

NCDHSR
Healthcare Planning
2704 Mail Service Center
Raleigh, NC 27699-2704
Via Email: DHSR.SMFP.Petitions-Comments@dhhs.nc.gov

SPRING PETITION TO MODIFY POLICY GEN-3 TO BECOME APPLICABLE TO ALL APPLICANTS

1. Identification of the Petitioner:

Name: Health Systems Management, Inc. on behalf of the Wake Forest Out-Patient Dialysis Centers

Attn: William F. McDonald, Director of Development and Kimberly A. Johnson, MBA, Sr. CON Specialist / Credentialing Coordinator

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2. **Statement of the Requested Change:** Modify GEN-3 such that it is applicable to **all** applicants and not just those responding to a need determination in the SMFP.

3. **Reasons for the Proposed Changes:** Responding to questions under GEN-3, which encompasses the Basic Principles of CON, is currently optional for all applicants who are **not** responding to a need determination published in the NC SMFP. GEN-3 as written requires modification to ensure **all** applicants address its Principles, the cornerstone of the CON Program in North Carolina. Applications based on ESRD-2, ESRD-3, and any future policies that result in changes in bed capacity, but are not related to a need determination in the SMFP are currently not required to respond to GEN-3. In order to increase transparency for all applicants, the CON analysts, and the public at large the change to GEN-3 to encompass all applicants, regardless of reason for filing a CON, is necessary.

Statement of Adverse Effects: Non-response to GEN-3 undermines the CON Program by failing to afford analysts the ability to fully evaluate applications and measure their conformity with the basic principles of CON.

Alternatives to the Proposed Changes that were considered and found not feasible:

- **Talk to the CON Section about our concerns:** We talked with the CON Section and were instructed that requests for policy changes must be submitted as a petition.
- **Do nothing:** Changes in methodologies related to CON have resulted in the ability to file applications without a need determination published in the SMFP. In order to maintain transparency of all applications, the change to GEN-3 is needed. Doing nothing will not result in greater transparency.

4. **Duplication of Services:** The proposed change to Policy GEN-3 will not result in duplication of services as the proposed change does not impact need determinations, or utilization standards. On the contrary, the proposed change to GEN-3 will result in greater transparency of all providers proposing to offer ESRD services and perhaps prevent duplicative services to a degree exceeding the current ESRD CON application's efforts.
5. **Safety and Quality, Access, and Value:** The proposed changes to GEN-3 will make GEN-3 applicable to all applicants and not just those responding to a need determination published in the SMFP. When Safety and Quality are enforced, Access and Value are more easily determinable.

(Proposed Revision) **Policy GEN-3: Basic Principles:** *Revise this policy to make it inclusive of all CON Proposals regardless of whether or not there is a need determination in the SMFP.*


"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."

Reason for the requested change: There are a number of ESRD CON application types that are not the result of a *"need determination in the North Carolina State Medical Facilities Plan."* Those are, ESRD-2 In-County Transfers of Dialysis Stations to develop a new facility, ESRD-2 Contiguous County Transfers of Dialysis Stations to develop a new facility, ESRD-3 Applications. By removing the quantifier of an SMFP Need Determination in Policy GEN-3, GEN-3 becomes applicable to all ESRD applications, increasing application transparency, and promoting the Basic Principles of CON.

Conclusion: The change requested in this petition is necessary to protect the safety of ESRD patients statewide, preserve the foundations of the CON program in North Carolina, allow for greater transparency of organizations requesting to provide ESRD services, and ensure North Carolinians requiring dialysis will have access to quality providers. Your favorable consideration of this petition is kindly appreciated.



William F. McDonald



Kimberly A. Johnson, MBA

Digitally signed by Kimberly A. Johnson, MBA
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