

## What Is “Past Quality of Care” in a Certificate of Need (CON) Review?

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Health Care

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?A recent **certificate of need (CON)** decision has muddied the waters further on the question of what constitutes past quality of care in a CON review. The case involved the Certificate of Need Section’s (CON Section or Agency) decision on competitive applications filed in 2012 seeking to develop hospital acute care beds and a separate application to relocate a hospital operating room in the Cumberland/Hoke County service area. A significant issue in the case was whether the Agency correctly concluded that the disapproved applicant did not conform with the statutory review criterion relating to quality of care, commonly known as Criterion 20. That criterion requires a CON applicant already engaged in the provision of health services to “provide evidence that quality care has been provided in the past.” In evaluating an applicant’s compliance with Criterion 20, the CON Section typically has focused on whether an applicant had any immediate jeopardy-level deficiencies within the 18 months before the application date at any facility in the county where the new beds or other facility being applied for are located. In the Cumberland/Hoke acute care bed case, the presiding administrative law judge (ALJ) rejected the Agency’s approach, finding that it was not supported by the Criterion 20 statute and that it was based upon an unlawful unpromulgated rule.

In the Cumberland/Hoke Review, the disapproved applicant had been subject to immediate jeopardy citations and findings that it was out of compliance with several Medicare Conditions of Participation (CoPs) several months before its application was submitted. In his decision issued September 17, 2013, the ALJ acknowledged that during the CON review, this applicant was subject to a Systems Improvement Agreement with the **Centers for Medicare & Medicaid Services**, which ended after the CON Section issued its decision. However, the ALJ pointed to certain events indicating the applicant was in compliance with all CoPs when the CON Section issued its decision, including a Joint Commission full survey determining that the applicant was in compliance with all CoPs before the CON application was filed; the Agency’s entry into a settlement agreement with the disapproved applicant in a separate CON review after receiving confirmation of Joint Commission accreditation which resulted in the issuance of a CON to develop 65 acute care beds; a survey by the N.C. Licensure and Certification Section finding the applicant in compliance with all CoPs more than two months before the Agency’s decision; and an e-mail from the Licensure Section to the CON Section confirming the applicant’s compliance with CoPs shortly before the Agency decision. The ALJ noted that in prior reviews the CON Section had found applicants conforming with Criterion 20 despite immediate jeopardy citations, provided there was information indicating the applicant was compliant at the time of the CON decision.

In rejecting the CON Section's interpretation of Criterion 20, the ALJ concluded that the law focuses on a demonstration of quality care generally and does not require a perfect record. The ALJ ruled that the disapproved applicant should have been found conforming and that the Agency incorrectly applied Criterion 20 in determining that a full validation survey was necessary for the disapproved applicant to demonstrate compliance. However, the applicant approved by the CON Section ultimately prevailed under the ALJ's decision, based upon comparative superiority, including on the quality care issue.

This most recent decision on quality of care in the CON context conflicts somewhat with a decision by another administrative law judge in the Wake County nursing home case which we wrote about earlier this year. In that case, the ALJ accepted the Agency's general approach of looking to past survey findings in connection with Criterion 20 but concluded that a CON applicant that is an existing provider must demonstrate a history of providing quality care at its facilities across the state (rather than just locally per the CON Section's policy) in order to be awarded a CON.

Appeals to the N.C. Court of Appeals are pending in both of these cases, so it appears the question of what Criterion 20 requires an applicant to show to demonstrate past quality care may well be decided there. Meanwhile, this most recent ALJ decision stands for the proposition that the CON Section's approach applied in the Cumberland/Hoke Review is unlawful. Only time will tell whether the CON Section elects to tweak its Criterion 20 analysis or application forms in response to the ALJ's decision in the Cumberland/Hoke Review.

CON applicants or competitive participants in CON reviews will need to weigh the details and distinctions of these two ALJ decisions in determining how best to proceed in analyzing and explaining a provider's past quality of care in CON applications and/or comments filed supporting their own application or addressing that of a competitor. Nursing facility providers and other long term care companies submitting CON applications should consider consulting with legal counsel before submitting CON applications to help make sure their applications appropriately and completely reflect a commitment to quality care in compliance with Criterion 20 in light of these recent ALJ decisions on this issue.

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