Prognosis

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The Chair's Comments



Van Der Vaart

As a member of the Health Law Section Council (the "council") for the past six years, it has been my pleasure to work with many talented and engaging health care attorneys from across the state, and I am honored to serve as the chair of the council for the 2011-2012 year. We continue to work toward increasing the diversity of the Health Law Section Council and are pleased to welcome the following new members to the council: Alicia Bowers, Frank Kirschbaum, Dina Marty, Lee Whitman, and Freddie Zufelt.

For those of you whom I have not had the pleasure of meeting, I would like to briefly introduce myself, and hope that I will have the opportunity to meet you during the coming year. I am General Counsel of LabCorp, a national medical laboratory testing company headquartered in Burlington. LabCorp has over 31,000 employees worldwide, with a staff of 44 employees in the Law Department, including 16 attorneys, most of who work in our corporate headquarters.

We are excited about the upcoming year and the progress that has already been made on a number of projects. This year we will complete and release a professionally-

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Voluntary Compliance Programs are a Thing of the Past

Make Way for Mandatory Requirements

By Sarah B. Crotts

We all know that compliance is important. Our clients all know that compliance is important. Yet, how many of your hospital and physician practice clients have a compliance program in place? Of those clients that have compliance programs, how many have compliance plans collecting dust on a shelf and how many are actually using them?

Section 6401(a) of the Patient Protection and Affordable Care Act (PPACA), enacted in 2010, requires providers or suppliers of medical or other items or services, *as a condition of enrollment* in Medicare, Medicaid, or the Children's Health Insurance Program (CHIP), to establish a compliance program that contains certain core elements. PPACA requires the Secretary of the Department of Health and Human Services (HHS), in consultation with the Office of the Inspector General (OIG), to establish the core elements for providers or suppliers within a particular industry or category.

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Chair's Comments

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prepared educational DVD as part of the council's End-of-Life Public Education Campaign. Following changes made to North Carolina's end-of-life/advanced directives laws in 2007, the council recognized the need to educate the general public, and not just health care providers, about the importance of having conversations with loved ones about end-of-life issues before a health crisis hits, as well as providing information about how to document one's preferences consistent with North Carolina law. The DVD, along with pre- and post-training materials, will provide information to assist patients, families, and caregivers in understanding available end-of-life care and planning options. We also have a dedicated website for the project, ***www.AGiftToYourFamily.org*** (primary) and ***www.AGiftToYourFamily.com*** (reserved to avoid others from reserving or using). In addition to hosting the DVD, the website will provide more in-depth information, forms, a toolkit, and perhaps e-learning modules.

The council also continues to support the Safe Haven Project, which has been one of the section's most high-profile public service projects for many years. It has focused on educating the public about North Carolina's infant abandonment law, which allows a parent to safely and anonymously give up a newborn child under seven days old without risking criminal prosecution. The council has a wide variety of information about this law on the North Carolina Bar Association's website and continues to produce and send out brochures and posters with this information to libraries and other organizations. An article about Safe Haven was published in the summer issue of Forum, the North Carolina Medical Board's newsletter. The council recently approved the purchase of additional posters for distribution and will work on disseminating the posters to appropriate sites across the state, as well as other materials.

The council's Special Projects Committee is exploring ways that the Health Law Section might work to help promote medical-legal partnerships in North Carolina. The medical-legal partnerships model is an interdisciplinary approach to health care for low income people, who often require some legal assistance to address underlying social or environmental problems that contribute to health issues.

In an ongoing effort to expand our outreach to law students interested in health law, the council is holding its February meeting at the Elon Law School in Greensboro, and worked with the Career Office there to coordinate a panel discussion on the practice of health law, which is open to all students. We are also exploring participation in a mentoring program for law students interested in health law. In addition, the section's Long-Range Planning Committee will evaluate a proposed new project to provide assistance in educating medical and nursing students (and potentially other health care providers in training programs) on health law topics.

The Health Law Section's Annual Meeting and CLE is scheduled for April 20, 2012 at the Bar Center in Cary. The CLE Committee, which includes Don Esposito, Alicia Gilleskie and Allyson Labban has lined up an excellent panel of speakers. Topics include fraud and abuse, social media, accountable care organizations and the use of mobile devices. Scholarships for the program are available to Section members who work for government or non-profit organizations, or who are currently unemployed, and to Section members who are North Carolina law students and members of the NCBA Law Student Division. The section is also working with the North Carolina Medical Society and the North Carolina Society of Health Care Attorneys on a joint CLE/CME program that targets both attorneys and physicians to be held on June 15, 2012.

The council is always interested in hearing from members of the Health Law Section about how we can better address your interests and needs. If you have any suggestions on programs or projects, or if you are interested in becoming more involved with the council, please feel free to contact me by phone at 336-436-5042 or email at *vaarts@labcorp.com.* •



Phelps

The President's Report

A Word from Melanie Phelps, President, N.C. Society of Health Care Attorneys

By the time you view this edition of Prognosis, the 2011 NCSHCA Annual Meeting will have come and gone. The Society will be under the capable leadership of new president Marie Moseley from University Health Systems of Eastern North Carolina. And while new Board members will be installed, bringing fresh ideas and energy to Society affairs, a number of dedicated leaders will rotate off the Board, including, immediate past president Bill Stewart of K&L Gates and past president Lou Patalano of Cape Fear Valley Health System. In addition, Board members Dean McCord, Wendy Greene, and Sean Timmons will conclude their many years of valued service to the Board. All five individuals have generously given their time and talent to the Society and will be greatly missed.

The Society has made some significant changes over the past year. Most notably, after many years with the same management firm, the Board voted unanimously to search for a new firm that could help reenergize the Society. After an extended search, the Board decided to engage the services of Colleen Kochanek and Elizabeth Taylor with Kochanek Law Group. Colleen and Liz, in the six months that they have been working with the Society, have introduced a new level of professionalism and service for which the Board is quite grateful.

In addition, the Society has focused its efforts on giving back to the community. We have made a $5,000 donation to the End-of-Life Care Public Education Initiative sponsored by the Health Law Section of the N.C. Bar Association along with numerous other partners from the legal and health care communities. Through this community partnership, a video and toolkit will be produced and disseminated that will educate the general public about the importance of communicating end of life wishes to loved ones before the need arises. Former Society presidents Ken Burgess and Chuck Hollowell have been instrumental in initiating this important and much needed project.

The Society also launched its law school clinic grant program this year. We received four grant applications for a Society grant of up to $2,500. We awarded two grants of $1,500 each. One went to Campbell University School of Law for its Minority Organ Donor Awareness Project, and the other was awarded to Duke University School of Law for its Duke AIDS Policy Initiative. Each clinic was provided the opportunity to give a brief overview of their projects at the Society's Annual Meeting on Oct. 28, 2011. Board member David Broyles is largely responsible for the success of this effort. Board member Claire Moritz and past president Ken Burgess also served on the Gifts and Grants Committee and contributed to this important project.

As I wrap up my final president's report, I would be remiss if I didn't recognize the many other members who contributed their time and effort to the Society over the past year. In addition to those I have already mentioned, Secretary-Treasurer Joe Kahn deserves special recognition for his service to the Society as do committee chairs Marcus Hewitt and Jessica Lewis as well as Board members Matt Fischer, Chris Evans, June Farrell, Ross Sallade, and Harriett Smalls. Also, Ashley Brathwaite, Colleen Crowley, and Freddie Zufelt continued their service as the Society's editors for Prognosis. Finally, I would like to thank Society members Gina Bertolini, Mike Gordon, Todd Hemphill, Kristi Huff, Linwood Jones, Steve Keene, Jodi Knox, and Robb Leandro for their participation on Society committees. Without our volunteers, the Society would be nonexistent. Thanks to all of you for a great year! •

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Mandatory Requirements

Continued from the front page

Earlier this year, the Centers for Medicare and Medicaid Services (CMS) stated that it will publish rulemaking on compliance program requirements in the near future. 76 Fed. Reg. 5862, 5941-5943 (Feb. 2, 2011). Even though regulations have not been published at this time, there is ample guidance available to begin the process of drafting and revising effective compliance plans now. Since it takes time to develop an organizational culture centered around ethical conduct and dedication to legal compliance, there is no need to wait until CMS publishes implementing regulations to begin this process.

Federal Sentencing Guidelines

Chapter Eight of the U.S. Federal Sentencing Guidelines Manual sets forth the main elements of an effective compliance program, focusing on an entity's commitment to ensuring legal compliance and preventing, detecting, and correcting illegal and unethical behavior. Federal Sentencing Guidelines Manual, § 8B2.1 (2010). These elements are listed below and described in more detail in the next section:

- establishment of standards, policies, and procedures to prevent and detect criminal conduct and inappropriate behavior;

- designation of a compliance officer who has day-to-day operational responsibility over the compliance program and who reports directly to the organization's governing body;

- use of reasonable efforts not to include within the substantial authority personnel of the organization any individual whom the organization knew, or should have known, has engaged in illegal activities or other conduct inconsistent with an effective compliance program;

- development and establishment of regular training programs for the governing body, high-level personnel, all employees, and, as appropriate, the organization's agents;

- regular monitoring and auditing to ensure the compliance program is followed and remains effective, including having a system in place that may allow confidential or anonymous reporting of suspected violations of law or of the compliance program without fear of retaliation;

- promotion and enforcement of the compliance program consistently throughout the organization through the use of appropriate incentives for compliance and disciplinary measures for violations; and

- appropriate investigation of and response to violations and prevention of further similar illegal or inappropriate conduct, including making any necessary modifications to the organization's compliance program.

The Federal Sentencing Guidelines Manual also emphasizes the importance of periodic assessment of the risk of illegal conduct and modification of the compliance program to reduce identified risks.

OIG Compliance Guidance

The OIG has published a broad range of compliance program guidance over the last decade. This article focuses on compliance guidance directed at physician practices and hospitals, but guidance also is available for nursing facilities, pharmaceutical manufacturers, clinical laboratories, hospices, and several other types of providers and suppliers. In general, the OIG's guidance focuses around the major elements set forth in the Federal Sentencing Guidelines Manual and provides explanation and specific direction regarding each element. The OIG's guidance also includes information regarding the specific risk areas that each type of provider should address in its compliance program. With regard to physician practices and hospitals, the OIG has acknowledged that it may not be feasible for all physician practices and hospitals to fully implement all of the major elements; until CMS publishes regulations concerning PPACA's mandatory compliance program requirements, it is unknown whether the final regulations will retain the same level of flexibility and understanding the OIG has noted concerning voluntary compliance programs. The OIG's guidance for each compliance program element is described below.

Developing Written Policies and Procedures

Each organization should address the areas for which it has the most risk of fraud and abuse through written policies, procedures, and practice standards. A code of conduct is one such policy and should emphasize the organization's commitment to compliance with the law, set forth the organization's mission, goals and ethical requirements of compliance, and require compliance with the law and with the compliance program. In addition to the code of conduct, an organization should develop written policies and procedures that address the regulatory exposure and risk for each function of the organization. Each organization should examine its practices to ensure that it addresses each area that has a heightened risk of fraud and abuse in order to prevent erroneous or fraudulent conduct. Some risk areas noted by the OIG include:

- coding and billing, including billing for items or services not actually rendered, double billing, upcoding the level of service provided, unbundling, and failure to properly use coding modifiers;

- reasonable and necessary services;

- documentation of diagnosis and treatment;

- improper inducements, kickbacks, and self-referrals, specifically involving financial arrangements, such as joint ventures, consulting contracts, and office and equipment leases, with other entities, such as hospitals, hospices, nursing facilities, home health agencies, durable medical equipment suppliers, pharmaceutical manufacturers, and vendors; and

- record retention, especially records related to patient care and

the organization's business activities.

With respect to hospitals, the OIG emphasizes some additional risk areas, including false cost reports; patients' freedom of choice upon discharge to home health agencies, long term care, and rehabilitation providers; failure to refund credit balances; joint ventures; financial arrangements with hospital-based physicians; and patient dumping.

Compliance Officer

Each organization should designate one individual as the compliance officer who is responsible for all aspects of compliance or several individuals who are each responsible for different compliance activities. Some of the compliance-related duties of the compliance officer(s) include:

- having day-to-day responsibility for the compliance program;
- overseeing and monitoring the compliance program's implementation;
- regular reporting to the organization's governing body regarding compliance issues
- periodically revising the compliance program to address changes in the law or the organization's needs;
- developing, coordinating, and participating in an educational and training program that focuses on the compliance program's components;
- ensuring that all employees, medical staff, and independent contractors have been screened against the OIG's List of Excluded Individuals and Entities and the General Services Administration's List of Parties Debarred from Federal Programs;
- coordinating internal compliance reviews, including annual or periodic department reviews and audits;
- developing processes that allow employees to report suspected fraud and other violations without fear of retaliation;
- investigating reports of actual or suspected violations of the law or of the compliance program; and
- monitoring corrective action and compliance after violations.

The OIG stresses the importance of giving the compliance officer(s) authority to review any and all documents relevant to compliance activities, such as billing records, patient records, and contracts.

Conducting Training and Education

A compliance program on paper is ineffective until the governing body, employees, and staff have been trained regarding its components. Organizations should conduct training at the time of or soon after initial employment and periodically thereafter to educate individuals regarding the compliance program's requirements and applicable laws and regulations. Employees should receive training that informs them of the reasons behind the need for a compliance program and the importance of legal compliance, especially with regard to fraud and abuse. While everyone should receive training regarding the compliance program itself, specific training sessions may be offered that are directed to those individuals whose job responsibilities overlap with risk areas, such as coding and billing. Compliance training should also include discussion of the consequences of compliance program violations, including information regarding the organization's various disciplinary measures. The OIG additionally recommends that organizations make attendance at training sessions and compliance with the compliance program a condition of continued employment. Compliance training and education can be accomplished through a variety of methods, such as in-person seminars, webinars, office bulletin boards, newsletters, videos, and electronic programs. The method of training is unimportant, so long as the organization is able to effectively communicate its standards, policies, and procedures. Additional training should be provided when the compliance program is updated or applicable laws and regulations change. The organization should maintain records of its training programs, including attendance logs and training materials.

Screening for Past Illegal Conduct

As previously mentioned, the compliance officer has the responsibility of ensuring that all employees, medical staff, and independent contractors have been screened against the OIG's List of Excluded Individuals and Entities, the General Services Administration's List of Parties Debarred from Federal Programs, and any other such lists and databases regarding each individual's licensure status and eligibility to participate in federal healthcare programs. This screening should be conducted upon each individual's employment with the organization and at least annually thereafter. In addition, employees should be required to report any indictment or serious healthcare offense, such as conviction of a criminal offense related to healthcare.

Internal Monitoring and Auditing

According the OIG, an ongoing evaluation process is vital to a compliance program's success. An organization should monitor the implementation of its compliance program to ensure that the compliance program is working effectively and is being updated and revised regularly to remain active and current. One type of audit involves a periodic review of the organization's policies and procedures to make certain that they are current, complete, and adequately addressing all identified risk areas. Another type of audit involves review of claims submissions. This audit may be internal or external and may include review of bills and medical records for compliance with applicable coding, billing, and documentation requirements. A further type of audit involves examining all money paid to or received from physicians to verify that such payments can be matched to Stark compliant agreements and that the payments are made in accordance with the agreements' terms. The audit process should serve to identify areas where corrective actions are necessary and the compliance officer should communicate those corrective actions to the organization's governing body and follow through in their implementation.

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Mandatory Requirements

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Developing Open Lines of Communication

The OIG repeatedly emphasizes in its guidance that there should be an open line of communication between the compliance officer and the organization's governing body, employees, and other staff. Organizations should have in place written confidentiality and non-retaliation policies to encourage individuals to report actual and suspected violations of the law or the compliance program with the understanding that anonymity may not be feasible under certain circumstances. The OIG notes that an organization may want to make a failure to report known or suspected violations a violation of the compliance program. It is also recommended that an organization have in place several different avenues through which individuals can make reports, such as direct lines to management, a compliance hotline, e-mails, and less formal approaches in smaller office settings, such as open door policies, compliance bulletins, and drop boxes for comments. The compliance officer should maintain a log of all reports received, including the nature of any investigation and its results.

Investigating Suspected and Actual Violations and Developing Corrective Action Initiatives

When the compliance officer receives a report of a suspected violation, he or she should promptly perform an investigation into the circumstances of the violation to determine whether an actual violation of applicable laws and regulations or the compliance program occurred. An investigation may involve interviews and a review of relevant documents; the compliance officer should maintain records of the investigation, including interview notes, copies of key documents, and a log of witnesses interviewed and documents reviewed. In addition, the compliance officer and entity should take appropriate steps to prevent the destruction of documents or other evidence. If there has been an actual violation, the compliance officer should take steps to correct the problem, since detection of a violation without correction threatens an organization's status and reputation. Corrective action should be determined on a case-by-case basis and may involve development of a corrective action plan, return of overpayments, self-report to the government, or referral to law enforcement authorities. If the violation is something that can be prevented in the future, the compliance officer should create or revise policies and procedures to address the situation and prevent reoccurrence.

Enforcing Policies Through Appropriate Disciplinary Measures

The OIG recommends that an organization publicize its disciplinary standards so that employees understand the consequences of legal and compliance program violations. An organization should determine discipline on a case-by-case basis while being consistent in its discipline and enforcement, but still allowing for flexibility to account for mitigating or aggravating circumstances. Discipline measures could range from additional training, warnings, reprimands, to suspension or termination, restitution of damages, or referral to law enforcement authorities for criminal prosecution.

Conclusion

Organizations should begin the process of performing internal audits and reviewing their existing policies and procedures to begin addressing the risk areas pertinent to their type of provider or supplier. The guidance referred to in this article is a starting point until CMS begins the rulemaking process for compliance program requirements. While CMS is expected to generally adhere to the elements included in the OIG guidance and Federal Sentencing Guidelines Manual, it is unknown whether CMS will impose additional requirements. Furthermore, the final compliance program requirements may vary depending upon the type of provider or supplier.

For more information regarding the elements of an effective compliance program, *see* Chapter Eight of the *2010 Federal Sentencing Guidelines Manual* (***http://www.ussc.gov/guidelines/2010_guidelines/Manual_PDF/Chapter_8.pdf***) and the OIG's index of compliance program guidance for various types of health care providers and suppliers (***http://oig.hhs.gov/compliance/compliance-guidance/index.asp***). •

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Oliver Wendell Holmes

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Myth Busting

Helping Minorities Uncover the Truth About Organ Donation

Campbell Law School Health Law Society received a grant to develop a community outreach program to educate and promote the benefits of organ donation among the Triangle's minority population

Nationally, there are over 100,000 people waiting to receive life-saving organ donations; sadly, 18 people die every day while waiting for an organ transplant in the United States. U.S. Government Information on Organ and Tissue Donation and Transplantation, ***http://www.organdonor.gov/Default.asp*** (last visited Sept. 23, 2011). This is a shocking statistic and leads to the question: what is the situation in North Carolina? Presently, over 3,700 North Carolinians await organ donations and a disproportionate number of them are African Americans and Latinos. Roughly 69 percent of North Carolinians waiting for an organ donation are African American or Latino, even though African Americans and Latinos comprise just 30 percent of our state's population. U.S. Census Data for North Carolina, ***http://quickfacts.census.gov/qfd/states/37000.html*** (last revised June 3, 2011). This racial disparity arises for a number of reasons: 1) diabetes is four to six times more prevalent in the African American/Latino population than the Caucasian counterpart; 2) high-blood pressure and heart disease affect minorities at a higher rate; and 3) minorities are proportionally underrepresented among organ donors.

Matching organs between members of the same racial and ethnic groups often enhances successful organ transplantations. However, because some minority groups are underrepresented on organ donation registries, minorities have a disproportionately high rate of death while awaiting an organ transplant. Increasing the rate of organ donations from minorities can lead to a significant reduction in the amount of time patients wait for an organ match. These decreases in wait times will hopefully translate into a reduction in the number of racial and ethnic minorities that languish, or possibly die, while waiting for a transplant.

In an effort to ameliorate the racial imbalance in North Carolina's organ donor population, Campbell Law's Health Law Society (HLS) has embarked on a partnership of awareness with the financial support of the North Carolina Society of Health Care Attorneys (NCSHCA). We are all familiar with national campaign drives seeking to raise awareness about the benefits of organ donation, but this local, student-driven effort will target the minority populations that remain underrepresented in North Carolina. With the assistance of health care professionals, transplant coordinators, and attorneys, Campbell law students are developing an outreach program aimed at educating Latinos and African Americans about this important issue.

Why is there a deficiency in the number of minorities registered as organ donors? The disparity and reluctance of minority organ donation is a multi-faceted problem. The donor gap is a result of legal, cultural, religious, and medical misconceptions. A few studies have identified specific concerns, some unique to African Americans and Latinos, and our program will address them in a trusted, community setting. Carmen Breitkopf, Attitudes, beliefs and behaviors surrounding organ donation among Hispanic women, 14(2) Current Opinion in Organ Transplantation 191 (Apr. 2009); C.O. Callender & A.W. Washington, Organ/Tissue Donation the Problem! Education the Solution: A Review, 89(1) J. Nat'l Med. Ass'n 689 (Oct. 1997); National Minority Organ Tissue Transplant Education Program, ***http://www.nationalmottep.org*** (last visited Sept. 23, 2011).

Common Organ Donation Misconceptions

Mistrust of the Medical Establishment. Unfortunately, African Americans and Latinos have been the target of racial discrimination from both private and government agencies throughout the history of the United States, particularly in the South. For a multitude of reasons, some members of minority populations still have mistrust towards the medical establishment. The concerns associated with this mistrust are:

- Medical professionals will not give a minority organ donor the best medical attention so as to ensure their death to take his/her organs;
- Only rich, white people will benefit from organs harvested from dead minorities;
- There really is not a medical need for minorities to be organ donors;
- Families of organ donors will be charged fees related to organ donation/transplant services;
- Organs can be sold, so there is no reason to "give them away;" and
- An open casket funeral is impossible because the organ donation process will mutilate the donor's body.

Vetta L. Sanders Thompson, Educating the African-American Community on Organ Donation, 85(1) J. Nat'l Med. Ass'n 17 (Jan. 1993). The Organ Donation Awareness Project will specifically address each of the concerns listed above by explaining that registering as an organ donor does not give hospitals or medical professionals the discretion to let someone die if medical treatments could save their life. In addition, potential organ donor recipients cannot buy their way to the top of the list. United Network for Organ Sharing (UNOS) is a highly respected organization that matches organ donor recipients based on medical need and availability of an organ donor match. These matches are highly regulated and monitored nationally and within each state according to its Uniform Anatomical Gift Act. N.C.G.S. § 130A-402 *et seq.*

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Organ Donation

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Cultural & Religious Barriers. Another reason why African American and Latino populations are reluctant to sign donor registration cards is due to deeply rooted cultural-religious beliefs. Among some of the most cited concerns are:

- Organs are needed to transport the souls of the dead to the afterlife;
- Catholic theology is against the practice of organ donation;
- If you come back to life, you need your original organs;
- Science and technology are interfering with the natural process of life; and
- Minorities receiving an organ may not "deserve" it or will not comply with treatment plans to preserve their second chance.

Addressing these specific concerns will be challenging and require coordination and cooperation with trusted figures in minority communities. The Latino community in North Carolina is overwhelmingly Catholic. HLS will partner with the Diocese of Raleigh and local Catholic parishes to clarify the Church's positive views on organ donation. Along similar lines, HLS will work with African American community leaders to develop materials specifically answering questions of the African American community. HLS strives to achieve strong relationships with well respected community organizations such as El Centro Para Familias Hispanas and Carolina Donor Services.

With respect to the Latino population, it will be vital to present the materials in Spanish when appropriate. HLS is partnering with Spanish-speaking law students through Campbell's Hispanic Law Student Association to provide translation and interpretation services.

Confusion about the Law. In addition to the above mentioned barriers, a final obstacle to securing registered minority donors is the confusion surrounding the law of organ donation. This last hurdle is not unique to ethnic minorities but adds another layer contributing to minority donor shortages. Legal concerns expressed include:

- Does the organ donor have to tell his/her family about this decision;
- Can a person under the age of 18 be an organ donor;
- Is the registry list accessible by immigration or other governmental agencies;
- Kidney donations are only allowed to be given to family members;
- Is DMV the place to become a donor;
- Can a person be a living donor; and
- Can an organ donor change his or her mind later?

At its core, this community outreach project seeks to dispel legal misconceptions about the organ donation process. In practice, there are various ways individuals can indicate they would like to be an organ donor: 1) registering online at ***https://www.donatelifenc.org/register***; 2) indicating their desire to donate at the DMV; 3) telling their family about their desire to donate; or 4) filling out and carrying a registered donor card available at ***http://www.organdonor.gov***.

Some of these misconceptions are historically based, so recent developments will be shared. For instance, while kidney donations were once limited to familial recipients, donors can now donate kidneys through certain transplant facilities after undergoing counseling and medical testing. Most of the concerns listed above are addressed by North Carolina's statutes governing anatomical gifts.

Overarching Goals

Campbell HLS has two primary objectives for this project: 1) provide outreach services to African American/Latino communities as well as those North Carolina patients waiting for organs; and 2) provide educational and practical experience to law students interested in Health Law. With the support of the NCSHCA, Campbell's HLS will provide direct community outreach with focused visits by law students, attorneys, and health care professionals. HLS students will work with area health care attorneys to interpret and understand laws surrounding organ donation. Campbell HLS students will develop an educational program on the legal and medical issues of organ donation and present the information in cooperation with community leaders and existing programs in the Triangle.

Together We Can Save Lives!
¡Juntos Podemos Salvar Vidas!

Organ donations are a necessary part of medical treatment and many minorities are dying needlessly as they wait for organ transplants. Generally, successful organ matches occur more frequently within the same racial and ethnic groups. Until North Carolina can successfully increase the number of minority organ donations, the disproportionate number of minority patient deaths occurring while waiting for a viable organ match will continue to rise.

If you are a health care attorney or medical provider and you are interested in providing community education or mentoring law students, Campbell HLS welcomes your interest and involvement. Not only will you be able to work with law students and provide much needed legal expertise, but you will also have a direct and lasting impact on a growing, vital minority client population in North Carolina.

If you are interested in participating in the Campbell HLS Organ Donor Awareness project, please contact third year law student, Chris Agosto Carreiro at ***cdagostocarreiro0608@email.campbell.edu***. •

Health Reform from a Provider's Perspective

By Scott Whisnant & Lori Feezor

Editor's Note: This article is presented as an op-ed, and does not necessarily reflect the views of the Health Law Section, the NCBA or the NCSHCA. We invite you to discuss these matters on the NCBA's Section LISTSERV at ***health@lists.ncbar.org.***

The word "mandates" has a decidedly un-American ring, and appears to be in direct opposition to the notion of "freedom." But ask any hospital, physician who has been on call for the emergency room, or private insurance company like Blue Cross, Cigna, or United, and they would tell you that mandates have been a way of life in the health care industry for some time. For hospitals with emergency rooms that accept government insurance (or, to put it another way, almost all of them), and the physicians who staff them, mandates have been a federal requirement since 1986. 42 U.S.C. § 1395dd.

The next time someone in your community who has a job and makes a little bit (but not much) money decides on his own volition to drive drunk and wrap his car around a tree, stop for a moment to consider whether your community hospital has a "mandate" to provide as much free care as that patient needs. The answer is of course it does. No one wants to live in a community where the hospital doesn't treat everyone – and that means everyone – who needs care, regardless of income, race, citizenship, or the fact that spectacularly poor decisions may have preceded the need for it.

The question that often gets neglected in the health care debate is who pays for this mandated care, and the answer is you do. By "you," that means everyone who either has insurance or has taken other responsible steps to afford health care. Just as stores charge more for products because of shoplifting, insured patients pay more for health care because of "cost-shifting," a polite phrase coined to cover the additional costs you pay for those who don't. Some cynics at this point may suggest that hospitals are large revenue-generators, and taking care of the poor is the cost of doing business. The fact is, in North Carolina, 95 percent of hospitals are nonprofit or government entities, and a substantial number of them operate in the red.

This system of health care has just about run its course. Insurance companies, through their business customers, have said "enough" to the cost-shift, as have Medicare and Medicaid. But that doesn't mean the costs go away; as a result, hospitals and physicians are getting more vocal about funding cuts, just as insurers and taxpayers are getting more vocal about the spiraling cost of health care.

All of which led us to health care reform. For much of the health care industry, the carrot at the end of the stick was the prospect of 32 million additional insured U.S. residents, which means when they access the health care system, they come with an income stream, or ability to pay. For this relief, the American Hospital Association, the American Medical Association, and many of the major insurers went "all in" on the plan. The hospital industry alone put $155 billion in cuts on the table as part of the negotiation, as long as the effort promised to do something about the uninsured and non-payor problem. *See, e.g.,* ***http://www.ama-assn.org/amednews/2009/07/20/gvsb0720.htm.***

This is the backdrop against which the mandate debate is set. At the time of this writing, three lower courts and one appeals court have upheld the constitutionality of the mandates, while two lower courts and one appeals court have not. **Thomas More Law Center v. Obama**, No. 10-2388 (6th Cir. June 29, 2011). One of these lower courts (in Florida) that struck down the mandates, ruled that because there is no severability clause that would allow invalidating this part of the law and retaining the rest, the entire health reform law must fail. That judge, Roger Vison, clarified that his decision should be stayed pending appeal. **Florida v. U.S. Department of Health and Human Services**, No. 3:10-cv-91-RV-EMT (N.D. Fla. March 23, 2010). On Aug. 12, 2011, the United States Court of Appeals for the Eleventh Circuit issued its ruling in which it agreed with Judge Vinson that the mandates were unconstitutional, but refused to uphold his decision regarding the lack of severability. F**lorida v. U.S. Department of Health and Human Services**, No. 11-11021 (11th Cir. Aug. 12, 2011).

The underlying arguments for and against the mandates are constitutional to be sure, and should be granted the weight and deliberation of any such challenge. No less than our sovereign rule depends upon it, not just for health care, but for other decisions that would implicate the reach of the federal government over its citizens. Therefore, it's worth examining these constitutional challenges.

At the heart of the matter are two constitutional concepts – the Supremacy Clause and the Commerce Clause. The Supremacy Clause essentially holds that, with regard to certain matters reserved to the federal government (including the right to regulate interstate commerce), the federal government shall have the right to enact laws "necessary and proper" and its law "shall be the supreme law of the land." U.S. Constitution, art. VI, cl. 2.

Before discussing the Commerce Clause, U.S. Constitution, art. 1, § 8, cl. 3, it is important to note that those opposing federal mandates conclude that nothing in the Constitution would prevent states from mandating – as Massachusetts famously has – insurance coverage for all its citizens. 2006 Mass. Acts, Ch. 324. The reasoning is found in the Supremacy Clause noted above. Even if the federal government is ultimately determined to have no right to mandate coverage (because it's not "commerce") the states could still do so.

So what is commerce, and does the failure to purchase health insurance amount to interstate commerce? That will be one of the quintessential questions in the health reform debate, that will likely be decided by the U.S. Supreme Court sometime this spring. If the answer is yes, then this part of the health reform law stands; if no, then at least the part of it addressing mandated insurance must fail.

Those that hold the mandated purchase of health insurance is not interstate commerce will argue that inaction (in this case, not buying insurance) cannot be, and never has been, deemed to be an economic act, and thus cannot be "commerce." *See, e.g.*, Testimony of Kenneth Cuccinelli, Virginia Attorney General, before the U.S. House Judiciary Committee on Constitutionality of Health Insurance Mandate, Feb. 16, 2011.

Those arguing that failure to purchase health insurance has an economic effect will point out that it is in fact a decision to self-in-

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sure, and that decision has significant financial consequences on everyone. Brief of American Hospital Association et al. as Amici Cur iae, Florida v. U.S. Department of Health and Human Services, No. 11-11021 (11th Cir. Aug. 12, 2011). They will note the implications in the scenario above. They will attempt to demonstrate that everyone who has insurance pays a higher bill because some individuals choose not to get coverage, and then come to hospitals that have an unfunded mandate to treat them.

All of it makes for interesting fodder in boardrooms, on Facebook, over backyard grills, or in bars. Meanwhile, our health care system is already treating those who exercise their "right" not to buy insurance and passing as much of the costs on to you as they can. Hospitals have already sacrificed $155 billion, and even if the Affordable Care Act is repealed, those cuts aren't coming back, and hospital care in every community will suffer. Our nation is piecing together a national health care system that is inefficient, costly, and unsustainable, and every day we weigh whether we can continue services that lose money.

If the mandate gets killed, if health reform gets killed, so be it. But from a provider's perspective, indeed from a societal perspective, something else needs to be done. The current system isn't working and won't pretend to for much longer. •

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The IACT Program
A New Model for Medical Transparency and Disclosure

By Christie M. Foppiano, Jessica S. Scott & Aida Doss Havel

Editor's Note: This article is presented as an op-ed, and does not necessarily reflect the views of the Health Law Section, the NCBA or the NCSHCA. We invite you to discuss these matters on the NCBA's Section LISTSERV at ***health@lists.ncbar.org.***

*"Finally he [the doctor] came out to tell us it was over... that there was nothing they could do. And as a grieving parent, we were very angry for a very long time but we really just wanted to know what happened and that was not afforded us."**

~ Sharon Delaney McCloud | Patient's mother

*"I had a patient about ten years ago who threatened to sue me. I felt the obligation to call my malpractice carrier at that time and the first thing they said was do not talk to the patient, do not write to them, do not do anything. We will handle everything. So they took away my humanity from this case."**

~ Robert Lacin, MD | Neurosurgeon

**Cases are unrelated*

In the event of an adverse medical outcome, patients often pursue litigation simply to obtain information that has been withheld. Research shows that the three things patients want most in the face of medical error are: information about what happened; a sincere apology; and measures to prevent the error from happening to someone else. Financial compensation is lower on their list. Patients generally seek attorneys out of anger rather than greed. When unanticipated adverse outcomes occur, error or not, doctors tend to distance themselves from patients and their families due to feelings of guilt and fear of malpractice litigation. However, this defensive response only fuels speculation that something went wrong; otherwise, patients assume that information would not have been withheld.

Lawsuits strongly affect doctors. Among physicians that have been sued for malpractice, data shows 97 percent experience significant physical or emotional reactions. They often feel unfairly targeted. Although actual rates of medical error are high, doctors tend to overestimate the rate of malpractice claims brought in response to those errors, perhaps because the impact is so devastating to them. A recent study in the New England Journal of Medicine found that 75-99 percent of physicians, depending on their specialty, are sued during their careers. Even seeing a colleague endure the process of litigation is quite painful and anxiety provoking. As a result, physician tolerance for uncertainty about medical outcomes is pushed to very low levels and some may practice medicine more defensively. After unanticipated bad outcomes, whether there has been an error or not, patients often become "potential plaintiffs" in the minds of physicians. In reality, according to statistics, only two to three percent of patients injured by medical mistakes actually file lawsuits and only half of those who bring a suit ever receive compensation.

On a national level, we are becoming increasingly aware of the frequency of medical errors. At least one study reports state medical errors are the eighth leading cause of death in this country, more than motor vehicle accidents and breast cancer combined. This statistic does not include the number of errors resulting in permanent injuries that do not result in a patient's death. Recent estimates, according to DHHS Secretary Sebelius, are that one in three hospitalizations result in a medical error. Tremendous efforts to increase patient safety have been directed at encouraging disclosure of errors and near misses in order to understand why they occurred and design safer systems. Patient safety improvements depend on the ability to learn from errors and near misses, yet disclosures, when they occur, are far from the norm. Fear of litigation creates secrecy and mistrust, and lack of disclosure creates frustrated, angry patients and families.

Why not consider another option? Consider one that encourages medical disclosure and transparency through a safe, supportive and highly effective process that addresses the individual needs of the patient and the physician and also the broader goals of disclosure and patient safety? Though appropriate for some cases, our tort system provides only one remedy, financial compensation. Medical malpractice claims are about so much more than money. We need to resolve conflicts early, through a process that brings parties together face-to-face to work toward conflict resolution and restoring relationships.

The Integrated Accountability & Collaborative Transparency Program (IACT Program). The IACT Program is an entirely new approach for disclosure and transparency that combines two successful models from different contexts for early dispute resolution in the health care setting. This innovative combination uses the disclosure-and-offer model (as exemplified by the University of Michigan), and builds upon it through the use of Collaborative Law (an alternative dispute resolution model used for the past 25 years in the family law arena). We believe the result is a safe and supportive resolution process that values transparency and early disclosure of medical errors for patients, doctors and health care organizations so that physical, emotional and financial stress for all parties will be minimized.

This model serves as an alternative to litigation meeting the needs of

- patients for full disclosure, understanding, and, in appropriate cases, an apology and timely compensation;
- physicians to proactively address issues and communicate with their patients in a safe and effective way so that both the physician and patient can gain closure;
- health care organizations to learn from errors and near misses to improve systems and processes in healthcare delivery; and
- society to increase patient safety and reduce costs simultaneously.

This model provides a formal program that is supportive and healing for patients, families and medical personnel through the use of skilled Collaborative Law attorneys and neutral medical experts dedicated to the resolution of conflict. Thus, when unexpected adverse

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outcomes occur, there is a safe and effective process for understanding and resolving complex and highly emotion-laden issues using interest-based negotiations, without increasing the likelihood of malpractice lawsuits.

The resulting breakthroughs can lead to increased health care quality and reduced costs to the medical system through improved processes and system design. In addition, cost savings are achieved through decreased dollars spent in the practice of defensive medicine, the expense of treating medical errors, and the costs associated with medical malpractice litigation.

How does the IACT Program work? *"The IACT program allows a safe harbor for all of the interested parties to share information, and see each other as human beings. IACT is the perfect forum for a physician or hospital to explain to an angry or confused patient that very few adverse outcomes are the result of negligence. Patients can see the process as a way to get factual answers to questions in an environment where they feel protected and supported."*

~ Christopher R. Nichols, JD | The Nichols Law Firm

The IACT Program uses specially trained Collaborative Law attorneys, coaches and neutral medical experts, who are committed to the peaceful, non-adversarial and cooperative resolution of conflict. The program focuses on interest-based, rather than positional, negotiations, as well as healing and closure for both patient and provider. Participation is voluntary and parties never give up their right to the tort system. If a mutually satisfactory resolution is not reached, the Collaborative Law attorneys must withdraw, as they are barred from litigating the case. Collaborative Law attorneys are settlement experts and if a case is impassed, the attorney may refer the party to litigating attorneys, if so requested.

Collaborative Law is not mediation. When parties mediate, they are often locked into positions, the attorneys do most of the talking, and much of the process takes place with the parties separated. In Collaborative Law, the parties sit together face-to-face and engage in difficult, but very much needed conversations. The Collaborative Law attorneys help to structure the conversation and guide each party to better understand and communicate underlying needs and interests to the other party. Patients may have the need for information and empathy, forgiveness of a bill, provision of follow-up treatment, or even compensation. Physicians also may need to share information about what happened and their feelings about the bad outcome; they may also need to apologize to gain closure. Both patient and doctor may have an interest in restoring their relationship and avoiding the stress of litigation. Finally, health care organizations may have the need to resolve conflict, to avoid negative publicity, and to learn about events to improve quality of care in an effective and efficient manner.

Collaborative Law attorneys then assist the parties during the Collaborative Conference to create a resolution that most adequately meets the needs of the parties. Medical professionals are often denied the chance to speak directly to patients and families, even when there has been no error, though having such a conversation would help all involved gain closure. Each is able to ask questions and share information he or she believes is important for the other to know. The IACT Program allows medical professionals the ability to engage patients and their families proactively after an unexpected adverse outcome, and it allows patients to do the same.

The IACT Program requires both parties to sign a Participation Agreement with a confidentiality clause regarding the information that will be discussed during the Collaborative Conference. The parties meet with their respective Collaborative Law attorneys and prepare for the Collaborative Conference when all parties will meet. Most cases involve between one and three conferences, each lasting two to three hours. A neutral medical expert with subject matter expertise provides information for both parties to review about the medical care. A Collaborative Coach meets with each party to assist the party in understanding and communicating his or her needs effectively in the conference. If resolution is reached during a conference, the attorneys draft a Health Care Settlement Agreement, which is then signed by the parties with a release of further claims relating to the matter at issue.

Conclusion and Final Thoughts. *"As a former hospital and physician practice administrator, I believe the IACT program represents an incredible opportunity for the healthcare provider community to move beyond traditional thinking and embrace an innovative model of risk management offering improved quality of care, enhanced public perception and financial savings."*

~ Timothy L. McNeill, JD, MHA | RTP Law/McNeill Law Offices, PLLC

When unexpected outcomes occur, the IACT Program provides a safe and effective process for understanding and resolving complex issues, whether there has been a medical error or merely an unanticipated adverse outcome. It offers the opportunity to share information and compensate a greater number of patients, while enhancing quality of care and reducing overall legal expenses.

Transparency also allows medical professionals and health care organizations to learn from errors, near misses, and adverse outcomes. Specifically, health care organizations will have the benefit of this information to improve systems and processes in healthcare delivery. In turn, improved systems help account for inevitable human error, but reduce the risk of catastrophic injury as a result of it. When health care professionals work in a culture that encourages disclosure and learning from errors, near misses, and adverse outcomes, patient safety improves and legal and healthcare costs decrease.

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Case Law Update

By Amy Mackin, Mark Bolin & Christina Simpson

North Carolina Court of Appeals

Watson v. Price, __ N.C. App. __, 712 S.E. 2d 154, No. COA10-1112 (April 19, 2011) | *Facts*: On Sept. 29, 2009, the plaintiff filed a complaint alleging medical malpractice against defendant physician and his neurosurgery practice. Prior to filing her complaint, the plaintiff had submitted to the trial court a motion to extend the statute of limitations in order to comply with the requirements of Rule 9(j). The trial court judge entered an order granting the plaintiff's motion and extending the statute of limitations to Oct. 2, 2009, but the plaintiff failed to file the order with the trial court. In response to the complaint, the defendants filed a motion to dismiss, pleading that the applicable statute of limitations barred the claim. After a hearing before the same judge who granted the extension, the court found that the plaintiff's claims were time barred and dismissed the plaintiff's action with prejudice. The plaintiff timely appealed.

Analysis: The Court of Appeals (the court) affirmed, holding that an order rendered in open court is not enforceable until it is entered, i.e., until it is reduced to writing, signed by the judge, and filed with the clerk of court. More specifically, the court held that a Rule 9(j) motion filed in advance of the complaint does not effectively extend the statute of limitations in a medical malpractice suit if an order is not filed with the clerk of court. The court analogized Rule 9(j) to Rule 58 governing entry of judgments, which explicitly requires that a judgment be written, signed by the judge, and filed to be effective. The court relied on **Webb v. Nash Hospitals, Inc.**, 133 N.C. App. 636, 516 S.E.2d 191, disc. review denied, 351 N.C. 122, 541 S.E.2d 471 (1999), which confirmed that the signature of a judge is insufficient to effectuate a judgment without entry with the clerk of court. The court also followed **West v. Marko**, 130 N.C. App. 751, 755-56, 504 S.E.2d 571, 573-74 (1998), which declared that the filing requirement of Rule 58 applies to both judgments and orders. Therefore, the court affirmed the dismissal of the case, because the plaintiff failed to extend the statute of limitations. However, the court explicitly left open the question of the effectiveness of a Rule 9(j) order filed after a complaint is filed. In a concurring opinion, one judge stated that although there is no explicit filing requirement in Rule 9(j), **Webb** is controlling precedent, and therefore such filing is required.

East Carolina Internal Medicine, P.A. v. NCDHHS, Certificate of Need Section, __ N.C. App. __, 710 S.E. 2d 245, No. COA09-1278 (May 3, 2011) | *Facts*: The petitioner, a physician-owned medical practice, applied for a Certificate of Need ("CON") for the purchase of a mobile MRI machine on Nov. 15, 2007. The CON Section denied the application, stating that the petitioner had failed to satisfy the statutory review criteria. The medical practice filed a petition for a contested case hearing, which was held before an Administrative Law Judge ("ALJ") in December 2008. The ALJ's recommended decision was to uphold the denial of the application. After the Department of Health and Human Services ("DHHS") issued a final agency decision affirming the denial of the CON, the petitioner appealed to the Court of Appeals (the court).

Analysis: The court affirmed DHHS's denial of the petitioner's CON application. The petitioner objected, claiming that DHHS used the wrong standard in reviewing the CON Section's decision. Specifically, the petitioner alleged that DHHS only considered whether the decision was arbitrary and capricious and not other ways in which the CON Section may have failed to comply with the CON statute and regulations. The court dismissed this argument, holding that the statute did not require DHHS to review each potential basis for an objection systematically, but instead DHHS needed only to address the specific allegations in the petition. The court also was not persuaded by the petitioner's argument that DHHS impermissibly gave a presumption of validity to the CON Section's decision, emphasizing that the petitioner bore the burden of proving error in the decision.

The petitioner also argued that a perfectly-compliant application was not necessary, given that the CON Section had issued conditional approvals to other applicants in the past. However, the court held that it was not unreasonable for the CON Section to deny the application rather than awarding conditional approval, given "the existence of numerous deficiencies" in the application. Additionally, the petitioner argued that the agency decision did not set forth specific reasons for rejecting certain findings of fact by the ALJ, in one case stating only, "I expressly reject the remaining Findings of Fact because they are unsupported by the clear preponderance of the evidence in this case." Nevertheless, the court held that the decision was adequate, because it was clear enough to permit a reviewing court and all interested parties to understand the agency's reasoning. Finally, the petitioner made a number of allegations that the agency gave too much deference to the CON Section's findings of fact and did not adequately consider those advanced by the petitioner. Using the whole record test, the court held that the agency's findings were supported by substantial evidence and that "the agency is not required to minutely analyze every factual dispute." **East Carolina Internal Medicine, P.A. v. NCDHHS**, Certificate of Need Section, __ N.C. App. __, 710 S.E. 2d 245, 259 n.6 (2011). Ultimately, the court found no error of law in the agency decision and therefore affirmed it.

Charlotte Mecklenburg Hospital Authority v. Talford, __ N.C. App. __, 714 S.E.2d 476, No. COA10-897 (Aug. 2, 2011) | *Facts*: The plaintiff hospital brought this action on Oct. 15, 2009 to collect on an unpaid bill in the amount of $14,419.57, and moved for summary judgment, claiming an implied contract, quantum meruit, and enforcement of the "guaranty" clause of its admission form signed by the defendant patient. To support its motion, the plaintiff appended a "Legal Account Balance Summary Sheet" stating the amount owed, along with affidavits from the hospital's Director of Revenue Management and Manager of Patient Financial Services, averring that the amount charged was reasonable and consistent with "charges rendered to all patients receiving similar types of services." The affidavits also stated that the charges reflected published billing regulations and industry guidelines. The plaintiff's motion did not include any independent corroboration of the plaintiff's employees' statements. The defendant challenged the amount owed, arguing that it "exceed[ed]… [the charges] paid by other patients in….defendant's medical condition." The defendant illustrated this claim by comparing the only identified and itemized charges on the balance sheet – the costs of drugs rendered during his hospital stay – to the rates at his local pharmacy for the same prescriptions. The trial court granted the plaintiff's

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motion for summary judgment, and the defendant appealed.

Analysis: The Court of Appeals (the court) reversed in part, holding that, where the reasonableness of damages is expressly challenged in a claim for quantum meruit, an invoice supplemented only by affidavits of the moving party's employees is insufficient to support summary judgment in the absence of additional corroborating documentation. The issue of damages (here, the value of a service rendered) is one requiring an assessment of credibility, and is therefore properly reserved for the trier of fact. While the Supreme Court has articulated narrow exceptions where credibility may be determined as a matter of law, these exceptions are restricted to instances where the moving party's credibility is "manifest." The court distinguished **Environmental Landscape Design v. Shields**, 75 N.C. App. 304, 307, 330 S.E.2d 627, 629 (1985), because in that case, the plaintiff submitted evidence that a different landscaper operating in the same area charged the same hourly rate for the same type of work. It was this independent corroboration of the reasonableness of the charges that the court noted was absent in the present action. The court concluded, "We do not believe the credibility of Plaintiff's employees, expressing their opinions that Plaintiff's charges were reasonable, is manifest as a matter of law." **Charlotte Mecklenburg Hospital Authority v. Talford**, __ N.C. App. __, 714 S.E.2d 476, 484 (2011).

The court also addressed the "Guaranty" section of the Hospital's "Request for Treatment and Authorization" signed admission form, but declined to enforce its terms, which would have enabled the plaintiff to collect costs. The court emphasized: (1) the absence of a secondary obligation created in a third party, as the plaintiff had signed as his own guarantor, and (2) the plaintiff's failure to allege breach of an express contract that might have triggered recovery under this provision. One dissenting judge would have held that the defendant's liability was based on an express contract and would have affirmed the trial court's finding on damages.

Ridge Care, Inc. et al. v. NC DHHS, Certificate of Need Section et al., __ N.C. App. __, 716 S.E.2d 390, No. COA10-1316 (Aug. 16, 2011) | *Facts*: In 1997, the North Carolina General Assembly imposed a moratorium on the development of adult care home facilities. Carillon Assisted Living, LLC ("Carillon") challenged the moratorium on constitutional grounds. The settlement of that case in 2000 gave Carillon the right to develop 19 facilities. In 2001, the General Assembly passed another law, which provided that the CON Law would apply to adult care homes after the moratorium was lifted, unless the developer had satisfied an exception to the prior moratorium and continued to meet certain other requirements. Carillon filed a second suit, asserting that the 2001 law did not apply to its 19 facilities that were subject to the 2000 settlement or to 43 other facilities for which Carillon had submitted plans during a gap in the moratorium. In that appeal ("Carillon I"), the Court of Appeals (the "court") held that the settlement gave Carillon the contractual right to develop the 19 facilities without CON approval. As a result of this decision, Carillon had the right to develop a total of 62 facilities, which would contain over 5,000 beds.

After the Department of Health and Human Services ("DHHS") appealed the result in Carillon I to the Supreme Court, the parties settled the case. Under that 2007 settlement, Carillon agreed to develop only 2,250 beds without CON approval, and DHHS agreed to dismiss its appeal. The petitioners in the present case were corporations that operate acute care facilities, and they challenged the 2007 settlement between Carillon and DHHS on multiple grounds. The petitioners' direct appeal to the court was dismissed ("Carillon II"). The final agency decision on the petitioners' claims granted summary judgment in favor of DHHS and Carillon. The superior court affirmed, and the petitioners appealed to the court.

Analysis: The court affirmed, finding no error in the approval of the 2007 settlement between Carillon and DHHS. The petitioners argued that DHHS improperly ceded its statutory responsibility to apply the CON Law when it entered into the settlement agreement. Citing DHHS's broad authority to settle cases, and relying heavily on the precedent of Carillon I, the court found no error. The court did not reach petitioners' constitutional claim regarding separation of powers, but in regard to the due process and equal protection arguments, the court emphasized that Carillon had given up a contractual right to develop all 5,000 beds and therefore did not receive any preferential treatment under the 2007 settlement. The court also held that the settlement agreement was valid, despite the fact that the Attorney General was not a party to its execution, since DHHS had its own authority to settle on behalf of the State. The petitioners argued that the settlement constituted Carillon's exemption from the CON Law, harming them as a matter of law. However, the court continued to characterize Carillon's rights as contractual, such that the petitioners needed to show economic damages in order to prove substantial prejudice. Finally, the court held that the petitioners failed to show that they were substantially prejudiced by the agency's decision.

Moore v. Proper, __N.C.App.__, 715 S.E.2d 586, No. COA10-1475 (Sept. 6, 2011) | *Facts*: On March 5, 2009, the plaintiff filed suit against the defendants, a dentist and the dentist's practice, alleging that they negligently fractured the plaintiff's jaw while extracting his tooth. Prior to filing the complaint, the plaintiff's counsel had filed a motion pursuant to Rule 9(j) to extend the statute of limitations to allow the plaintiff to find an appropriate expert witness. The plaintiff's complaint, when filed, stated that the plaintiff's expert was "reasonably expected" to qualify as an expert witness under Rule 702 and would be willing to testify that the defendants did not apply the applicable standard of care. The defendants then served interrogatories on the plaintiff's expert dentist. In his responses, the proposed expert indicated that he had retired in 1997 and that he was not in a teaching position. These responses indicated that he would not qualify as an expert under Rule 702. At a later deposition, the proposed expert testified that he had practiced dentistry for fewer than five percent of days in the preceding year. He maintained that for the days he did practice, though, he spent 100 percent of his time in clinical practice.

The defendants moved for summary judgment, contending that the proposed expert witness's testimony could not support a medical malpractice claim. In response, the plaintiff filed a motion under Rule 702(e), requesting that the proposed expert be qualified as an expert witness despite not meeting the requirements of Rule 702. Accompanying the Rule 702(e) motion was an affidavit from the proposed expert testifying that he spent 100 percent of his professional time in the clinical practice of dentistry and that all of his other activities were personal. The trial court granted summary judgment in favor of the defendants and dismissed the complaint, concluding that "no reasonable person would have expected" the proposed expert to qualify under Rule 702. The trial court also ruled that no extraordinary circumstances existed that justified qualifying the proposed expert under Rule 702(e).

Analysis: The Court of Appeals (the court) reversed the trial court's rulings, holding that the trial court had applied the wrong standard for determining whether the complaint was adequate. Reviewing de novo the issue of whether the plaintiff could reasonably have expect-

ed the proposed expert to qualify under Rule 702, the court noted a reasonable expectation of qualification is a materially different concept from whether the expert actually qualifies. According to the court, whether the proposed expert in fact qualifies is an issue to be decided after discovery is completed.

The court adopted the proposed expert's contention, contained in both his deposition and affidavit, that 100% of his professional time was spent engaged in the clinical practice of dentistry, despite his having practiced relatively few days. The court noted that the expert's estimate that only five percent of his time was spent in the clinical practice of dentistry was actually an estimate of five percent of his time covering activities "as a human being," not five percent of his professional time. Further, the court noted that the language of Rule 9(j) does not require the use of a "standard" workweek for purposes of computing an expert's professional time. Rather, the statute must be interpreted on a case-by-case basis. The court concluded that summary judgment was inappropriate where there was a disputed fact about whether "no reasonable person" could conclude the expert would qualify under Rule 9(j) and Rule 702.

In dissent, one judge argued that the plaintiff had failed to meet the heightened pleading requirements of Rule 9(j). Noting that the dispositive question is whether the expert is "reasonably expected" to qualify, the dissent performed a fact-specific analysis of the proposed expert's testimony and found that the expert could not reasonably have been expected to qualify. Assuming a 32-hour workweek for argument's sake, the dissent pointed out that the proposed expert would only have spent 1.6 hours per week in the clinical practice of dentistry based on his testimony that he spent 5% of his time as a dentist. The dissent also advocated a broader definition of "professional time" and emphasized the requirement that the practice be "active." Based on the apparent unreasonableness of the plaintiff's expectation at the time of filing, the dissent found that the trial court appropriately granted summary judgment for the defendants.

Wake Radiology Services, LLC et al. v. NCDHHS, Certificate of Need Section et al., ___ N.C. ___, 716 S.E.2d 87, No. COA10-1129 (Sept. 6, 2011) (unpublished) | *Facts*: In June 2009, the Department of Health and Human Services ("DHHS") awarded a certificate of need ("CON") to Pinnacle Health Services of North Carolina, LLC ("Pinnacle") for the purchase and operation of a mobile MRI scanner in Wake and Johnston Counties. The petitioners filed a motion for a contested case hearing in regard to Pinnacle's CON. The administrative law judge ("ALJ") recommended that the decision of the CON Section be affirmed, and DHHS adopted this recommendation as its final agency decision. The petitioners appealed to the Court of Appeals (the court).

Analysis: Without reaching the merits, the court affirmed the final agency decision by holding that the petitioners had not shown substantial prejudice to support their standing to bring the case. The court held that the petitioners must show that they were "affected persons" and that they were "substantially prejudiced" by the agency's action in order to initiate a contested case hearing. Parkway Urology v. NCDHHS, 696 S.E. 2d 187 (2010). The court concluded that it was not an error of law for DHHS to determine that the petitioners had not made the required showing. In particular, the court found that the petitioners had not produced evidence of a causal link between the agency's issuance of the CON and their actual harm, emphasizing that Pinnacle was offering similar services prior to receiving the CON, so the agency decision could not have been the cause of any alleged harm. The court also noted that the petitioners relied on their own volume and payor mix data rather than calling a health planning expert and producing independent data. Characterizing the petitioners' arguments as speculation about the effects of market competition on their business, the court affirmed DHHS.

In a related case, petitioner Wake Radiology Services, LLC ("Wake Radiology") also appealed DHHS's final agency decision denying Wake Radiology's own CON application for the purchase of a digital mammography machine to replace its existing analog equipment. **Wake Radiology Services, LLC v. NCDHHS**, Certificate of Need Section et al., 713 S.E.2d 250, No. COA10-933 (May 17, 2011) (unpublished). The court upheld the agency's conclusion that Wake Radiology failed to document the need for the service, even though the CON would have involved only the replacement of existing equipment rather than the acquisition of an additional machine. Finally, the court held that Pinnacle's motion to intervene had been properly granted, even though it was supported by an affidavit rather than oral testimony.

District Court

York v. Health Management Associates, Inc., ___ F.3d ___, No. 5:10-CV-94-RLV (W.D.N.C. August 19, 2011) | *Facts*: The plaintiff, an orthopedic surgeon practicing in Arizona, entered into an employment contract with the defendant's agent on Jan. 26, 2007, wherein the plaintiff would relocate to North Carolina and open a practice in Statesville. Under this contract the plaintiff was entitled to a base annual salary, relocation expenses, and a signing bonus. The contract, however, did not specify that the plaintiff must first receive a North Carolina medical license as a precondition to the contract. The contract also included job duties that did not require a medical license.

Accordingly, the plaintiff relocated to North Carolina in the summer of 2007, submitted his application for a medical license, and began to perform the administrative duties required under the contract. The defendant subsequently informed the plaintiff that no payments, including those covering relocation expenses and the signing bonus, would be made until he received his North Carolina medical license. The plaintiff continued to pursue such approval, but by November 2007, frustrated with the delay, he terminated his employment. The plaintiff brought suit for breach of contract, and the defendant filed a motion to dismiss, claiming the plaintiff had failed to satisfy a necessary condition precedent of the employment agreement, namely the receipt of a license to practice medicine in North Carolina.

Analysis: The District Court (the court) denied defendant's motion to dismiss, in part because North Carolina does not "favor" implied conditions precedent in contracts. Citing **Harris v. Stewart**, 193 N.C. App. 142, 666 S.E.2d 804 (2008), the court noted that conditions precedent are not recognized in the absence of clear language requiring such a construction. Insofar as a license is necessary in order to practice medicine, the law creates a covenant to obtain a license within a reasonable period of time in order to avoid a breach of contract. However, the court held that the contract was effective despite plaintiff's failure to obtain a medical license prior to terminating the agreement, and his claim under the employment contract was allowed to proceed. •

Mackin and ***Bolin*** are members of the Research Triangle Office of K&L Gates LLP and Simpson is with the N.C. Department of Justice.

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