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

January 2013

Save the Date!

2013 Annual Meeting

April 10, 2013

PNC Bank Arts Center

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From the Statehouse Advocacy and Management Group

NO HEALTH EXCHANGE FOR NEW JERSEY

Earlier this month, Governor Christie vetoed legislation that would enact New Jersey's health benefit exchange-a key component of the Affordable Care Act. Christie stated that he was waiting for answers from the U.S. Department of Health regarding the cost of the exchange to the state. Those answers did not come soon enough, and New Jersey did not meet the December 14 deadline for states to determine whether they will operate their own exchange. But New Jersey is not alone. Only 18 states and the District of Columbia will have a state run exchange in 2014. The U.S. Department of Health and Human Services will fully run or co-run the exchanges for the remaining states. New Jersey is one of four states that has not announced whether it will allow the federal government to fully run the exchange or whether it will participate in a state-federal partnership.

FISCAL CLIFF THREATENS RESIDENCY FUNDING

Among the many uncertainties caused by the potential "fiscal cliff," New Jersey graduate medical education funding could also be at risk. Based on a recent report by NJBiz, New Jersey could see a $67 million budget cut that will threaten the state's funding to train new physicians. The cut would come out of Medicare funding to the state, which also supplements new physician training. In 2012, New Jersey received more than $250 million from Medicare for such training. The state receives approximately $526 million annually to fund residencies from Medicare, Medicaid, charity care and other sources. It is estimated to cost nearly $1.2 billion annually to train the over 3,000 residents in the state, according to the New Jersey Council of Teaching Hospitals.

Legal Report **Kern Augustine Conroy & Schoppmann, PC**

FDA Issues Warning on Foreign-Supplied Botox: On December 19, 2012, the U.S. Food & Drug Administration (FDA) issued an alert regarding the risks of purchasing unapproved versions of Botox™ and other medications from foreign or unlicensed suppliers. Specifically, the FDA announced that on November 30, 2012, it sent letters to 350 medical practices across the United States that it believed had received such unapproved medications. The letter advised that medications obtained from Quality Specialty Products (QSP), A+ Health Supplies, QP Medical, Bridgewater Medical, Clinical Care, or other foreign or unlicensed suppliers may be from unknown sources, may have unknown ingredients, may be counterfeit, or may not have been manufactured, transported or stored under proper conditions as required by U.S. law, regulations, and standards. The FDA alert urges the health care community to examine its purchasing practices to make sure that products are purchased directly from the manufacturer or from state-licensed wholesale drug distributors in the United States. In addition, the receipt of suspicious or unsolicited offers from unknown suppliers should be questioned, and extra caution should be taken when considering them. To read the alert and link to a January 2012 FDA letter on how to identify whether drug distributors or the products received from them are legitimate, go to the FDA's webpage at: http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm330610.htm#2. To verify that a wholesale drug distributor is licensed in New Jersey, check http://web.doh.state.nj.us/apps2/FoodDrugLicense/fdSetSearch.aspx.

DOJ Sets Record for Health Care Fraud Recoveries: The U.S. Department of Justice (DOJ) has announced that FY2012 was another record-breaking year, securing $4.9 billion in settlements and judgments in civil cases involving fraud against the government. DOJ's 2012 efforts included a second straight year of record recoveries for health care fraud, where recoveries topped $3 billion for the first time in a single fiscal year. The increased incentives for whistleblowers have led to an unprecedented number of investigations and greater recoveries. Of the $4.9 billion in fiscal year 2012 recoveries, a record $3.3 billion was recovered in whistleblower suits. In fiscal year 2012 alone, relators filed 647 *qui tam* suits. At the same time, in its Semiannual Report to Congress, the Department of Health & Human Services Office of Inspector General (OIG) announced expected recoveries of about $6.9 billion from audits and investigations for the second half of FY 2012 alone. In FY 2012, OIG excluded 3,131 individuals and entities from participation in Federal health care programs and reported 778 criminal actions

against individuals or entities that engaged in crimes against HHS programs and 367 civil actions, which include false claims and unjust enrichment lawsuits filed in Federal district court, civil monetary penalties settlements, and administrative recoveries related to provider self-disclosure matters. See the report at: https://oig.hhs.gov/reports-and-publications/archives/semiannual/2012/fall/sar-f12-fulltext.pdf

Sales Rep's Off-Label Promotion Upheld:
The Second Circuit Court of Appeals, in U.S. v. Caronia, has overturned the criminal conviction of a pharmaceutical sales representative who promoted a drug for "off-label use," i.e., for a purpose not approved by the U.S. Food & Drug Administration (FDA). A jury found the representative guilty of conspiracy to introduce a misbranded drug into interstate commerce. The FDA construes the Food Drug & Cosmetic Act provisions that prohibit the misbranding of drugs to also prohibit off-label promotion by pharmaceutical manufacturers and has successfully prosecuted manufacturers and their representatives for "misbranding" drugs based on their off-label promotion. In Caronia, however, the Court's majority held that the conviction violated the sales representative's First Amendment free speech rights. A dissenting opinion held that the majority's ruling would undermine the FDA approval process. The government may seek a rehearing before the Second Circuit and, ultimately, U.S. Supreme Court review. While the FDA does not prohibit a physician from prescribing an approved drug for an off-label use the physician deems medically appropriate, licensing boards have prosecuted physicians for such actions. This remains an unsettled area of the law and physicians should continue to proceed cautiously.

HHS Offers Tips on How to Secure Mobile Devices: The U.S. Department of Health and Human Services has launched an educational initiative that includes a set of online tools to give health care professionals practical tips on ways to protect their patients' protected health information when using mobile devices such as laptops, tablets, and smartphones. The program, called "*Mobile Devices: Know the Risks. Take the Steps. Protect and Secure Health Information,"* is available at http://www.healthit.gov/providers-professionals/how-can-you-protect-and-secure-health-information-when-using-mobile-device

For more information on the above items, contact Kern Augustine Conroy & Schoppmann at 1-800-445-0954.