New Jersey Academy of Otolaryngology-Head & Neck Surgery New Jersey Academy of Facial Plastic Surgeons

March 2014

Save the Date!

2014 Annual Meeting Friday, June 13, 2014

Please note new location!

Seaview Hotel & Golf Club

Galloway, NJ



From the Statehouse

Advocacy and Management Group

CHRISTIE FOCUSES ON MEDICAID IN FY2015 BUDGET MESSAGE

On February 25, Governor Christie presented his Budget Address for Fiscal Year 2015 before the New Jersey State Legislature. For the fifth year in a row, the Governor has proposed a policy of "no new taxes." The Fiscal Year 2015 budget includes \$34.4 billion in spending, which is 4.2 percent higher than the FY 2014 budget signed by Governor Christie.

The Governor proposed additional funding for New Jersey education, totaling \$12.9 billion with \$9 billion in direct school aid. He proposed more than \$1.2 billion in direct property tax relief to New Jersey's homeowners, seniors and disabled residents. An additional \$4.5 million has been recommended to expand New Jersey's mandatory drug court program and funding for substance abuse treatment centers. Approximately \$8.5 million has been suggested to assist local

governments engaged in consolidation and shared service.

Governor Christie discussed the \$12 billion in federal and state funding to provide coverage for 1.4 million New Jerseyans on Medicaid and NJ FamilyCare, with a \$21 million increase to NJ Family Care. New Jersey will receive matching dollars from the federal government due to the state's participation in the Medicaid expansion offered through the Affordable Care Act.

The highest costs in Medicaid and FamilyCare come from individuals with chronic emergency room visits, repeat inpatient hospital stays, and those who face complications of treatment for multiple complex behavioral, mental health and substance abuse conditions.

- More than 16,000 Medicaid recipients visited emergency rooms six or more times last year.
- Almost 7,000 Medicaid recipients had 3 or more hospital inpatient stays last year.
- More than 5,000 of the highest use Medicaid recipients had care for a primary behavioral health diagnosis.
- 5% of New Jersey's Medicaid recipients account for 50% of the programs costs.
- More than 27% of New Jersey's Medicaid and FamilyCare spending is dedicated to just 1% of enrollees.

New Jersey will look to address ways in which to make the system more cost effective, while preserving standards.

A three year accountable care organization pilot program is in place to assess how care management and coordination has assist in lowering costs. Rutgers Biomedical and Health Sciences, University Hospital and Rutgers Camden will join New Jersey's Medicaid managed care organizations to devise a program to innovate and improve health care delivery under Medicaid and FamilyCare. The Center for Medicare and Medicaid Services (CMS) recently awarded Rutgers with a \$14 million grant to study strategies for "super-utilizers" to decrease costs and improve quality of care. Rutgers' examination will result in recommendations to the Governor and the Commissioners of the Department of Human Services and Department of Health for enhancing New Jersey's programs, improving quality of care, advancing preventative care and lowering costs.

These budget proposals, as well as others, will be considered by the legislature in April 2014. The budget must be signed before July 1, 2014.

BOARD OF MEDICAL EXAMINERS DEBATES USE OF "DR."

In February, the New Jersey State Board of Medical Examiners (BME) discussed whether physician assistants with doctoral degrees are permitted to be called "doctor" in hospitals, medical offices and other clinical settings. Many, including BME Board Member Kevin Walsh, a physician assistant, claimed that the proposal would avoid confusion among patients. The Medical Society of New Jersey also supported limiting the use of the term to M.D.s and D.O.s only. If approved by the BME, physician assistants would also be barred from using the title on stationary and prescriptions. The BME Executive Committee will consider the proposal and may recommend adoption at a future meeting.

ACA UPDATE: EMPLOYER MANDATE DELAYED

In February, the Obama Administration announced yet another delay to the Affordable Care Act, this time delaying the mandate for medium size employers. The employer mandate, which was expected to take effect January 2014, has been delayed to 2015.

- Employers with 50-99 employees will not have to comply with the coverage requirement until 2016, but will have reporting requirements.
- Employers with 100+ employees will need to offer coverage to 70 percent of full-time employees in 2015 and 95 percent in 2016 and later years, or be subject to tax penalties.
- Employers with fewer than 50 employees are exempt from the requirement to offer coverage or fill out any forms in 2015 or thereafter.

ALERT: FDA CRACKS DOWN ON SALE OF ILLEGALLY IMPORTED DRUGS

The US Food and Drug Administration and other law enforcement agencies are cracking down on physicians who are buying illegally imported drugs and selling them in the United States.

In November, the Food and Drug Administration's Office of Criminal Investigations announced guilty pleas by several individuals for importing and selling misbranded drugs. This followed an August announcement from the US Department of Justice that seven Ohio doctors were charged with violating the Food, Drug and Cosmetic Act (FDCA) by importing cancer medications that had not been approved by the FDA, as well as the guilty plea of a Florida man for conspiring to import unapproved foreign oncology drugs.

As is the adage, "if it is too good to be true, it probably is," so is the purchasing of illegally imported drugs. This illegal practice, which is driven globally by criminal syndicates, violates Federal and State law and places medical professionals in danger of losing their medical license or litigation if a patient suffers injury from using these illegally imported products.

How does this happen? As is common practice, pharmaceutical companies ship their products all over the globe. Some foreign governments have the ability to apply cost controls to the sale of these products, thus selling them for a cost far below the market dictated price. When these products are delivered to a medical professional wholesaler, they are then being re-sold - in many cases to organized crime - and thus leaving the secure supply chain of custody. Once in the hands of these unscrupulous actors, they are being shipped back to a remote a location, often times without the safety precautions that are provided by drug companies and are required by the FDA. Once secured at an undisclosed location, they are illegally imported into the United States, many times through a "Canadian Pharmacy."

Why is this a concern? First and foremost, the aforementioned practice violates several Federal and State laws -and as has happened - could subject a medical professional to prosecution and/or loss of their medical license. Patient safety is also an enormous concern. The FDA places several specific requirements on pharmaceutical companies to ensure that the public is going to receive products that are safe to ingest/inject. By removing these products from the chain of custody, there is little assurance that these products have not been tampered with or adulterated in some manner.

In the last several months, we have witnessed these illegal actors going to great lengths in an attempt to make their business practices look legitimate. This includes using counterfeit packaging, false advertising and in some cases actually hiring a sales staff to visit medical professionals.

As a result, the Food and Drug Administration ("FDA") and Department of Justice ("DOJ") have started to track down these illegal actors. There have been instances where illegal importing companies have been raided and have had their operations destroyed. More importantly, law enforcement is also investigating medical professionals and, as a result, several indictments have been issued against those who have shown a blatant disregard for the law.

If you are e-mailed/faxed/approached to purchase a pharmaceutical product and it seems "to good to be true" make sure you contact the maker of that product to ensure its legitimacy.

If you believe you have been sold, or solicited to purchase, illegally imported drugs, you can report this suspected criminal activity to the FDA's Office of Criminal Investigations (OCI) by calling 1-800-551-3989 or visiting the OCI website.

Legal Report

Kern Augustine Conroy & Schoppmann, PC

DaVita Announces Settlement in Works

DaVita HealthCare Partners has reportedly announced to its shareholders that it has agreed to a framework for settling federal investigations into its arrangements with referring physicians. DaVita states it will pay \$389 million to settle criminal and civil anti-kickback charges and will unwind eleven joint ventures with nephrologists involving 28 dialysis clinics. The settlement also will include the appointment of an independent compliance monitor as well as restrictions on future joint ventures with physicians.

OIG Releases Work Plan for 2014

The U.S. Department of Health & Human Services Office of Inspector General (OIG) has issued its Fiscal Year 2014 Work Plan. The Work Plan provides a map of the areas of continuing or new scrutiny by the OIG. Among the areas being scrutinized, OIG will review the extent to which physicians and suppliers participated in Medicare and accepted claim assignment during 2012 and assess the effects of their participation and claim assignments on the Medicare program (such as noncompliance with assignment rules) and on beneficiaries (such as excessive billing of beneficiaries' share of charges). Another continuing area of focus is physician place-of-service coding errors. The OIG will review physicians' coding on Medicare Part B claims for services performed in ambulatory surgical centers and hospital outpatient departments to determine whether they properly coded the places of service. Other areas under review are sleep testing, high cost diagnostic radiology testing, and electrodiagnostic testing. A new area of focus is CMS payment for compounded drugs. The Work Plan can be accessed at: http://ow.ly/tL1Lx. Physicians should study the Work Plan to better focus their own compliance efforts.

CMS Clarifies "Two Midnight" Rule

The Centers for Medicare & Medicaid Services (CMS) issued its so-called "two midnight" rule last fall as

part of the 2014 Inpatient Prospective Payment System Final Rule. The rule sets forth the requirements for physician documentation regarding the expectation of a patient's length of hospital stay. A patient must stay in a hospital for two consecutive midnights before CMS will reimburse the hospital at inpatient rates. Implementation of the rule has now been delayed until October 2014. CMS has issued further clarification of the two midnight rule. Among other things, CMS has clarified that, although other practitioners can enter admission orders into the record, an admitting physician must countersign the order before the patient is discharged. For more details, see: http://ww.ly/tL1Qy.

Chiropractic Board Proposes Amendments to Testing Rules

The New Jersey Board of Chiropractic Examiners has proposed readoption of its practice rules, including a proposal to amend the definition of "special examination" to confirm the Board's approval of vestibulo-ocular nystagmus testing as a special examination that chiropractors may perform. The Board also proposes an amendment to require that licensees who seek to perform electrodiagnostic tests or specific special examinations complete a course, preapproved by the Board, that consists of course work and practical, hands-on instruction and an examination that demonstrates that the licensee is capable of recognizing scientifically supportable and practical indications for the test; has knowledge in the proper administration of the test; possesses skill at proper interpretation of the test; and has obtained training in how to integrate the test results into management of the patient's condition and further would require that a licensee apply to the Board for certification to perform electrodiagnostic tests or special examinations within 60 days after successful completion of an approved course. See the proposal at: http://ow.ly/tL1Va.

For more information on the above items, contact Bob Conroy (<u>RConroy@DrLaw.com</u>) or Nan Gallagher-Auferio (<u>NGallagher@DrLaw.com</u>) at Kern Augustine Conroy & Schoppmann, P.C. at 1-800-445-0954 or via email at info@DrLaw.com.