

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 health 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 health 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
<p>1. Develop recommendations for standard definitions and verifiable economic measures for evaluating charity and under compensated care in planning and review process.</p> <ul style="list-style-type: none"> 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 		
<p>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.</p> <ul style="list-style-type: none"> 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
<ul style="list-style-type: none"> 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 		
<p>3. Develop recommendations for reporting performance data based on SHCC adopted quality and safety measures</p> <ul style="list-style-type: none"> 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. 		