FORUM
NORTH CAROLINA MEDICAL BOARD
FOR THE BENEFIT AND PROTECTION OF THE PEOPLE OF NORTH CAROLINA
NO. 3 2014

Advances in hepatitis C: Pg. 6

"For the benefit and protection of the people of North Carolina..."

How far should the Board go to fulfill its mandate?

Paul S. Camnitz, MD
NCMB President

As you know, the Medical Board's mission is to protect the public. One of the most important ways it does this is by intervening to protect unsuspecting patients from treatments that are outside accepted standards of care and, at times, risky.

This may not sound controversial, but it can quickly become so when we delve into specifics. In this article, I will give you my personal take on how the Board attempts to balance challenging and sometimes competing interests when considering cases that involve nonstandard treatments.

Medicine by its nature is constantly evolving and new treatments and modalities are developed on an almost daily basis. The best of these are hailed as innovations that extend and improve life – and some even live up to their promise. The worst are eventually denounced as snake oil that, at best, empty patients' pockets while filling them with false hopes and, at worst, harm or kill them.

Often, though, things are not so black and white. Some cases the Board reviews involve treatments that are apparently without scientific basis, yet relatively benign and, at times, anecdotally effective. When reviewing these situations, Board Members must ask this important and difficult question: When should the Board interfere with a patient's freedom to choose in order to protect them from financial exploitation or false hope when the potential for harm is low?

The HCG example

In 2013, the Policy Committee of the Board amended its position statement entitled, "The treatment of obesity," to indicate that the Board does not consider human chorionic gonadotropin (HCG) to be an appropriate treatment for obesity. The decision, which the full Board approved, was based on two main factors: 1. The Board's belief that there is no proven scientific basis for the treatment of obesity with HCG and 2. Some evidence of risks associated with the therapy.

Months after the amended position statement was approved, the Board reviewed a complaint regarding a licensee who prescribed HCG for weight loss. This prompted a reexamination of information about the treatment. And while nothing changed the Board's view of the efficacy of this treatment, upon further review of the risks, the Board concluded that the potential for patient harm is not as significant as initially perceived. The Board voted to strike the language referring to using HCG for weight loss as inappropriate from the Board position statement.

It's somewhat unusual for the Board to reverse course on an issue in such a relatively short period of time. But the case of HCG is an excellent example of the type of issue the Board is required to make decisions about on a regular basis. *(Continued on page 2)*

IN THIS ISSUE

“When should the Board interfere with a patient’s freedom to choose in order to protect them from financial exploitation or false hope when the potential for harm is low?”

Should patients be free to consent to treatments that we, as trained medical professionals, find to be entirely without scientific basis? Should patients and their medical providers have total freedom to decide what treatments are used? Or are some controls acceptable? For example, should the Board give its blessing for providers to give patients their treatments of choice as long as they are adequately informed that the care falls outside of accepted standards? How does risk factor into the Board’s obligation to protect? How much risk is acceptable for the patient to assume?

Treatment cost is yet another consideration. Current law gives the Board the authority to protect patients from financial exploitation by licensees. A review of cases over the years provides numerous examples of situations where the Board has stopped licensees from benefiting from the aggressive marketing of costly therapies of unproven clinical value. Should the Board always step in to protect patients’ pocketbooks? Only when large sums of money change hands? Only when there is no informed consent or there is a vulnerable patient?

The issues the Board considers go well beyond whether a particular weight loss treatment safely melts pounds. The Board has made difficult decisions in cases involving nonstandard treatments in the fields of oncology, infectious disease and mental health, just to name a few.

These decisions are never made lightly or easily. And, the Board is rarely of one mind at the outset of these discussions. At times, some Board members are strongly motivated to act to protect patients not only from physical harm or financial exploitation but also from the false hopes promised by a treatment in which the Board has no confidence. Others on the Board are inclined to stay out of such situations, provided the threat of patient harm is minimal. Regardless of Board members’ individual views, the NCMB employs the same objective framework when evaluating these difficult cases. At minimum, the Board weighs the following factors:

1. Does it work? In evaluating any case that involves clinical medicine, the Board considers accepted and prevailing standards of care and, in the specific instance of care that is experimental or otherwise unestablished, available evidence that demonstrates the treatment’s safety and efficacy. The Board acknowledges that many, many treatments and modalities are used successfully and on a routine basis without the benefit of placebo controlled double blind clinical trials. That said, we look to published research and authoritative consensus statements when considering any therapy.

2. What are the risks? All medical care, at the end of the day, is a balance between the potential benefits and the recognized risks. When considering the appropriateness of any treatment under review, the Board always considers known risks to the patient as well as information regarding potential benefits and clinical efficacy.

North Carolina Medical Board Forum Credits

Volume XVII | No. 3 2014

Board officers

President
Paul S. Camnitz, MD | Greenville

President Elect
Cheryl Walker-McGill, MD | Charlotte

Secretary/Treasurer
Pascal Udekwu, MD | Raleigh

Immediate Past President
William A. Walker, MD | Charlotte

Board members
Michael J. Arnold, MBA | Wake Forest
Debra A. Bolick, MD | Hickory
Eleanor E. Greene, MD | High Point
Subhash C. Gumber, MD, PhD | Cary
A. Wayne Holloman | Greenville
Timothy E. Lietz, MD | Charlotte
Thelma Lennon | Raleigh
Helen Diane Meelheim, FNP | Beaufort
Barbara E. Walker, DO | Kure Beach

Forum staff

Publisher
NC Medical Board

Editor
Jean Fisher Brinkley

Editor Emeritus
Dale G. Breaden

Contact Us

Street Address
1203 Front Street
Raleigh, NC 27609

Mailing Address
PO Box 20007
Raleigh, NC 27619

Telephone / Fax
(800) 253-9653
Fax (919) 326-1130

Web Site:
www.ncmedboard.org

E-Mail:
info@ncmedboard.org

Have something for the editor?
forum@ncmedboard.org

The *Forum* of the North Carolina Medical Board is published four times a year. Articles appearing in the *Forum,* including letters and reviews, represent the opinions of the authors and do not necessarily reflect the views of the North Carolina Medical Board, its members or staff, or the institutions or organizations with which the authors are affiliated. Official statements, policies, positions, or reports of the Board are clearly identified.

We welcome letters to the editor addressing topics covered in the *Forum*. They will be published in edited form depending on available space. A letter should include the writer’s full name, address, and telephone number.

Primum Non Nocere

Should patients have the right to choose a treatment the Board believes to be "snake oil?"

3. Is the cost exploitive? The cost of treatments under review is often an important consideration, particularly in situations where care may be outside accepted standards and/or those where care is not covered by medical insurance. In the past, the Board has taken action to intervene when it determines that licensees have exploited patients financially by recommending costly treatments that either don't conform to the standard of care or have been used in an overaggressive manner.

4. Is the patient informed? As part of its review of any case involving experimental or nonstandard treatments, the Board carefully examines the licensee's process for obtaining informed consent from patients. It is the Board's position that any patient who is considering a nonstandard treatment should be clearly and thoroughly informed that the treatment falls outside of the norm well in advance of making a final decision. The licensee should clearly explain all potential benefits and all recognized risks of treatment. In numerous cases the Board has reviewed, the Board has permitted licensees to continue offering nonstandard therapies as long as a robust informed consent process is in place – especially when the nonstandard therapy is used in combination with other established treatments.

These factors provide a solid framework for evaluating and making decisions in cases that involve new and nonstandard treatments that come to the Board's attention. These cases are rarely easy, and I don't see that changing. Options for complementary and alternative therapies abound and Internet access plus the general tendency and expectation for patients to take greater command of their health keeps patient demand for these treatments soaring. Add to this the economic realities of medicine, which motivate licensees to provide treatments that are in demand and, often, more lucrative than established therapies since they are usually not covered by health insurance. These factors, along with innovation in medicine, will keep the Board busy well into the future.

Now, I'd like to hear what you think. How far does the Board's obligation to protect the public from nonstandard treatments and modalities extend?

Send comments to *forum@ncmedboard.org*

Board elects officers to serve in 2014-2015

The NC Medical Board elected officers for the coming year at the July meeting of the Board. Officers begin their terms November 1. Cheryl Lynn Walker-McGill, MD, of Charlotte, will serve as president; Pascal Osita Udekwu, of Raleigh will serve as president-elect and Eleanor Greene, MD, of High Point will act as secretary/treasurer. Two at-large members have also been named: Timothy E. Lietz, MD of Charlotte, and Michael J. Arnold, a public member, from Raleigh. Together, the officers serve on the NCMB's Executive Committee, which sets Board priorities and handles governance responsibilities. Officer terms expire October 31, 2015.

2015 BOARD MEETINGS

January 21-23	July 15-16
March 18-19	September 16-18
May 13-15	November 18-19

2015 BOARD HEARINGS

February 19-20	August 20-21
April 16-17	October 22-23
June 18-19	December 10-11

Cheryl Lynn Walker-McGill, MD, MBA, President

Cheryl Walker-McGill, MD
NCMB President

Dr. Walker-McGill, MD, is a Medical Director for Daimler Trucks, NC, Gastonia and Mt. Holly facilities. Previously on faculty at the Northwestern University School of Medicine and the University of North Carolina School of Medicine, Dr. Walker-McGill is currently an adjunct professor at the Wingate Graduate School of Business in Charlotte, North Carolina. Her current activities include corporate health and wellness, developing strategies for improving quality of healthcare delivery in targeted populations and healthcare provider education.

Dr. Walker-McGill serves on the board of the Mecklenburg County Medical Society and the Old North State Medical Society. Dr. Walker-McGill is a Fellow of the American Academy of Allergy, Asthma and Immunology and the American College of Physician Executives.

Dr. Walker-McGill earned her undergraduate and medical degrees from Duke University. She completed her residency and subspecialty training at Northwestern University and she received her MBA from the University of Chicago. Dr. Walker-McGill resides in Charlotte, NC and she is married to Dr. Paul A. McGill.

Pascal Osita Udekwu, MD

Pascal Osita Udekwu, MD
NCMB President Elect

Dr. Udekwu has practiced at WakeMed Health & Hospitals in Raleigh since 1991. He completed residency training in pediatrics and in general surgery at the University of Chicago, a fellowship in trauma and surgical critical care at the University of Pittsburgh, and earned a master's degree in business administration and health administration from Pfeiffer University in Misenheimer, NC.

Dr. Udekwu holds multiple leadership roles including Director of Trauma, Vice Chairman of Medical Staff Quality Improvement and Director of Surgical Critical Care, all at WakeMed Health & Hospitals. He is also Associate Director of the Surgical Residency Program at the University of North Carolina, Chapel Hill.

Dr. Udekwu currently serves as an adjunct professor at UNC-Chapel Hill and is an adjunct professor at Campbell University's College of Pharmacy and Health Sciences. He is triple-board certified with certifications from the American Board of Pediatrics, the American Board of Surgery and the American Board of Surgery—Surgical Critical Care.

Dr. Udekwu has authored numerous papers and abstracts for scholarly journals and is a member of several professional organizations. He is a fellow of both the American College of Surgeons and of the American College of Chest Physicians and is actively interested in regional and national Health Policy.

In addition, Dr. Udekwu served in the United States Army Reserve from 1988-2005 deploying to Bagram Afghanistan as Chief of Surgery in 2003. He currently serves as a Colonel in the United States Air Force Reserve at Joint Base Andrews, Maryland.

Eleanor E. Greene, MD, MDH

Eleanor E. Greene, MD, MPH
NCMB Secretary/Treasurer

Dr. Greene, MD, of High Point, earned a BS degree in medical technology from the former Bowman Gray School of Medicine (now Wake Forest University School of Medicine) in Winston-Salem, NC. She received her MD and a Master of Public Health in Maternal and Child Health from the University of North Carolina, Chapel Hill, and completed residency in obstetrics and gynecology at the Ohio State University in Columbus, OH. She currently practices with Bethany Medical Center in High Point.

Dr. Greene is a member of the North Carolina Medical Society, Doctors for America, North Carolina Obstetrics and Gynecology Society, and the National Medical Association, where she served on the Board of Directors, Finance and Health Policy Committees. She serves on the Piedmont Health Services and Sickle Cell Agency. She served on the North Carolina Advisory Committee on Cancer Coordination and Control, on the Board of Directors of the Healthy Start Foundation, completing two terms on each. Dr. Greene is past president of the Old North State Medical Society, and continues to serve on its current Executive Committee. She is a fellow of the American College of Obstetrics and Gynecology.

Dr. Greene is the first physician from High Point, NC, and the first African American female physician to serve on the NC Medical Board. She speaks on the topic of Women's Health and Women in Medicine at numerous church and community forums. Dr. Greene recently served as moderator for a conversation on Women's Health and the Affordable Care Act featuring the Department of Health and Human Services Director, Secretary Kathleen Sebelius.

Dr. Greene was appointed to the Board in 2010. She serves on the Review, Executive and Policy Committees.

Timothy E. Lietz, MD

Timothy E. Lietz, MD
NCMB Executive Committee

Dr. Lietz currently practices with Mid-Atlantic Emergency Medical Associates in Charlotte and serves as President and CEO and is a member of the practice's Board of Directors. He is former Chairman of the Department of Emergency Medicine for the Southern Piedmont Region of Novant Health.

Dr. Lietz earned his medical degree from the Ohio State University School of Medicine in Columbus, Ohio. He completed an internship with the Eastern Virginia Medical School Department of Internal Medicine and residency training with the same institution's Department of Emergency Medicine. He served one year as chief resident.

Dr. Lietz is certified by the American Board of Emergency Medicine. He is a member of the North Carolina Medical Board and of the NC Academy of Emergency Physicians (ACEP).

Michael J. Arnold, MBA

Michael J. Arnold, MBA
NCMB Executive Committee

Mr. Arnold, of Wake Forest, has worked as a policy, research and public affairs professional at high levels of state government for more than two decades, first serving nine years as a university administrator and on faculty at the University of North Carolina at Wilmington and then later as a high-ranking senior official in the Executive branch of state government.

In addition to his on-going role as an adjunct faculty member at Duke University's Sanford School of Public Policy, Mr. Arnold currently serves as Senior Advisor for Policy & Government Relations to Secretary of State Elaine Marshall. Prior to that, Mr. Arnold served as Senior Advisor for Policy and Research with Governor Beverly Perdue. He also served in the same role during Perdue's term as Lt. Governor.

Mr. Arnold has also worked as Senior Research Director for the NC Health and Wellness Trust Fund, which was one of three entities created by the NC General Assembly to invest North Carolina's portion of the Tobacco Master Settlement Agreement. Prior to that, he served in a public affairs and development role for the Alice Aycock Poe Center for Health Education in Raleigh, one of the state's largest health education centers.

Mr. Arnold earned a bachelor's degree in Communication Studies from the University of North Carolina, Wilmington, and a master of business administration from the same institution. He also earned a certification in Nonprofit Management, with an emphasis on communications and strategic planning from Duke University.

Hepatitis C: everyone deserves a chance at cure

Michael W. Fried, MD, Director, UNC Liver Center

New all-oral therapies for hepatitis C can permanently cure over 90 percent of infections in the United States. Health care providers in North Carolina must recognize patients who should be screened for hepatitis C infection, counseled about lifestyle interventions, and then linked to appropriate care for possible treatment with these remarkable new medications.

Many North Carolinians suffer from hepatitis C

The It is estimated that nearly 2 percent of the U.S. population, or 3-4 million individuals, have been infected with hepatitis C[1,2]. In North Carolina, approximately 150,000 people may be living with hepatitis C infection. These figures likely underestimate the actual incidence of hepatitis C infection, since certain at-risk populations were not included in the major national epidemiologic studies. For many years, the impact of hepatitis C on morbidity and mortality has also been underestimated. Complications of hepatitis C include progression to cirrhosis, liver failure, and hepatocellular carcinoma (HCC). Chronic hepatitis C infection is driving the increased incidence of hepatocellular carcinoma in the U.S. The importance of hepatitis C as a public health concern is highlighted by recent data demonstrating that the annual age-adjusted mortality rate for hepatitis C is higher than for HIV infection[3].

All Baby Boomers should be tested for HCV

Even more striking is that over half of the patients infected throughout the U.S. are unaware that they have hepatitis C, despite the availability for more than 20 years of sensitive and specific tests for the diagnosis of this chronic viral disease. Until recently, screening strategies for hepatitis C focused on ascertainment of risk factors for infection þ rior history of injecting drug use or blood transfusion prior to 1992 as the major risks for infection). However, the CDC and the U.S. Preventative Services Task Force have augmented this risk-based screening strategy with additional recommendations based upon the high prevalence of hepatitis C in the "Baby Boomer" generation: Any person born between 1945 and 1965 should have a one-time anti-HCV screening test for hepatitis C[4]. Patients testing positive should then be tested for HCV RNA to determine if the viral infection is still present. An alcohol assessment and counseling regarding the detrimental effects of alcohol use should be provided concurrent with linkage to HCV care.

Hepatitis C should be cured in order to improve patient outcomes

Sustained virological response (SVR) is defined as the absence of HCV RNA in blood when measured 12 weeks after the end of treatment and is considered as evidence of cure of HCV infection. Long-term follow-up studies have demonstrated that this short-term surrogate endpoint used in clinical trials of antiviral drugs is durable and that the likelihood of HCV relapse beyond this time frame is nil. The benefits of achieving SVR are myriad[5,6].

Hepatitis C can be cured with all-oral regimens and minimal side effects

Treatments for hepatitis C have evolved rapidly over the last several years with new drugs developed specifically to inhibit replication of the hepatitis C virus. These direct acting antiviral agents (DAAs) are focused on three specific regions of the hepatitis C virus that are critical to viral functions. Thus, NS3 protease inhibitors, NS5A replication complex inhibitors, and NS5B polymerase inhibitors have been combined with or without ribavirin in order to achieve all oral therapeutic with high rates of *(Continued on page 8)*

1 Thomas DL. Global control of hepatitis C: where challenge meets opportunity. Nature medicine 2013;19:850-8.
2 Denniston MM, Jiles RB, Drobeniuc J, et al. Chronic hepatitis C virus infection in the United States, National Health and Nutrition Examination Survey 2003 to 2010. Ann Intern Med 2014;160:293-300.
3 Ly KN, Xing J, Klevens RM, Jiles RB, Ward JW, Holmberg SD. The increasing burden of mortality from viral hepatitis in the United States between 1999 and 2007. Ann Intern Med 2012;156:271-8.
4 Rein DB, Smith BD, Wittenborn JS, et al. The cost-effectiveness of birth-cohort screening for hepatitis C antibody in U.S. primary care settings. Ann Intern Med 2012;156:263-70.
5 Van der Meer AJ, Veldt BJ, Feld JJ, et al. Association between sustained virological response and all-cause mortality among patients with chronic hepatitis C and advanced hepatic fibrosis. JAMA 2012;308:2584-93.
6 Backus LI, Boothroyd DB, Phillips BR, Belperio P, Halloran J, Mole LA. A sustained virologic response reduces risk of all-cause mortality in patients with hepatitis C. Clin Gastroenterol Hepatol 2011;9:509-16 e1.

Michael W. Fried, MD

Michael W. Fried, MD, is a professor of medicine at the University of North Carolina, Chapel Hill, where he is director of the UNC Liver Center. His primary clinical interests are the management of viral hepatitis and chronic liver disease. Dr. Fried's research includes clinical studies on new treatments for viral hepatitis. His work has helped to define the latest standards of care for patients with chronic hepatitis C and hepatitis B.

Hepatitis C (HCV) screening recommendations

- All adults born during 1945 through 1965 should be tested once (without prior ascertainment of HCV risk factors)
- HCV-testing is recommended for those who:
  - Currently inject drugs
  - Ever injected drugs, including those who injected once or a few times many years ago
  - Have certain medical conditions, including persons:
    - who received clotting factor concentrates produced before 1987
    - who were ever on long-term hemodialysis
    - with persistently abnormal alanine aminotransferase levels (ALT)
    - who have HIV infection
  - Were prior recipients of transfusions or organ transplants, including persons who:
    - were notified that they received blood from a donor who later tested positive for HCV infection
    - received a transfusion of blood, blood components or an organ transplant before July 1992
  - HCV-testing based on a recognized exposure is recommended for:
    - Healthcare, emergency medical, and public safety workers after needle sticks, sharps, or mucosal exposures to HCV-positive blood
    - Children born to HCV-positive women

Note: For persons who might have been exposed to HCV within the past 6 months, testing for HCV RNA or follow-up testing for HCV antibody is recommended.

Persons for Whom Routine HCV Testing is of uncertain need

- Recipients of transplanted tissue (e.g., corneal, musculoskeletal, skin, ova, sperm)
- Intranasal cocaine and other non-injecting illegal drug users
- Persons with a history of tattooing or body piercing
- Persons with a history of multiple sex partners or sexually transmitted diseases
- Long-term steady sex partners of HCV-positive persons

Persons for Whom Routine HCV Testing is Not Recommended (unless other risk factors present)

- Health-care, emergency medical, and public safety workers
- Pregnant women
- Household (nonsexual) contacts of HCV-positive persons
- General population

Source: U.S. Centers for Disease Control and Prevention

Hepatitis C: everyone deserves a chance at cure

(Continued from page 6)

sustained virological response. Combining drugs from different classes is very important in order to hit multiple targets to increase the efficacy of these drugs and also to diminish the risk of viral resistance. These drugs should never be used as single agents due to the immediate risk of selecting for resistant virus.

It is anticipated that two all-oral regimens will be approved in the last quarter of 2014. Sofosbuvir is a nucleotide polymerase inhibitor that has been combined with ledipasvir (NS5A inhibitor) to achieve a once-daily single pill regimen for the treatment of hepatitis C. SVR was achieved in 94 to 99 percent of patients who were treated for only 12 weeks in phase III clinical trials of sofosbuvir and ledipasvir[1,2]. Another regimen that combined ABT-450 (protease inhibitor, boosted with ritonavir), with ombitasvir (NS5A inhibitor), dasabuvir (non-nucleoside polymerase inhibitor), and ribavirin, yielded SVR rates between 92 and 96 percent[3,4]. At least two other all-oral regimens are in late stage clinical trials but are not expected for FDA approval until sometime in 2015.

These all-oral therapies are extremely well tolerated with low rates of generally mild adverse events (headache, fatigue, nausea, possibly anemia with ribavirin) or treatment discontinuations and represent major advances in HCV therapeutics. Indeed, few patients will have contraindications to this new generation of antiviral therapy, in glaring contrast to the rigorous interferon-based regimens for which many patients were not suitable candidates or preferred not to experience the harsh adverse effects.

Evidence continues to accrue about the substantial improvements in hepatic and non-hepatic outcomes among patients who are cured from chronic hepatitis C. The availability of simplified all-oral regimens that minimize adverse events and achieve near universal SVR will encourage health care providers to screen appropriate patients for HCV infection and will lead to more patients undergoing successful, and potentially life-saving, antiviral therapy.

Disclosures: Dr. Fried receives research grants and serves as ad hoc consultant to AbbVie, Bristol-Myers Squibb, Genentech, Gilead, Janssen, Merck, and Vertex

1 Afdhal N, Reddy KR, Nelson DR, et al. Ledipasvir and sofosbuvir for previously treated HCV genotype 1 infection. N Engl J Med 2014;370:1483-93.

2 Afdhal N, Zeuzem S, Kwo P, et al. Ledipasvir and sofosbuvir for untreated HCV genotype 1 infection. N Engl J Med 2014;370:1889-98.

3 Feld JJ, Kowdley KV, Coakley E, et al. Treatment of HCV with ABT-450/r-ombitasvir and dasabuvir with ribavirin. N Engl J Med 2014;370:1594-603.

4 Zeuzem S, Jacobson IM, Baykal T, et al. Retreatment of HCV with ABT-450/r-ombitasvir and dasabuvir with ribavirin. N Engl J Med 2014;370:1604-14.

Update your licensee information page with a photo

Log in to your Licensee Information page to upload your picture. Visit *www.ncmedboard.org* and select Update Licensee Info Page from the green Quick Links box at the right of the home page to log in. Photos submitted for inclusion on the licensee information page must comply with the following guidelines. The NCMB reserves the right not to post photographs that do not meet guidelines.

1. The photo should be a color head shot (head, neck and shoulders in frame) that is in focus. The individual pictured should not be wearing sunglasses, a hat or any other item that obscures the face or alters his or her normal appearance.

2. The licensee should be the only individual in the photograph. The licensee should be looking straight ahead, with both eyes open and a natural facial expression.

3. The licensee should be in professional dress equivalent to his or her everyday attire for work in a clinical setting.

DEA makes tramadol a Schedule IV drug

The U.S. Drug Enforcement Administration has published a Final Rule that switches tramadol from a legend drug to a Schedule IV controlled substance, effective August 18, 2014.

As of the effective date, all drug manufacturers will be required to print the designation "C-IV" on every bottle of medication and it will be unlawful for commercial containers of tramadol to be distributed without that designation. In addition, all DEA registrants will be required to take an inventory of all tramadol stock.

Tramadol's new status may have implications for some licensees who may prescribe the drug to family members or to themselves.

According to administrative rules 32B .1001, 32s .0212, and 32M .0109 licensees are expressly prohibited to prescribe controlled substances to themselves or to immediate family members. The Board's position statement entitled, "*Self-treatment and treatment of family,*" cautions against treating and prescribing for oneself and for immediate family members except in emergencies or for minor, acute illnesses. Licensees who may have self-prescribed tramadol in such circumstances should be advised that doing so will be prohibited once the drug's new status is in effect.

To read the DEA's Final Rule regarding tramadol, visit *http://www.deadiversion.usdoj.gov/fed_regs/rules/2014/fr0702.htm*

What is a Schedule IV drug?

Schedule IV drugs, substances, or chemicals are defined as drugs with a low potential for abuse and low risk of dependence.

Some examples of Schedule IV drugs are: Xanax, Soma, Darvon, Darvocet, Valium, Ativan, Talwin, Ambien

Source: U.S. Drug Enforcement Administration

The North Carolina Medical Board is pleased to provide Board Members and/or Board staff to speak to professional groups and other audiences: medical students, residents, professional meetings and conferences, hospital grand rounds,and practice meetings or retreats.

Most programs provide a general overview of the Board's structure, mission and responsibilities as well as in depth discussion around important issues in medical regulation. The Board is also able to develop programs tailored to specific audiences and events upon request.

If you are interested in scheduling a speaker, please contact the Board's Public Affairs Director: Jean Fisher Brinkley, Director, 919-326-1109 x230 or *jean.brinkley@ncmedboard.org*

Towards ensuring continued competence: where the Board stands on MOL and CME

The topic of how best to ensure the continued competence of medical professionals over the course of their careers remains an area of active and, at times, heated discussion among stakeholders nationally and in North Carolina.

For many years, the NCMB, like other state medical boards, has encouraged ongoing competence among its licensees through requirements that compel physicians and physician assistants to earn a certain number of hours of practice relevant continuing medical education (CME). Over the last several years, however, discussion among leaders in medical regulation has turned toward a different approach that emphasizes continuing education linked to specific areas of practice, assessment of knowledge gaps and measurement of improvement and outcomes. This approach is generally known as maintenance of licensure (MOL).

Although it has no plans to establish an MOL-based program in North Carolina, the NCMB has participated in national conversations regarding MOL in the past and has thoroughly considered the proper place, if any, it has in medical regulation. Many licensees are understandably concerned at the prospect of new, rigorous MOL requirements being adopted in North Carolina, and the NCMB continues to field occasional questions on the Board's current position on the matter.

This article is offered as clarification of the Board's current position on MOL and CME.

Maintenance of Licensure

What is maintenance of licensure? As defined by the Federation of State Medical Boards, MOL is "a system of continuous professional development for physicians that supports, as a condition for license renewal, a physician's commitment to lifelong learning that is relevant to their area of practice and contributes to improved health care." The FSMB adopted an MOL framework in 2010 to guide state medical boards interested in adopting MOL programs.

What would an MOL program consist of? At the most basic level, MOL programs require licensees to demonstrate their commitment to lifelong learning and continued professional development. States that pursue MOL are free to determine the specific ways for licensees to do this. The FSMB has established an MOL resource center that state medical boards may, but are not required to, access as they make adjustments to their efforts to ensure continued competence among licensees.

Will the NCMB establish MOL requirements for licensees? Establishing MOL, either as a condition of initial licensure or license renewal, is not under consideration in North Carolina. In the years leading up to and shortly after the adoption of the FSMB's MOL framework, the NCMB studied, considered and discussed whether MOL made sense for North Carolina. In Nov. 2011 the Board voted not to pursue MOL in the state, and the issue has not been reopened since that time.

Current continued competence requirements in NC

North Carolina continues to encourage licensees to maintain their competence through earning CME hours. The Board amended regulations regarding CME in 2012, eliminating the obligation to report Category 2 CME hours while maintaining the requirement for physician licensees to complete a minimum of 60 Category 1 hours relevant to the licensee's area of practice.

The 2012 CME rule changes established exemptions for certain licensees, including those physicians who are currently engaged in a program of recertification or maintenance of certification (MOC) through an ABMS, AOA or RCPSC specialty board. These licensees are exempt from reporting CME to the NCMB for the three year cycle in which they are involved in recertification/MOC. Physicians who have been "grandfathered" or awarded lifetime certification by an ABMS, AOA or RCPSC specialty board do not qualify for the exemption and will be required to report CME.

This exemption was created to reduce the administrative burden on physicians who choose to participate in a recognized MOC program. At no time has the Board contemplated requiring participation in a MOC program as a condition of licensure.

North Carolina Medical Board

Quarterly Board Actions Report | February - April 2014

The Board actions listed below are published in an abbreviated format. The report does not include non-prejudicial actions such as reentry agreements and non-disciplinary consent orders. Recent Board actions are also available at *www.ncmedboard.org*. Go to "Professional Resources" to view current disciplinary data or to sign up to receive notification when new actions are posted via the RSS Feed subscription service.

Name/license#/location	Date of action	Cause of action	Board action
ANNULMENTS			
[None]			
SUMMARY SUSPENSIONS			
[None]			
REVOCATIONS			
EAKINS, Darrin Franklin, MD (009800521) Steamboat Springs, CO	04/04/2014	MD was convicted of Felony Possession of Cocaine in State of North Carolina vs. Darrin Franklin Eakins, case numbers 11CRS061574 and 12CRS050668.	Entry of Revocation
SUSPENSIONS			
AGHA, Maher Salah, MD (009601206) Charlotte, NC	04/07/2014	The Board received a complaint that MD was coming in to work with alcohol on his breath; a Board investigator made an unannounced visit to MD's practice on two occasions in October 2013 to collect urine samples. Both samples tested positive for alcohol consumption. MD signed a private agreement with the Board on October 28, 2013, not to practice until permitted to do so by the Board. MD was assessed and diagnosed with severe alcohol use disorder and subsequently completed 90 days of inpatient treatment. The Board obtained six patient charts, which were reviewed by the Board's medical director. The Board is concerned about MD's prescribing of controlled substances and pain management practice.	Indefinite suspension of NC medical license
FINCH, Sudhir Eugene, MD (200101336) Fayetteville, NC	02/20/2014	History of arrest in March 2012 for Domestic Abuse Battery. In addition, MD entered into a consent order dated June 22, 2010, related to findings that he prescribed controlled substances to his spouse and other close family members without maintaining proper medical records. The order reprimanded MD, required him to complete CME in appropriate prescribing and ordered him to strictly comply with the Board's position statement on prescribing to family and related administrative rules, which expressly forbid the prescribing of controlled substances to a spouse. During the Board's investigation of MD's arrest it was found that MD continued to prescribe controlled substances to his spouse in violation of the 2010 order.	Indefinite suspension of NC medical license
GOOTMAN, Aaron Harvey, MD (200200534) Fayetteville, NC	03/03/2014	Inappropriate and excessive prescribing of controlled substances for the treatment of chronic pain	Indefinite suspension of NC medical license
JONES, Enrico Guy, MD (009700302) Greensboro, NC	04/09/2014	MD prescribed controlled substances to patients with the understanding that patients would either share or give MD some or all of the drugs; Diversion of controlled substances for personal use/abuse.	Indefinite suspension of NC medical license
LARSON, Michael Joseph, MD (000028661) Raleigh, NC	03/07/2014	History of alcohol dependency and substance abuse	Indefinite suspension of NC medical license

Name/license#/location	Date of action	Cause of action	Board action
LONG, Mareen Ann, MD (200300059) Greenville, NC	03/05/2014	MD suffered a traumatic brain injury in November 2007, while training in family medicine at East Carolina University. She was able to complete her residency, but has not practiced clinical medicine since completing residency training. In January 2013 MD was hospitalized for an illness that renders her unable to practice medicine with reasonable skill and safety.	Indefinite suspension of NC medical license
MARTIN, Carol Ann, MD (009901651) Cary, NC	04/11/2014	Inappropriate prescribing of controlled substances; MD prescribed excessive amounts, failed to confirm diagnoses, failed to coordinate care outside of her specialty, failed to demonstrate appropriate pharmacovigilance and failed to recognize abuse of medications prescribed.	12-month suspension of NC medical license, stayed. MD must complete 10 hours of CME in each of the following subjects: medical record keeping and controlled substances prescribing.
MEYER, Graham Scott, MD (009500405) Elizabethtown, NC	02/20/2014	In July 2012, MD was charged with misdemeanor assault on his wife; the Board ordered MD to present to NCPHP for an examination within 30 days of receipt of the order. MD failed to comply. He was examined by NCPHP in October 2013 and thereafter tested positive for marijuana. MD was assessed for substance abuse and completed inpatient treatment for substance abuse in February 2014. MD signed a private Non-Practice Agreement in November 2013.	Indefinite suspension of NC medical license, immediately stayed; MD enters into a Public Non-Practice Agreement that shall remain in effect until he is cleared for practice by NCPHP and his NPA is dissolved by the Board. Note: NPA was dissolved April 2, 2014.
POLYZOS, Panagiotis, PA (000101403) Monroe, NC	03/11/2014	Multiple allegations by female patients that PA inappropriately touched them	Indefinite suspension of NC physician assistant license
STRATTA, Robert Joseph, MD (200101283) Winston-Salem, NC	04/11/2014	Between March 2010 and December 2012, MD was involved in a romantic relationship with a patient. MD self-reported the relationship to the Board in December 2012. MD has successfully completed a course on maintaining proper boundaries with patients and has attended a comprehensive assessment and treatment program at the Professional Renewal Center in Kansas.	NC medical license suspended for six months, stayed but for a period of 60 days to begin on April 12, 2014, and end on June 10, 2014.
TATE, Denny Cook, MD (000029427) Graham, NC	04/14/2014	MD inappropriately prescribed controlled substances to a patient with a history of mental illness and prescription pill abuse. The patient was diagnosed and treated for breast cancer in 2012. Due to her history of drug abuse, the treating oncologist prescribed Ibuprofen only for pain. When the patient contacted MD complaining of pain, MD authorized prescriptions for morphine. On August 8, 2012 MD prescribed 60 tabs of morphine with instructions to take one pill twice daily. The patient was found unresponsive on August 18, 2012, with the pill bottle nearby; only eight pills of morphine remained. The patient was taken to the hospital, where she died.	NC medical license suspended for one year, immediately stayed. MD must complete CME in prescribing controlled substances and register to use the NC Controlled Substances Reporting System.
PROBATIONS			
[None]			
REPRIMANDS			
CALAYCAY, Regulo, MD (201101521) Milton, FL	04/15/2014	MD entered into a consent order with the Florida Board of Medicine related to MD's inappropriate prescribing of weight loss drugs, wherein MD accepted a reprimand and a prohibition on his ability to prescribe controlled substances for the treatment of obesity.	Reprimand
COX, (Jr.), Benjamin Gould, MD (200701629) Menifee, CA	02/21/2014	MD entered into an order with the California Medical Board that restricted his prescribing authority and required him to relinquish his DEA permit.	Reprimand
DIXON, Donovan Dave, MD (201001347) Pembroke, NC	04/28/2014	Inappropriate prescribing of controlled substances, including but not limited to: failing to evaluate the cause of patients' pain, failing to review prior medical records to support a diagnosis, failing to employ appropriate pharmacovigilance with pain patients and failing to attempt non-opioid therapy before prescribing controlled substances.	Reprimand; MD must complete 10 hours of CME in controlled substances prescribing and 10 hours of CME in general family medicine.

Name/license#/location	Date of action	Cause of action	Board action
FOSTER, Darryl L., PA (001000668) Pinehurst, NC	04/03/2014	Inappropriate prescribing of controlled substances; PA prescribed escalating doses of opioids without sufficient evidence of a legitimate medical purpose and without taking steps to avoid patient abuse, misuse or addiction. In addition, medical record-keeping was inadequate.	Reprimand; PA shall not prescribe controlled substances until such time as he completes sufficient CME in prescribing controlled substances as determined and approved by the Board's Medical Director. Must meet other conditions.
KEENAN, Joseph Gerard, MD (009700610) Nags Head, NC	02/20/2014	In 2012, MD began an inappropriate personal relationship with a patient while a physician-patient relationship existed between them. MD then transferred the patient's care to another physician in the same practice. In early 2013, while the patient was still being treated by his practice, MD began a romantic relationship with the patient. The patient is no longer treated at MD's practice.	Reprimand; MD shall complete a course on maintaining proper boundaries.
MADDOX, Charles Deaton, MD (000017503) Arden, NC	04/14/2014	Concerns about quality of care; inappropriate prescribing of controlled substances, including failure to respond to indications that patients were abusing controlled substances that MD had prescribed.	Reprimand; MD is restricted from prescribing Schedule II and Schedule III controlled substances. In addition, MD must complete CME in medical record keeping, treatment of diabetes and treatment of hypertension.
OMAN, Timothy Roy, MD (000028069) Gloucester, MA	02/05/2014	MD was reprimanded by the Massachusetts Board related to inappropriate prescribing of controlled substances to two patients.	Reprimand
RUMLEY, Richard Lee, MD (000023874) Greenville, NC	02/10/2014	Concerns about quality of care provided in the areas of infectious disease, pain management and internal medicine; inadequate medical records documentation.	Reprimand; MD must complete a total of 10 hours of CME in each of the following areas: medical records documentation, infectious disease, controlled substances prescribing and internal medicine.
WENN, Timothy Peter, MD (000027103) Salisbury, NC	03/31/2014	MD failed to appropriately diagnose and treat a vascular occlusion in a patient's right lower leg; MD acknowledged that this was due to an error in that he apparently failed to note a radiologist's conclusion that there was no apparent flow in the patient's right superficial femoral artery. The patient was treated by another physician for the vascular occlusion and subsequently underwent amputation of the right lower leg.	Reprimand
DENIALS OF LICENSE/APPROVAL			
WICHSER, James Allen, MD (N/A) Grundy, VA	04/16/2014	Multiple nondisclosures of material information on NC license application	Denial of application for NC medical license
SURRENDERS			
FRAZIER, Charles Earl, MD (000018591) Greensboro, NC	03/06/2014		Voluntary surrender of NC medical license
HOWARD, (III), Willard Howe, MD (009801678) Tryon, NC	02/28/2014		Voluntary surrender of NC medical license
PUBLIC LETTERS OF CONCERN			
ANG, Joel Chua, MD (200300117) Washington, DC	02/03/2014	MD entered into a public consent order with the DC Medical Board.	Public letter of concern
BLANTON, James Wayne, PA (000101269) Charlotte, NC	02/26/2014	PA practiced at multiple practice sites without following applicable rules and regulations, including waiting to begin practice before receiving acknowledgement of Intent to Practice from the Board.	Public letter of concern; $1,000 fine

Name/license#/location	Date of action	Cause of action	Board action
CARR, Emily Kathleen, MD (N/A - RTL) Winston-Salem, NC	04/30/2014	MD failed to comply with a March 8, 2012, consent order that required her to abide by the terms of her NCPHP consent order, including keeping NCPHP advised of significant changes in her mental or physical health. MD did not notify NCPHP when she was hospitalized with a serious illness for an extended period of time. The Board is further concerned that the circumstances leading up to the hospitalization suggest that MD may be trying to work when it is medically unsafe for her to do so.	Public letter of concern
EVANS, Ricky Lee, MD (009600266) Burlington, NC	03/25/2014	After a patient with a history of dyspareunia did not respond to conservative treatment measures, MD performed a pudendal nerve block with a combination of Marcaine and Kenalog. The nerve block injections continued for a period of about three months, after which MD noted that the patient had experienced significant weight gain. Laboratory tests indicated decreased ACTH levels. MD referred the patient to an endocrinologist, who treated the patient for iatrogenic adrenal insufficiency. After one year, the patient still had not fully recovered from the prolonged steroid injections. The Board is concerned that MD did not continue to pursue more conservative treatments and his decision to treat with increasing doses of Kenalog.	Public letter of concern
HOLLEMAN, (Jr.), James Bennett, MD (009800281) Columbus, NC	03/12/2014	The Board is concerned about the care MD provided to a patient treated for a pancreatic pseudocyst. The patient experienced complications after the placement of a subclavian venous catheter that had been repositioned by MD. The Board is concerned that MD did not order a follow up chest x-ray to confirm accurate placement of the catheter. The central line stopped functioning on postoperative day 2 and the patient developed severe respiratory distress that required intubation. Resuscitation was attempted but was unsuccessful and the patient died.	Public letter of concern
KWIATKOWSKI, Timothy Carl, MD (009701443) Charlotte, NC	04/23/2014	The Board is concerned that MD's care of patient whom MD treated in the ER for presumed allergic reaction to a medication prescribed by another physician did not meet accepted standards of care. MD failed to reevaluate the patient, although nursing staff informed MD that the patient's condition had changed to include sweating and radiating chest pain. The patient died in the hospital and autopsy determined the cause of death to be severe coronary artery disease and acute myocardial infarction.	Public letter of concern
KWON, Andrew, MD (201400661) Lakewood, WA	04/09/2014	The Board is concerned that MD entered into an order with the State of Washington Quality Assurance Commission in January 2011 related to an incident in a nursing home where MD was medical director. MD was required to complete CME and pay a $2,500 fine. The Board is also concerned that MD failed to disclose the Washington order on his NC license application; MD also failed to disclose a leave of absence during medical school.	Public letter of concern; $1,500 fine
MALONE, Patrick Thomas, MD (000015972) Chapel Hill, NC	03/04/2014	The Board is concerned that MD was not attentive to signs that some of the patients he was prescribing benzodiazepines to may, in fact, have been selling those medications.	Public letter of concern
MCDONOUGH, Mark David, MD (200501378) Orlando, FL	02/24/2014	While practicing in Florida, MD exchanged pre-signed prescription blanks with another physician and then used the blanks to fill prescriptions for medications including Adderall, a Schedule II controlled substance with high risk for abuse. This led the Florida board to restrict MD's prescribing authority so that he is prohibited from prescribing controlled substances.	Public letter of concern

Name/license#/location	Date of action	Cause of action	Board action
POINTS, (II), Gerald Lee, MD (000015260) Wilmington, NC	04/28/2014	MD prescribed a significantly excessive dose of an opioid medication (100 mg of morphine sulfate twice daily and Naprosyn to an elderly patient with a history of obesity, diabetes, hypertension, chronic kidney disease and obstructive sleep apnea when the patient complained of low back pain. The patient presented to an ER obtunded, hypotensive, hypoxic, and dehydrated with acute renal failure attributed to rhabdomyolysis. The Board is concerned that MD's prescribing of opioids may have contributed to the patient's deterioration and renal failure.	Public letter of concern
RAO, T. Hemanth Prabhakar, MD (009600280) Charlotte, NC	03/12/2014	MD failed to comply with Medicare regulations that require physicians to directly supervise the treatment of intravenous immunoglobulin therapy; MD entered into an agreement with the US government to pay $2.5 million.	Public letter of concern
TEMPLETON, Thomas Wesley, MD (200401138) Winston-Salem, NC	03/05/2014	MD consumed alcohol while on-call. MD indicated that he had a colleague covering for him but acknowledged that he did not inform the hospital of this alternate coverage.	Public letter of concern
MISCELLANEOUS ACTIONS			
FROELICH, Mary E., MD (009300121) Mt. Airy, NC	04/28/2014	Prior history of alcohol dependence	Non-Disciplinary Consent Order; MD shall not practice more than 40 hours per week. MD shall abide by all terms of her NCPHP contract.
CONSENT ORDERS AMENDED			
[None]			
TEMPORARY/DATED LICENSES: ISSUED, EXTENDED, EXPIRED, OR REPLACED BY FULL LICENSES			
CADE, Jerry David, MD (000019787) Spruce Pine, NC	02/19/2014	Prior history of alcohol/substance dependence	Temporary license issued; Expires 08/19/2014. MD shall maintain a contract with NCPHP and abide by all terms.
HART, Darlington Ibifubara, MD (009800560) Charlotte, NC	04/08/2014	MD has not practiced clinical medicine since June 1, 2011, when he surrendered his NC medical license amid allegations of professional sexual misconduct. MD denies all allegations of professional sexual misconduct. The Board issues the temporary license based on multiple mitigating factors. MD has never been convicted of any crime involving sexual misconduct or found to have committed sexual misconduct. In addition, several witnesses, including a female employee, testified that MD is of good moral character and is a good physician.	MD is issued a temporary medical license; MD shall complete a program of reentry.
COURT APPEALS/STAYS			
[None]			
DISMISSALS			
[None]			

FINES

The NCMB issues non-disciplinary administrative fines in certain cases where incorrect and/or incomplete information on a medical licensing application causes Board staff to spend an inordinate amount of time resolving the issue(s).

Date	Reason	Amount
02/26/2014	Unprofessional conduct	$1,000.00
05/27/2014	Unprofessional conduct	$2,000.00

North Carolina Medical Board
1203 Front Street
Raleigh, NC 27609

Prsrt Std
US Postage
PAID
Permit No. 2172
Raleigh, NC

LIKE US ON FACEBOOK
facebook.com/ncmedboard

FOLLOW US ON TWITTER
@NCMBActions

BOARD MEETING DATES

September 17-19, 2014 (Full Board)
October 16-17, 2014 (Hearings)
November 19-20, 2014 (Full Board)
December 11-12, 2014 (Hearings)

Meeting agendas, minutes and a full list of meeting dates can be found on the Board's website
ncmedboard.org

Visit the Board's website at *www.ncmedboard.org* to change your address online. The Board requests all licensees maintain a current address on file with the Board office. Changes of address should be submitted to the Board within 30 days of a move.

Copies of NCMB Annual Report now available

This year the NCMB published its first agency annual report, reflecting the Board's work during calendar year 2013. The Board has published a limited number of paper copies, which are available upon request. To request a hard copy, email your name and mailing address to *public.affairs@ncmedboard.org*

The NCMB has a long history of publishing annual data regarding the public actions taken by the Board each year. The annual report continues this tradition, while substantially increasing the scope of data released about the Board's activities. The Board thinks this format offers a more complete summary of its work in a given year.

The Annual Report features data on complaints and other investigative information received by the Board, data on malpractice reports received by specialty area of practice and information on the number of private actions taken by the Board. The new report also includes information about policy initiatives and licensing program activity, as well as demographic information about the Board's licensees.

VIEW ONLINE: Visit *www.ncmedboard.org/disciplinary_reports* and select the tab labeled "Annual Reports."