



## Vascular Society of New Jersey

### Monthly Report- September 2011

#### From the President

Paul B. Haser, MD

As the summer ends, activities at VSNJ are heating up. The October 27 Fall dinner is evidence of this, and it will be the first time that spouses and significant others are encouraged to attend. Hopefully, your membership dues are up to date as this will lead to significant cost savings for you to attend. The board has been busy getting the word out to referring physicians and the public that vascular care is delivered best by vascular surgeons in New Jersey.

Through continuation of your past presidents' efforts, a planned upgrade to the website, (including increased linking to the national websites), and increased member participation, these efforts will be strengthened.

You'll see below that the newsletter is chocked full of useful information. As November approaches with new local elections, the lobby group met to discuss the agenda for hot topics in medicine. Gov. Christie signed several bills into legislation, which may affect your practice. You are encouraged to attend upcoming fundraisers, and to discuss these issues with the candidates. The VSNJ administration is actively monitoring The Department of Banking and Insurance's activities. And speaking of banking, below you will find some solid financial advice below.

Please do take a moment to complete your membership dues if you haven't had the chance, and I look forward to seeing you on October 27th.

#### **REGISTER NOW**

### Vascular Society of New Jersey Annual Meeting **October 27, 2011**

NEW LOCATION  
**LIBERTY HOUSE RESTAURANT**  
Jersey City, NJ

with keynote speaker:

**Martin Chalfie**

*Nobel Laureate, Chemistry 2008*

*William R. Kenan, Jr. Professor of Biological Sciences at Columbia University  
Chair of the Department of Biological Sciences*

**Don't Miss - Your Opportunity to Meet with the Decisionmakers!**

AMG and the physician community is hosting four important fundraisers this Fall - providing you with the opportunity to meet with key elected officials and discuss what's on your mind.

Join us! Any and all physicians are invited to participate. In most cases, your society's PAC will cover your participation. Simply RSVP to the AMG staff so we can plan accordingly.

- Senate Minority Leader Tom Kean, Jr., and key Senate Republicans, including Sen. Gerry Cardinale and Senate candidate John Driscoll (who is challenging Senate Health Committee member, Sen. Bob Gordon) - Monday, September 12 - 6 pm, Forsgate Golf Club, Jamesburg
- Former Governor/Senator Richard Codey - Tuesday, September 13 - 6 pm, Forsgate GC
- Chairman of the Assembly Health Committee, Assemblyman Herb Conaway MD - Thursday, September 22-6pm, Forsgate GC
- Chairwoman of the Senate Health Committee, Senator Loretta Weinberg - Tuesday, October 4 - 6 pm, Carlyle Restaurant, E. Brunswick Hilton (off NJT exit 9)

For more information, contact Advocacy & Management Group at 609/392-7553; and click on [www.amg101.com](http://www.amg101.com) Or contact: [Bev@amg101.com](mailto:Bev@amg101.com)

**What's "hot" with the House of Medicine?**

The physician lobbying community came together in late August to discuss the "hot" issues facing the house of medicine, and craft strategy and action plans to combat or support these issues. The full agenda includes: newly proposed PIP regulations, which include a new medical fee schedule for physicians and facilities; the licensing of ambulatory surgery centers; a pilot program that would triage emergency patients away from EDs; insurance fraud legislation; and newly introduced "truth in advertising" legislation.

**Truth in Advertising**

The "truth in advertising" legislation (A-4195) requires certain health care professionals, while working in an office, to disclose to patients their name, type of license and highest level of academic degree, either in a prominent display in their office or in writing to a patient on that patient's first office visit. The bill also requires a person licensed to practice medicine or surgery by the State Board of Medical Examiners who is certified in a medical specialty to disclose, while working in an office, the name of the certifying board or association.

Additionally, the bill requires an advertisement by a health care professional for health care services to include the health care professional's name, type of license and highest level of academic degree. The bill requires certain health care professionals who provide information regarding health care services on an Internet website that is directly controlled or administered by that health care professional or that health care professional's office personnel, to prominently display on that Internet website their name, type of license and highest level of academic degree.

**September Statehouse Activities Fire Back Up Again - With Eye Towards November Election**

Now that the summer is behind us, and with it earthquakes and hurricanes (!), we focus on the end of the two year legislative session. All 120 members of the NJ State Legislature will be on the ballot this November - and we anticipate significant changes in leadership and committee appointments leading into 2012.

There will be limited activity between Labor Day and the election cycle, and following the election, we enter the crazy "lame duck" season. A rare late August Senate session prompted some activity of interest: Legislation sponsored by Sen. Loretta Weinberg which would create the New Jersey Health Care Reform Implementation Council in order to position the State to comply with new rules and regulations and reap additional federal assistance from national health care reform was approved by the Senate on August 25. It now moves to the Assembly for consideration. The bill, S-2239, would establish the NJ Health Care Reform Implementation Council as a 29-member panel of experts, policymakers, health care providers, academics and advocates to make recommendations for keeping New Jersey in compliance with the provisions of federal health care reform and ensure the State maximizes federal aid for which it is entitled. Under the bill, council members would serve for a period of five years, with the expiration of the first term in office staggered to continue the operations of the council, and would not receive compensation for their service, beyond being reimbursed for expenses incurred by them in the performance of their duties. The Council would be required to report to the Governor and the Legislature annually as to their activities and recommendations for policy.

**And over the summer...Gov. Christie inked several bills of note to the physician community:** **S-2443**, creates the "Medicaid Accountable Care Organization Demonstration Project" to ensure that Medicaid recipients in New Jersey have access to high-quality, cost-effective medical care. The law establishes a demonstration project within the Department of Human Services to increase access to primary care, behavioral health care, and dental care by Medicaid recipients in a particular region. The law will also improve the quality of health care by establishing objective metrics and relying on patient experience, and will reduce unnecessary and inefficient care without interfering with a patients' access to the health care providers and services they need to stay healthy.

The bill would authorize Accountable Care Organizations (ACOs), defined as nonprofit corporations, to provide coordinated, high-quality care to Medicaid recipients in a municipality or defined geographic region with more than 5,000 Medicaid recipients. If the program proves successful in lowering costs and improving care, the sponsors said they would consider working with the Department to establish a permanent program.

**S-2829**, criminalizing the manufacturing, distribution, sales, and possession of designer drugs labeled as "bath salts" in New Jersey. The bill, known as "Pamela's Law," was named in memory of Pamela Schmidt, a Rutgers student and resident of Warren Township, who was believed to have been murdered by an individual under the influence of "bath salts." The measure codifies previous action taken by the Division of Consumer Affairs in the Department of Law and Public Safety.

These designer drugs, labeled as "bath salts," have been associated with intense, severe side effects that have led to suicidal thoughts, self-mutilation, and violent outbursts. They are frequently marketed as "cocaine substitutes" and recently had been available for purchase on the internet and in retail establishments such as gas stations, convenience stores, and smoke shops. Unlike other legitimate substances that are misused to produce a high, like glue or gasoline, these "bath salts" have no other legitimate purpose other than as a synthetic drug.

The new law makes the following chemicals Schedule I Controlled Dangerous Substances (CDS):

- \* 3,4 - Methylenedioxypropylamphetamine (MDPV)
- \* 4 - Methylmethcathinone (Mephedrone, 4-MMC)

\* 3,4 - Methylenedioxymethcathinone (Methylone, MDMC)

\* 4 - Fluoromethcathinone (Flephedrone, 4-FMC)

\* 3 - Fluoromethcathinone (3-FMC)

\* 4 - Methoxymethcathinone (Methedrone, bk-PMMA, PMMC)

The contents of individual packets of designer drugs labeled as "bath salts" vary, but have generally been found to include at least one of these chemicals. The chemicals are synthetic derivatives of cathinone, which is already a Schedule I CDS under Federal law.

**S-2199 / A-3839** will establish the New Jersey Advisory Council on End-of-Life Care in the Department of Health and Senior Services. The advisory council will be charged with conducting a thorough and comprehensive study relative to the quality and cost-effectiveness of, and access to, end-of-life care services for all residents in New Jersey. The council will also be required to develop and present policy recommendations relating to state agencies, policymakers, health care providers, and third party payers.

In developing its recommendations, the advisory council's overriding concern will be to promote an end-of-life care paradigm in which patients' wishes are paramount and they are provided with dignified and respectful treatment that seeks to alleviate their physical pain and mental anguish as much as possible.

The advisory council will be comprised of 21 members, including: the Commissioners of Health and Senior Services and Human Services, or their designees; two members each from the Senate and the General Assembly to be appointed by the President of the Senate and the Speaker of the General Assembly, respectively, who in each case are to be members of different political parties; the Ombudsman for the Institutionalized Elderly or his designee; and 14 public members who are residents of New Jersey, to be appointed by the Governor with the advice and consent of the Senate, with a wide variety of specified backgrounds related to end of life care.

The advisory council will be required to report to the Governor and the Legislature no later than 18 months after the date of its organization on the results of its activities.

## **LEGAL REPORT**

**MARK E. MANIGAN, ESQ.**

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### **Reducing the Gap: OIG Permits Waiver of In-Patient Deductible**

In a recent Advisory Opinion (11-09), published in near identical form to an opinion issued in 2009, the Office of Inspector General ("OIG") of the U.S. Department of Health & Human Services stated that it does not object to an arrangement whereby a company licensed to provide Medigap policies contracts with hospitals to reduce or eliminate the Medicare in-patient deductible. This deductible, which would otherwise be covered under the Medigap plan, would be reduced up to 100% when an insured is admitted to an in-network hospital participating in a preferred provider organization ("PPO"). The Medigap provider would pay the PPO an administrative fee each time it receives this discount from an in-network participating hospital. Further, the savings would be shared with the policyholder in the form of a \$100 premium credit.

While the Anti-Kickback Statute prohibits remuneration in the form of waivers of Medicare cost-sharing amounts, regulations provide a safe harbor for inpatient deductibles when they are part of an arrangement with an insurer. In addition, the law provides a statutory exception for differentials in coinsurance and deductibles as part of a benefit plan design, thus allowing for the premium credit.

### **OIG: DME Supplier Arrangements with IDTFs May Implicate Anti-Kickback Statute and Trigger Sanctions**

The Office of Inspector General ("OIG") of the U.S. Department of Health & Human Services recently posted Advisory Opinion 11-08 which addresses both an existing and proposed contractual arrangement between a durable medical equipment ("DME") supplier and independent diagnostic testing facilities ("IDTFs"). The OIG determined that both arrangements could potentially generate prohibited remuneration under the federal Anti-Kickback Statute which would trigger sanctions if the requisite intent was present.

The Medicare-enrolled DME supplier sells, among other things, continuous positive airway pressure ("CPAP") blower units. Once prescribed by a physician, the patient chooses a DME supplier. Under the existing arrangement, a DME supplier enters into contracts with IDTFs, many of which have physician investors. Each contract is in writing, for a term of at least one year, and non-exclusive. Federal health care program beneficiaries are excluded from the existing arrangement. In exchange for providing services to non-federally insured patients, the DME supplier pays the IDTF a per-patient fee that reflects fair market value. The proposed arrangement was similar to the existing arrangement except: (1) federal health care beneficiaries would be included; (2) the IDTF would be paid a flat monthly/annual fee, that the DME supplier could not certify as fair market value; and (3) the IDTF would have the right to terminate the contract if it was not satisfied with the number of patients receiving services.

The OIG concluded that the circumstances surrounding the arrangements could create more than a minimal risk of fraud and abuse. In arriving at its conclusion, the OIG determined that: (1) the carve-out of federal business was not dispositive of whether the federal Anti-Kickback Statute could apply and, while the existing arrangement excluded federal health care program beneficiaries, participating IDTFs could still influence referrals of federal health care program beneficiaries to the DME supplier; (2) the arrangements do not qualify for safe harbor protection because they do not meet all of the safe harbor's required conditions; (3) direct payments to IDTFs may be problematic where IDTF staff may be in a position to influence federal health care beneficiary selection of the DME supplier's products and when physicians with financial interests in IDTFs are prescribing the DME products; and (4) the consignment component of the fee poses fraud and abuse risks because it is part of the total package of services and thus comprises some portion of the fees paid to the IDTF.

### **SHOP and Exchange - Adding Up the Change in a State-Run Insurance Market**

Progressing toward putting America's healthcare system overhaul into action, the U.S. Department of Health & Human Services ("DHHS") announced draft guidelines for states to follow in crafting state-run insurance exchanges. The Affordable Care Act ("ACA") mandates that states offer a competitive marketplace for consumers and small businesses to compare and purchase health insurance. States will host two exchanges, one for individual consumers, and one available for small businesses. States are required to go live by January 1, 2014.

Standards that employers must meet to participate in SHOP ("Small Business Health Options Program"), standards for establishing an exchange, basic functions of an exchange, and health plan participation criteria have each been illuminated as key areas by DHHS. For instance, health plans offered on the exchange must be certified as Qualified Health Plans ("QHP"), which must meet minimum standards stipulated by the ACA and the proposed rules in order to participate. Small businesses will be eligible to receive tax credits for insurance purchased on exchanges for employees.

To reduce administrative duplication of efforts, states will be permitted to partner with the federal government, or states can develop their own exchanges in conformance with federally-mandated rules. The proposed rules allow states to select whether to have the insurance exchanges run by a non-profit in partnership with other states (i.e., regional) or part of an existing state agency. The federal government has offered grants, and 48 states, including New Jersey, have accepted such grants, to plan and run insurance exchanges. Presently, Rutgers University is examining implementation strategies for New Jersey in a project commissioned by Governor Chris Christie. DHHS is accepting comments to the proposed rules until September 24, 2011.

### **CMS Releases Proposed Rules for 2012 Medicare Payments**

The Centers for Medicare & Medicaid Services ("CMS") recently published proposed rules for Medicare payments in calendar year 2012 for physician services, outpatient hospital services and ambulatory surgery services. The final rules will be published sometime in November 2011. The following summarizes some of the key proposals:

#### Physician Fee Schedule:

- Unless Congress enacts legislation otherwise, reduces Medicare payments by 29.5% due to the Sustainable Growth Rate ("SGR") formula imposed under the Balanced Budget Act of 1997
- Expands the Multiple Procedure Payment Reduction ("MPPR") policy, which currently reduces payment for the technical component associated with certain procedures performed on the same patient, on the same day and in the same setting, to include a 50% reduction in payment for the professional component for CT, MRI and ultrasound services
- Solicits comments regarding CMS's proposal to possibly expand its MPPR policy to the technical component of all imaging services, the professional component of all imaging services and/or to the technical component of all diagnostic tests, including radiology, cardiology and audiology
- Provides criteria for performing health risk assessments as part of the annual wellness visit
- Updates the Physician Quality Reporting System ("PQRS"), the e-Prescribing incentive program ("eRx"), and the Electronic Health Records ("EHR") incentive program
- Provides for quality and cost measures for a new value-based modifier ("VM") that will reward physicians for providing higher quality and more efficient care. Under this proposal, CMS would use calendar year 2013 data for purposes of adjusting payments in calendar year 2015

#### Hospital Outpatient Prospective Payment System:

- Increases Medicare payments by 1.5% for hospitals publicly reporting data on 23 quality measures, and decreases Medicare payments by 0.5% for hospitals not submitting such data
- Increases the number of quality measures that must be reported under the hospital quality reporting program; nine new measures would be added in 2012, and one new measure would be added in 2013
- Proposes a new independent review process to determine the appropriate level of physician supervision needed for outpatient therapeutic services

#### Ambulatory Surgery Services:

- Increases Medicare payments by 0.9%. This takes into account the Consumer Price Index for Urban Consumers (a 2.3% increase), as well as the productivity reduction under the Affordable Care Act (a 1.4% decrease)
- Proposes eight quality measures for implementing a quality reporting program for ASCs in 2014; ASCs that do not report quality measures would receive reduced Medicare payments

#### **CMS Releases Proposed Rules on Insurance CO-OPs**

CMS has issued proposed rules for the operation of Consumer Oriented and Operated Plans ("CO-OPs") along with standards for qualifying for nearly \$4 billion in repayable loans to help start up and capitalize on these new health plans. CO-OPs are private, non-profit insurers governed by their members and offering affordable health insurance options. The proposed rules provide an outline of the minimum standards that the applicant must satisfy in order to be eligible for a loan from the CO-OP program. The applicant must be a non-profit entity with policies and procedures in place that will foster and ensure member control of the organization. The proposed rules also contain requirements for the board of directors of the applicant.

Applicants may apply for two types of loans under the proposed program: (1) start-up loans, to assist with costs associated with establishing a CO-OP; and (2) solvency loans, to assist the applicant in meeting the solvency requirements of states in which the applicant seeks to be licensed to issue CO-OP qualified health plans. These loans must be repaid within 5 and 15 years, respectively, and the interest rates on the loans will be benchmarked to the average interest rate on marketable Treasury securities of similar maturity. Loan recipients will also be subject to

strict monitoring, audits and reporting requirements for the length of the loan repayment plus 10 years.

### **Medicaid RAC Program is Underway in New Jersey**

On July 7, 2011, the New Jersey Medicaid Fraud Division, in association with the Division of Medical Assistance and Health Services ("DMAHS"), implemented the Medicaid Recovery Audit Contractor ("RAC") program. Additionally, DMAHS is expected to issue a provider alert to introduce the choice of HMS Government Services as New Jersey's Medicaid RAC.

The Centers for Medicare & Medicaid Services ("CMS") has yet to issue final regulations governing the Medicaid RAC program. CMS has, however, advised states that they can proceed with implementation. New Jersey has chosen to move forward utilizing the proposed Medicaid RAC rules and the structure of the Medicare RAC program as the basis for the Medicaid RAC program.

### **NJ Supreme Court Upholds Denial of Property Tax Exemption for Non-Profit Entity with For-Profit Affiliates**

In a recent majority decision, the New Jersey Supreme Court held that a non-profit entity was properly denied a property tax exemption due to commingling with its for-profit affiliates. The court, in *Int'l Schools Servs., Inc. v. West Windsor Township*, found that the municipality properly denied a property tax exemption to a non-profit entity because the commingling of effort and entanglement of activities and operations between the non-profit and its for-profit affiliates was significant and substantial, with the benefit in the form of direct and indirect subsidies flowing only one way from the non-profit to the for-profit entities, conferring a competitive advantage at the expense of the taxpaying public.

### **Third Circuit Recognizes Implied False Certification Liability under the False Claims Act**

The U.S. Third Circuit Court of Appeals recently held, in *Wilkins v. United Health Group, Inc.*, that a plaintiff may bring a claim under the federal False Claims Act ("FCA") even without evidence that a claimant for government funds made an express false statement in order to obtain those funds. In doing so, the court joined other circuit courts in holding that a plaintiff may bring a FCA suit under the so-called implied false certification theory of liability. Under this theory, a FCA violation occurs when a claimant seeks and makes a claim for payment from the government without disclosing that it violated regulations that affected its eligibility for payment from the government.

In *Wilkins*, two relators brought a qui tam action alleging violations of the FCA by their former employers, alleging that they violated the FCA by offering illegal kickbacks to physicians in violation of the federal Anti-Kickback Statute and by failing to comply with Medicare marketing rules. In determining whether compliance with a regulation is a condition of payment from the government, the court distinguished between statutes and regulations which are conditions of payment of Medicare funds from those that are only conditions of participation in the Medicare programs. The court found that whereas compliance with the marketing regulations is only a condition of participation, compliance with the Anti-Kickback Statute is a condition of payment under Parts C and D of Medicare. In addition, Medicare regulations specifically name the Anti-Kickback Statute as a statute that is designed to prevent or ameliorate fraud, waste, and abuse.

### **Medicare Fraud Scheme Foiled: New Jersey Man Admits Posing as Doctor and Treating Elderly Patients**

On July 11, 2011, Patrick Lynch of Toms River, New Jersey pled guilty and admitted to unlawfully treating patients, prescribing medicine and ordering procedures while posing as a licensed physician. Pursuant to documents filed in the case and statements made during the guilty plea proceeding, Lynch created Visiting Doctors of New Jersey to provide medical care for elderly home-bound patients in the Monmouth and Ocean County areas. Since Lynch was neither a licensed physician nor a nurse practitioner, he hired licensed individuals to conduct patient visits. However, when Lynch failed to pay the licensed physicians and nurse practitioners, they quit. Lynch continued to carry on the business by posing as the licensed professionals, using their names and government-issued identification numbers to write prescriptions and submit billings to Medicare. Sentencing (including determinations of possible jail time, monetary penalties and restitution) is scheduled for October 17, 2011.

### **New Jersey Bill Establishes ED Triage Referral Pilot Program**

A bill sponsored by Senators Robert W. Singer and Joseph F. Vitale (S2973) was recently introduced that would

establish a two-year "Emergency Department Triage Referral Pilot Program" in the New Jersey Department of Health and Senior Services ("DHSS").

The purposes behind the program are (1) to evaluate the feasibility of curbing inappropriate use of hospital emergency departments by mandating the referral of patients who seek non-emergency or non-urgent care at emergency departments to federally qualified health centers ("FQHCs") and other primary care providers, and (2) to ensure that patients receive treatment and follow-up care that is more suitable to their needs and in a cost-effective manner.

The pilot program would be established in six general hospitals in the state, two in each of the northern, central and southern areas of the state. A general hospital in the state interested in participating in the pilot program would apply directly to DHSS. We will continue to monitor the progress of this bill as it continues through the legislative process.

### **New Physician Assistant Rules Adopted in Part and Rejected in Part**

Last year, the New Jersey State Board of Medical Examiners ("BME"), in consultation with the Physician Assistant Advisory Committee, proposed two amendments to N.J.A.C. 13:35-2B, concerning physician assistants ("PAs"). The first amendment would have allowed PAs to refer patients to health care practitioners, facilities and other appropriate agencies and resources in the community, instead of "facilitating the referral" of such services. The second amendment provided for the supervisory ratio of four PAs to one physician in all settings. Under the then-current rules, in a private practice the supervisory ratio was two PAs to one physician, and in all other settings the ratio was four PAs to one physician.

Commenters to the proposed rules remarked that allowing PAs to make referrals would be in direct violation of the PA licensing Act at N.J.S.A. 45:9-27.16a(6), which specifically limits the referral power of PAs to facilitating the referral of patients. The BME agreed with the commenters and decided not to adopt that proposed amendment.

However, the BME did adopt the amendment relating to the supervisory ratio of four PAs to one physician in all settings. Certain commenters had objected to this amendment as well, but the BME stated that this was a maximum ratio and that a physician could still limit his or her supervision of PAs based upon his or her professional judgment and bearing in mind that the physician retains full responsibility for the practice of the PAs that he or she supervises. The BME also made clear in its comments that the supervisory relationship is no more than four PAs to one physician at any one time and that a physician may actually work with more than four PAs, so long as he or she is not supervising more than four at the same time.

### **Volatile Markets**

In my last article I discussed some of the economic concerns that I have. The fear being that anyone of them could lead to a decline in the markets and your portfolios. Especially for those of you invested in the typical long-only mix of stocks, bonds, and cash. I recommended that now could be a good time to add some "alternative" investments to your portfolio. The benefit being that many alternatives don't move in the same direction as the market. Many of them can actually make money when the markets are going down.

Here is how a few of the alternative investments fared over the last 4 weeks ending 8/26/11.

Hedged Equity	+5.20%
Global Macro	+3.26%
Precious Metals	+2.65%
Managed Futures	+2.34%

Compare these numbers to the negative (11.45%) that the S&P returned over the same time period. Obviously, past performance does not guarantee future returns. However, having exposure to alternatives has proven to reduce volatility and provide better protection during market declines.

Bill Gross, of PIMCO, has frequently stated, that "we are in a new normal". He predicts that the next decade will be one of slow or non-existent growth, high unemployment, and sub-par market

returns. Slow economic growth typically does not bode well for portfolios that invest in the typical mix of stocks, bonds, and cash. In order to be successful investors will also need to have exposure to other asset classes and strategies. If you have yet to implement some of the "alternative" investments now might be a good time to do so.

As always, if you have any questions or would like a 2nd opinion on your current situation, please contact me at (877)972-7900 or [dvargo@varbeco.com](mailto:dvargo@varbeco.com)

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