

CON APPLICATION PROCESS & GENERAL PROCEDURES			
Concern	Options	Changes required	Misc.
<p>CON process is no longer needed for certain services:</p> <ul style="list-style-type: none"> Air Ambulance Solid Organ Transplant 	<p>No longer require CON for air ambulances or solid organ transplant services.</p>	<ul style="list-style-type: none"> Remove air ambulance from CON statute. Remove Solid Organ Transplant services from CON statute. 	<ul style="list-style-type: none"> <i>Med-Trans Corp. v. Benton</i>, 591 F.Supp.2d 812, (E.D.N.C., 2008) indicates that air ambulances are under the purview of the FAA, not state regulation. CMS has tightened regulations for solid organ transplants. Medicare Conditions of Participation for organ transplant programs were established in 2007.
<p>The diagnostic service center requirements under CON are difficult to enforce and rarely reported.</p>	<ul style="list-style-type: none"> Eliminate diagnostic service centers from CON requirements. Increase the threshold amount. Eliminate "clinical laboratories" from definition 	<ul style="list-style-type: none"> Delete all references to diagnostic service centers. Make conforming changes to 131E-176(7a). 	<p>Currently a diagnostic service center must obtain a CON when the total cost of all medical diagnostic equipment utilized by the facility that cost \$10,000 or more exceeds \$500,000.</p>
<p>No statutory requirement deadline for letters of review, CON Exemption requests or Material Compliance Requests.</p>	<ul style="list-style-type: none"> Create a deadlines Require fee for such determinations. 	<ul style="list-style-type: none"> Codify for letters of review and create deadline. Add deadlines for other requests. Add authorization for to charge fees for such requests. 	<ul style="list-style-type: none"> Letters of review are not currently statutorily required.

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Applications are required to be submitted in hard copy.	Allow for or require electronic submissions of applications.	<ul style="list-style-type: none"> Direction to Agency to accept or to require electronic forms. Make modifications to 131E-182(b) requiring or allowing for electronic submission. 	Consider technological ability of current system.
More transparency is needed in the CON process.	Require all applications/determination requests/requests for review as well as Agency decisions to be posted on website.	<ul style="list-style-type: none"> Direction to Agency to post all applications, determination requests, decisions, responses, etc. on their website. Add statutory language to 131E-185 directing Agency to post this information on website. Add statutory language indicating all information submitted to CON/DHSR is public information. 	
Monetary threshold for projects requiring a CON under 131E-176 of 2 million dollars is too low.	<ul style="list-style-type: none"> Increase the threshold amount. Account for inflation. 	Make conforming change to 131E-176(16) and 131E-184(e).	
Monetary threshold for expedited review of less than 5 million dollars is too low.	<ul style="list-style-type: none"> Increase the threshold amount. Account for inflation. 	Make conforming change to 131E-176(7b)(b) and 131E-185(a1)(2).	
Monetary threshold for major medical equipment requiring a CON is too low at \$750,000.	<ul style="list-style-type: none"> Increase the threshold amount. Account for inflation. 	Make conforming change to 131E-176(14o).	
Monetary threshold for replacement equipment is too low at 2 million dollars.	<ul style="list-style-type: none"> Increase the threshold amount. Account for inflation. 	Make conforming change to 131E-176(22a).	

APPEALS PROCESS			
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Appeals cause delays in provision of needed facilities and or services.	<p>Eliminate stays. A CON issued by the State takes effect immediately upon issuance.</p> <p>Mississippi model: The filing of an appeal from a final order of the statutorily specified body or tribunal shall not stop the purchase of medical equipment or development or offering of institutional health services granted in a CON issued by the State.</p>	Create new section declaring that no stay shall be granted upon a party's appeal from a final agency decision or order.	
Bond requirements are inadequate.	<ul style="list-style-type: none"> • Increase the threshold amount of required appeal bond. • Account for inflation. • Amount of bond in discretion of board or court, with requirement that any appeal of a final order in a CON proceeding requires the giving of a bond sufficient to secure the appellee against the loss of costs, fees, expenses and attorney's fees incurred in defense of the appeal, approved by the appellate court within five (5) days of the date of filing the appeal. • Require a separate bond for each petition filed. 	Make conforming change to 131E-(a1) and 131E-(b1)(1).	

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Frivolous appeals cause unnecessary delays.	<ul style="list-style-type: none"> • Prevailing party gets costs and attorneys' fees. • Increase penalties for frivolous appeals. • Stricter enforcement of imposed penalties. 	Make conforming change to 131E-188(a1).	
Too many parties have the ability to file an appeal.	Redefine and limit "affected person" and "aggrieved party" for purposes of standing to file an appeal.	Make conforming changes to 131E-188 and Chapter 150B.	Give only the applicant standing to appeal. Eliminate intervenors from the appeals process.
The appeals process is too lengthy.	<ul style="list-style-type: none"> • Appeal from a final order or decision of the Department in a CON denial case goes to a contested case hearing before OAH and from there, directly to the Supreme Court. • Time limits for appeals decisions. <p>e.g., Georgia model: Certificate of Need Appeal Panel consists of independent hearing officers appointed by the Governor in order to review the Dept's initial decisions to grant or deny a Certificate of Need. The decision of the appeals panel hearing officer is final unless objection is filed with the Commissioner within 60 days. Commr reviews and can award attorneys' fees and expenses if determines appeal was made for purposes of delay or harassment. Commr's Decision final unless appealed to Superior Court. However, if the Court does not hear the case within one hundred and twenty (120) days of the date of docketing in the Superior Court, the decision of the Dept. shall be considered affirmed by operation of law unless a hearing originally scheduled to be heard within the 120 days has been continued to a date certain by order of the Court.</p>	<ul style="list-style-type: none"> • Make conforming changes to 131E-187, 131E-188. • Make conforming changes to 7A-29(a) and (b). 	

STATE HEALTH COORDINATING COUNCIL			
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State Ethics Act should apply to SHCC members.	Require Council to be subject to all or part of the Act.	Statutory change would be required. By current definition the SEC does not have the authority to subject SHCC to the Act.	Potential conflicts between current Executive Order and Chapter 138A exist.
Appointments should be made by legislature and Governor.	Divide membership appointments among Governor, Senate, and House of Representatives	Likely would need to codify SHCC and then in its establishment set appointing mechanism.	Consider role of Advisory Committees within the Executive Branch.
SHCC members may have an affiliation with or be employed by providers applying for CON.	Extend prohibition in 131E-191.1 to include persons employed or affiliated with XXXX.	Statutory change would be required.	Consider desired knowledge base of Advisory Committee.
Determinations of need made by the SHCC are "outcome determinative" with respect to any CON application.	Make need determinations presumptively correct and rebuttable by evidence of specific circumstances involved in a CON application.	Amend G.S. 131E-183(a)(1) to conform.	

STATE MEDICAL FACILITIES PLAN			
Concern	Options	Changes required	Misc.
Policies adopted in the SMFP are not considered rules under the APA.	<ul style="list-style-type: none"> • Include under the APA. • Direct that certain portions of APA apply. • Establish SHCC by law. 	Statutory change would be required.	<ul style="list-style-type: none"> • Consider timing requirements under the APA. • Consider Rules Review Commission's impact on policy.
The SMFP contains exceptions.	<ul style="list-style-type: none"> • Recommend language from H743. • Eliminate/limit certain plan exemptions (AC-3). • Develop non-subjective criteria to qualify for exemptions. 	Legislative direction.	
Current target occupancy tiers result in difficulties for small hospitals.	<ul style="list-style-type: none"> • Create occupancy tiers for hospitals with 100 beds or less and tiers for hospitals with greater than 100 beds 	Legislative direction.	
No recognition for beds that play dual roles of observation/inpatient care that is more prevalent in small hospitals.	<ul style="list-style-type: none"> • Count the dual beds in the census count for hospitals with 100 beds or less. • Create a new system of classifying beds that accounts for dual purpose beds. 	Legislative direction.	