Vascular Society of New Jersey

Monthly Report- July/August 2011

From the President — Paul B. Haser, MD

As Lady Liberty celebrates her 125th birthday, (and the Nation its 235th), the VSNJ is moving into its 34th year of existence, running parallel to the beginning of formalized training fellowships for vascular surgery. While the issue of improving education and funding/reimbursement remain central to our Society's goals, so do the ideas of membership, collaboration - (especially strength through numbers), and expanding our presence in the care of an increasing number of patients we will be required to see. I would urge you to celebrate your participation in VSNJ as you celebrate our Independence Day. You do make a difference! Pass this along to the other vascular surgeons you work with on a day-to-day basis.

Below you will find valuable information from both the political, legal and financial experts - these things bear reading and are part of the value-added worth of your membership. Be assured, your board of directors is working very hard to try to protect your rights and champion your concerns.

SAVE THE DATE

October 27, 2011

Vascular Society of New Jersey
Annual Meeting

with keynote speaker:

Martin Chalfie

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

From the Statehouse — Bevery Lynch & AJ Sabath, Advocacy & Management Group

November 8, 2011 … an important day to the New Jersey physician community! The entire New Jersey State Legislature (all 80 members of the Assembly and 40 members of the State Senate) are on the State ballot.

With the breadth and scope and severity of issues facing the New Jersey physicians, it's imperative that we (a) VOTE, and (b) work together to elect legislators who are supportive of your issues.

We have been hosting "Physicians for..." receptions over the past few years - and they are meeting with resounding success. It's an opportunity for you to speak directly with key legislators (who serve on health and

insurance-related committees, and serve in leadership) about the house of medicine and your specialty.

This Fall, prior to the elections, we will be hosting several new events. Mark your calendar now:

- ✓ Senate Minority Leader Tom Kean, Jr., and the Senate Republicans - Monday, September 12 - Forsgate Golf Club, Jamesburg
- ✓ Former Governor/Senator Richard Codey - Tuesday, September 13 - Forsgate GC
- ✓ Chairman of the Assembly Health Committee, Assemblyman Herb Conaway MD - Thursday, September 22, Forsgate GC
- ✓ Chairwoman of the Senate Health Committee, Senator Loretta Weinberg - Tuesday, October 4 - Central Jersey Location to be determined

More information to follow....but for now, please plan to attend these important educational events.

Bill to License One-Room Surgical Practices Advances

The Senate has passed a bill (S-2780) that would license one-room surgical practices and require the same level of oversight and regulation reserved for larger facilities. The measure is sponsored by Senator Joseph F. Vitale, the vice chairman of the Senate Health, Human Services and Senior Citizens Committee.

The bill would make changes to the laws governing regulation and licensing of health care facilities in New Jersey. Under the bill, all health care facilities in New Jersey would be required to possess a valid license from the State Department of Health and Senior Services which specifies the kind of services the facility is authorized to provide. Amendments were made to the bill to require all one-room surgical practices to be certified by the Centers for Medicare and Medicaid Services (CMS) or seek a waiver from the Commissioner of the Department of Health and Senior Services. The Ambulatory Surgery Tax would not apply to one-room surgical practices that would be licensed under the amended bill.

According to Senator Vitale, the legislation was prompted by New Jersey Health Care Quality Institute report on random inspections conducted by the Department of Health. Of the 40 one-room facilities, which were inspected for the report, 17 were found to be in "immediate jeopardy" and seven were temporarily closed. According to the report, violations included: not having mandated emergency equipment and medications on site; no tracking of controlled and regulations medications such as narcotics; physicians and staff not having proper licenses or credentials; not cleaning or sanitizing surgical instruments correctly; and using single use items more than once, on more than one patient.

Out of State Benefit Ban Nixed

The much ballyhooed reform of State health and pension benefits has been signed into law, without the controversial ban on securing health care outside of the New Jersey State borders. That provision was removed from the final version of the bill.

SURGICAL TECH CERTIFICATION ADVANCES

The New Jersey Senate and Assembly have passed legislation (S-2817/A-3946) that would prohibit a health care facility from employing or retaining an individual to perform surgical technology unless the individual has:

- ✓ successfully completed a nationally accredited education program for surgical technologists and holds and maintains a certified surgical technologist credential administered by the National Board of Surgical Technology and Surgical Assisting, its successor, or a nationally accredited credentialing organization;
- ✓ completed an appropriate training program for surgical technology offered by a branch of the military or the United States Public Health Service Commissioned Corps;
- ✓ provided evidence of employment practicing surgical technology in a health care facility on the effective date of the bill; or
- ✓ practiced surgical technology within the scope of his official duties as a federal employee.

Under the bill, an individual may continue to be employed or contracted to practice surgical technology in a health care facility in this State during the 12-month period immediately following his successful completion of a surgical technology program; however, the individual may not maintain employment with the health care facility beyond that 12-month period without providing the employer with documentation of the certified

surgical technologist credential.

Individuals who have completed training via a branch of the armed forces or the United States Public Health Service Commissioned Corps, or who provide evidence that they were employed to practice surgical technology in a health care facility on the effective date of the bill must complete 15 hours of continuing education annually. The bill further provides that a health care facility that employs individuals to practice surgical technology must verify, where applicable, that they meet the continuing education requirements, and, where applicable, have successfully completed a nationally accredited educational program for surgical technologists and possess the requisite credential.

The term "surgical technologist" is defined in the bill to mean a person who practices surgical technology. "Surgical technology" means surgical patient care that includes, but is not limited to, the following tasks or functions:

(1) preparing the operating room by ensuring that surgical equipment is functioning properly and safely;

(2) preparing the operating room and sterile field by preparing supplies, instruments, and equipment using sterile technique;

(3) anticipating the needs of the surgical team based on knowledge of human anatomy and pathophysiology and their relation to the patient and the procedure; and

(4) as directed, performing various tasks at the sterile field.

LEGAL REPORT MARK E. MANIGAN, ESQ.

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OIG Continues to Scrutinize Contractual Joint Ventures

In its Advisory Opinion No. 11-03, the Office of Inspector General (OIG) indicated that it will continue to scrutinize suspect contractual joint ventures, finding that a proposed arrangement whereby a long-term care pharmacy would enter into a new business with the owners of its long-term care facility customers, to provide the same services currently provided by the pharmacy, could potentially generate prohibited remuneration under the federal anti-kickback statute and subject the parties to administrative sanctions.

The requestor, a long-term care pharmacy that provides pharmaceutical products and services to long-term care facilities, sought guidance as to a proposed arrangement whereby one of its employees, together with the owners of its long-term care facility customers, would form a new long-term care pharmacy to provide the services that the requestor currently provides to these same customers. Under the proposed arrangement, the new company would not have any employees, but instead would enter into a management agreement with the requestor (with a management fee at fair market value) pursuant to which the requestor would provide all personnel and day-to-day services necessary for the new company to service its long-term care facility customers. The new company would engage in the same exact business as the requestor, and any dividends or distributions in the new company would be paid to its owners in proportion to share ownership in the new company.

The OIG first addressed problematic contractual joint ventures in a 1989 "Special Fraud Alert on Joint Venture Agreements" (reprinted in 1994), citing concerns about certain problematic joint venture agreements between those in a position to refer business and those furnishing items or services for which Medicare or Medicaid pays, especially when all or most of the business of the joint venture is derived from one or more of the joint venturers. The OIG issued additional guidance on suspect contractual joint ventures in 2003 in a Special Advisory Bulletin titled "Contractual Joint Ventures," finding that these problematic arrangements typically exhibit certain common elements: (i) a health care provider in one line of business expands into a related health care business which is dependent on referrals from, or other business generated by, the provider's existing business; (ii) the provider neither operates the new business itself nor commits substantial financial, capital, or human resources to the venture (instead contracting

out substantially all the operations of the new business); (iii) the manager of the new business is an established provider of the same services as the provider's new line of business; (iv) the provider and the manager share in the economic benefit of the provider's new business; and (v) the aggregate payments to the manager typically vary with the value or volume of business generated for the new business by the provider (despite certain fees, like management service fees, being fixed).

The OIG felt that the proposed arrangement in this case had many of the common elements that are found in suspect joint ventures. Like the provider in the Special Advisory Bulletin, the long-term care facility owners in the proposed arrangement would be expanding into a new line of business that would be dependent on referrals from the long-term care facilities, they would not actually participate in the operations of the new pharmacy but rather would contract out substantially all of the company's operations to the requestor, and the actual financial and business risk to the long-term facility owners would be minimal or non-existent because they would control the amount of business they would refer to the new pharmacy. Based on these facts, the OIG found that there was a significant risk that the proposed arrangement would be an improper joint venture that would be used as a vehicle to reward the long-term care facility owners for their referrals.

Proposed Registration Requirements for Surgical Practices - What Now?

Surgical practices may soon be required to comply with new registration requirements recently proposed by the New Jersey Department of Health and Senior Services (DHSS). While providing some guidance, the proposed regulations also leave many questions unanswered.

Under the proposed regulations, a one-room surgical practice that is designed to furnish invasive diagnostic and surgical procedures must register with the DOHSS. It is unclear what type of invasive diagnostic procedures will require registration. Existing surgical practices must register within 90 days of the effective date of the regulation, once adopted. A proposed surgical practice that had its plans filed prior to September 17, 2009, must register prior to commencing operations.

Registration includes completing a Surgical Practice Application form, which includes identifying the class of operating room, as defined by the then-current Guidelines for Design and construction of Health Care Facilities, published by the American Society of Healthcare Engineering of the American Hospital Association (the "Guidelines"). Operating rooms are classified as A (minimal sedation), B (moderate sedation), or C (deep sedation). It is unclear whether all classes of operating rooms must be registered, how the DOHSS will distinguish between these operating room classes, and whether square footage and other requirements set forth in the Guidelines will impact registration.

In registering, the surgical practice must also disclose: (1) the number of surgical patients served by payment source, such as private insurance, medically indigent, Medicare, Medicaid, and private pay; (2) the number of surgical patients accepted since the prior registration; (4) the number of surgeons, anesthesiologists, other physicians, advanced practice nurses, physician assistants, and registered nurses involved in the surgical practice; and (4) verification of certification by the Center for Medicare and Medicaid Services or by an appropriate accrediting organization. Registration must be renewed annually.

The proposed regulations also set for guidance for transfers of ownership, as well as relocations of an existing registered surgical practice, which may be permitted within 20 miles of the practice's existing location or to an underserved area designated by the DOHSS.

Any suspension, revocation, or denial of a registration will be subject to appeal under the New Jersey Administrative Procedure Act.

Federal EMTALA Law Trumps New Jersey State CON Requirement

An administrative law judge (ALJ) found that a New Jersey hospital's obligation to obtain a state Certificate of Need (CON) before performing angioplasties was pre-empted by the federal Emergency Medical Treatment and Active Labor Act (EMTALA), which requires hospitals to give emergency care to anyone needing treatment, regardless of ability to pay. Under the New Jersey Health Care Facilities Planning Act, a hospital is required to obtain a CON before constructing or expanding facilities or instituting new services.

In *Warren Hospital v. Dept. of Health and Senior Services*, HLT 13991-08, the ALJ reversed a $5,000 fine imposed by the Department of Health and Senior Services (DHSS) on Warren Hospital, located in Phillipsburg, for performing angioplasties on two emergency room patients despite not possessing a CON to perform cardiac surgery or primary angioplasty. Instead of transferring the patients to nearby Easton Hospital in Pennsylvania, as is the usual procedure for patients at Warren Hospital who require cardiac surgery and primary angioplasty, the treating cardiologist performed the angioplasties because he believed that each patient would have died without such care.

The ALJ found that the hospital had a legal duty under EMTALA to stabilize the patients before releasing or transporting them. Because the enforcement of the CON requirement was in direct conflict with this duty, the ALJ held that EMTALA pre-empted this requirement and that Warren Hospital acted appropriately under the circumstances. The case will be forwarded to the Commissioner of the DHSS, who can accept, modify or reject the findings.

Worker and Community Right to Know Act Rules Adopted without Change

The New Jersey Department of Health and Senior Services (DHSS) adopted, without change, the Worker and Community Right to Know Act rules found at N.J.A.C. 8:59. The purpose of the act is to provide for the disclosure of information about hazardous substances in the workplace and in the community, as well as provide public access to this information. The act also provides local health, fire, police, safety and other government officials with the identity, characteristics, and quantities of hazardous substances used and stored in communities within their jurisdictions, in order to adequately plan for and respond to emergencies.

The adopted rules will continue to impose certain labeling requirements on both private and public employers regarding hazardous substances in the workplace and in the environment that are not found under federal law. Requirements under the rules include the maintenance of an inventory of hazardous substances at public employer facilities on survey forms, labeling of containers at covered private and public employer facilities and making surveys and hazardous substance fact sheets available to employees, emergency responders and community residents.

The DHSS claims that despite the additional costs to employers associated with complying with the rules, the rules have reduced illnesses and injuries among public employees, have prevented and reduced damage to physical facilities and the environment and have enabled emergency responders to respond more appropriately and quickly to reduce personal injury and damage to physical property and the environment from fires and spills involving hazardous materials.

CMS Rule Allows States to Stop Payments for Preventable Conditions

On June 1, 2011, the Centers for Medicare & Medicaid Services (CMS) issued a final rule that provides states with the capacity to curtail Medicaid payments to doctors, hospitals and other providers for services that result from certain preventable health care acquired conditions. The final rule will be effective July 1, 2011, but states have until July 1, 2012 for full implementation.

The final rule enacts a provision of the federal health reform law that bars states from paying health care providers for conditions deemed reasonably preventable. It uses Medicare's list of preventable conditions in inpatient hospital settings as the base (adjusted for the differences in the

Medicare and Medicaid populations) and gives states the flexibility to identify additional preventable conditions and settings for Medicaid payment denial.

Pursuant to the final rule, states are required, at a minimum, to adopt the Medicare list, but it also permits them to implement more rigorous laws or regulations if approved by CMS. Conditions on the list where payments will be denied include the following:

- Foreign Object Retained After Surgery
- Air Embolism
- Blood Incompatibility
- Stage III and IV Pressure Ulcers
- Falls and Trauma
- Catheter-Associated Urinary Tract Infection (UTI)
- Manifestations of Poor Glycemic Control
- Surgical Site Infection
- Deep Vein Thrombosis (DVT)/Pulmonary Embolism

Proposed HIPAA Regulations Would Allow People to Discover Who Accessed Their PHI

On May 31, 2011, the Office of Civil Rights issued a Notice of Proposed Rulemaking ("NPRM") amending certain HIPAA regulations, pursuant to the HITECH Act, that would give an individual the right to obtain a report from a covered entity that explains who has electronically accessed the individual's protected health information ("PHI"). The access report would be required to contain: (a) the date of access; (b) the time of access; (c) the name of the natural person or entity accessing the information; (d) a description of the information that was accessed; and (e) a description of any actions taken by the user (e.g. modifying, adding, or deleting information). The proposed rule would require a covered entity to provide an individual with a report within 30 days of receipt of a request. An individual may request one access report within a 12-month period at no charge, with any subsequent requests subject to a reasonable fee.

The NPRM also affords an individual the right to receive from a covered entity, a written accounting of disclosures of PHI made within three years of the date of the request for the following reasons: (1) for public health activities; (2) for judicial and administrative proceedings; (3) for law enforcement purposes; (4) to avert a serious threat to health or safety; (5) for military and veterans activities; or (6) for workers' compensation. For each disclosure, the accounting must include: the exact date, if known, or if not known the approximate date of the disclosure; the name and address of the entity or natural person who received the disclosure; and a brief description of the type of PHI that was disclosed. Similar to the access report, the accounting must be received within 30 days of the receipt of the request. Also, the first accounting report delivered to an individual will be at no charge, but a covered entity may charge a reasonable fee for subsequent requests in the same 12-month period.

Comments to the NPRM are due on or before August 1, 2011, and may be submitted electronically through the Federal eRulemaking Portal at http://www.regulations.gov, or by regular, express or overnight mail to: U.S. Department of Health and Human Services, Office for Civil Rights, Attn: HIPAA Privacy Rule Accounting of Disclosures, Hubert H. Humphrey Building, Room 509F, 200 Independence Avenue SW, Washington D.C. 20201.

The Department of Health and Senior Services is urging seniors that are Medicare Part B beneficiaries take a pledge that they will call their doctor within the next 30 days to make an appointment for their annual wellness visit, a new, free service covered by Medicare Part B.

Additionally, DHSS is trying to ensure seniors are aware of other preventive services available to Medicare Part B beneficiaries that effective January 1, 2011 are now free or at a reduced-cost. These services include specific health screenings, diagnostic tests and immunizations.

Please review the links to the brochure & wellness pledge:
http://nj.gov/health/senior/documents/wellness_brochure.pdf
http://web.doh.state.nj.us/apps2/seniorpledge/index.aspx

Nine Causes of Slow Global Growth in Future Years

One of the primary risks to your assets is a declining or sideways investment market. There are many potential obstacles that could stand in the way of the success of the typical long-only, buy and hold, stocks/bond/cash portfolio. Besides my 3 biggest concerns- the high unemployment rate, our high debt levels, and the European crisis- economist Gary Shilling gives us 9 more issues to keep an eye on.

1. U.S. consumers will shift from a 25-year borrowing-and-spending binge to a saving spree. This will spread abroad as American consumers curtail the imports of the goods and services many foreign nations depend on for economic growth.

2. Financial deleveraging will reverse the trend that financed much global growth in recent years.

3. Increased government regulation and involvement in major economies will stifle innovation and reduce efficiency.

4. Low commodity prices will limit spending by commodity-producing lands.

5. Developed countries are moving toward fiscal restraint.

6. Rising protectionism will slow-even eliminate-global growth.

7. The housing market will be weak due to excess inventories and loss of investment appeal.

8. Deflation will curtail spending as buyers anticipate lower prices.

9. State and local governments will contract.

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 that I have previously written about now might be a good time to do so.

As always, if you have any questions or would like any additional information please contact me at (877)972-7900 or dvargo@varbeco.com.

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