Prognosis

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The Chair's Comments

Sissy Holloman

The 2013-2014 year is well underway for the Health Law Section with several projects in the works which will benefit our community. The Health Law Section has been focusing this year on pro bono projects associated with advance directives and other needs associated with critical illness. Our site for advance directives on the North Carolina Bar Association website (***www.AGiftToYourFamily.org***) has been up and running for several months with helpful information on advance care planning and documenting wishes about end of life treatment in advance directives. Many of our members have been busy volunteering with the Cancer Center Pro Bono Legal Project, a joint initiative of Duke and UNC Law Schools and the cancer centers associated with the two institutions, for which practicing attorneys supervise law students in educating patients about their rights and assisting with the creation of advance directives.

The Council is planning a "Summit on Pro Bono Efforts related to Critical Illness" on February 18th at the Bar Center to bring together interested attorneys to discuss coordinating our existing pro bono projects and developing new projects that can make a difference to those living with critical illness. We will provide more information on this meeting in the next couple of weeks. We hope many of you will join us to discuss these important initiatives.

Members of the Health Law Council participated in discussions at Wake Forest Law School during its "Table Talk" initiative to bring practicing attorneys to the law school for practical discussions with law students. In addition, the Health Law Council will hold its February meeting at Wake Forest Law School and will meet with students before our council meeting to discuss health law and the practice of law in general. Also,

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Double Immunity: Protecting the Corrective Action Process Under State and Federal Law

By Jay Salsman

In North Carolina, a physician seeking to challenge the outcome of a corrective action proceeding taken against the physician's hospital privileges faces substantial obstacles. The Health Care Quality Improvement Act establishes a presumption of immunity for a professional review body participating in a corrective action, and the physician has the burden of overcoming this immunity. Additionally, North Carolina law establishes a broad grant of immunity to medical review committee members in corrective action proceedings. Importantly, the North Carolina peer review statute also creates an evidentiary privilege preventing the introduction of evidence of the proceedings of a medical review committee, inclusive of the records and materials it produces. When combined with the presumption of immunity under the HCQIA, the evidentiary privilege creates a powerful shield from liability for defendants.

The Immunity Statutes

N.C.G.S. § 131E-95(a). The North Carolina peer review statute provides a broad grant of immunity to hospital medical review committee participants. A medical review committee member who acts without malice or fraud, "shall not be subject to liability for damages in any civil action on account of any act, statement or proceeding undertaken, made, or

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as part of our long range plan, following the success of last year's in depth discussion on joint ventures with law students from Elon and UNC Law Schools, we intend to hold additional educational sessions with law students on specific health law topics.

The Council will soon be taking nominations for new members of the Council, and we hope many of you will consider this service to our Section. In addition, we are always looking for new committee members and others interested in working on specific projects of the Section. If you are interested in serving on the Council or wish to nominate someone else, please contact me (hollome@labcorp.com) or any Council member. We welcome your ideas and input. Thanks to all of you for your involvement in the Section.

NCSHCA – President's Report (January 2014)

Marc C. Hewitt

Marc Hewitt

I write this report in the waning days of December as I look back on the year. 2013 was a challenging year for healthcare providers nationwide, and saw several major events here in North Carolina, for example:

- The State elected in February not to expand Medicaid following the 2012 U.S. Supreme Court decision striking down part of the Affordable Care Act;
- North Carolina hospitals faced significant allegations of improper billing, in administrative, civil and criminal proceedings;
- N.C. DHHS's problem-plagued rollout of the NCTracks Medicaid payment system under a $494 Million contract with a private vendor, as detailed by the NC State Auditor; and
- A U.S. District Court entered a judgment for over $270 Million against a South Carolina hospital for alleged Stark violations under the Federal False Claims Act (OK, this one was in South Carolina, but it is in the Fourth Circuit).

As healthcare lawyers, we have both the challenge and opportunity to practice in a difficult economic and regulatory climate, in which North Carolina's healthcare providers need good lawyers more than ever. Against that background it is particularly humbling to represent so many excellent lawyers as I take over as president NC Society of Healthcare Attorneys from Joe Kahn, one of the best I know. Many thanks to Joe for his leadership and fine example during 2012-2013.

The Coming Year | This year the Society will focus mainly on healthcare issues relevant to North Carolina providers. We will not ignore Federal issues, but in light of the consistent flow of information and analysis of Federal issues from AHLA and other organizations, we think we can provide the most benefit to our membership by emphasizing North Carolina issues.

The Society will continue its educational mission by providing several CLE opportunities via live programs and webinars, plus regular publications and news alerts. The first webinar will cover N.C. Medicaid hot topics, which promises to be a very timely discussion of controversial issues, co-presented by Knicole Emanuel and Robb Leandro. It is tentatively set for midday on February 27, so please mark your calendars.

We are excited about the recent launch of the N.C. Society of Healthcare Attorneys LinkedIn group, led by David Broyles, to provide a platform for discussion and the rapid release of news and alerts. We have also formed an Alerts Committee, co-chaired by Amy Flanary-Smith and Susan Hackney, to collect and distribute alerts from our members on important healthcare developments. We enthusiastically invite any members of the Society and/or the Health Law Section to get involved with these efforts. Just contact the point persons or me – our contact information is on the Society's web site (www.ncshca.org).

The Society also continues its financial support of deserving healthcare-related causes with grants and donations. At the close of 2013 the Society donated $5,000 to the N.C. Partnership for Compassionate Care, whose mission is to provide statewide initiatives for the community, professionals, and healthcare systems to ensure that patients' end-of-life care choices are discussed, documented and honored (see http://www.ncmedsoc.org/blog/wp-content/uploads/2013/07/NCPCC-Description.pdf).

Invitation to Join and Participate | The Society's diverse mix of in-house, private practice, government and academic lawyers provides a tremendous opportunity to learn, network and develop professionally. Thanks to all the Society's members, and especially those who gave their time to serve on committees and our board of directors, for helping the North Carolina Society of Healthcare Attorneys thrive in 2013. As we welcome 2014, I urge our members who are not already active in committees or the Society's projects to reach out and get involved, and to invite any non-members interested in healthcare to join.

Double Immunity, continued from the front page

performed within the scope of the functions of the committee." *Id.* A medical review committee is defined to include, among other things, a committee of a hospital or a hospital medical staff formed for the purpose of evaluating quality, cost, or necessity of health care, including medical staff credentialing. N.C.G.S. § 131E-76(5). Similar statutes provide immunity to physician practices, skilled nursing facilities, and certain other providers. *See e.g.*, N.C.G.S. §§ 90-21.22A; 131E-107.

On its face, the statute's immunity applies to "[a] medical review committee member." Does the statute provide immunity to the hospital which forms the committee? While no North Carolina case has expressly addressed this issue, there is authority which implicitly supports the proposition that a hospital is entitled to immunity under the statute. In **McKeel v. Armstrong**, 96 N.C. App. 401, 386 S.E.2d 60 (1989), the Court of Appeals affirmed summary judgment in favor of a defendant-hospital on immunity grounds under Section 131E-95(a) without specifically analyzing whether a hospital falls within the scope of the immunity provision. Similarly, in **Philips v. Pitt County Mem'l Hosp., Inc.**, — N.C. App. —, 731 S.E.2d 462 (2012), the Court of Appeals found the defendant-hospital immune under Section 131E-95(a), again without any analysis of the statute's application to a hospital. Notwithstanding, a convincing argument can be made that to further the clearly defined goals of the statute, the immunity must be afforded to a hospital which forms a medical review committee. Otherwise, the immunity could be easily avoided, and the legislative intent behind enactment of the statute frustrated, merely by suing the hospital instead of the committee members who may be acting as agents of the hospital or medical staff in carrying out their committee responsibilities.

Thus, when a physician files suit seeking damages resulting from corrective action proceeding (assuming the defendants fall within the purview of the statute), the pertinent issue becomes whether the plaintiff is able to establish malice or fraud to overcome the immunity. In **McKeel**, 96 N.C. App. at 408, 386 S.E.2d at 64, the Court of Appeals recognized that "in almost any situation [involving a corrective action], opportunities [exist to] compromise the investigation if the persons involved [are] motivated by malicious intent[.]" However, the court refused to infer malice or fraud from such opportunities since the plaintiff "failed to produce any evidence of such intent." Thus, the plaintiff must allege and provide specific evidence demonstrating the hospital or members of the medical review committees acted fraudulently or with malicious intent. **Philips**, 731 S.E.2d at 472.

The Health Care Quality Improvement Act (42 U.S.C. § 11111, et seq.) (HCQIA). Under HCQIA, these review bodies are protected from damages for professional review actions taken:

> (1) in the reasonable belief that the action was in the furtherance of quality health care,
> (2) after a reasonable effort to obtain the facts of the matter,
> (3) after adequate notice and hearing procedures are afforded to the physician involved or after such other procedures as are fair to the physician under the circumstances, and
> (4) in the reasonable belief that the action was warranted by the facts known after such reasonable effort to obtain facts and after meeting the requirement of paragraph (3).

42 U.S.C. § 11112(a); *see also* 11111(a)(1). HCQIA immunity is not dependent on a hospital's compliance with its bylaws, but rather, provides a uniform set of national standards. **Wahi v. Charleston Area Med. Ctr., Inc.,** 562 F.3d 599, 609 (4th Cir. 2009). There is a presumption that these requirements have been met. 42 U.S.C. § 11112(a). The plaintiff bears the burden of proving that immunity does not attach. **Bryan v. James E. Holmes Reg'l Med. Ctr.,** 33 F.3d 1318, 1333 (11th Cir. 1994).

The first element for HCQIA immunity is met if "the reviewers, with the information available to them at the time of the professional review action, would reasonably have concluded that their action would restrict incompetent behavior or would protect patients." **Bryan**, 33 F.3d at 1334-35. Because the standard is an objective one, assertions of hostility or bad faith are irrelevant to immunity analysis. **Poliner v. Texas Health Sys**., 537 F.3d 368, 378 (5th Cir. 2008). The Act does not require an actual improvement in health care, nor does it require that the conclusions reached by the reviewers be correct. *Id.*

Secondly, HCQIA immunity requires that the action be taken after a reasonable effort to obtain the facts of the matter. 42 U.S.C. § 11112(a)(2). HCQIA only requires the totality of the process leading up to the professional review action be evidenced by a reasonable effort to obtain the facts of the matter. **Gabaldoni v. Washington Cnty. Hosp. Assoc.,** 250 F.3d 255, 261 (4th Cir. 2001).

The third requirement for immunity under HCQIA is that the action be taken "after adequate notice and hearing procedures are afforded to the physician involved or after such other procedures as are fair to the physician under the circumstances." 42 U.S.C. § 11112(a)(3). There are "safe harbor" provisions established by 42 U.S.C. § 11112(b) which, if satisfied, result in the reviewing body being deemed to have met the adequate notice and hearing requirements as a matter of law. However, failure to satisfy the safe harbor provisions does not mean the reviewing body failed to provide adequate notice and hearing procedures, so long as the procedures were fair under the circumstances. HCQIA recognizes two exceptions to the prior notice and hearing requirement—one allowing immediate suspension to avoid imminent danger and another permitting a 14-day suspension or restriction to allow an investigation. *Id.* at 11112(c).

Finally, the analysis under § 11112(a)(4) closely tracks the analysis under § 11112(a)(1). **Poliner**, 537 F.3d at 384. To the extent the inquiry differs at all from that under § 11112(a)(1), courts tend to examine whether the specific action taken was tailored to address the health care concerns raised. *Id.*

The Evidentiary Privilege under N.C.G.S. § 131E-95(b) and its application in actions challenging the corrective action process

N.C.G.S. § 131E-95(b) provides:

> The proceedings of a medical review committee, the records and materials it produces and the materials it considers shall be confidential . . . and shall not be subject to discovery or introduction into evidence in any civil action against a hospital . . . or a provider of professional health services which results from matters which are the subject of evaluation and review by the committee. No person who was in attendance at a meeting of the committee shall be required to testify in any civil action as to any evidence or other matters produced or presented during the proceedings of the committee or as to any findings, recommendations, evaluations, opinions, or other actions of the committee or its members . . . A member of the committee or a person who testifies before the committee may testify in a civil action but cannot be asked about the person's testimony before the committee or any opinions formed as a result of the committee hearings.

On the face of the statute, the privilege is broad and absolute. But does the privilege apply when the corrective action itself is being challenged? The answer, it appears, is yes. However, application of this privilege can severely handicap a plaintiff-physician's ability to overcome the immunity provided by state and federal law.

The purpose of the Hospital Licensure Act, under which Section 131E-95 is codified, is "to promote the public health, safety and welfare and to provide for basic standards for care and treatment of hospital patients." **Shelton v. Morehead Mem'l Hosp.**, 318 N.C. 76, 82, 347 S.E.2d 824, 828 (1986). The privilege was enacted because of fear that access to peer review investigations would stifle candor and inhibit objectivity. *Id.* "The Act represents a legislative choice between competing public concerns. It embraces the goal of medical staff candor at the cost of impairing plaintiffs' access to evidence." *Id.* There is no exception to this rule when the peer review itself is being challenged as the privilege applies to "any civil action." **Virmani v. Presbyterian Health Svs. Corp.**, 350 N.C. 449, 515 S.E.2d 675 (1999). Unlike the immunity provision under Section 131E-95(a), there is no "malice or fraud exception" to the evidentiary privilege under Section 131E-95(b).

Similar evidentiary privileges generally have been upheld in other jurisdictions, even when the corrective action is being challenged. For example, in **Patton v. St. Francis Hosp**., 539 S.E.2d 526 (Ga. Ct. App. 2000), a physician filed suit against a hospital related to the termination staff privileges. Through discovery, the plaintiff sought information related to the peer review process which resulted in the termination of his privileges, but the court held that such information was immune from discovery under the Georgia peer review statute. Even assuming that the hospital acted with malice, the privilege nonetheless applied. To allow an allegation of malice to destroy the discovery shield would result in full discovery in virtually all peer review cases, contrary to the intent behind enactment of the statute. *Id.* at 528. Moreover, the failure of a hospital to comply with its bylaws does not destroy the privilege, as allowing such an exception "would virtually destroy the candor sought in the setting of hospital peer review." The court also rejected the plaintiff's argument that the privilege should not apply when the peer review process itself is challenged. To allow such an exception would similarly "swallow the rule," as it is a "rare case in which disciplined physicians do not challenge the peer review process." *Id.* at 529-30.

Similarly, in **Holly v. Auld,** 450 So.2d 217 (Fla. 1984), the Florida Supreme Court upheld a statutory peer review discovery privilege in a suit alleging defamation against members of a hospital's credentials committee, after the plaintiff's application for staff privileges was denied. The court held that the peer review discovery privilege applied, even in the face of a defamation claim. The court reasoned as follows:

> Inevitably, such a discovery privilege will impinge upon the rights of some litigants to discovery of information which might be helpful, or even essential to their causes. We must assume that the legislature balanced this potential detriment against the potential for health care cost containment offered by effective self-policing by the medical community and found the latter to be of greater weight. It is precisely this sort of policy judgment which is exclusively the province of the legislature rather than the courts.
> *Id*. at 20.

At least one state, however, has adopted a physician-plaintiff exception. In **Hayes v. Mercy Health Corp.**, 739 A.2d 114 (Pa. 1999), the Pennsylvania Supreme Court held that the confidentiality provisions of its state peer review statute did not apply where a physician challenged his own peer review process. Instead, the court reasoned that the privilege applies only in actions where an outside party seeks to hold a health care provider liable for negligence.

In North Carolina, the Court of Appeals recently considered the privilege in a case where a physician brought suit against a hospital and several medical review committee members after a series of corrective actions resulted in revocation of the physician's staff privileges. In **Philips v. Pitt County Mem'l Hosp., Inc**., — N.C. App. —, 731 S.E.2d 462 (2012), the trial court entered a protective order pursuant to Section 131E-95(b), finding the documents generated by various medical review committees were privileged. In light of the protective order, the entry of which the plaintiff failed to challenge on appeal, the plaintiff was unable to produce any evidence of malice or fraud sufficient to overcome the immunity afforded by Section 131E-95(a). Further, the plaintiff was not able to offer evidence of allegedly defamatory testimony of several defendants presented before various medical review committees involved in the corrective action proceedings. Thus, the court applied the evidentiary privilege even though it deprived the plaintiff of crucial evidence. *See also* **Virmani**, 350 N.C. at 464, 515 S.E.2d at 686 (rejecting argument that the privilege under Section 131E-95(b) applies only to third party malpractice plaintiffs).

Practical Implications

Philips highlights the challenges a plaintiff faces when attempting to overcome statutory immunity, both under state and federal law, because the plaintiff lacks the ability to obtain or introduce evidence of the very proceedings the plaintiff is challenging. This difficulty is compounded by HCQIA's presumption of immunity, which the plaintiff bears the burden of rebutting.

A defense lawyer may be poised to defend a case by establishing that the corrective action taken against a physician's privileges was the "correct" decision based upon the evidence developed during the corrective action proceeding. However, the hospital should carefully balance the need for this evidence against the plaintiff's ability to prosecute his case in the absence of evidence concerning the proceedings. It often will be difficult for a plaintiff to produce evidence to overcome statutory immunity when the evidentiary privilege prevents discovery of the proceedings. This decision will likely need to be made early in the litigation, perhaps before filing an answer to the complaint, so as to avoid a claim that the privilege was waived. Nevertheless, there is some question as to whether this privilege can be waived. *See* **Virmani v. Presbyterian Health Services Corp.**, 305 N.C. 449, 515 S.E.2d 675 (1999) (addressing peer review materials, which were attached to the complaint in the public court file).

Additionally, in situations where removal to federal court is a consideration (whether in a diversity case or in action brought pursuant to 42 U.S.C. § 1983), the parties need to determine at the outset of the case whether the privilege is a significant issue. Federal courts are hesitant to recognize this evidentiary privilege and have refused to do so in many cases. *See, e.g.,* **Virmani v. Novant Health Inc.**, 259 F.3d 284 (4th Cir. 2001). Accordingly, a hospital may prefer to remain in state court to protect these documents.

Finally, it is important to keep in mind that the proponent of the privilege has the burden of establishing its application. ***Hammond v. Saini***, — N.C. App. —, 748 S.E.2d 585 (2013); **Bryson v. Haywood Reg'l Med. Ctr.**, 204 N.C. App. 532, 536, 694 S.E.2d 416, 420 (2010). Thus, the defendant must establish that the committees in question meet the statutory definition of "medical review committees" and that the documents at issue fall within the purview of Section 131E-95(b). This will likely be done through affidavits, with the privileged documents submitted under seal for in camera review. Providers should be sure to submit enough information to allow the trial court, and ultimately an appellate court, to confirm application of the privilege.

Conclusion

Application of the evidentiary privilege under N.C.G.S. § 131E-95(b) deprives a plaintiff of crucial evidence which may be necessary to overcome the statutory immunities afforded to defendants. This can be a harsh result and one which plaintiffs and their counsel will likely view as unjust. However, an examination of the legislative histories of the North Carolina peer view statute and HCQIA suggest that the goal of these laws is to favor effective and candid peer review over a plaintiff's access to critical evidence.

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Realizing the Promise of Advance Directives: A New Option for North Carolinians

"Life is pleasant. Death is peaceful. It's the transition that's troublesome." --Isaac Azimov

By John C. Moskop and Beth M. Gianopulos

Introduction | Patients nearing the end of life, and the representatives of patients who lack decision-making capacity, often face difficult decisions about whether to pursue life prolongation or relief of symptoms and quality of life as primary goals of treatment. More than 30 years ago, the North Carolina General Assembly enacted our state's first set of advance directive statutes, the Right to a Natural Death Act, to help patients communicate their end-of-life treatment preferences. Since that time, the Natural Death Act has been revised multiple times, and in 1991, state legislation recognized a second type of advance directive, the Health Care Power of Attorney. The current statutes include a set of model advance directive forms, but, these forms are still complicated and hard for the average layperson to understand. Even experienced attorneys struggle to explain the statutory model forms.

A Piedmont Triad Initiative | Advance care planning facilitators in North Carolina have long complained that the statutory model forms are too long and complicated, the literacy level of the forms is simply too high for many people, and that some of the form options are very confusing. In the face of general dissatisfaction with the model forms, a group convened in early 2012 to explore options for improving advance care planning and advance directives in the Triad region. The group included representatives from Wake Forest Baptist Health, Novant Health, High Point Regional Health, Cone Health, and Hospice and Palliative CareCenter of Winston-Salem. Participants came from multiple disciplines, including physicians, hospital legal counsel, private elder law and estate planning attorneys, patient representatives, chaplains, and bioethicists.

After reviewing existing advance directive forms, the group chose to draft a new form for regional use. The new form was tested at several Triad medical centers and was strongly preferred by patients and facilitators to the statutory model forms used previously. The new form is now in use at three of the Triad's largest hospitals: Wake Forest Baptist Medical Center, Novant Health Forsyth Medical Center, and High Point Regional Hospital.

The New Advance Directive Form | The Triad working group had five major goals for its new advance directive form:

1. The form should be understandable by the vast majority of those who undertake this planning.
2. The form should be relatively brief and easy to complete.
3. The form should include all of the essential elements of the two main types of advance directives: living wills and health care powers of attorney.
4. The form should meet North Carolina statutory requirements for advance directives and thus provide the statutory protections for health care providers who honor advance directives.
5. The form should promote discussion of future treatment wishes, especially between the principal and the person he or she appoints as health care agent.

With these goals in mind, the Triad group crafted a new advance directive form with these major features:

1. Since most people who complete the planning process prepare both a living will and a health care power of attorney, the new form combines these two directives in a single document. This makes the document easier to complete and avoids the need for separate signatures and notarization. The document also clearly allows the principal to complete only one of the two directives, if he or she so prefers, by marking through the undesired directive. The advance directives statutes explicitly state that these two directives may be combined in a single document. N.C.G.S. § 321(j); N.C.G.S. § 32A-26.
2. The language of the new form is simplified for easier understanding. Here are two examples of parallel passages:

Statutory model forms	New advance directive form
"I DO want to receive BOTH artificial hydration AND artificial nutrition (for example, through tubes) . . ."	"I DO want to receive tube feeding . . ."
"I, _____, being of sound mind, hereby appoint the following person(s) to serve as my health care agent(s) to act for me and in my name (in any way I could act in person) to make health care decisions for me as authorized in this document."	"My name is _____. My birth date is ____. The person I choose as my health care agent is . . ."

3. The form is shortened to five pages, from the 10-pages of the statutory model forms. There are two pages of instruc-

tions that describe the purpose of the document and define key terms like "health care agent" and "life-prolonging measures," one page for the health care power of attorney, one page for the living will, and the execution page for the signatures of the principal and the two witnesses and the notarization information.

Meeting Statutory Requirements | The Triad working group recognized that a major function of the North Carolina advance directives statutes is to encourage health care professionals to honor patients' directives by providing immunity from liability for professionals who do so. The working group drafted the new advance directive form with the clear intention to meet statutory requirements and thereby provide the statutory protections to providers relying on it. The statutory requirements for living wills and for health care powers of attorney in North Carolina are described in the North Carolina Right to Natural Death Act (N.C.G.S. § 90-320 through 90-322) and the North Carolina Health Care Power of Attorney statutes (N.C.G.S. § 32A-15 through 32A-27). Although statutory model forms exist, use of the model forms is optional. N.C.G.S. § 90-321(i); N.C.G.S. § 32A-25.1(b). Alternative forms also provide the statutory protections for health care professionals who honor them, as long as they meet certain statutory requirements. N.C.G.S. § 90-321(h); N.C. G.S. § 32A-24(d). For instance, the statutes require that both living wills and health care powers of attorney be notarized and signed by two witnesses who meet certain qualifying criteria. N.C.G.S. § 90.321(c)(4); N.C.G.S. § 32A-16(3) and (6).

Encouraging the Conversation | Although advance directives are clearly an important part of the advance care planning process, the members of the Triad initiative believe that these written plans are not the most important step in that process. It is neither feasible nor desirable to attempt to capture most people's considered and nuanced preferences regarding goals of care and treatment options near the end of life in a lengthy written document. Such a document would be both difficult for most people to prepare and difficult for physicians to understand and implement. The most important steps in the planning process are to choose a health care agent who is willing and able to carry out one's preferences and to engage in an extended conversation about treatment preferences in different circumstances.

The Triad initiative sought, therefore, to emphasize the importance of careful choice of one's health care agent and of thoughtful discussion about one's preferences with that agent. To guide people in these key steps in the planning process, the group developed an informal document for those who prepare health care powers of attorney to present to their chosen health care agents. That document includes a description of the role of the health care agent, including a list of the kinds of health care decisions agents are authorized to make. It also includes the following statement: "I am relying on you to make health care choices on my behalf if I am no longer able to do so. I ask that you make treatment choices for me based on my goals and desires about what kind of care I should receive. It is very important, therefore, that we take time to discuss my desires, goals, and hopes for medical treatment so that you will know what kind of care I want." At the bottom of the document is a space for the signature of the health care agent, immediately following the statement "I accept appointment as your health care agent." The Triad group believes that this document will encourage principals to engage in conversation with their health care agents and will encourage health care agents to take this responsibility seriously.

The Bottom Line | We believe that use of the new advance directive form described above will enable many more North Carolinians to complete the process of advance care planning and to realize its substantial benefits. Therefore, we recommend use of this form for anyone assisting in this planning process, including estate law and elder law attorneys and health system advance care planning facilitators. For a copy of the new form, please go to the website www.ncadvancecareplanning.com and look under "Documents for Download" at the top of the webpage.

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Keep up with the P.A.C.E.: An Overview of Comprehensive, Cost-Effective Managed Care for the Elderly in North Carolina

By Katie Jones

The Program for All-Inclusive Care for the Elderly ("P.A.C.E."), a Medicare/Medicaid managed care benefit, enables frail adults to continue to live in the community. The benefit is available only to adults aged fifty-five years and older who are certified by the state as requiring skilled-nursing level care and who choose to live in the community instead of a nursing facility or other institutional setting. The goal of the program is to promote independence and quality of life, through the efforts of an interdisciplinary team which coordinates medical and social services for program participants. The program philosophy is simple: senior citizens with chronic care needs and their families can be better served in their community whenever possible.

P.A.C.E.: A Brief History

The model of care for P.A.C.E. began in the 1970s, when San Francisco's Chinatown-North Beach community recognized that families with elderly members had increasing needs for long term care services. A committee formed in 1971 investigated solutions for this increased need. The nonprofit corporation On Lok Senior Health Services ("On Lok") was formed as a result of the committee's efforts to create a community-based system of care. "National Pace Association: Who, What and Where is PACE?," Aug. 30, 2013, http://www.npaonline.org. The committee studied the feasibility of building a nursing home in the community, but found that this was not a financial or cultural option. Instead, with the assistance of the University of California at San Francisco, On Lok secured funding to train health care workers and outlined a comprehensive system of care that combined housing, medical, and social services based on the British day-hospital model. *Id.*

By 1973, On Lok opened one of the nation's first adult day centers in San Francisco and began receiving Medicaid reimbursement for adult day health services in 1974. *Id.* As the 1970s progressed, On Lok saw the following additional advancements: (1) addition of a social day care center and inclusion of in-home care, home delivered meals, and housing assistance; (2) expansion of its model of care to include comprehensive medical care and social support for nursing home eligible seniors; and (3) receipt of a four-year Department of Health and Human Services grant to develop a consolidated model of delivering care to individuals with long term care needs. *Id.*

Ten years after opening its first adult day center, On Lok, in 1983, tested a new financing system that paid the program a fixed amount each month for each participant. Three years later, federal legislation extended this financing system and allowed ten additional organizations to duplicate On Lok's service delivery and funding model in other parts of the country. By 1990, the first Program for All-Inclusive Care for the Elderly received Medicare and Medicaid waivers to operate these programs, and, in 1994, with On Lok's support, the National P.A.C.E. Association was formed. By this point, nine states had eleven fully operational P.A.C.E. organizations. Just two years later, in 1996, P.A.C.E. organizations had nearly doubled in size to twenty-one operational organizations in fifteen states. "National Pace Association: Who, What and Where is PACE?," Aug. 30, 2013, http://www.npaonline.org.

The Balanced Budget Act of 1997 (Pub.L. 105–33, enacted August 5, 1997) established the P.A.C.E. model as a permanently recognized provider-type under both Medicare and Medicaid. Between 1999 and 2012, P.A.C.E. grew substantially--from thirty operational programs in nineteen states to eighty-eight programs in twenty-nine states. During this time, interim and final regulations for the program were published, and the program received grants and funds from Congress and other foundations to support expansion into rural areas and extension of benefits to more families in need.

P.A.C.E. Development in North Carolina | Following this trend, North Carolina has implemented several P.A.C.E. programs, the first of which, Elderhaus of Wilmington, opened in 2008 as a result of a North Carolina Department of Health and Human Services pilot program to implement P.A.C.E. As of the date of this publication, North Carolina has the following P.A.C.E. programs:

1. Elderhaus, Inc., Wilmington;
2. Carolina Senior Care, Lexington;
3. LIFE St. Joseph of the Pines, Fayetteville;
4. PACE @ Home, Inc., Newton;
5. PACE of the Southern Piedmont, Charlotte;
6. PACE of Guilford and Rockingham Counties (d/b/a PACE of the Triad), Greensboro;
7. Piedmont Health SeniorCare, Burlington;
8. Piedmont Health SeniorCare, Pittsboro;
9. Senior CommUnity Care of North Carolina (PACE); Durham; and
10. Senior Total Life Care, Gastonia

Additionally, the following P.A.C.E. programs are currently under development:

1. CarePartners Health Services, Asheville;
2. StayWell Senior Care, Asheboro.

Only public and private not-for-profit organizations can develop and operate a P.A.C.E. program, which requires approval by both the federal Centers for Medicare and Medicaid Services ("CMS") and the state administering agency (Medicaid, or Division of Medical Assistance "DMA"). 42 CFR § 460.60(a). State and federal agencies are required to monitor the programs on a regular basis to ensure compliance with state and federal regulations and further ensure that members receive quality care and services. 42 CFR §§ 460.190-460.196.

Every P.A.C.E. program must define its service area, which also requires approval by CMS and Medicaid. 42 CFR § 460.22. Additionally, each program must include a P.A.C.E. center that provides for a primary care clinic, areas for therapeutic recreation, restorative therapies, socialization, personal care, and dining. 42 CFR § 460.98. These centers serve as the primary areas for coordination and implementation of most P.A.C.E. services. The programs also provide in-home care to individuals in their homes, including in-home personal care services and home health care. Finally, the programs arrange, manage, and pay for all care referred to community providers for services such as hospitalization, nursing facility care, emergency room services, physician visits, and ancillary services. 42 CFR § 460.180.

Consistent with the requirements of federal regulations, P.A.C.E. programs provide the following comprehensive assortment of services to their members/ participants:

1. All Medicaid covered services as indicated in the state's approved Medicaid plan;
2. Multi-disciplinary assessment and treatment planning; primary care, including physician and nursing services;
3. Social work services;
4. Restorative therapies, including physical and occupational therapy and speech-language pathology services;
5. Personal care and supportive services;
6. Nutrition counseling;
7. Medical specialty services including, but not limited to, anesthesiology, audiology, cardiology, dentistry, dermatology, gastroenterology, gynecology, internal medicine, nephrology, oncology, ophthalmology, oral surgery, orthopedic surgery, otorhinolaryngology, plastic surgery, pharmacy consulting services, podiatry, psychiatry, pulmonary disease, radiology, rheumatology, general surgery, thoracic and vascular surgery, and urology;
8. Recreational therapy;
9. Transportation;
10. Meals;
11. Laboratory tests, x-rays, and other diagnostic procedures;
12. Drugs and biological;
13. Prosthetics, orthotics, durable medical equipment, corrective vision devices, dentures;
14. Acute inpatient care to include ambulance service, emergency room care and treatment, semi-private room and board, general medical and nursing services, medical surgical, intensive care, and coronary care unit, laboratory tests, x-rays, and other diagnostic procedures, drugs and biological, blood and blood derivatives, surgical care and anesthesia, oxygen, physical, occupational, and respiratory therapies and speech language pathology services, and social services; and
15. Nursing facility care including semi-private room and board, physician and skilled nursing services, custodial care, personal care and assistance, drugs and biological, physical, occupational, recreational therapies, and speech language pathology if necessary, social services, medical supplies and appliances, and other services determined necessary by the interdisciplinary team to improve and maintain the member's overall health status. 42 CFR § 460.98

P.A.C.E. uses the interdisciplinary care team to manage all of these services, which are provided or arranged by the program for each member. Federal law requires the interdisciplinary care team to be comprised of individuals in the following specialties: (1) primary care physician; (2) registered nurse; (3) master's-level social worker; (4) physical therapist; (5) occupational therapist; (6) dietitian; (7) recreational therapist or activity coordinator; (8) P.A.C.E. center manager; (9) home care coordinator; (10) personal care attendant; and (11) driver. 42 CFR § 460.102(b).

N.C. P.A.C.E. Program Eligibility Requirements | In North Carolina, as in other states, only those individuals fifty-five years of age or older who are certified as requiring skilled nursing level care, live in an approved P.A.C.E. service area, and can be safely served in the community are eligible for participation in P.A.C.E. programs. 42 CFR § 460.150.

The North Carolina Division of Medical Assistance Medicaid and Health Choice Clinical Coverage Policy No. 3B (Revised March 12, 2012), (the "Clinical Coverage Policy") governs eligibility requirements and service coverage for existing programs in our state. In general, North Carolina Medicaid recipients must be enrolled on the date of service, and must meet both the federal eligibility requirements set out at 42 CFR § 460.150, and the financial eligibility requirements for Long-Term Care Medicaid/PACE established for North Carolina Medicaid by the Division of Medical Assistance (DMA), as documented in 10A NCAC 21B.0101 and .0102. The general criteria for coverage of a procedure, product, or service under the Clinical Coverage Policy are as follows:

"Procedures, products, and services related to this policy are covered when they are medically necessary and

1. the procedure, product, or service is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the recipient's needs;
2. the procedure, product, or service can be safely furnished, and no equally effective and more conservative or less costly treatment is available statewide; and
3. the procedure, product, or service is furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker, or the provider."

In addition, the following specific coverage criteria apply according to subsection 3.2 of the Clinical Coverage Policy:

"Medicaid pays a monthly capitation fee to the PACE organization for eligible recipients participating in the PACE program when the service is medically necessary and

1. the individual meets Medicaid's requirements for nursing facility level of care, as determined by Medicaid's level of care screening tool . . . ;
2. the level of care determination is confirmed by a comprehensive assessment conducted by the PACE organization . . . ; and
3. the recipient meets the requirements [for federal and financial eligibility]."

Before an individual can enroll in P.A.C.E., Medicaid must certify, in accordance with 42 CFR § 460.152(a)(3), that the applicant meets the state's nursing facility level of care criteria. Additionally, on an annual basis, the P.A.C.E. organization must rescreen each individual using a level of care screening tool and submit the results for each individual to allow Medicaid to verify that the participant continues to meet the nursing level of care criteria. 42 CFR § 460.160(b). If, after enrolling in a P.A.C.E. program, a member no longer meets the nursing facility level of care criteria, he may still be deemed eligible for participation in P.A.C.E. if the state determines that the cessation of P.A.C.E. services would cause the individual's health status to deteriorate such that the individual would qualify for P.A.C.E. services within six months following disenrollment. N.C. DMA Medicaid and Health Choice Clinical Coverage Policy No. 3B, Section 3.3(Revised Mar. 12, 2012).

Once Medicaid certifies that an individual meets nursing facility level of care requirements, the P.A.C.E. interdisciplinary team, under the direction of the medical director, must complete a comprehensive physical, functional, and psychosocial assessment of the individual in accordance with 42 CFR § 460.104, which includes, at a minimum, the following: (i) physical and cognitive function and ability; (ii) medication use; (iii) participant and caregiver preferences for care; (iv) socialization and availability of family support; (v) current health status and treatment needs; (vi) nutritional status; (vii) home environment, including home access and egress; (viii) participant behavior; (ix) psychosocial status; (x) medical and dental status; and (xi) participant language.

In addition, a comprehensive health and safety assessment must be conducted, which ensures that the individual's health, safety, and welfare will not be jeopardized by living in the community. The health and safety assessment must include: (1) an on-site evaluation of the individual's residence; (2) an evaluation of the individual's social support system, including the capabilities and willingness of all informal caregivers; and (3) an evaluation of whether the individual can be safely transported to the P.A.C.E. center. N.C. DMA Medicaid and Health Choice Clinical Coverage Policy No. 3B, Section 5.6.2(Revised Mar. 12, 2012).

Enrollment in P.A.C.E. may be denied if the program is unable to ensure the health, safety, and well-being of the individual under certain circumstances, including the following: (1) the individual is considered to be unsafe when left alone, with or without a personal emergency response system; (2) the individual lacks the support of a willing and capable caregiver who must provide adequate care to ensure the health, safety, and well-being of the individual during any hours when P.A.C.E. services are not being provided; (3) the system of services currently available cannot support the individual's needs; (4) the individual's residence or residential environment is uninhabitable or is unsafe to the extent it would reasonably be expected to endanger the health and safety of the individual, the individual's caregivers, or the P.A.C.E. organization staff if P.A.C.E. services are to be provided in the residence; (5) the individual's behavior is threatening or disruptive or is otherwise harmful (i.e. suicidal, injurious to self or others, or destructive to environment); or (6) there is a high risk of an existing condition of abuse, neglect, or exploitation as indicated by an assessment. *Id.*

After required assessments are complete, P.A.C.E. organizations must first develop a plan of care. The plan of care for each participant must be developed on an electronic health record, or on a form approved by DMA, and then submitted to DMA for approval. The plan must also be updated and submitted to DMA semi-annually for approval as required by 42 CFR § 460.106(d). N.C. DMA Medicaid and Health Choice Clinical Coverage Policy No. 3B, Section 5.7 (Revised Mar. 12, 2012). Additionally, a benefits package must be provided to participants. The P.A.C.E. benefit package provided to all participants must include items and services as indicated under 42 CFR § 460.90, 42 CFR § 460.92, and 42 CFR § 490.94, regardless of the source of payment. *Id.* at Section 5.8. P.A.C.E. programs must also arrange and provide for all in-home and referral services that may be required for participants. 42 CFR § 460.94. In-home and referral services are provided by P.A.C.E. programs that have a home care agency licensed under 10A NCAC 13J, or by community providers under contract with the P.A.C.E. programs. See, 42 CFR § 460.70; 42 CFR § 460.71. Lastly, P.A.C.E. programs must establish and maintain a written plan to provide for emergency care at the P.A.C.E. center and at those times when a participant is not present at the P.A.C.E. center in accordance with 42 CFR § 460.100. This plan must include procedures to access emergency care both in and out of the P.A.C.E. service area, and the program must ensure that participants and caregivers know when and how to access emergency care services. Charges for all emergency care must be paid by the P.A.C.E. program. *Id.*

Finally, participants may voluntarily disenroll from P.A.C.E. at any time without cause in accordance with 42 CFR § 460.162. However, it is important to note that participants may also be involuntarily disenrolled from P.A.C.E. programs. Reasons for involuntary disenrollment may include the following: (1) failure to pay after a thirty day grace period; (2) disruptive or threatening behavior that jeopardizes the participant's health or safety or the safety of others; (3) consistent refusal to comply with an individual plan of care or the terms of the P.A.C.E. enrollment agreement, if the participant has decision-making capacity (including repeated noncompliance with medical advice, repeated failure to keep medical appointments, and relocation outside of the service area); and (4) non-renewal or termination of the program agreement, which occurs when the P.A.C.E organization program-agreement with CMS and the state administering agency is not renewed or is terminated. 42 CFR § 460.164.

If a P.A.C.E. organization proposes to disenroll a participant for disruptive, threatening, or non-compliant behavior, certain documentation requirements apply, and the decision may be subject to review and final determination by the state administering agency. *Id.* In the event a participant is involuntarily disenrolled, both DMA and the P.A.C.E. organization must assist the participant in securing alternate care and services that will meet the participant's medical, functional, psychological, social, and personal care needs. 42 CFR § 460.168.

Financing P.A.C.E. | P.A.C.E. is a fully capitated program, not a fee-for-service model, which provides predictability and also results in a significant reduction in costs. In most cases, P.A.C.E. participants are dually eligible for Medicare and Medicaid benefits. The P.A.C.E. program utilizes monthly capitated payments from Medicare and Medicaid to provide an integrated and comprehensive medical and social service delivery system for participants. Under a P.A.C.E. three-way program agreement, CMS establishes and makes a prospective monthly payment to the P.A.C.E. organization of a capitation amount for each Medicare participant in a payment area, and each state also establishes and makes a prospective monthly payment to the P.A.C.E. organization of a capitation amount for each Medicaid participant. 42 CFR § 460.180 and § 460.182. A P.A.C.E. program is authorized to receive monthly capitated payments from Medicaid for participants who are Medicaid eligible or dually eligible for both Medicare and Medicaid when: (1) the organization has been approved by DMA as a P.A.C.E. provider; (2) the organization has been approved by CMS as a P.A.C.E. provider; and (3) all parties have properly executed the three-way agreement between CMS, DMA, and the P.A.C.E. organization. N.C. DMA Medicaid and Health Choice Clinical Coverage Policy No. 3B, Section 6.3.2 (Revised Mar. 12, 2012). The P.A.C.E. program must accept the capitation payments from Medicare and Medicaid as payment in full for all services required by the participant. Id.

Medicare and Medicaid capitation payments are combined at the provider level, which creates a feasible option for funding primary, acute, and long-term care services. The goal of rate setting for P.A.C.E. is to establish capitation rates that are agreeable to both providers and payers. This goal serves three specific program-objectives: (1) to establish incentives for providers to behave appropriately (i.e. provide high quality care, serve frail members of the population, etc.); (2) to be cost effective for payers relative to current Medicare and Medicaid expenditures; and (3) to give providers sufficient resources to meet participants' needs for comprehensive acute and long-term care services. National Pace Association: State Work Group on PACE Issue Brief #3: PACE Capitation Rate Setting at 1, Aug. 1999.

While CMS determines the P.A.C.E. reimbursement capitation rate through a combination of two formulas, negotiations between the P.A.C.E. organization and the state Medicaid agency determine the monthly capitation rate for Medicaid. 42 CFR § 460.180 and § 460.182. The negotiated Medicaid capitation amount is specified in the P.A.C.E. program agreement and must be less than the amount the state would otherwise have paid under the State plan if the recipients were not enrolled in P.A.C.E., taking into account the comparative frailty of P.A.C.E. participants. 42 CFR § 460.182. For many states, P.A.C.E. is an attractive alternative payment model to consider, as payments under P.A.C.E. are higher than payments under Medicare+Choice programs for the frail elderly living in the community. This is because P.A.C.E. applies risk adjusted capitation rates, whereas Medicare+Choice does not adjust for higher costs associated with these frail elderly who continue to live in the community.

P.A.C.E. programs are currently saving the State of North Carolina money, as the payment rates for P.A.C.E. are less than other options for the frail elderly, such as skilled nursing facilities and fee-for-service payments by Medicaid. According to a March, 2013 letter submitted by Linda Shaw, Executive Director for the North Carolina PACE Association, in response to a NC Department of Health and Human Services, Division of Medical Assistance Request for Information, North Carolina saves between $14,315.00 to $18,400.00 annually for each person P.A.C.E. keeps out of a skilled nursing facility, as a result of the capitated financing system. RFI-DMA 100-13; NC PACE Association; Linda S. Shaw, at 5. North Carolina uses an upper payment limit methodology for calculating costs of other Medicaid services for beneficiaries eligible for nursing home level of care. As of the date of Shaw's letter, the Medicaid only upper payment limit for those fifty-five years of age and older was $4,733.00, and the North Carolina Medicaid only P.A.C.E. capitated rate was $3,562.00, which amounts to a 25% savings to North Carolina. *Id.* The P.A.C.E. capitation rate for dually eligible individuals over sixty-five years of age was $300.00 per year per person less than the dual eligible upper payment limit, which amounts to a six figure savings for the state. *Id.* Moreover, because P.A.C.E. programs assume the full risk for patient care at a fixed monthly rate, the cost to North Carolina for each individual is predictable and consistent, providing budgeting certainty throughout the year. *Id.* All of the above factors, combined, make the P.A.C.E. capitated financing system a cost-effective, fiscally sound, and advantageous system of health care delivery for the State, providers, and participants.

Pick up the P.A.C.E. | The P.A.C.E. program model is more cost effective for providers and the state than the traditional fee-for-service model, provides a full range of services to the elderly, and is consistent with evolving health care needs in our society. The continuous development of P.A.C.E. programs across the United States underscores the value of the high quality, individualized care P.A.C.E. provides to its participants, and furthers the program's goal of allowing the frail elderly to continue to live in their communities as long as they are able to do so. North Carolina, therefore, should continue development of P.A.C.E. programs, picking up the pace and emerging as a leader in the future of long term care through the P.A.C.E. managed care model.

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The October 2013 Tuomey Order: What Happened, What Can We Learn and What's Next

By Karen A. Gledhill, John B. Garver, III and Amit Bhagwandass

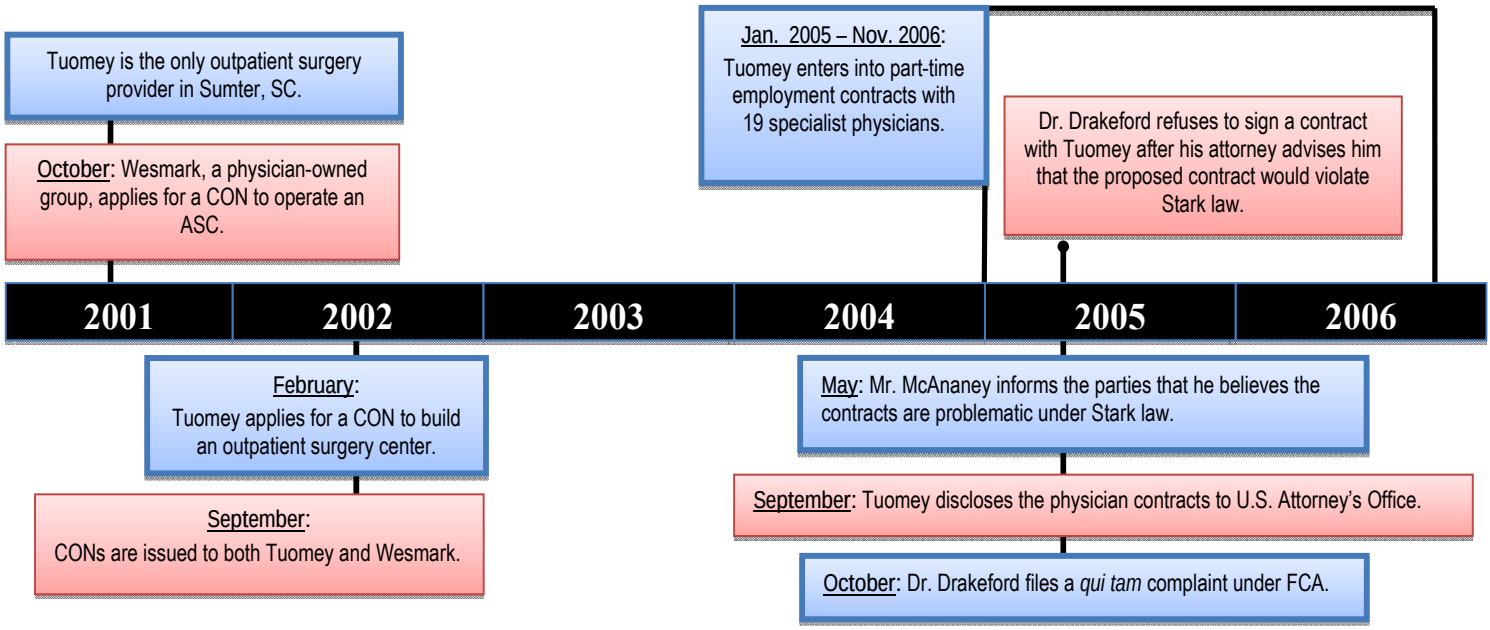
On Oct. 2, 2013, almost eight years to the day from the filing of the relator's complaint, Tuomey Healthcare System's hard fought qui tam action took its latest turn when the District Court upheld a jury verdict and ordered Tuomey to pay damages of $237.4 million. **U.S. ex rel. Drakeford v. Tuomey,** CA 3:05-2858-MBS, 2013 WL 5503695, (D.S.C. Oct. 2, 2013). That total figure exceeds Tuomey's 2011 annual revenues of $202 million (its total assets as of as of September 2011 were only slightly greater -- $275 million). Tuomey immediately appealed and requested a stay of judgment. Unless the parties reach a settlement (and both have publicly stated they would entertain one), the Fourth Circuit will review the case for the second time. *See*, **U.S. ex rel. Drakeford v. Tuomey Healthcare Sys., Inc.**, 675 F.3d 394 (4th Cir. 2012). This article brings the reader up to date on the case and offers practical advice for steering clear of problems such as those now faced by Tuomey.

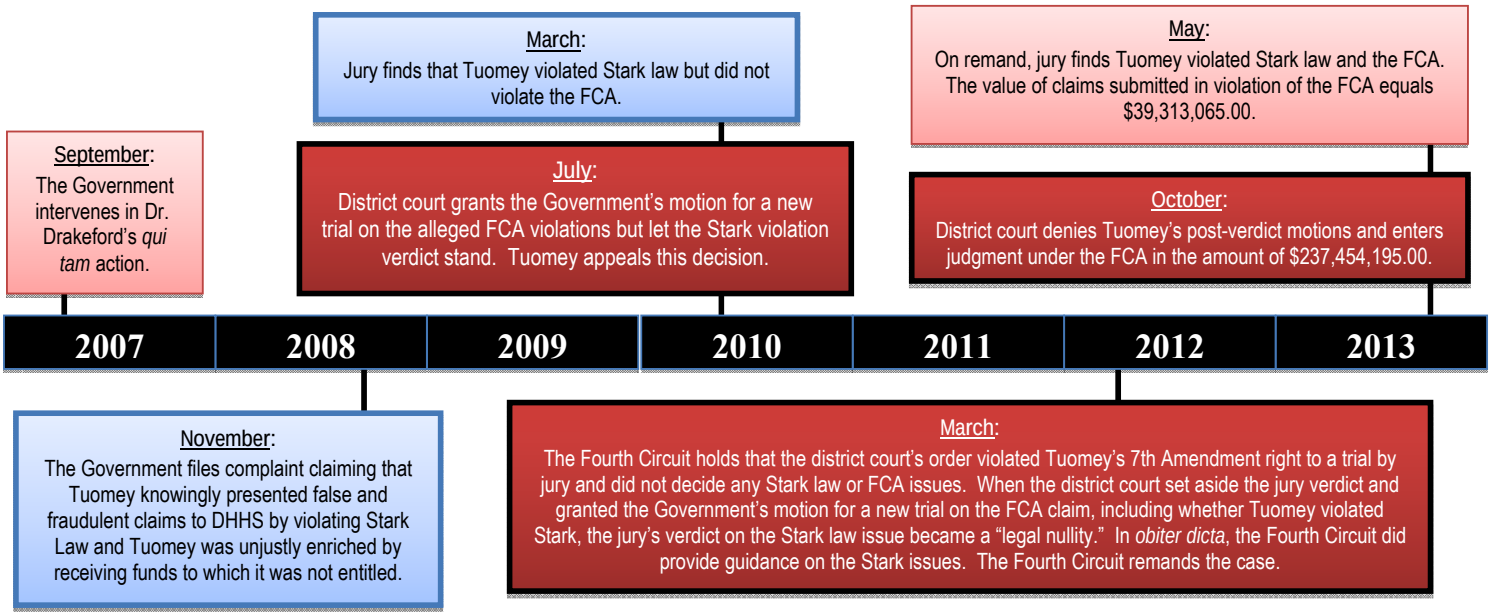
Background to Date. In 2002, both Tuomey and an independent physician group in Sumter, South Carolina were awarded separate certificates of need for new outpatient/ambulatory surgery centers. Tuomey calculated the projected loss in revenues if local surgeons moved their endoscopy cases to the physician-owned ASC and, in response, initiated a program to enter into part-time employment arrangements with surgeons. According to briefs filed by the parties, under these arrangements, physicians were retained as part-time employees for ten years, with compensation consisting of a base salary, a productivity bonus equal to 80% of net collections of professional fees, and an incentive bonus of up to 7% of the productivity bonus. The physicians were contractually committed to perform all of their outpatient endoscopies at the Tuomey facility during the ten-year term plus two years thereafter. The aggregate compensation paid to physicians was set at 131% of their net collections, even though the market data summarized in the valuation opinion obtained by Tuomey showed that, on average, gastroenterologists received compensation of 49-63% of their net collections. Tuomey had obtained valuation opinions and legal opinions to support its program. Second Amended Complaint at ¶¶ 80; 73, **U.S. ex rel. Drakeford v. Tuomey**, No. 3:05-CV-2858-MJP, Nov. 12, 2008.

One of the physicians Tuomey approached about entering into a part-time arrangement was Michael Drakeford, M.D. Tuomey, however, failed to reach agreement with Dr. Drakeford, in part, because his counsel raised compliance issues. During the course of the negotiations, Tuomey hired two of Dr. Drakeford's partners. On Oct. 4, 2005, Dr. Drakeford filed a qui tam action challenging Tuomey's physician arrangements and the Government intervened in December, 2007. (See Timeline, below (and on next page), for a visual summary of the case history).

The District Court's most recent decision dealt with five post-trial motions made by Tuomey and the Government in the wake of a May 8, 2013, jury verdict, finding that Tuomey had violated the Stark law and the False Claims Act, that 21,730 claims were illegally submitted, and that the value of the claims equaled $39,313,065.00. After the adverse jury verdict, Tuomey had moved for judgment in its favor as a matter of law. Therefore, given the standard of review, the District Court was not engaged in making direct findings of fact, but instead was tasked with ruling on whether the jury's findings on the issues were reasonable.

Stark Law Issues. In this case, the contracts were between wholly owned subsidiaries of Tuomey and the physicians, and thus were analyzed as indirect compensation arrangements. An indirect compensation relationship exists under Stark if, inter alia, the referring physician receives aggregate compensation that varies with or reflects the volume





or value of referrals or other business generated by the referring physician for the entity furnishing designated health services. 42 C.F.R. § 411.354(c)(2)(ii).

The jury found that Tuomey violated the Stark Law, because it determined that the arrangements did constitute indirect compensation arrangements subject to Stark, and that they failed to satisfy the Stark law exception for indirect compensation arrangements, which requires that (1) the compensation equal fair market value, (2) the compensation not be determined in any manner that takes into account the volume or value of referrals or other business generated, and (3) the arrangement is commercially reasonable. In its motion, Tuomey had argued that the jury could not have reasonably reached a verdict on the Stark issues in favor of the Government because (1) the arrangements were not indirect compensation arrangements as defined in Stark, i.e. Stark did not apply, (2) even if the arrangements were governed by Stark, they met the exception for indirect compensation arrangements, and (3) the Government did not establish that the attending physicians were, in fact, the referring physicians, i.e. that referrals were even made. The District Court rejected all of these arguments.

The District Court focused on the jury's findings on this key question: Did physician compensation vary with or take into account the volume and value of the physicians' referrals to Tuomey? The jury answered this question in the affirmative and the District Court held that the jury's findings were reasonable. The Government showed that physician compensation under the part-time employment arrangements increased each time a physician performed a procedure in Tuomey's facility, *i.e.* each time Tuomey received a facility fee. Additionally, the Government showed that the physicians made referrals of the technical component of their endoscopy procedures to Tuomey. **Drakeford v. Tuomey**, WL 5503695 at *6 (D.S.C. Oct. 2, 2013). The District Court also recited the Government's allegations that the compensation paid to physicians was designed, on average, to equal 131% of the net collections projected by Tuomey for the physicians' professional services. *Id.* at *2. As such, the jury found that physician compensation did reflect the volume or value of referrals and thus, constituted indirect compensation arrangements that did not satisfy the indirect compensation exception.

Tuomey also made a motion for a new trial on the grounds that the verdict was against the clear weight of the evidence regarding damages. Tuomey argued that some of the 21,730 cases identified by the Government were not done pursuant to a referral under Stark. In other words, the Government should have been required to produce a claim-by-claim analysis showing that each claim resulted from a referral by a part-time employed physician. In some cases, Tuomey argued, the attending physician was not the referring physician, and in other cases, the patient "self-referred" by showing up in the Tuomey emergency room. The District Court held that the jury's verdict on the calculation of damages was not against the clear weight of the evidence and pointed out that Tuomey did not offer any alternate methodology for calculating damages and did not elect to challenge the Government at trial regarding the calculations.

False Claims Act Issues. Tuomey made two arguments under the False Claims Act to support its motion. First, it argued the "advice of counsel defense" to the scienter requirements under the FCA. Under the FCA, the Government must prove that Tuomey had the requisite scienter to engage in fraudulent conduct. Tuomey argued that it had relied on the advice of its legal counsel, including advice about how to assess advice obtained from other attorneys who raised red flags about the arrangements. The District Court held that once Tuomey had legal advice raising red flags about the arrangement, Tuomey had the requisite scienter. The decision explains that Tuomey's counsel disagreed with advice that Tuomey and Dr. Drakeford's counsel jointly obtained from Kevin McAnaney. Mr. McAnaney is a solo practitioner in D.C. who worked as Chief of the Industry Guidance Branch of the Office of Counsel to the Inspector General from its creation in 1997 until May 2003. Mr. McAnaney expressed several concerns to Tuomey and Dr. Drakeford's counsel about the arrangement. The District Court noted that Tuomey and its legal counsel had asked Mr. McAnaney not to put his views in writing. Instead, Tuomey then obtained advice from another attorney who determined that the Stark Law did not apply to the arrangement.

Tuomey's second argument was that the Government had no damages under the False Claims Act since they paid for health care services actually rendered. The District Court quickly refuted this argument by pointing to the Stark Law's strict prohibition on payments of impermissible claims.

Calculation of Damages. In its motion for a new trial, Tuomey argued that the treble damages under the False Claim Act violated the Eighth Amendment excessive fines clause. The District Court concluded that the trebling of damages was compensatory and remedial, aimed at compensating the Government for its costs and inconveniences, as well as to counterbalance the fact that the False Claims Act allows partial recovery of the damages by the qui tam relator, does not provide for interest, and does not provide for consequential damages. Damages were calculated as follows:

$119,515,000.00 (21,730 impermissible claims X $5,500.00, the minimum civil penalty under the FCA)
+
$117,939,195.00 (three times the jury verdict of $39,313,065.00 in improper claims)
=
$237,454,195.00

Practical Advice. Commentators have written, and will continue to write, about Tuomey takeaways. (*See, e.g.*, "Tuomey Revisited Key Takeaways for Health Care Attorneys," Prognosis, August 2013). There is a lot of practical advice for health care lawyers as we watch the Tuomey case wind its way through the courts. In particular:

1. If two parties to a transaction seek a third legal opinion on an issue, be wary of ignoring that advice. Avoid the appearance of shopping for the legal opinion that you want.

2. Do not be reluctant to change course, even if you feel your initial judgment was correct. Risks change over time, and some commentators have suggested that Tuomey should have modified the physician arrangements as the compliance risks escalated. The Government may have been influenced heavily by the fact that Tuomey was unwilling to change course when, as months and years went by, there were increasing questions about the commercial reasonableness of the physician arrangements. Instead, Tuomey stuck to its guns and passed on several opportunities to change course and thereby, passed on opportunities to demonstrate their efforts to comply with the law. After receiving the cautionary oral advice from Mr. McAnaney, Tuomey obtained a separate opinion from another firm advising that Stark did not apply, but even so, Tuomey did not modify the arrangements to reflect certain recommendations of that firm. For example, that firm recommended that the physician contracts be modified, first, to allow the physicians a carve-out to the exclusivity requirement to use Tuomey's facilities where the patient expresses a different preference or where the referral to Tuomey is not in the patient's best medical interest, and, second, to amend the compensation under the contracts with the gastroenterologists to conform to the other contracts under which compensation was based on revenue collected, not the number of procedures performed. The Government's Complaint explains that none of these suggested changes were made. By sticking to its guns, Tuomey passed up an opportunity to demonstrate its commitment to compliance issues by amending its contracts. Second Amended Complaint at ¶ 100, No. 3:05-CV-2858-MJP, Nov. 12, 2008.

3. Be prepared to make the case for commercial reasonableness. While Tuomey had legal opinions and valuation reports that supported the physician arrangements, their liability may hinge on lack of commercial reasonableness, i.e. that the business justification for the arrangement was to influence referrals. The acid test is whether they would have done the deal absent referrals. The Government focused on several facts that may not support a finding of commercial reasonableness. For example: (1) Physicians were approached based on their referrals; and (2) The compensation paid to physicians produced significant operating losses within the physician practice operations of the health system.

4. When faced with the threat of a qui tam relator, some clients may focus too much on the personal failings of a qui tam relator. Qui tam relators may be former employees with personal vendettas or compliance problems of their own, or they may simply be difficult individuals. Tuomey explained that it failed to reach agreement with Dr. Drakeford on his part-time employment contract because Dr. Drakeford "demanded better financial terms." Answer and Defenses, No. 3:05-CV-2858-MJP, Nov. 19, 2008. Tuomey also pointed out that Dr. Drakeford filed his qui tam suit "after two of Dr. Drakeford's physician employees voluntarily left his practice and went to work for Tuomey. None of this mattered. Tuomey shows that the Government will ignore the fact that a relator may be unpleasant, may have disciplinary issues, and may have acted wrongly. In other words, the Government will look to the substance and ignore qualitative factors regarding a qui tam relator.

5. Similarly, the Government may not consider the good works and financial struggles of the defendant. Tuomey's first defense in its answer to the Government's complaint focused on its charitable mission, its founding in 1913, the volunteer status of its Board, and the facts that Sumter is a medically underserved area with an acute shortage of physicians, a disproportionate number of indigent patients and a patient population that includes military personnel from Shaw Air Force Base. *Id.* at 1-10. Tuomey argued that the part-time employment contracts "have actually benefited the United States" by allowing Tuomey to deliver services to those in need. *Id.* (emphasis in original). The court opinions do not embrace any of these factors. The point is not that it is error to put these points in front of a decision maker, but that it would be error to put much faith in them as a defense; here they apparently provided no mitigation.

6. Self-disclosure to Government attorneys weeks prior to the filing of a qui tam action may not support an argument that the qui tam relator is not the original source. Tuomey's attorneys began meeting with U.S. Attorneys in Columbia in August 2005 and made disclosures about the physician contracts prior to the filing of Dr. Drakeford's complaint in October 2005. As such, Tuomey argued that Dr. Drakeford was not the original source of the information in his complaint. Irrespective of Tuomey's disclosures to the Government, Dr. Drakeford remained a party to the suit.

7. Do not neglect to fully examine your hospital board's indemnity rights (under law and as provided in the charter documents) as well as their director's and officer's insurance coverage. (See sidebar regarding article to appear in next issue of Prognosis.)

How should hospital counsel analyze and manage the personal risk that nonprofit hospital directors may have in a situation like Tuomey? In an opinion issued in September 2013, the South Carolina Attorney General concluded that South Carolina law did not permit Tuomey to indemnify its directors for legal expenses and potential personal liability when such individuals had not been made a party to the qui tam suit. In the next issue of Prognosis, we will explore the following under North Carolina law:

- How are claims against nonprofit directors likely to arise, i.e. who has standing to sue?
- To what extent are nonprofits directors immune from personal liability or entitled to mandatory indemnification?
- What are the limits of permissive indemnification and what steps are needed to authorize permissive indemnification?
- How would the question addressed by the South Carolina Attorney General be answered under North Carolina law?
- What are the issues in evaluating and negotiating the limits of D&O insurance coverage?

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Medicare Reimbursement in 2014: A Risk Management Roadmap for Attorneys

By John Cattie and Katie Hosty

If you are an attorney handling a liability case that involves Medicare beneficiaries, or represent a party likely to be Medicare enrolled in the next few years, you should be well-versed in federal law enabling Medicare to recover payments for injury-related care if beneficiaries receive settlement proceeds for those injuries from a third party (a/k/a Medicare's "Recovery Claim").

Since the 1980s, Congress has been expanding Medicare's Recovery Claim rights. Under current law, Medicare must be reimbursed for any past medical care it has funded stemming from its beneficiary's underlying injury. 42 U.S.C. § 1395y(b)(2)(B)(ii). If that does not occur, the government can file suit to recover Medicare's payment amount plus interest and in some cases double damages. 42 C.F.R. § 411.24(c)(1)-(2); *see also* 42 C.F.R. § 411.24(m). Additionally, Medicare has a right to refuse payment for future medical care linked to the underlying injury if those treatment costs should have been – but were not – addressed as part of the judgment or settlement. 42 USC § 1395y(b)(2)(A)ii. In this article, we will provide an overall risk management roadmap for attorneys – both plaintiffs' and defense counsel – on how to comply with federal laws governing Medicare reimbursement, and address the funding for any future Medicare costs within those settlements.

How It All Began | When the Medicare program first began, it served as the principal source of healthcare funding for its beneficiaries, whether the patient had private health insurance or not. As the program's costs steadily climbed, Congress passed a law in 1980 aimed at reducing the amount of Medicare payouts overall, by making Medicare's coverage secondary to other sources. The Medicare Secondary Payer Act (MSP) purported to ensure that if Medicare beneficiaries received coverage from another entity, then Medicare would not bear the burden of those expenses. 42 U.S.C. § 1395y(b)(2).

The law and its related regulations have particular significance in personal injury litigation, where cases often involve damages for medical care. Attorneys handling cases where Medicare beneficiaries are alleging physical or mental injuries should review Medicare's potential reimbursement rights in each case, and determine whether another entity, besides Medicare, is assuming legal responsibility (via the settlement, judgment, or damage award) for a beneficiary's specific medical costs. For ease of reading, the authors will use the word "settlement" to collectively refer to a settlement, judgment, or damage award throughout this paper, although Medicare's right to reimbursement under the MSP pertains to settlements, judgments, and damage awards – not just settlement proceeds.

Under the MSP, if Medicare pays for treatment for which its beneficiaries later receive compensation, then Medicare has both a subrogation right and an independent right of recovery to recoup those costs. These upfront payments by Medicare are referred to as conditional payments, because they are subject to another party assuming primary coverage of those costs. Consequently, if a third party ultimately provides settlement proceeds related to injuries involving treatment conditionally paid for by Medicare, Medicare's so-called lien must be repaid.

Another federal law ensures that Medicare is notified of any settlements or damage awards, so that the government is aware of potential payments for which it should be reimbursed. Under the Medicare, Medicaid and SCHIP Extension Act of 2007 (MMSEA) insurance carriers and self-insured defendants that actually pay a settlement to a Medicare beneficiary must report those payments (and other information) on a quarterly basis to the Secretary of Health and Human Services, so that the government is cognizant of Medicare treatment it funded for which its beneficiaries later received a third-party payment (i.e. the conditional payments). Pub. L. No. 110-173, 121 Stat. 2492, codified at 42 U.S.C. § 1395y(b)(8). The U.S. government has the right to file suit to recoup these Medicare funds, only if parties have not previously arranged to reimburse Medicare for these expenses.

Where Medicare Reimbursement Stands Today | Medicare's recovery right pertains to both past medical expenses paid and future medical expenses Medicare is likely to pay. In order to comply with the MSP's reimbursement requirement, you should evaluate the case to determine whether Medicare has funded any past medical expenses, and if so, how much Medicare has spent, so that you can determine how much Medicare will in turn need to be paid back. Medicare's recoupment of past medical expenses takes priority over any potential future medical costs, and those past conditional payments must be addressed as a case nears resolution and settlements are negotiated. Keep in mind that, depending on the amount of the settlement and the extent of a claimant's injury, it is possible that Medicare's lien could exceed the amount of a litigant's overall recovery or settlement. In those circumstances, parties can seek a waiver or a compromise of Medicare's lien for past care. After a settlement, judgment or award, Medicare may grant a full or partial waiver of its recovery amount with respect to the beneficiary. There are two options for Waiver: §1870 (c) Waiver and §1862 (b) Waiver. Criteria for such waivers generally include: 1) the beneficiary being without fault and the recovery, 2) effecting financial hardship or being against equity and good conscience. Prior to a settlement, judgment or award, Medicare also may enter into pre-settlement discussions regarding a compromise of Medicare's reimbursement claim.

Future Medical Costs | While reimbursement of Medicare's past medical costs takes priority over the funding of future medical care, the issue of whether any settlement funds exist for future care is a determination that counsel should make in all cases involving Medicare beneficiaries. In the context of future medical care, the

key inquiry is whether money is available and should be identified as payments for future care, in an account known as a Medicare Set-aside Arrangement or MSA. An MSA, in its simplest form, is an interest bearing checking account containing settlement funds which will be used to pay for future injury-related care Medicare would otherwise cover. Essentially, it operates like a deductible the claimant pays before getting benefits from Medicare again. Once an MSA is established, and its funds are spent down and exhausted appropriately, Medicare may then be billed for a beneficiary's injury-related care.

It is important to note that, as of the publication of this article, CMS has not issued any formal regulations for the structure or establishment of MSAs in liability cases – although officials are expected to do so later this year. This article reflects current guidance as of the date of its publication.

We do have an idea of what the MSA regulations could look like, given the Advance Notice of Proposed Rulemaking (ANPRM) CMS issued in 2012. On June 15, 2012, CMS released an ANPRM which outlined when a claimant would be required to address the MSA issue. The ANPRM contains broad language which indicates MSAs could be appropriate in an increasing number of cases, if the currently proposed wording is fully adopted.

The ANPRM indicates that there are three overall conditions which, if present in a claim, potentially merit the establishment of an MSA. First, future medical care must be addressed as a component of damages – specifically or generally – in the pleadings, release language, judgment, or damage award. Second, the settling party/defendant/third party has accepted responsibility for future medical costs linked to the underlying injury. Third, there are monies available to fund the specific future medical costs which Medicare would otherwise cover. The ANPRM states:

> **"If an individual or Medicare beneficiary obtains a 'settlement' and has received, reasonably anticipates receiving, or should have reasonably anticipated receiving Medicare covered and otherwise reimbursable items and services after the date of 'settlement,' he or she is required to satisfy Medicare's interest with respect to 'future medicals related to his or her 'settlement' using any one of the following options."**

See, Advance Notice of Prop. Rulemaking, Fed. Reg., pages 35917-35921 (June 15, 2012)

Under the ANPRM's wording, the first question which must be answered is whether future medical costs are pled, released, or reasonably anticipated to be released in a settlement. Next, the individual or Medicare beneficiary must reasonably anticipate receiving Medicare covered items or services post-settlement. If a settlement generally or specifically addresses future medical care in the original pleadings or the release, that demonstrates reasonable anticipation of future care.

In terms of particular wording, a general – or implicit – reference would, for example, be a release to any and all future claims. A specific – or explicit – reference is one in which the settlement award has a particular designation or dollar value identified for future medical expenses. For instance, if, after a hearing on the merits of the case, a judge or jury has earmarked a specific amount as compensation for the claimant's future medical expenses, then the parties can view that amount as an explicit allocation. Whether the reference is implicit or explicit, the bottom line is that if future care is reasonably anticipated via identification in the pleadings or the release language as a component of the items for which the primary payer or its insured accepted responsibility, then you should address whether funds exist to pay for Medicare's future treatment.

This determination is easier in cases where future care is specifically delineated, as the amount and cost of future care has already been set. Most settlements, however, do not contain such precise identifiers. If that's the case for a claim you're handling, you should still evaluate whether the settlement agreement contains an implicit designation of future medical costs. *See*, **Early v. Carnival Corporation**, No. 12-20478-CIV-Goodman (S.D. Fla. February 7, 2013); *see also*, **Guidry, et al. v. Chevron USA, Inc.**, Civ. No. 6:10-cv-00868, 2011 U.S. Dist. LEXIS 148942 (W.D. La. December 28, 2011); **Sterrett v. Klebart**, 2013 Conn.Super. LEXIS 245 (filed February 5, 2013)(unreported). Plaintiff's counsel should determine whether, within that undifferentiated sum of settlement money, there is an amount which could be reasonably viewed as compensation for future medical expenses, as opposed to other types of damages (such as pain and suffering) pled and released. While the undifferentiated sum of money may be intended to be consideration for the release of the defendant's liability for future medical expenses, the challenge is determining whether or not some portion of the undifferentiated sum can be reasonably identified as comprising future medical expenses as opposed to the myriad other damage components pled and released. Later in this article, we'll explain step-by-step how this process works.

However, there's an important prerequisite that needs to be addressed first. Before conducting this analysis, the parties should establish whether all conditional payments to Medicare have been satisfied. Any reimbursement obligations to Medicare for a beneficiary's past medical costs must be addressed before any funds are put toward the beneficiary's future medical care. Federal statutes and court rulings establish that the reimbursement of any conditional payments Medicare made for past treatment takes priority over the allotment of any future medical costs within a settlement. So, if a claimant's Medicare lien obligations for past care exceed the total amount of compensation (whether explicitly provided or implicitly allocatable) for medical care within a settlement, Medicare's conditional payments must be satisfied before any funds are disbursed for future care.

For example, if there is a $10,000 sum of money in the settlement viewed as compensation for medical care, but the claimant owes Medicare $15,000 for the reimbursement of past medical care, then the potential allocation for any future medical costs has effectively been depleted by the outstanding debt to Medicare for past treatment. There are no funds available for future medical care once Medicare's past reimbursement claims are taken into account.

Ultimately, the ANPRM would apply in cases where a settlement award is obtained, and the pleadings or release language identify (either explicitly or implicitly) future medical expenses as a component of the items or services over which the primary payer or its insured accepted responsibility, and in which funds are available for that purpose.

Of course, the ANPRM is currently a proposal, rather than black letter law. Nevertheless, we believe the ANPRM reflects the path CMS is likely to follow. Consequently, attorneys need to be aware of how their clients' liability cases are likely to be impacted once regulations are fully enacted.

Achieving Compliance | Although the process for evaluating future medical claims is complicated, it is important for attorneys to understand. After resolving these issues in thousands of settlements nationwide, we at the Garretson Resolution Group (GRG) recommend using a four step approach to ensure MSP compliance on the future medicals issue:

1. Screen to determine if the claimant is a Medicare candidate;
2. Analyze whether the gross award contains funds available to pay for a claimant's future medical expenses;
3. Value the claimant's actual future cost of care needs; and
4. Educate the claimant and parties about MSA obligations.

This formal approach allows the parties to determine exactly what action is required. Let's look at this process step-by-step:

Step 1 - Screen | First, you must determine if the claimant is a candidate for Medicare coverage. So, you'll need to review the facts of your case to determine or verify the claimant's Medicare enrollment status. If a plaintiff is currently a Medicare beneficiary, you'll need to ensure past Medicare conditional payments have been satisfied, and evaluate the future medical costs issue and the potential need for an MSA. Additionally, if your client is likely to become entitled to Medicare coverage within 30 months of the resolution of the case, that indicates eligibility for Medicare and the same need for MSP compliance. 42 U.S.C . § 1395(c). To that end, if a claimant is 62 ½ or older, has permanent kidney failure requiring dialysis or a transplant, has ALS or Lou Gehrig's disease, or has applied for Social Security Disability Insurance, you should likewise evaluate the propriety of an MSA because these circumstances also trigger Medicare eligibility. Id.

In fact, if the claimant meets at least one of the factors listed above for Medicare eligibility, you should proceed with the MSA analysis. But, if your client does not meet any of these criteria for Medicare coverage, an MSA is likely not appropriate. If a claimant has no basis for Medicare eligibility, you should retain records in your file which reflect the question-and-answer/verification process with your client, to establish the steps taken to assess and protect Medicare's interests.

To continue with the MSA analysis, the next step is to determine if Medicare could be liable for the claimant's future medical costs. Counsel for the parties, along with the treating physicians, will need to evaluate the claimant's injury, and the need for future treatment linked to the underlying injury. If it is determined that, because of the injury at issue, a claimant will need future medical treatment funded by Medicare, then the claimant could be considered a potential candidate for an MSA. If this is the case, then you should move to the next stage of the evaluation.

However, if you determine the claimant is not a potential candidate for an MSA, then you should document the basis for that conclusion in your file. We recommend that you retain records which demonstrate what materials you reviewed to ensure that Medicare's interests were adequately protected and, in light of that review, how you established that an MSA was not needed. These records often include reports from treating physicians, and other factual evidence. That way, you will have sufficient support if CMS later requests a review of your MSA decision.

Step 2 - Analyze | If the claimant is a candidate for Medicare enrollment, the parties must next determine if the (potential) gross settlement proceeds contain sufficient dollars available to fund any MSA obligation. To do this, parties should assess the claimant's full measure of damages sustained and compare those to the (potential) gross award. The parties should then use that comparison to conclude whether: i) the (potential) gross award actually contains dollars available for future medicals; or ii) whether the claimant is not being compensated for future medicals although future medicals are a damage component being pled and released or there is evidence that the claimant may need future injury-related care.

Again, this review should only occur if the claimant has been determined to be a candidate for Medicare as outlined above, and there is an undifferentiated lump sum damage award. This analysis will help the parties evaluate whether the settlement implicitly contains funds reasonably intended to compensate for future medical costs which Medicare would otherwise cover. This calculation of available funds should include an evaluation of how much, if any, of the settlement proceeds are needed to pay past medical expenses and out-of-pocket future medical costs, including co-payments, special medical equipment, and any nonmedical expenses that are reasonably anticipated as a result of the underlying injury (for example, home modifications or special needs items). Keep in mind that, under the facts of the case, the proceeds may not contain funds for future medical care even though the release may state it pertains to "all claims past and future," or contains language to that effect.

The initial step in this analysis is to conduct a damages evaluation which determines the total potential damages in the case, in comparison to the net amount of funds actually being awarded in the settlement. In calculating this figure for total compensable damages, the parties should evaluate each type of particular damage identified in the pleadings – for instance, loss of earning capacity, pain and suffering, etc., and also take into account any jurisdictional limits or caps limiting the maximum amount of damages which can be awarded for certain types of injuries, and then make a reasonable good-faith estimation of the total value of each category of damages identified in the pleadings. This total value can be determined by using figures identified in the pleadings and/or using relevant jury verdicts in cases with similar facts.

Once the total compensable damages have been established, then that number needs to be compared to the amount of total damages being recovered, so the percentage of total or gross recovery can be calculated. This gross recovery value is critical. If this figure shows that a claimant is recovering all or nearly all of the damages pled, then the parties' attorneys can use a reasonableness standard to determine whether a portion of the gross recovery is definitive compensation for future injury-related care. On the other

hand, if there's a significant difference between the total potential damages and the recovered damages, then the gross recovery percentage can be used to help the attorneys evaluate whether there is an implicit allocation for future medical costs within a settlement.

If, after completing this damage allocation analysis, a reasonable person would conclude that the gross award does not contain an implicit identification of the payment of future medical costs, then an MSA would likely not be needed. *See*, **Sterrett et al. v. Klebart et al.**, 2013 Conn. Supp. LEXIS 245 *4-5 (February 5, 2013), where the Court concluded that no liability MSA was needed based on the parties' efforts to identify that the gross award was not paid in order to compensate the claimant for future medicals. By conducting this analysis and reaching this conclusion, the settling parties have taken steps to consider and account for Medicare's interests, and thus, have met their obligations under the MSP. Before closing their files, the parties should retain their records of the future medical costs analysis.

However, if a reasonable person would likely conclude that part of the settlement can be implicitly allocated for future medical costs - despite a lack of concrete wording to that effect in the settlement agreement - then the MSA evaluation should continue. The next step is for the parties' attorneys to assess how that future care is to be funded, and whether the burden will be on Medicare or another insurance carrier or entity to pay for it. If Medicare is to be the primary payer for that future healthcare, then an MSA may well be appropriate. Subsequently, the parties' attorneys need to determine the appropriate amount for the MSA by calculating the dollars available to fund future care, plus the type and amount of future injury-related care for which Medicare would otherwise be responsible. We will walk you through this process in Step 3.

Step 3 - Value | The valuation phase involves identifying the amount of funds needed for the MSA. We recommend using a future cost of care analysis to calculate the appropriate funding level. It's critical to properly fund an MSA in order to protect a claimant's future Medicare benefits, because Medicare could withhold future coverage if officials determine the program's interests were not adequately addressed in the MSA. As such, we believe the best way to ensure the proper funding amount is to identify all future injury-related care services/expenses the claimant is reasonably expected to incur. Once those future costs of care are tallied, the sum for those services/expenses should be apportioned between Medicare and non-Medicare covered services/expenses. Next, counsel should compare the total amount of dollars available within the settlement to fund future medical costs (Step 2) to the total amount of injury-related and Medicare-covered services from the future cost of care analysis (Step 3). Whichever amount is lower is the appropriate amount for the MSA.

Step 4 - Educate | At this point you've established that an MSA is appropriate and calculated the amount needed for the MSA. The next step is determining how to administer and finance the MSA. MSA administrators determine the timing and amount of payments from the account. Although all MSA accounts must be insured, MSAs in liability cases may be either self-administered or administered by a professional custodian. In terms of financing, liability MSAs may be funded either with a full lump sum dollar amount upfront or with a structured plan involving periodic payments, such as an annuity.

Now that you know the importance of accounting for Medicare's interest in future medical costs, and you've learned the in-depth process needed to evaluate the propriety of an MSA in relevant cases, you may be thinking that it's too much to handle on your own. If this is the case, you may want to consider outsourcing in order to meet your MSP compliance burden.

Is it Ethical to Outsource MSA Analysis? | Ethics opinions from the American Bar Association (ABA) and other legal groups indicate that outsourcing work to non-lawyers is permitted provided certain conditions are met. In 2008, the ABA issued a formal opinion which outlined the ways attorneys can outsource with integrity. The opinion noted that outsourcing is sanctioned as long as the outsourcing lawyer a) delegates tasks to individuals who are qualified to perform them, and b) confirms that those tasks are properly completed. The outsourcing lawyer remains directly accountable for the services rendered to his/her client, and the competency of the work performed on his/her client's behalf.

Then in 2012, the ABA's Ethics Commission approved Comments to the Model Rules of Professional Conduct regarding outsourcing, which noted that "lawyers increasingly need to go outside their own firm to ensure" their clients receive competent and efficient service. The new Comments basically reiterate that lawyers who outsource need to make "reasonable efforts" to ensure the outsourced work contributes to the overall representation of their clients. If non-lawyers are utilized, the outsourcing lawyer needs to ensure the services are provided in a compatible manner with the lawyer's obligations, including that of confidentiality.

The question of whether to seek help on the MSA issue becomes a simple business decision: do I build an MSA solution internally or do I buy an MSA solution from someone experienced in this area?

If you decide to partner with an outside group to handle MSAs (and lien resolution), first ask the group to provide all the information needed for due diligence. For example, does this company offer deep subject matter expertise? Can it demonstrate fully-developed work flow and lien audit models? Has its work product and methodology been vetted by third party neutrals (such as a U.S. federal court)? Also, make sure you understand when and how that outside group's fees could be passed through as a case expense to your client.

Conclusion | Navigating the MSA issue is a complicated but critical component of settlement resolution in today's litigation realm. By determining if an MSA is appropriate under your case-specific facts and documenting your file with the result of that analysis, you will have met your compliance obligations under the MSP. If analyzing the future cost of care issue is not part of your standard protocol for resolving personal injury claims, it's time to address this issue and potentially update your case intake procedures so as to capture needed data.

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Case Law Update

By Matthew A. Fisher and David R. Broyles

Robinson and Robinson v. Duke Univ. Health Systems, Inc., et al., ___ N.C. App. ___, 747 S.E.2d 321 (Aug. 20, 2013) *Facts*: Patient and her husband (plaintiffs) brought a medical malpractice action against defendant hospital and physicians after patient's colectomy in which her physician mistakenly connected her small intestines to her vagina during the procedure.

The defendants first moved to dismiss the case in April of 2011 with a motion to dismiss pursuant to **Rules 9(j)**, **12(b)(2)**, **12(b)(5)**, **12(b)(6)**, and **41(b)**, arguing that the factual issues pled by the plaintiffs did not fall within the narrowly prescribed parameters of the doctrine of *res ipsa loquitur*. The plaintiffs argued that understanding the factual allegations required no sophistication, training or expertise since the complaint alleged that all adult persons know the elementary anatomy of the body. Judge Hobgood agreed, concluding that dismissal under **Rule 9(j)**, **12(b)(6)** and **41(b)** was not supported since the plaintiffs' complaint alleged some facts giving notice of negligence under the existing common law doctrine of *res ipsa loquitur*.

After a year of discovery, Defendants moved for summary judgment in April of 2012. Defendants asserted that plaintiffs failed to comply with **Rule 9(j)(1)** of the North Carolina Rules of Civil Procedure for medical malpractice claims; that the doctrine of *res ipsa loquitur* did not apply to plaintiffs' action; and that plaintiffs could not forecast evidence to satisfy each and every element of their medical negligence claim. Assessing the evidence adduced in discovery, Judge Hudson granted defendants' motion for summary judgment, pursuant to **Rules 9(j)** and **56**.

Following the ruling and grant of summary judgment in July of 2012, the defendants filed a motion with the Superior Court pursuant to **Rule 60(b)** of the NCRCP seeking an advisory opinion and/or a supplemental order with findings of fact and conclusions of law to aid in the review by the appellate court. The appeal was stayed pursuant to the **Rule 60(b)** motion, and the Superior Court entered a supplemental order including the findings of fact and conclusions of law supporting the grant of summary judgment in November of 2012.

On appeal, plaintiffs asserted that the Superior Court erred in granting summary judgment in favor of defendants, claiming that their complaint stated a cause of action for medical negligence under the common law theory of *res ipsa loquitor*, and therefore their complaint complied with **Rule 9(j)(3)**. Further, they claimed that they presented evidence establishing the elements of a medical negligence claim, thereby creating a genuine issue of material fact for trial.

The North Carolina Court of Appeals affirmed the Superior Court's dismissal of the action against two of the individually named physicians (Patel and Hodgins) and Duke University Affiliated Physicians, and affirmed dismissal plaintiffs' punitive damages claim. The Court vacated the Superior Court's grant of summary judgment in favor of the other named defendants based on the plaintiffs' compliance with **Rule 9(j)**. Finally, the Court reversed the trial court's order dismissing the action against the other two named physicians (Mantyh and Huang) and Duke University Health Systems, Inc. d/b/a Duke University Medical Center and remanded the case for further proceedings consistent with the Court's analysis.

Analysis: The analysis provided by the Court included the following:

1. The dismissal of plaintiffs' complaint on the grounds that it failed to comply with the required **Rule 9(j)** certifications for a malpractice action was precluded because the doctrine of *res ipsa loquitur* was applicable in the medical malpractice action;
2. The statute regarding requisite standards of health care was satisfied by doctor's testimony in a medical malpractice case as to the standard of care;
3. Summary judgment was precluded because a genuine issue of material fact existed as to whether doctors violated the standard of care during a colectomy; and
4. Summary judgment on a claim against the hospital under principles of vicarious liability was precluded because a genuine issue of material fact existed as to whether the doctor was an employee or agent of the hospital.

The Court began by reviewing what it deemed inconsistent rulings by the Superior Court on plaintiffs' compliance with **Rule 9(j)**. The Court, however found that Judge Hudson improperly resolved contested issues of fact in his supplemental order/advisory opinion by addressing issues related to the applicability of the doctrine of *res ipsa loquitur*. Despite the fact that Judge Hudson's ruling was pursuant to **Rule 56** (as opposed to **Rules 12(b)(6)** and **41(b)**), the Court nonetheless found that Judge Hudson's order attempted to overrule the prior Order entered by Judge Hobgood in violation of **Adkins v. Stanly Cnty. Bd. of Educ.**, 203 N.C. App. 642, 692 S.E.2d 470 (2010). Thus, the Court reversed Judge Hudson's grant of summary judgment on this point.

The Court then looked to the propriety of Judge Hobgood's conclusion regarding the applicability of the doctrine of *res ipsa loquitur*. Although the plaintiffs' complaint was void of any specific assertion that the care was reviewed by an expert who would testify regarding the compliance with applicable standards of care (per the **Rule 9(j)(1)** requirement), the Court applied a *de novo* review standard to the question of whether the plaintiffs' complaint alleged facts establishing negligence under the doctrine of *res ipsa loquitur* because of the plaintiffs' assertion that their medical negligence complaint complied with **Rule 9(j)(3)**. The Court found that the plaintiffs' complaint and forecast of evidence both satisfied the **Rule 9(j)(3)** requirements to survive the defendants' motion for summary judgment on the issue of whether the doctrine *res ipsa loquitur* may be asserted.

The Court acknowledged that case law in North Carolina has urged trial courts to proceed cautiously in permitting the use of

res ipsa loquitur as an option for liability in medical malpractice cases other than those circumstances where it has been expressly approved. Those cases are ones where the injuries result from (1) surgical instruments or other foreign objects being left in the body following surgery and (2) where injuries are sustained to a part of the patient's anatomy outside of the surgical field.

The Court, however, went on to state that any limitation of the application of the doctrine *res ipsa loquitur* to only those two situations is not supported by the case law in North Carolina. The Court focused on the fact that, if proper inferences may be drawn by ordinary men, then there is no reasonable argument not to apply the doctrine. *Citing* **Mitchell v. Saunders**, 219 N.C. 178, 13 S.E.2d 242 and Parks v. Perry, 68 N.C. App. 202, 314 S.E.2d 287. The Court held that while caution is to be exercised in applying the doctrine, the argument that the doctrine should be limited to the two situations above is without merit.

The Court also disagreed with the defendants' claim that the medical treatment at issue in this case involved a complex surgical procedure, which requires an expert to testify so that average jurors can have the requisite knowledge to identify and distinguish necessary anatomy to enable them to make their decision regarding negligence. In this regard, the Court opined that it is common knowledge and experience that the intestines are meant to connect to the anus, not the vagina. Further, the Court distinguished defendants' arguments by indicating that an understanding of the procedures and techniques involved in a colectomy procedure is not required for a layman to determine that the result of a patient's intestine being connected to her vagina following surgery does not occur in the absence of negligence. Finally, the Court explained that the plaintiffs' proffer of expert testimony with all of the specific anatomy and potential results has no bearing on the fact that a layperson can understand that the intestine should not attached to the vagina following the surgery without such expert advice.

The Court further disagreed with defendants' argument that because plaintiffs offered direct proof of Robinson's injury—in the form of expert physician testimony—the doctrine of *res ipsa loquitur* is inapplicable in the present case. The Court opined that defendants' argument improperly conflated evidence of the "cause" of the patient's injury with the injurious condition itself. The Court concluded that the proffer of expert testimony by the plaintiffs did little more than show evidence of how the injury might have occurred. That, combined with the fact that patient was unconscious during the procedure and would have had no way of presenting direct evidence as to the human cause of the injury was reason enough for the Court to feel the plaintiffs' reliance on the expert was reasonable while still permitting the use of on the doctrine of *res ipsa loquitur*.

The defendants argued that the expert testimony given by the plaintiffs' expert did not meet the requirements of **N.C.G.S. §90-21.12**. In their argument, the defendants pointed out that the plaintiffs' expert applied a national standard of care and offered no testimony of his familiarity with the experience and training of Dr. Mantyh, nor did the plaintiffs' expert offer any testimony regarding the community standard of care for Durham, NC or any similar community. (Judge Hudson's order granting summary judgment on this issue to Dr. Mantyh also incorporated Dr. Huang, but the Court here only explained the details of the plaintiffs' expert testimony as to Dr. Mantyh; the reversal of Judge Hudson's order applied to both physicians, Mantyh and Huang.) The plaintiffs' expert testified that he knew nothing about Dr. Mantyh at the time, had never visited Duke University Hospital System and knew nothing about the surgical facilities of Duke other than the fact that it had a great reputation and a national reputation. Following his deposition, the plaintiffs' expert submitted an affidavit that stated he was familiar with the applicable standard of care for physicians like Dr. Mantyh practicing in the area and similar communities, and explained that since his deposition, he had confirmed his opinion with internet research about Duke University Hospital.

The Court, however, indicated that the use of a national standard of care alone is not fatal to an expert's testimony that otherwise meets the requirements of N.C.G.S. **§ 90-21.12** in situations where the standard of care is the same across the country. The Court further rejected the defendants' argument that the plaintiffs' expert's affidavit was impermissible because it contradicted his former deposition testimony. In rejecting that argument, the Court actually found that the affidavit supplemented/reinforced the deposition testimony, the affidavit reaffirmed his belief on the applicable standard of care for facilities with which he was familiar, and that he confirmed his belief through internet research. Therefore, the Court found that Judge Hudson erred in granting summary judgment in favor of the two physician defendants on this issue.

The Court also found error in Judge Hudson's grant of summary judgment in favor of defendant Duke University Health Systems, Inc. ("DUHS") because of Hudson's conclusion that Dr. Mantyh had no relationship with DUHS at the relevant time. The Court found that the evidence presented by the plaintiffs showed that Dr. Mantyh was the chief surgeon in the applicable department at DUHS, was an assistant professor with tenure, was listed on the DUHS website as a physician, and that the patient was referred in the past to DUHS and/or Dr. Mantyh for evaluation. As a result, the Court found that plaintiffs continually asserted that Dr. Mantyh is an agent and/or employee of DUHS and, therefore, DUHS's dismissal was improper.

The plaintiffs did not present any argument regarding the Superior Court's grant of summary judgment on the plaintiffs' punitive damages claim, as to defendants Duke University Allied Physicians, Inc., and Dr. Patel. Likewise, plaintiffs did not appeal the Superior Court's grant of defendants' motion to dismiss as to Dr. Hodgins. Therefore, the Court found the Superior Court's orders on those issues to be proper and affirmed them.

WakeMed v. N.C. DHHS, DHSR, CON Section, ___ N.C. App. ___, 737 S.E.2d 754 (Jan. 15, 2013) *Facts:* The CON Section conditionally approved a non-competitive CON application by Rex Hospital, Inc. for Rex to construct an addition to its hospital, including the expansion and consolidation of surgical and cardiovascular services, a new main entrance, and a public concourse. WakeMed filed a petition for a contested case, in which Rex intervened. The ALJ issued a Recommended Decision granting a joint motion to dismiss in favor of the N.C. Department of Health and Human Services (the "Department") and Rex

on the grounds that WakeMed failed to show either substantial prejudice or agency error. The Director of the Division of Health Service Regulation ("DHSR") issued a Final Agency Decision ("FAD") dismissing WakeMed's case and awarding the CON to Rex. WakeMed appealed to the North Carolina Court of Appeals. The North Carolina Court of Appeals affirmed the Final Agency Decision in favor of the award of the CON to Rex.

Analysis: Rex argued that the Court did not need to reach WakeMed's allegations of the Department's error because WakeMed had not been substantially prejudiced by the issuance of the CON to Rex. The Court, however, chose to address Agency error without first resolving whether or not WakeMed was substantially prejudiced. WakeMed argued that the Department failed to apply the express language of **N.C.G.S. 131E-183(a)(13)(a)** ("Criterion 13(a)") to Rex's application. **Criterion 13(a)** requires an applicant to demonstrate "[t]he 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 me*dically underserved*." *Id.*

WakeMed argued that the comparison required by **Criterion 13(a)** should be based on data for the medically underserved populations facility-wide. In contrast, based upon the prefatory language of the statute, the CON Section interpreted **Criterion 13(a)** to apply to the services proposed in the CON and found that it was impossible for Rex to provide such data since it was not publicly available for the services in question. Further, the CON Section found that Rex provided sufficient information on payor mix and documentation of non-discrimination in its services. The Department found that half of North Carolina hospitals would fail **Criterion 13(a)** if it were interpreted in the manner argued by WakeMed. The Court affirmed the Department's interpretation. The Court also agreed that the CON Section could not conduct a service-line specific comparison because the data needed to do so was not publicly available.

Finally, the Court held that the Department's interpretation of **Criterion 13(a)** to Rex's application was consistent with its interpretation in its prior review of an application submitted by the Hillcrest Convalescent Center. The Court found that the data at issue in the case of the Hillcrest Application was publicly available, which was distinguishable from the instant case, where it was not. Thus, the Court affirmed the Director's decision.

AH North Carolina Owner LLC d/b/a The Heritage of Raleigh, et al. v. N.C. DHHS, DHSR, CON Section, 12 DHR 08666, 08669, & 08691 (June 20, 2013) *Facts:* In August of 2011, five skilled nursing facility providers filed applications seeking a CON to develop a new nursing facility ("NF") in Wake County. In total, there were 16 applications filed by 10 applicants. Only five of the applicants were involved in the appeal of the Agency's decision. The 2011 State Medical Facilities Plan ("SMFP") included a special need determination for a total of 240 new NF beds for Wake County. After reviewing the competing applications, the CON Section notified the applicants on Jan. 27, 2012 of its decision to approve the applications of BellaRose and Britthaven, and to conditionally approve the application of Universal Properties, Fuquay-Varina, LLC. The applications submitted by The Heritage, Hillcrest, and Liberty were disapproved. These determinations were set forth in the Required State Agency Findings, issued by the CON Section on Feb. 3, 2012. The Heritage, Hillcrest, and Liberty appealed the Agency Decision. Universal Properties, Fuquay-Varina, LLC. was a Respondent-Intervenor in the appeals, but was dismissed pursuant to settlement after mediation.

In a hearing spanning nearly 4 months, the evidence focused in particular on issues surrounding **Criterion 20** and **Criterion 13(c)**. *See* **N.C.G.S. § 131E-183(a)(20)** & **131E -183(a)(13c)**. In particular, the parties raised issues regarding:

Criterion 20 requires "*An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.*" **N.C.G.S.** § 131E-183(a)(20). To assess whether the applicants have conformed to the requirements of this criterion, the Agency's application form required all applicants to disclose their history of providing quality care during the 18 months immediately preceding the submittal of the application. The Agency witnesses testified that they also inquired with the NC DHSR Nursing Home Licensure and Certification Section as to any quality of care problems for which any of the applicants had been cited for 18 months preceding the decision date.

The application submitted by Britthaven disclosed its past quality of care issues for some, but not all of its facilities; in particular it omitted all quality of care issues arising from facilities outside of Wake County. Seven Britthaven facilities had experienced 11 events constituting substandard quality of care during the 18 months prior to the application date. All other applicants provided the information requested in the application form, including Liberty, which identified three substandard quality of care events.

The Agency witnesses testified that they only examine whether an applicant has had a substandard quality of care event in the most recent 18 months and only within the service area for the facility proposed in the application. Thus, any quality of care issues arising outside of the geographic service area for the proposed project, or arising prior to 18 months before the submission of the application(s), or arising after the submission of the applications had no bearing on the ultimate Agency Decision.

In its Findings, the Agency found Britthaven conforming with **Criterion 20** and found Liberty non-conforming with **Criterion 20**. As a result of the Agency's conclusion that Liberty was non-conforming with **Criterion 20**, the Agency found, by derivative, that the Liberty application was therefore non-conforming with Statutory Review Criteria 1, 4, and 18a.

The Court examined whether the geographic and temporal limitations imposed by the Agency on its review of applicants' conformity with **Criterion 20** constituted Agency error.

Criterion 13(c) requires applicants to demonstrate that their proposal will serve the elderly and medically underserved. As the Agency witnesses testified, to determine conformity with this criterion in a NF review, the CON Section examines the percentage of service to Medicaid and Medicare recipients proposed by the applicant.

As a proposed new provider in the service area, The Heritage based its projected service to Medicare and Medicaid recipients on the Wake County average Medicare and Medicaid percentages for all skilled nursing facilities, with the exclusion of Continuing

Care Retirement Communities ("CCRCs") which cannot serve Medicaid recipients.

The Agency witnesses testified that the methodology for projecting service to Medicare and Medicaid patients used by The Heritage was a reasonable approach for an applicant to take. Yet, as part of its review, the CON Section analyst excluded all Medicaid percentages for hospital-affiliated NFs when calculating the Wake County average for Medicaid service. As a result, the Medicaid projections in the application submitted by The Heritage fell below the adjusted Wake County average calculated by the analyst. Accordingly, the Agency concluded that The Heritage did not adequately demonstrate that its proposal would serve the elderly and medically underserved and, thus, was found non-conforming with **Criterion 13(c)**. As a result of the Agency's conclusion that The Heritage was non-conforming with **Criterion 13(c)**, the Agency found, by derivative, that the Heritage application was therefore non-conforming with Statutory Review Criteria 1, 4, and 18a.

The ALJ reversed in part and affirmed in part the Agency Decision, finding that the Agency erred by:

Criterion 20

- Failing to review past quality of care event information from across the state, as opposed to just the geographic service area for the proposed service;
- Failing to consider information provided in response to questions found in the application form promulgated by the Agency; and
- Failing to perform a meaningful and substantial analysis of the applications under **Criterion 20**

Criterion 13(c)

- Computing the county average service to Medicaid under **Criterion 13(c)** differently for hospital-affiliated nursing facilities and those that are not hospital-affiliated.
- As to the Conformity of the Applicants:
- The Agency erred in finding the Liberty Application non-conforming with **Criterion 20**, and thus erred by derivative in finding Liberty non-conforming with **Criteria 1 (Policy GEN-3)**, **4**, and **18a**, and 120 beds were awarded Liberty;
- The Agency erred in finding the Britthaven Application conforming with **Criterion 20**, and thus erred by derivative in finding Britthaven conforming with **Criteria 1 (Policy GEN-3)**, **4**, and **18(a)**;
- The Agency erred in finding the Heritage Application non-conforming with **Criterion 13(c)** and thus erred by derivative in finding The Heritage non-conforming with **Criteria 1 (Policy GEN-3)**, **4**, and **18(a)**; and
- The Agency did not err in determining that the BellaRose Application was conforming with all the Statutory Review Criteria, and 100 beds were awarded to BellaRose.

Analysis: The ALJ was heavily critical of the Agency on numerous fronts by calling into question its whole approach to applying both **Criterion 20** and **Criterion 13(c)**.

The ALJ first looked to the language of **Criterion 20**, and found that the Agency erred in imposing a geographic limitation on its analysis of past quality of care events that conflicted with the language of the statute. Since, for some of the Statutory Review Criteria, the General Assembly had seen fit to impose geographic limitations tied to the applicants proposed service area, the ALJ reasoned that—under the Canons of Construction—the omission of any such limitation for **Criterion 20** must be given meaning and interpreted as intentional. Without any statutory basis for limiting its review of past quality of care issues to only the applicants' proposed service area, the ALJ reasoned that this approach was plain error. Thus, he held that the Agency was required to assess quality of care information on a statewide basis.

The ALJ further chided the Agency for including in its application form a series of questions which sought quality of care event information for the entire state, yet ignoring this information during its review. On this point, the ALJ concluded that the Agency was arbitrary and capricious by creating a policy by which it ignores and treats as unnecessary information that is specifically requested in its application form. The ALJ held that it was contrary to **N.C.G.S. § 131E-182(2)** for the Agency to implement review policies which serve to make irrelevant information specifically requested in the Agency's own application form. In so holding, the ALJ stated that, irrespective of past Agency practice, the burden of providing the information requested in the application form rested on the applicants, and their failure to provide meaningful and material information could serve as the basis for a finding of non-conformity. Thus, the failure of Britthaven to supply the requested information on a statewide basis rendered its application non-conforming with **Criterion 20**.

As for the temporal limitation of 18 months utilized by the Agency under **Criterion 20**, here the ALJ found that the statutory language did not provide a specific time period for the Agency to use in determining conformity with **Criterion 20**. As a result, unlike the impermissible geographic limitations employed by the Agency, its 18 month look-back period was both reasonable and consistent with its application form. Thus, the Agency did not err in this regard.

Nonetheless, the ALJ did conclude that the Agency erred in failing to consider information regarding quality of care events occurring after the submission of the applications but prior to the issuance of the Agency's decision. In this respect, the ALJ held that the Agency erred in failing to take such information into account as part of its analysis.

As for the analytical metrics employed by the Agency to determine whether an application conforms with **Criterion 20**, the Court held that a "zero-tolerance" approach to past quality of care events is not required by statute and would be both unreasonable and impractical. Thus, according to the ALJ, the determination of whether the available quality of care event information renders an application non-conforming with **Criterion 20** apparently rests in the discretion of the Agency.

Reviewing the Agency's analysis under **Criterion 13(c)**, the ALJ held that the exclusion of hospital-affiliated patients from the Wake County Medicaid averages for NFs was arbitrary and capricious. In particular, the Court stated that despite the fact that hospital-affiliated NFs often have different admission patterns than non-hospital-affiliated NFs, all NFs are regulated in the same manner and are required to meet the same CON, licensure, and

certification requirements. Furthermore, the Agency witnesses testified that they conducted no analysis comparing the percentage of Medicaid patients served by hospital-affiliated NFs versus those served by non-hospital-affiliated NFs. The Agency witnesses further stated that, had a hospital-affiliated NF application been submitted, then they would not have excluded the hospital-affiliated data from the average. If this had been the Agency's approach during the review, the result would have been that The Heritage would have been conforming with **Criterion 13(c)**. Thus, the Court held that it was erroneous for the Agency to analyze whether an applicant is conforming with **Criterion 13(c)** based on whether or not a hospital-affiliated entity has applied.

The Heritage, Britthaven, and the CON Section appealed the case in part to the Court of Appeals. The award of 100 beds to Bella Rose was not appealed. This case is still pending before the Court of Appeals.

CaroMont Health, Inc., Gaston Memorial Hospital, Inc. and CaroMont Ambulatory Services, LLC d/b/a CaroMont Endoscopy Center v. N.C. DHHS, DHSR, CON Section and Greater Gaston Center, LLC, ___ N.C. App. ___, ___ S.E.2d ___, No. COA12-1044 (Dec. 3, 2013)

Facts: Petitioners, CaroMont, et. al. (collectively "CaroMont") appealed to the N.C. Court of Appeals from a Final Agency Decision ("FAD") entered in March, 2012 which adopted the ruling of an Administrative Law Judge ("ALJ") that dismissed their Petition for Contested Case Hearing under Rule 41(b) of the North Carolina Rules of Civil Procedure ("NCRP"). The CaroMont Petition asserted that the N.C. DHHS, DHSR, Certificate of Need Section ("the Agency") erred in granting a Certificate of Need ("CON") for the development of two gastrointestinal ("GI") endoscopy rooms to Respondent-Intervenor Greater Gaston Center, LLC ("GGC") and that CaroMont suffered substantial prejudice from the granting of the CON to GGC, LLC.

In 2007, CaroMont perceived the need for a freestanding ambulatory surgery center and applied to move two licensed GI endoscopy rooms from the Gaston Memorial Hospital main campus to a freestanding GI clinic called CaroMont Endoscopy Center. That CON was granted in December, 2008. In October, 2010, GGC filed a CON application to develop a freestanding ambulatory surgery center with two GI endoscopy procedure rooms in Gaston County. The Agency conditionally approved the GGC CON application in March, 2011. (As of April, 2011 when the GGC CON application was approved and CaroMont filed its Petition, CaroMont subsidiary Gaston Memorial Hospital, located in Gastonia, was the only licensed provider of GI endoscopy rooms in Gaston County, North Carolina. Gaston Memorial Hospital had eight licensed GI endoscopy rooms at the time of their application to move two rooms to the freestanding clinic in 2008. The freestanding clinic was still in development and not yet operational by 2011 when the GGC CON application was approved.)

CaroMont filed its Petition for Contested Case Hearing, challenging the approval of GGC's CON application, and GGC intervened by consent in May, 2011. ALJ Joe L. Webster then held a three-day contested case hearing. At the close of CaroMont's evidence, the Agency and GGC moved for dismissal of CaroMont's Petition. ALJ Webster then issued a Recommended Decision in January, 2012, dismissing CaroMont's petition under Rule 41(b) for (1) failure to demonstrate that its rights were substantially prejudiced by the Agency's decision; and (2) failure to demonstrate that the Agency committed error in making its decision. In March, 2012, following CaroMont's submission of written exceptions to ALJ Webster's recommended decision to the Final Agency Decision-maker, Drexdal Pratt, Director of DHSR, issued a FAD adopting ALJ Webster's Recommended Decision. CaroMont timely appealed to the North Carolina Court of Appeals in April, 2012.

The North Carolina Court of Appeals affirmed the FAD which adopted the ruling of ALJ Webster dismissing the case for CaroMont's failure to show substantial prejudice by the FAD and CaroMont's failure to show Agency Error.

Analysis: The Court based its decision on the North Carolina Court of Appeals opinion in **Parkway Urology, P.A. v. N.C. DHHS,** 205 N.C. App. 529, 696 S.E. 2d 187 (2010), which held that an ALJ must determine whether a non-applicant Petitioner (such as CaroMont) met the burden of showing both that the Agency action substantially prejudiced the Petitioner's rights and that the Agency acted erroneously in making its decision. (The language used by the Court from the Parkway Urology case specifically quotes the two-prong test for a petitioner's burden found in **Britthaven, Inc. v. N.C. Dep't of Human Res.**, 118 N.C. App. 379, 382, 455 S.E. 2d 455, 459 (1995).) The Court found **Parkway Urology** to be controlling, and thus required CaroMont to prove that it was substantially prejudiced by the FAD granting GGC a CON. In analyzing whether there was adequate evidence that CaroMont failed to prove that it was substantially prejudiced, the Court applied the whole record test.

Despite acknowledging that CaroMont did offer evidence of specific harm (unlike the petitioner in **Parkway Urology**) the Court concluded that all of the harms that CaroMont claimed were little more than the product of normal competition introduced by GGC's CON approval. This conclusion rejected the contention by CaroMont that the economic harms acknowledged in **Parkway Urology** could serve as the basis for a showing of substantial prejudice if those harms were quantified. The Court in **Parkway Urology** had found that the petitioner failed to quantify the economic harms claimed in that case, but rather relied solely on its status as an affected person. *See* **N.C.G.S. § 131E-188**. In addition, the Court found that the harms claimed by CaroMont were not caused by the approval of the GGC CON application, but rather were due to existing changes in patient referrals and the introduction of a new competitor into the market.

On the issue of Agency error, the Court found that the Agency made a reasonable health planning judgment in deciding that there was sufficient volume for a total of 10 endoscopy rooms in Gaston County. This finding essentially adopted the findings related to Agency error in the FAD, which found CaroMont's expert testimony too unreliable and insufficient to establish error on the part of the CON Section. While CaroMont pointed out that its expert witness' testimony relied upon historical data and was not contradicted by the Agency, the Court found that the Agency was entitled to determine whether it was credible. The Court adopted a deferential stance with respect to Agency determinations

regarding the credibility and weight given evidence offered for the purpose of proving Agency error. Nonetheless, the Court found that the Agency's analytical approach to evaluating the projections found in the GGC Application was both rational and supported by substantial evidence, thus satisfying the whole record test.

Holly Springs Hospital II, LLC, et. al. v. N.C. DHHS, DHSR, CON Section, ___ N.C. App. ___, ___ S.E.2d ___, No. COA13-367 (Dec. 17, 2013) *(unpublished) Facts:* The 2010 State Facilities Medical Plan ('SMFP") identified a need for 101 additional acute care beds in Wake County. Six Certificate of Need ("CON") applications were filed, with each applicant seeking a portion of the additional beds identified in the SMFP. The CON Section's decision was to conditionally approve WakeMed Raleigh's CON application for 29 beds, conditionally approve WakeMed Cary's CON application for 22 beds and conditionally approve Rex Holly Springs' CON application for 50 beds. Petitioner Holly Springs Hospital II, LLC's ("HSH") CON application was denied by the CON Section. HSH appealed the decision of the CON section and in March, 2012 HSH moved for summary judgment in its case.

Following HSH's motion for summary judgment, the Recommended Decision of an Administrative Law Judge ("ALJ") found that the Agency erred in finding the HSH CON application to be non-conforming with certain statutory review criteria found in **N.C.G.S. §131E-183(a)**. However, the CON Section, together with WakeMed and Rex, appealed the Recommended Decision of the ALJ. Subsequently, the Final Agency Decision ("FAD") entered in September, 2012 rejected the ALJ's Recommended Decision and affirmed the CON Section's decision. HSH then appealed the FAD to the North Carolina Court of Appeals ("the Court"). The Court affirmed the FAD, which rejected the ALJ's Recommended Decision, and upheld the CON Section's denial of HSH's CON application.

Analysis: The Court first noted that the findings of fact from the FAD were binding on the Court, since HSH did not challenge them as being unsupported by substantial evidence, and the Court applied the whole record test in its review. *See* **Good Hope Health Sys., LLC v. N.C. Dep't of Health & Human Servs.**, 188 N.C. App. 68, 658 S.E.2d 665 (2008). The FAD relied heavily on the lack of letters of support from physicians in HSH's CON application in finding that HSH failed to project the necessary utilization to conform with **Criterion 3** under **N.C.G.S. §131E-183(a)**. HSH asserted that this reliance is *"akin to relying on an unpromulgated rule"*. The Court rejected this contention, concluding that letters of support are some evidence of the existence or non-existence of the need as required by CON Statutory Review Criterion 3. *See* **Charter Pines Hospital, Inc. v. North Carolina Dep't of Human Resources**, 83 N.C. App. 161, 170, 349 S.E.2d 639, 645 (1986). As a result, the Court found it entirely reasonable that the FAD considered physician support letters when addressing whether HSH sufficiently showed that it could meet utilization and market share projections.

In addition to the finding that the Agency's consideration of the lack of physician support letters was reasonable, the Court further noted that the FAD also included separate findings pointing to HSH's failure to provide adequate documentation of its ability to provide the services proposed in its CON application. More specifically, the FAD addressed the lack of a recruitment plan and lack of any documentation of support for the project by Wake County physicians. The FAD concluded that this lack of physician support documentation further justified the CON Section's decision. The Court found substantial evidence to support the FAD and affirmed the FAD as to HSH's failure to satisfy Criterion 3. The Court did not address the remaining issues on appeal.

State Health Plan For Teachers & State Emps. v. Barnett, ___ N.C. App. ___, 744 S.E.2d 473, No. COA12-999 (May 7, 2013) | *Facts*: Plaintiff health plan brought an action against defendant plan member and her attorney ("Ellison") to recover on its medical lien for defendant's recovery from settlement with third party tortfeasor in an automobile accident, pursuant to subrogation rights under **N.C.G.S. §135-45.15**. After multiple notices and requests following settlement, Attorney Ellison disbursed the proceeds from settlement (after payment of attorney's fees, certain medical expenses and rental car costs) to defendant, without paying plaintiff. Defendant signed a disbursement summary purporting to release Ellison from any other obligation as to the medical bills or liens from any other insurance providers. Defendant was informed by Ellison of the plaintiff's lien on her settlement funds, but she directed Ellison not to disburse any proceeds to plaintiff.

Plaintiff's suit was filed against both the plan member and attorney Ellison. The defendant plan member filed for bankruptcy, staying the proceedings against her. The trial court entered summary judgment against attorney Ellison and ordered Ellison to reimburse plaintiff the amount of plaintiff's lien.

Analysis: The North Carolina Court of Appeals affirmed the Superior Court's grant of summary judgment in favor of the plaintiff, requiring Ellison to reimburse plaintiff the medical lien amount. The Court rejected Ellison's argument that **N.C.G.S. § 135-45.15** does not authorize recovery of settlement proceeds directly from an attorney who represents a member of the State Health Plan. Specifically, § 135-45.15(d) presumes notice of the lien when a member of the plan is represented by an attorney and mandates that the attorney disburse proceeds pursuant to the section. The Court noted that it is well established in North Carolina that attorneys representing injured parties are responsible for repaying lienholders from award and settlement monies, regardless of a client's instructions against disbursement to a lienholder. *See* **N.C. Baptist Hospitals, Inc. v. Mitchell**, 323 N.C. 528, 374 S.E.2d 844 (1988); **Triangle Park Chiropractic v. Battaglia**, 139 N.C. App. 201, 532 S.E.2d 833 (2000) (each addressing the requirements of **N.C.G.S. §44-50**). The Court made it clear that any deviation from that procedure places direct responsibility on an attorney. Ellison's argument that North Carolina State Bar RPC 69 excuses this obligation because of the duty to disburse according to a client's instruction was rejected because RPC 69 provides an exception where a medical provider has perfected a valid lien.

Kohn et al. v. First Health of the Carolinas, Inc., ___ N.C. App. ___, 747 S.E.2d 395, No. COA13-168 (Aug. 20, 2013) | *Facts*: Plaintiff physician specializing in obstetrics and gynecology and two patients brought an action against defendant Moore Regional

Hospital, alleging that the hospital violated the "public duty" or "public utilities" doctrine by denying physician staff privileges at hospital. The Superior Court granted defendant's motion to dismiss for failure to state a claim and dismissed claims by the patient-plaintiffs on standing grounds. Plaintiffs appealed the dismissal claiming that defendant is the only secondary care hospital with full surgical specialty facilities in Moore County. Thus, plaintiffs argued that defendant controls a market lacking feasible alternatives for Moore County residents, which imposes a public duty upon the hospital to provide the public utility it controls to plaintiffs. Plaintiffs contended that defendant unreasonably and unlawfully denied its public utility in violation of this duty.

Analysis: The North Carolina Court of Appeals affirmed the trial court's dismissal in favor of defendant for failure to state a claim. Plaintiffs' appeal relied upon the contention that an entity can still be considered a public utility even if it does not meet the requirements of **N.C.G.S. §62-3(23)**. Plaintiffs asserted that if the entity holds itself out as providing services to the general public, rather than specific individuals, then they are, by necessity, a public utility. Here, plaintiffs claimed that Moore Regional was the only secondary care hospital serving a significant geographical area, so it should be seen as owing those same duties as a public utility would owe. The Court rejected plaintiffs' argument that, merely by virtue of being the only secondary care hospital serving a particular geographical area, the hospital should be seen as owing those same duties as a public utility would owe.

The Court noted that no court in North Carolina has suggested that a hospital (or any entity outside of those set forth in **N.C.G.S. § 62-3(23))** should be considered a public utility. In matter-of-fact fashion, the Court held that it is the prerogative of the General Assembly—and not the Court—to expand the language of that requirement. The Court declined to rule upon the standing issue. Since the plaintiffs failed to provide any authority that demonstrated that the defendant hospital was a public utility, it affirmed the trial court's dismissal of plaintiffs' claim based upon the public utility doctrine.

Housecalls Home Health Care, Inc. v. State of North Carolina Department of Health and Human Services et al., ___ N.C. App. ___, 738 S.E.2d 753, No. COA12-839 (Feb. 5, 2013) | *Facts*: Plaintiff, a home health provider, brought an action against the Department of Health and Human Services ("DHHS") seeking: (1) an injunction compelling DHHS to show whether a fraud investigation of plaintiff was ongoing; (2) a hearing to determine whether DHHS owed any monies to plaintiff; and (3) a determination of the amount of any money owed to plaintiff. The parties had been involved in prior state and federal actions related to certain of these issues. Plaintiff moved to compel discovery, and DHHS moved for a protective order, dismissal and summary judgment. The Superior Court granted plaintiff's motion to compel, entered a qualified protective order, denied defendant's motion to dismiss, and denied summary judgment. DHHS appealed from these rulings.

Analysis: The North Carolina Court of Appeals held that the plaintiff's action was precluded by *res judicata*. Thus, it reversed the trial court's order to compel discovery from defendant, entry of a qualified protective order, denial of defendant's motion to dismiss, and denial of defendant's motion for summary judgment, and remanded the case for further proceedings. This case (or "saga" as the Court calls it in one part of the opinion) began in early 1997 when defendant attempted to revoke plaintiff's license and certification. Plaintiff passed the review procedures and maintained its license and certification at that time. At that same time, the Medicaid Investigative Unit (MIU) withheld and seized all Medicaid reimbursements to plaintiff due to alleged fraud, and plaintiff filed an action with the Office of Administrative Hearings. That action was later dismissed in 1998 due to failure to prosecute and to exhaust administrative remedies. The record on appeal indicates that there was no contact between the parties for nearly five and a half years, and that, in the meantime, plaintiff did not pursue further action in the courts and went out of business.

This appeal stems from an action in Guilford County in which plaintiffs sought an injunction to compel defendant to address numerous items, including alleged payment obligations and due process violations. From the various orders entered by the trial court, defendant brought an interlocutory appeal, arguing, among other things, that: (1) the trial court erred in denying defendants motion for summary judgment based on *res judicata* and collateral estoppels; (2) denying its motion to dismiss based on sovereign immunity; and (3) denying its motion for protective order preventing disclosure of criminal investigation records subject to statutory protections. The Court held that prior federal and state court cases brought by plaintiff over the preceding years already determined that plaintiff could not recover "withheld" funds or monetary damages from defendants. Thus, the claims for injunctive relief—which sought a determination regarding monies allegedly owed by one party to the other and the release of funds—were barred by *res judicata*. The Court rejected plaintiff's claim that it was not seeking a determination on the funds themselves, but rather a determination on the violation of their due process rights. Therefore, the Court reversed and remanded for dismissal of all claims and declined to address defendant's remaining issues on appeal.

In The Matter of Lawrence Bullock III, ___ N.C. App. ___, ___ S.E2d ___, 2013 WL 4714209, No. COA13-149 (Sept. 3, 2013) | *Facts*: Respondent was found not guilty by reason of insanity of first degree burglary and second degree kidnapping in 1999. Respondent was then involuntarily committed to the forensic unit at Dorthea Dix Hospital ("Dix"). Respondent has had recommitment hearings each year, at a minimum, and was recommitted following each of those hearings. Respondent has been at either Dix or the forensic unit at Central Regional Hospital since 1999. The most recent recommitment hearing for Respondent was May 25, 2012.

At the Respondent's May 2012 recommitment hearing, his sister testified about changes and improvements that she had seen with Respondent in the past several years due to his ability to leave the unit(s) and visit with family and friends at various outings. Respondent's doctor testified about Respondent's condition generally at the same hearing, focusing on his diagnosis and the ramifications if Respondent were to ever stop taking his medications. Respondent's physician testified that Respondent did not understand that he needed to take his medications and

disclosed a specific incident which demonstrated that Respondent's current medication level was ineffective at controlling his behavior. The trial court concluded that Respondent failed to show that he no longer suffered from mental illness and was no longer a danger to others. The Court recommitted Respondent to the forensic unit for another year and Respondent appealed.

Analysis: The North Carolina Court of Appeals reversed the trial court's order recommitting Respondent to a forensic unit in a psychiatric hospital, but remanded the case for entry of a revised recommitment order. The Court noted that Respondent failed to timely file his appeal within 30 days of the entry of judgment pursuant to **N.C.R. App. P. 3(c)(1)**, but nevertheless granted Respondent's petition for *writ of certiorari*. The Court reviewed the recommitment order just as it would an original commitment order. The standard of review was whether there was competent evidence to support the trial court's findings of fact and whether those findings supported the trial court's conclusion.

The Court focused on the requirement that the trial court make sufficient findings of fact and conclusions of law to allow the reviewing court to determine whether the judgment and legal conclusions were supported and correctly applied. *See* **Spicer v. Spicer,** 168 N.C. App. 283, 607 S.E.2d 678 (2005). The Court distinguished findings of fact from recitations of witness testimony by a trial judge, and found that the majority of the trial court's findings were merely recitations of testimony. Nonetheless, the Court concluded that, while the trial court failed to make sufficient findings to support its conclusion, there was sufficient evidence in the record to support those findings. As a result, the Court remanded the case for entry of a revised order supported by adequate findings.

The Respondent raised two additional issues: (1) whether the trial court erred in refusing to rule on a conditional release for Respondent; and (2) whether Respondent's due process rights were violated because he was placed in the more restrictive forensic unit during the recommitment hearings. On the first issue, the Court held that the trial court was not required to make a finding regarding any conditional release of the Respondent because there was no evidence presented showing that was medically appropriate. As for Respondent's due process rights, the Court noted that when an acquitee is charged with a crime involving the infliction of serious injury or death (like the Respondent), absent a specific statutory or regulatory requirement, the trial court may leave the placement to the discretion of the treating professionals.

North Carolina State Bd. of Dental Examiners v. FTC, 717 F.3d 359 (4th Cir., May 31, 2013) | *Facts*: On June 17, 2010, the Federal Trade Commission ("FTC") issued an administrative complaint against the North Carolina State Board of Dental Examiners (the "Board"), charging it with violating the FTC Act (codified at 15 U.S.C. § 45), by directing non-dentists to stop providing teeth whitening services or products, discouraging or barring the provision of those goods and services, or communicating to certain third parties that non-dentist teeth whitening goods or services violated the North Carolina Dental Practice Act (codified at Chapter 90, Article 2 of the North Carolina General Statutes). The Board moved to dismiss the complaint, arguing that the FTC lacked jurisdiction over it and, alternatively, that it was exempt from the federal antitrust laws under the "state action" doctrine. A Federal Administrative Law Judge ("ALJ") denied the motion, and the FTC affirmed. In response, the Board filed a federal declaratory action, raising the same grounds and requesting that a federal court stop the administrative proceeding against it. The United States District Court for the Eastern District of North Carolina dismissed that action as an improper attempt to enjoin ongoing administrative procedure. *See* **North Carolina State Bd. of Dental Examiners v. FTC**, 768 F.Supp.2d 818 (E.D.N.C. 2011).

The ALJ then held a trial and issued an opinion finding that the Board violated the FTC Act. On appeal, the FTC—applying a *de novo* standard of review—affirmed and entered a final decision against the Board, which included a cease-and-desist order enjoining the Board from, *inter alia*, continuing to unilaterally issue extra-judicial orders to teeth-whitening providers in North Carolina. *See* **In re North Carolina State Bd. of Dental Exam'rs,** 2011–2 Trade Cases P 77705, 2011 WL 6229615, at 2–5 (F.T.C. December 7, 2011). The Board petitioned for review of the FTC's final order, raising three arguments: (1) the Board is exempt from the antitrust laws under the "state action" or "Parker" doctrine; (2) the Board did not engage in concerted action under § 1 of the Sherman Act; and (3) the Board's activities did not unreasonably restrain trade under § 1 of the Sherman Act. The FTC issued a stay pending appeal.

Analysis: The Fourth Circuit Court of Appeals denied the Board's Petition, effectively affirming the FTC Final Order. The Court addressed each of the Board's arguments directly. The Court first looked to see if the Board was exempt from the antitrust law under the "state action" doctrine, under which, "the antitrust laws do not apply to anticompetitive restraints imposed by the States as an act of government." This doctrine was announced in **Parker v. Brown,** 317 U.S. 341, 352, 63 S.Ct. 307, 87 L.Ed. 315 (1943). Noting that "state-action immunity [is] disfavored," the Court noted three situations in which the Parker doctrine may apply:

(1) A state's own actions "ipso facto are exempt" from the antitrust laws. *See* **Hoover v. Ronwin**, 466 U.S. 558, 568, 104 S.Ct. 1989, 80 L.Ed.2d 590 (1984);

(2) Private parties can claim the Parker exemption if acting pursuant to a "clearly articulated and affirmatively expressed as state policy" and their behavior is "actively supervised by the State itself." *See* **California Retail Liquor Dealers Ass'n v. Midcal Aluminum, Inc.**, 445 U.S. 97, 105, 100 S.Ct. 937, 63 L.Ed.2d 233 (1980); and

(3) Municipalities and "substate governmental entities do receive immunity from antitrust scrutiny when they act pursuant to state policy to displace competition with regulation or monopoly public service." *See* **FTC v. Phoebe Putney Health Sys., Inc.**, ––– U.S. ––––, 133 S.Ct. 1003, 1010, 185 L.Ed.2d 43 (2013).

The Court concluded that, since the Board is operated by dentists, hygienists, and consumers, which it deemed "market participants," it did not qualify as a "state" actor. Thus, as a "private" actor, the Board was required to meet the standard set forth in the second prong under **Midcal**, 445 U.S. 97 (1980). In holding that the Board was not entitled to exemption under the Parker doctrine,

the Court found that the State of North Carolina had done far less supervision of the Board than was present in the **Midcal** case, where the **Parker** doctrine did not apply. The Court agreed with the FTC that, "[t]his sort of generic oversight, however, does not substitute for the required review and approval of the 'particular anticompetitive acts.'" *See* **FTC Interlocutory Order**, 151 F.T.C. at 630 (quoting **Patrick v. Burget**, 486 U.S. 94, 101 [108 S.Ct. 1658, 100 L.Ed.2d 83] (1988).

The Court then turned to the FTC's findings as to the violation of the FTC Act, noting that these factual findings are conclusive if supported by substantial evidence and that, despite a *de novo* review, deference is given to the FTC's "informed judgment". Again, the Court agreed with the FTC that "Board members were capable of conspiring because they are actual or potential competitors." *See* **FTC Final Order**, 2011 WL 6229615, at *20 (applying ***American Needle, Inc. v. National Football League***, 560 U.S. 183, [130 S.Ct. 2201, 176 L.Ed.2d 947] (2010). The Court noted that the Board members operated private dental practices and had a personal financial interest in excluding non-dentist teeth whitening services since many Board members offered similar services. The Court further agreed with the FTC that this conspiratorial interest was amplified by the "degree of control exercised by dentist members of the Board with respect to the challenged restraints." Ultimately, the Court held that concerted action existed by the Board members who, by agreement, deprived "the marketplace of independent centers of decision making." *See* **Robertson v. Sea Pines Real Estate Co.**, 679 F.3d 278, 285 (4th Cir.2012) (quoting American Needle, 130 S.Ct. at 2212). The Court further opined that the Board's members were "separate economic actors who cannot escape liability under § 1 simply by organizing under a 'single umbrella.'" *See* **American Needle**, 130 S.Ct. at 2212.

As to whether there a conspiracy existed, the Court found the conclusions of the FTC supported by substantial direct and circumstantial evidence. Namely, the evidence suggested that the Board "engaged in a consistent practice of discouraging non-dentist teeth whitening services" with the common objective of closing the market. *See* FTC **Final Order**, 2011 WL 6229615, at *23.

The Court noted that the US Supreme Court had cautioned that "certain practices by members of a learned profession might survive scrutiny ... even though they would be viewed as a violation of the Sherman Act in another context." However, the Court agreed that, under any analytical approach, the Board's conduct was likely to cause significant anticompetitive harms, as prohibited by the Sherman Act. *See* **Nat'l Soc'y of Prof'l Eng'rs v. United States**, 435 U.S. 679, 686, 98 S.Ct. 1355, 55 L.Ed.2d 637 (1978).

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