Dear Health Law Section Members:

The Section website has been updated with articles on significant developments in the health law arena that may be of interest to you in your practice. These summaries are presented for general information only as a courtesy to Section members and do not constitute legal advice from The Florida Bar or its Health Law Section. On behalf of the Section, we extend our deepest appreciation to the following volunteers who have generously donated their time to prepare these summaries for your review:

Andrew S. Feldman, Esq.
Jamie B. Gelfman, Esq.
Rodney Johnson, Esq.
Jennifer Jordan, Esq.
Shantal Henriquez, Third Year Law Student
Anushree Sagi Nakkana, Esq.
Christian Perez Font, Esq.
Elizabeth Scarola, Esq.
Michael Smith, Esq.

Thank you.
Kimberly Speer Sullivan, Esq.
Malinda R. Lugo, Esq.

You can download a copy of this month's update using the links below or read the updates in this article on the Section website.

FRAUD AND ABUSE

Indicting Medical Malpractice in Florida and Nationwide

Recently, the Criminal Division of the Department of Justice has bulked up on its health care fraud indictments against physicians for performing medically unnecessary surgeries or procedures. Indeed, Assistant Attorney General Leslie Caldwell reinforced during the ABA's National Institute on Health Care Fraud and Abuse in May of this year that the Department is committed to aggressively prosecuting fraud that compromises patient safety. So far, the list of defendants includes interventional cardiologists, dermatologists, and spinal surgeons.

Nonetheless, more doctors turned defendants are forcing the government to prove their guilt beyond a reasonable doubt at trial in these cases. In September, esteemed ophthalmologist, Dr. David Pon, was convicted of 20 counts of health care fraud following a month long trial in Jacksonville, Florida. The evidence adduced at trial demonstrated that Pon intentionally misdiagnosed more than 500 Medicare beneficiaries as suffering from wet macular degeneration, a degenerative and incurable disease, and then used his false diagnoses to bill the Medicare program for unnecessary diagnostic testing and unwarranted laser treatments. *See* http://www.justice.gov/usao-mdfl/pr/federal-jury-finds-doctor-guilty-20-counts-health-care-fraud.

Similar to Dr. Pon, last month, cardiologist, Dr. Harold Persaud was also convicted of multiple counts of health care fraud based on evidence at trial demonstrating that Dr. Persaud falsely diagnosed patients and falsified documentation in order to implant cardiac stents in patients when stents were unnecessary. *See* http://www.justice.gov/usao-ndoh/pr/westlake-cardiologist-convicted-overbilling-7-million-worth-unnecessary-procedures. Significantly, at trial, Dr. Persaud asserted that he had a "good faith" defense to the health care fraud accusations reasoning that any surgeries were performed through mistakes or carelessness and were not performed to cheat or deceive the Medicare program and draining U.S. tax dollars.

The above physicians are not alone though. Future medical necessity prosecutions abound, including a health care prosecution targeting a South Florida ophthalmologists' use of Lucentis injections to treat macular degeneration, *see* http://www.justice.gov/opa/pr/south-florida-doctor-indicted-medicare-fraud, and a prosecution of a dermatologist premised on the performance of alleged unnecessary Mohs surgeries. *See* http://www.justice.gov/usao-edva/pr/northern-virginia-dermatologist-charged-health-care-fraud. Both cases are set for trial in 2016.

Thus, in 2016, it is anticipated that the Department will continue to investigate and prosecute fraud in connection with the performance of unnecessary surgeries or procedures.

Reported by Andrew S. Feldman, Esq.

LIFE SCIENCES

Brief Summary and Adequate Directions for Use: Draft Guidance by the FDA on the Disclosure of Risk Information in Consumer-Directed Print Advertisements and Promotional Labeling for Prescription Drugs

In early August, 2015, the FDA issued a draft revised guidance on the disclosure of risk information to consumers in print advertisements and promotional labeling of prescription drugs. Under the Federal Food Drug and Cosmetic Act (21 U.S.C. ch. 9 § 301 et seq), printed advertisements of prescription drugs must contain, among others, a true statement of the product's name, its quantitative composition, information relating to side effects, contraindications and product effectiveness. The specific requirement for disclosure of the side effects, warnings, precautions and contraindications is generally referred to as the *brief summary requirement*.

The new draft guidance continues to support the idea that rather than including the complete risk-related sections of the PI to fulfill the brief summary requirement, consumers would be better served if manufacturers use consumer-friendly language in all consumer-directed materials, a conclusion that is supported by recent social science research studies. In this regard, the new draft guidance specifically states that "*The consumer brief summary should be written in language designed for understanding by a broad target audience with various levels of literary skills*".

To this effect, the draft guidance is now advocating for the use of prescription drug facts boxes and question and answer formats as opposed to traditional brief summaries or the complete risk related sections of the PIs.

The complete text of the draft guidance is available at:
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM069984.pdf

Reported by Christian Perez Font, Esq.

Philips Healthcare to Acquire Florida-based Blue Jay Consulting

Philips Healthcare, one of the world's major manufacturers of clinical imaging systems and informatics has acquired Orlando-based Blue Jay Consulting, LLC. The transaction, which is due to close in the fourth quarter of 2015, will boost the Dutch giant's $500 MM deal signed in June of this year to provide clinical consulting and imaging services, as well as patient monitoring, telehealth and clinical informatics solutions to the Westchester Medical Center Health Network in NY. Blue Jay Consulting was founded in 2006 by Mark Feinberg and Jim Hoelz.

Reported by Christian Perez Font, Esq.

Florida Medical Marijuana Amendment Fights for a Second Chance

The United for Care campaign, run by the interest group People United for Medical Marijuana, has spearheaded a new ballot initiative to get the Florida medical marijuana constitutional amendment back on the ballot. The language in the amendment has been revised to address previous concerns. In the new proposed amendment, the Florida Department of Health ("FDOH") will be the deciding factor as to how many medical marijuana patients a caregiver can have at one time in addition to the requirement that FDOH perform background checks on those caregivers. The new amendment also requires doctors to receive in-person, informed parental consent before prescribing medical marijuana to minors. There is also the additional change that with the new amendment, if passed, medical marijuana can only be prescribed to patients diagnosed with a "debilitating disease," a term that has been defined within the amendment's text.

To see the full text of the proposed amendment, please visit: http://www.unitedforcare.org/ballot_language_1.

The ballot initiative has received 73,713 validated petitions as of August 31, 2015; 609,436 are required by January to place the amendment on the 2016 ballot. Having obtained greater than the requisite number of petitions, the Florida Supreme Court will now review the amendment to ensure it meets constitutionality requirements.

Reported by Shantal L. Henriquez, Third Year Law Student

LICENSURE

1Telemedicine or Malpractice?

An Administrative Law Judge from the Division of Administrative Hearings recently held a physician was in violation of the medical practice act because the physician prescribed a legend medication without documenting a physical examination of the patient and without an evaluation of the patient's medical history. Department of Health v. Bennett, Case No.15-2318PL (Fla. DOAH July 29, 2015). The physician prescribed PRED FORTE®, which is an ophthalmic suspension containing prednisolone acetate and a legend drug. The only encounter the physician had with the patient was through an audio-only telephone call. The physician did not perform a physical examination of the patient before prescribing the medication, and the physician did not document a physical examination of the patient, a review of any of the patient's medical records, or an examination of any photograph or other image of the patient's eye. During the hearing, the physician testified that the patient refused to be seen, and that the patient refused to go to the emergency room. The physician also testified that the standard of care did not require the physician to physically examine the patient before prescribing the medication. The Administrative Law Judge rejected the physician's testimony and legal arguments on all those points. The case was decided based upon the Rule 64B8-9.014, which was the rule in effect at the time the physician prescribed the medication. The new Rule establishing the Standards for Telemedicine Practice became effective on October 26, 2014. As yet, the Board of Medicine has not considered the Administrative Law Judge's Recommended Order.

Reported by Michael L. Smith, Esq.

HEALTH INFORMATION TECHNOLOGY

DHHS Office for Civil Rights Confirms Second Phase of HIPAA Compliance Audits to Commence Early 2016

In the wake of strong criticism received about the Department of Health and Human Services' Office for Civil Rights' ("OCR") HIPAA enforcement and oversight activities, the Director of the OCR, Jocelyn Samuels, recently confirmed by way of letter to the HHS Inspector General that the OCR's second phase of HIPAA-compliance audits will commence in early 2016, with no expected delays.

This announcement comes on the heels of a report released by the Office of the Inspector General ("OIG") for the Department of Health and Human Services ("HHS") on September 28, 2015, which criticized the OCR's enforcement and oversight of covered entities' compliance with the HIPAA Privacy Rule (a copy of the report can be found at http://oig.hhs.gov/oei/reports/oei-09-10-00510.pdf). In preparing its report, the OIG examined statistical samples of privacy cases investigated by the OCR from September 2009 through March 2011, surveyed OCR staff, interviewed OCR officials, and surveyed a statistical sample of Medicare Part B providers.

The OIG report concluded, among other significant findings, that the OCR's oversight is "primarily reactive," in that it investigates possible HIPAA noncompliance largely in response to complaints. Specifically, the OIG found that in 98 percent of all closed privacy cases, the OCR initiated its investigations because of complaints, and the remaining 2 percent in response to tips or media reports. Further, the OIG found that the OCR did not have complete documentation of corrective actions taken by covered entities in 26 percent of closed privacy cases, and in about 50 percent of such cases, the OCR had determined that covered entities were noncompliant with at least one privacy standard.
Based on this finding, the OIG found that OCR has "not fully implemented the required audit program to proactively assess possible noncompliance [with the HIPAA privacy standards] from covered entities," which was mandated under Section 13411 of the HITECH Act to commence in 2010. To date, the agency has only launched a pilot audit program and evaluated the results ("Phase I Audits"). As such, the OIG recommended that the OCR implement the required audit program to enable proactive identification of noncompliance.

According to Samuels, the OCR, in launching the second phase of OCR audits in early 2016 ("Phase II Audits"), is moving forward with establishing a "permanent audit program." The Phase II Audits will concentrate on high-risk areas to the security of protected health information and on pervasive non-compliance based upon findings of the Phase I Audits; will include on-site visits, voluminous records and data requests, and "desk reviews"; and will include both covered entities and business associates. In addition, Samuels warned that covered entities will be assessed based upon their current state, as well as their efforts in attempting to comply with the HIPAA Rules from a historical perspective. Further, and most significantly, covered entities should be aware that even organizations that have just become HIPAA compliant may be held accountable for lack of past efforts to comply with the HIPAA privacy standards.

Reported by Jamie B. Gelfman, Esq.

HHS Official Testifies Before Senate Regarding Medical Identity Theft

On October 7, 2015, Gary Cantrell, Deputy Inspector General for Investigations, Office of Inspector General, Department of Health and Human Services submitted testimony before the United States Senate Special Committee on Aging titled "Protecting Seniors from Identity Theft: Is the Federal Government Doing Enough?" Medical identity theft includes the theft of all Personally Identifiable Information ("PII") including, but not limited to, Social Security numbers, dates of birth and credit card and bank account information. It may also include Protected Health Information ("PHI") (e.g. health history, medical diagnoses, services rendered, billing information or payment information). In his testimony, Mr. Cantrell cited an example demonstrating how theft of PII or PHI can cause significant harm to Medicare and its beneficiaries. Mr. Cantrell stated,

> "[i]n one case, a transnational criminal organization established a "ghost" medical clinic using stolen information from a physician in the local area. Members of the conspiracy enrolled the clinic in Medicare, established bank accounts, linked the bank accounts to a fictitious address (a mailbox store), registered the clinic with the Secretary of State, and began to bill Medicare. All together, the "ghost" clinic billed Medicare over $1 million, with Medicare paying about $350,000 worth of claims. The money that was paid was laundered through out-of-state banks and shell businesses by members of the conspiracy. The supervisor of the conspiracy was sentenced to 57 months in prison and others have been indicted."

In addition, Mr. Cantrell's written testimony also directed attention to The Medicare Identity Prevention Act of 2015, proposed legislature designed to prevent the threat of fraud by removing social security numbers from patients' Medicare cards. See http://oig.hhs.gov/testimony/docs/2015/cantrell10-06-2015.pdf.

Reported by Anushree Sagi Nakkana, Esq.

PUBLIC HEALTH

Proposed Changes to the Common Rule Could Streamline Public Health Surveillance

The U.S. Department of Health and Human Services and 15 other Federal Departments and Agencies recently proposed changes to the Common Rule — a federal rule that protects study participants in federally sponsored research programs and safeguards protected health information. The changes may impact the way public health agencies conduct research and carry out other public health functions. A notice of proposed revisions was recently published in the Federal Register.

The proposed changes cover many important aspects of human subjects' research protection and many of these changes, if adopted, could have profound effects on public health activities and research. One of the most important potential changes to public health is the exclusion of public health surveillance activities from the Common Rule. Public health surveillance is an activity that has fallen within a gray area — is it research or is it a public health function, or both?

Reported by Rodney Johnson, Esq.

Ebola Monitoring and Movement Protocols: TEDMED/Ignite Video

As a result of concerns about the potential impact of inconsistencies between state and federal monitoring and movement policies, CDC's Public Health Law Program assessed jurisdictional differences among publically available monitoring and movement policies by systematically reviewing and evaluating policies for each state and territory. This presentation describes the role CDC plays in our public health and legal systems and explains how this

affected the state Ebola monitoring and movement protocols. Data contained in this presentation were current as of March 9, 2015. For the most recent data, visit the Ebola Movement and Monitoring Policies web page at http://www.cdc.gov/phlp/news/current.html.

Reported by Rodney Johnson, Esq.

THIRD PARTY PAYOR

OIG Asks CMS to Reform Payment to Skilled Nursing Facilities

The Office of Inspector General of the U.S. Department of Health and Human Services (OIG) issued a report on September 30, 2015, which called for the Centers for Medicare and Medicaid Services (CMS) to reform payment for Skilled Nursing Facility (SNF) services. In its study, the OIG focused on SNF billing, the method of paying for therapy, and the extent to which Medicare payments exceed SNFs' costs.

Medicare pays SNF's a daily rate for nursing, therapy, and other services, primarily based on the amount of therapy provided. This rate is set without regard to specific beneficiary characteristics or care needs. The OIG found that under the current payment system SNFs billed for the highest level of therapy even though the key beneficiary characteristic remained substantially the same. In its review of therapy billings, the OIG discovered that a disproportionate number of beneficiaries received 720 minutes of therapy during the assessment period, which is exactly the number of minutes required for an "ultra-high" categorization and results in a higher level of resource utilization group, leading to higher reimbursement.

The OIG concluded that the current method of paying for therapy coupled with the significant difference between therapy payments and costs creates a strong financial incentive for SNFs to bill for higher levels of therapy than necessary. The OIG found that increases in SNF billing resulted in $1.1 billion in Medicare payments in FYs 2012 and 2013.

The OIG called for CMS to take the following steps:

- Evaluate the extent to which Medicare payment rates for therapy should be reduced.
- Change the method of paying for therapy by shifting away from a volume based methodology to one based primarily on beneficiary characteristics.
- Adjust Medicare payments to eliminate the effect of "case mix creep."
- Strengthen oversight of SNF billing.

Reported by Jennifer Jordan, Esq.

CMS Publishes Proposed Rule Regarding Clinical Laboratory Fee Schedule

On October 1, 2015, CMS published a proposed rule regarding the Clinical Laboratory Fee Schedule. The proposal restructures payment rates for diagnosing laboratory-testing beginning on January 1, 2017 and creates new reporting requirements for "Applicable Laboratories." Applicable Laboratories are (1) laboratories as defined by the *Clinical Laboratory Improvement Amendments of 1988* ("CLIA"); (2) laboratories that report tax-related information to the IRS under a TIN with which all NPIs are associated; and (3) laboratories that receive (in aggregate with all associated NPI entities) greater than 50% of Medicare revenues from the Clinical Laboratory Fee Schedule or Physician Fee Schedule. New payment rates for diagnostic laboratory tests would be set at the weighted median of private payer rates as reported by Applicable Laboratories.

The proposed law would require Applicable Laboratories collect data for the period between July 1 and December 31, 2015 and report data to CMS from January 1 through March 31, 2016. CMS would use the reported data to determine payment rates for years 2017-2019. Civil monetary penalties would be applied to any Applicable Laboratory that failed to submit required reports.

CMS is taking comments on the proposed rule through Wednesday, November 25, 2015.

For the proposed rule, visit: https://www.federalregister.gov/articles/2015/10/01/2015-24770/medicare-program-medicare-clinical-diagnostic-laboratory-tests-payment-system

Reported by Elizabeth Scarola, Esq.