Acute Care Services Committee Agency Report for Petition to Modify Policy GEN-3 in the Proposed 2025 State Medical Facilities Plan

Petitioner:

Health Systems Management Wake Forest University

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Request:

Health Systems Management (HSM) requests to modify Policy GEN-3: Basic Principles ("Policy GEN-3") in the *North Carolina 2025 State Medical Facilities Plan (SMFP* or "*Plan*").

Background Information:

Chapter Two of the 2024 SMFP provides that "[a]nyone who finds that the North Carolina State Medical Facilities Plan policies or methodologies, or the results of their application, are inappropriate may petition for changes or revisions. Such petitions are of two general types: those requesting changes in basic policies and methodologies, and those requesting adjustments to the need projections." The annual planning process and timeline allow for submission of petitions for changes to policies and methodologies to the State Health Coordinating Council (SHCC) in the spring.

The 2024 SMFP includes the following:

Policy GEN-3: Basic Principles

A certificate of need 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 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 certificate of need 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 certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.

Policy GEN-3 was first included in the 2007 SMFP. The policy required certificate of need (CON) applicants applying to meet the need for new healthcare facilities, services or equipment to be consistent with the three basic principles governing the SMFP. The governing principles were described as the promotion of cost-effective approaches, the expansion of health care services to the medically underserved, and the encouragement of quality healthcare services. In 2008, the Quality, Access and Value Workgroup convened to propose a restatement of these principles as Safety and Quality, Access, and Value. The SHCC also approved technical edits to Policy GEN-3 to correspond with the addition of the restated basic principles. In the 2024 SMFP, they are described in Chapter 2 as the "Basic Principles Governing the Development of the SMFP".

Analysis/Implications:

HSM is concerned that CON applications that are not the result of a need determination are not required to abide by Policy GEN-3. Therefore, the Petitioner requests a modification to the first sentence of Policy GEN -3 such that it applies to all CON applicants. The proposed revision is below.

A certificate of need 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 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.

The Petitioner states that this modification will increase transparency for CON applicants, CON analysts and the public by requiring all CON applicants to comply with Policy GEN-3.

HSM identifies "Policy ESRD-2: Relocation of Dialysis Stations" and "Policy ESRD-3: Development or Expansion of a Kidney Disease Treatment Center on a Hospital Campus" as policies that exempt applicants from the requirements set forth in Policy GEN-3 because these policies allow for changes in dialysis services without a need determination being placed in the Plan. However, it is worth noting that these are only two of several policies in the *SMFP* that allow for changes in health service capacity without regard to a need determination.

Policy GEN-3 is also duplicative of the CON statutory criteria used to evaluate CON applications. In 2021, the Healthcare Planning and Certificate of Need Section revised its CON applications to include a list of the 14 CON statutory criteria. Eleven of those criteria encompass the SMFP's basic principles (See the addendum). A CON applicant must document how their proposed projects are conforming with the criteria, and the Agency- in order to approve a CON application- must make a finding of conformity with all of the criteria. Thus, even when a CON application for a health service does not arise from an SMFP need determination, the CON applicant is still required to address the three basic principles of the *SMFP* in its application.

Agency Recommendation:

The Agency supports all policies for health services and equipment in the *SMFP*. The Agency also appreciates the concerns raised by the Petitioner. Given the available information submitted by the March 20, 2024, deadline, and in consideration of factors discussed above, the Agency recommends denial of the Petition. As GEN-3 is duplicative of the CON statutory criteria, the Agency further recommends removing, in its entirety, Policy GEN-3 from the *2025 SMFP*.

Addendum

Below are the relevant North Carolina Certificate of Need Statutes cited in the Healthcare Planning and Certificate of Need Section's certificate of need (CON) applications. The underlined segments correspond to the basic principles, which are described in both Chapter 2 of the *SMFP* and in Policy GEN-3.

Section C – Criterion (3)

G.S. 131E-183(a)(3)

The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, ... persons [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed.

SECTION D - CRITERION (3a)

G.S. 131E-183(a)(3a)

In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

SECTION E - CRITERION (4)

G.S. 131E-183(a)(4)

Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

SECTION G - CRITERION (6)

G.S. 131E-183(a)(6)

The applicant shall <u>demonstrate that the proposed project will not result in unnecessary</u> duplication of existing or approved health service capabilities or facilities.

SECTION H - CRITERION (7)

G.S. 131E-183(a)(7)

The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

SECTION I - CRITERION (8)

G.S. 131E-183(a)(8)

The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

SECTION J - CRITERION (9)

G.S. 131E-183(a)(9)

An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

SECTION K - CRITERION (12)

G.S. 131E-183(a)(12)

Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

SECTION L - CRITERION (13)

G.S. 131E-183(a)(13)

"The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and ... persons [with disabilities], which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;
- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and ... persons [with disabilities] to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;
- (c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and
- (d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians."

SECTION N - CRITERION (18a)

G.S. 131E-183(a)(18a)

O SECTION O - CRITERION (20)

G.S. 131E-183(a)(20)

"An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past."