. Present draft of metrics and strategies, with staff recommendations, to SHCC committees and full SHCC for review		

TASKS	RESPONSIBLE ENTITY	ANTICIPATED COMPLETION DATE
h. Present draft product of SHCC to public for comment at public hearings i. Develop final product for first priority metrics and incorporate in the applicable methodology in the SMFP j. Amend instructions for SMFP petitioners to implement use of metrics k. Develop recommendations for amendments to CON rules, which shall be consistent with SMFP, for purpose of evaluating applicants with regard to quality metrics l. Review metrics every two years and make revisions as necessary to better reflect the most appropriate measures for quality and safety		
3. Develop recommendations for reporting performance data based on SHCC adopted quality and safety measures a. Obtain legal advice from Attorney General's Office regarding permissible procedures for obtaining data on quality measures from providers b. Evaluate Agency authority for and feasibility of requiring approved CON applicants once services are operational to submit on an annual basis established quality and safety data for that facility or service, and for any other facility or service in the same service category and in which the applicant has a greater than 25% ownership interest. When an applicant is a partnership or joint venture, such requirement will apply to any party with a 25% or greater equity interest in the applicant partnership or joint venture. c. Evaluate Agency authority for and feasibility of requesting, though not requiring not requiring, current CON holders to report performance data for the SHCC adopted safety, quality, and patient satisfaction metrics. d. Develop recommendations for changes in CON law or administrative rules, if changes are determined to be necessary to implement recommendations regarding reporting. e. Develop recommendations for revision of the CON application form to request applicants to provide performance data, if available, for the SHCC adopted quality and safety metrics, for any person that has a 25% or greater ownership stake in the new entity. f. Develop recommendations for revision of the CON application form to request applicants without prior quality and safety performance records to describe specific and detailed plans documenting how SHCC adopted quality and safety standards and metrics will be met or exceeded if their proposed project is approved.		

DRAFT POLICY GEN-3: SAFETY AND QUALITY, ACCESS AND VALUE

A CON applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan (SMFP) shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A CON applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A CON applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the SMFP as well as addressing the needs of all residents in the proposed service area.