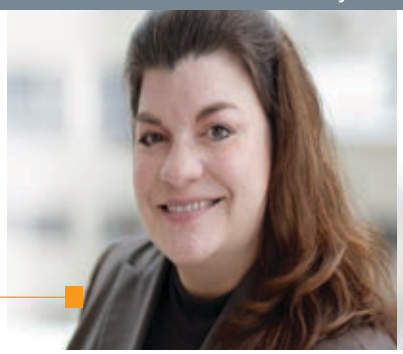
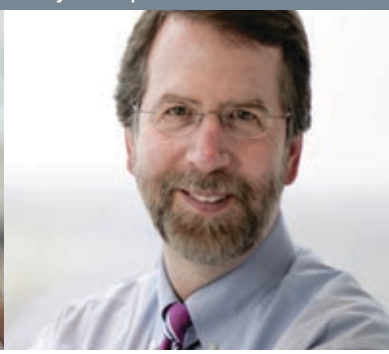
SHORTS ON LONG TERM CARE
for the North Carolina LTC Community from Poyner Spruill LLP





The End of the Agency's Second Bite at the Apple

by Pam Scott and Tom West

"It ain't over 'til it's over." Since the inception of North Carolina's Administrative Procedure Act (APA) over 30 years ago, the State's executive branch agencies have been able to live by this famous Yogi Berra adage because, in most instances, they had the final say in cases challenging their actions or decisions. But no more. As part of the General Assembly's regulatory reforms in the 2011 session, legislators took this final decision authority away from the agencies (with the exception of occupational licensing board cases) and gave it instead to administrative law judges (ALJs) in the state's Office of Administrative Hearings. This change will have important legal and practical ramifications for future cases challenging state agency actions and decisions, including licensure, certificate of need and other types of disputes impacting long term care providers.

Historically under the APA, a contested case challenging a North Carolina agency's decision or action has been heard by an ALJ who is not a part of the agency that made the decision or took the action being challenged. After hearing and considering the factual evidence and legal arguments of the parties, the ALJ would determine whether the agency decision at issue was correct. However, the ALJ's decision has not been final, but rather has been a recommendation sent back to the agency for a final decision. In practice, the director of the agency whose decision was being challenged often reversed an ALJ's recommended decision that recommended overturning the agency's initial decision, frustrating litigants who thought they had won, only to find their "winning decision" reversed by the very agency they were suing. For many years, some advocates for businesses regulated by state agencies ridiculed this procedure as being a bit like the fox guarding the hen house. On the other side, agencies maintained it was appropriate for them to have the final say due to their expertise in the area of law at issue and their delegated role as interpreter and enforcer of that law. The political climate was ripe in the 2011 legislative session for the final decision authority to be transferred to ALJs.

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NOTE FROM KEN BURGESS

Shorts on Long Term Care is back from summer vacation. This month, our health law group brings you three articles on important developments potentially impacting all long term care providers. We hope you've had a great summer. If you need anything at all, any one of our writers are happy to help. Here's to a happy and healthy Fall!

~Ken

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General Assembly Regulates the Regulators

By Pam Scott and Tom West

The North Carolina General Assembly's historic 2011 session included sweeping reforms to curtail the regulatory authority of all state agencies, including the Division of Health Service Regulation and its Licensure and Certificate of Need Sections, the Division of Medical Assistance, and other agencies directly affecting the operation of long-term care providers in our state. Among the most important legislative changes impacting agencies' regulatory powers is the new rulemaking framework that takes effect October 1, 2011.

Focus on Economic Impact

A common thread interwoven throughout the new rulemaking laws is a heightened focus on economic impact. One of the key changes is a requirement that prohibits agencies from adopting a new rule that will have an aggregate financial impact of $500,000 or more in a 12-month period, unless the rule is required to respond to: (a) a serious and unforeseen threat to public health, safety or welfare; (b) an act of the General Assembly or U.S. Congress that specifically requires the agency to adopt rules; (c) a change in federal or state budgetary policy; (d) a federal regulation; or (e) a court order. Given the relatively low economic impact threshold that will trigger these rule-making constraints, these limitations will likely apply to the majority of new rules of any substance. The new $500,000 significant economic impact floor is a substantial reduction of the $3 million level that existed under the prior law.

Additional new fiscal-related requirements for agency rulemaking include:

- A mandate that the agency consider at least two alternatives before adopting a rule with an economic impact of $500,000 or more per year and explain why those alternatives were rejected;
- A requirement that the agency proposing a rule prepare any required fiscal note for approval by the Office of State Budget and Management (OSBM);
- Provisions for increased critical review and analysis of any fiscal note prepared for a proposed rule;
- A requirement that for a proposed rule with an economic impact of $500,000 or more per year, the agency must, among other things, (a) describe the persons who would be subject to the proposed rule and the types of expenditures those persons would have to make; and (b) estimate additional costs that would result from implementation of the proposed rule, including both economic and opportunity costs; and
- Provisions to facilitate public comment and input on a proposed new rule as well as any related fiscal note.

Other New Rulemaking Mandates

Along with these changes keyed to economic impact, the General Assembly adopted a new slate of rulemaking principles. These principles applicable to all proposed new rules provide:

- An agency may adopt only those rules that are expressly authorized by federal or state law and that are necessary to serve the public interest;
- An agency must seek to reduce the burden on persons and entities that will have to comply with the rule;
- Rules must be written in a clear manner and must be reasonably necessary to implement or interpret federal or state law;
- An agency must consider the cumulative effect of all its rules related to the specific purpose for which the new rule is proposed and cannot adopt a rule that is unnecessary or redundant;
- When appropriate, rules must be based on sound and reasonable scientific, technical, economic, and other relevant information; and
- Rules must be designed to achieve the objective in a cost-effective and timely way.

Agencies will now be required to post proposed new rules on their websites, along with an explanation of the proposed rules and the reasons behind them, any fiscal notes or federal certifications for the proposed rules, and instructions on how and where to submit comments on the proposed rules. These general rulemaking guideposts adopted by the General Assembly essentially codify the regulatory principles established by Governor Perdue as part of her regulatory reform initiative under Executive Order No. 70 issued in October 2010.

Annual Review of Existing Rules

In addition to changes governing future rules, the General Assembly adopted a new statute governing the Rules Modification and Improvement Program (RMIP) which will be coordinated and overseen by OSBM. Many of the statutory requirements relating to the RMIP essentially adopt as state law the regulatory changes that were originally established as part of the RMIP under the Governor's Executive Order No. 70. Under the new statute, each agency must conduct a critical review of its existing rules each year to identify any rules that are unnecessary, unduly burdensome, or inconsistent with the new general rulemaking principles. The OSBM will invite public comments on existing rules, assemble and evaluate public comments received, and forward any comments it deems to have merit to the agency at issue for further review. Each agency must review the public comments and report on whether any of the public's recommendations have merit or justify further action. Agencies must repeal any nonconforming rules identified in this review.

Only time will tell what the actual practical and legal ramifications, costs, benefits, and efficiencies of our state's new rulemaking framework will be. Meanwhile, long term care providers and other regulated businesses in North Carolina have a new playbook to follow, which includes increased opportunities for commenting on existing and proposed rules and their economic impact and for understanding the agencies' reasoning behind both existing and proposed new rules.

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Second Bite of the Apple

(continued from page 1)

Beginning with contested cases filed on January 1, 2012, the ALJ's decision in a case will be final, subject to any further appeal to court. This substantial change in the law will apply to all executive branch agencies and all types of contested cases subject to the APA, with the limited exception of cases involving occupational licensing boards. Unlike past APA amendments aimed at strengthening the weight and force of an ALJ's decision, there is no carve out to exclude certificate of need disputes from this momentous change.

The move to ALJ final decisions is certain to trigger a corresponding shift in the course and tactics of hearings in contested cases challenging agency actions. Agency expertise and whether the agency's interpretation of the law is supported by controlling statutes and rules will likely become more critical aspects of contested case hearings. Agencies and private parties aligned with them will no longer have an opportunity at the final decision stage to bring ALJ decisions in line with the agencies' perspective on the law. This will make it important for parties on both sides of the case to put on evidence regarding how the agency decision being challenged fits (or not) within the law as well as any agency expertise or lack thereof.

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OCTOBER 2011

No Harm, No Foul in CON Challenges

by Pam Scott

The North Carolina Court of Appeals recently issued a decision making crystal clear that in order to successfully challenge the approval of a non-competitive certificate of need application, a petitioner must show how its rights have been substantially prejudiced by the CON approval. *Wake Radiology Services LLC et al. v. N.C. Department of Health and Human Services et al.* (N.C. Court of Appeals Case No. COA10-1129, Sept. 6, 2011) involved an appeal from a decision to award Pinnacle Health Services of North Carolina, LLC a CON to purchase a mobile MRI scanner for use in Wake and Johnston Counties. Pinnacle essentially proposed to acquire its own mobile MRI scanner to replace the leased MRI scanner it had been using to provide services at three sites in Wake and Johnston. Wake Radiology Services, LLC and affiliated entities challenged the approval of Pinnacle's non-competitive application. In upholding the decision to award the CON to Pinnacle, the Court of Appeals focused on the statutory requirement that a party appealing a decision to approve a CON application must demonstrate how the decision "substantially prejudiced" its rights.

The court rejected Wake Radiology's theory that its status, under the CON Law, as an entity that could challenge the Pinnacle decision automatically established the substantial prejudice component of its case. The court concluded that Wake Radiology's standing to appeal the CON decision in no way obviated the need to prove that its rights were substantially prejudiced by the decision.

After reviewing DHHS's findings regarding the testimony of Wake Radiology's president concerning a past decline in Wake Radiology's MRI volumes and an increase in the percentage of lower paying patient groups (Medicare, Medicaid, and self-pay patients) after Pinnacle first began offering mobile MRI services in Wake and Johnston Counties, the Court of Appeals agreed with the department that this evidence failed to demonstrate substantial prejudice resulting from the CON decision. The court noted that because Wake Radiology's evidence of harm was based exclusively on its own internal data, it left open many possible causes from other market conditions for the changes in MRI volume and patient mix. The court also pointed to the fact that Wake Radiology's testimony focused on past events that pre-dated the CON decision at issue, and noted the absence of any evidence other than speculation by the company's president regarding how Wake Radiology would be harmed by the award of the CON to Pinnacle. The *Wake Radiology* decision is the strongest articulation to date of the Court of Appeals' position, reflected in earlier opinions, that a petitioner challenging the approval of another provider's non-competitive CON application must show substantial prejudice through proof which must amount to something more than existing market conditions and competitive impact.

Ken's Quote of the Month

"Dreams come in a size too big so that we can grow into them."

Anonymous