

## **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. DHSR recognizes that while safety, clinical outcomes, and satisfaction may be conceptually separable, they are often interconnected in practice. The methodologies for the formulation of the North Carolina State Medical Facilities Plan and for the awarding of Certificates of Need should seek to 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 will 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. The SHCC, with the advice of DHSR, will develop a schedule for adoption of quality and safety metrics for the regulated service to be completed as soon as feasible. Suggestions for appropriate metrics will be solicited from providers and experts in quality assessment, evaluated and recommended by staff, discussed by the respective SHCC committees and the full SHCC, and presented for public comment at public hearings, before being approved and incorporated into the recommended methodology for the NCSMFP. At regular intervals, no less than every two years, the metrics applicable to quality and safety should be reviewed and revised with the addition of new metrics to better reflect the most appropriate measures while continuing those previously incorporated to ensure the consistency of ongoing comparisons.

In order to facilitate growth of a robust quality and safety database for use by citizens, providers, and regulators, applicants for CONs for any facility or service for which quality and safety metrics are established, will be required 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.

When performance data on established quality and safety metrics as identified by the SHCC are available for a CON applicant, they should be required and considered by the CON Section in

evaluating the quality of service provided by that applicant. This requirement will apply to any party with a 25% or greater ownership stake in the new entity. Applicants without prior quality and safety performance records will be eligible for a CON, but must include in their application specific and detailed plans documenting how prevailing quality and safety standards and metrics will be met or exceeded. As experience with the application of quality and safety metrics to the CON process grows, the SHCC should revise need methodologies such that they will also address persistent and significant deficiencies of safety and quality in a particular service area.