December 2, 2016

Dear Health Law Section Members:

The Section website has been updated with the October / November 2016 articles on significant developments in the health law arena that may be of interest to you in your practice. These summaries are presented to Section members for general information only and do not constitute legal advice from The Florida Bar, its Health Law Section, or the authors of these summaries.

HLS thanks the following volunteers who have generously donated their time to prepare these summaries for our members:

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COMPLIANCE

Draft Guidance by the FDA on the Clinical Evaluation of Software as a Medical Device (SAMD)

On October 14th, 2016, the FDA issued a draft guidance on the standards for clinical evaluation of software as a medical device (SaMD). The guidance, originally prepared by the International Medical Device Regulators Forum (IMDRF), seeks to establish "a common and converged understanding of clinical evaluation and principles for demonstrating the safety, effectiveness and performance of software intended for medical purposes." But, what is SaMD you may ask? To put it in simple terms, SaMD is software that utilizes an algorithm (logic, set of rules, or a model) that uses data input to produce medically valuable information intended to be used to: (i) treat or diagnose a disease, (ii) drive the clinical management of a disease, or (iii) provide relevant clinical information to assist in the management of a disease. Examples of SaMD include software that uses data from individuals to predict risk scores for developing a particular disease in order to create prevention or treatment strategies or software that performs an analysis of bodily fluids to diagnose a particular disease. The FDA has long recognized (at least since 1989) that in some cases software alone can be considered a medical device and, therefore, has exercised regulatory authority in this area. The draft guidance recognizes that the risks and benefits of SaMD are closely related to the intended use of the SaMD and, therefore, sets different standards for clinical evaluation depending on intended use. Specifically, the guidance states that "this statement of intention is the most important starting point for considering the level of evidence necessary and in the choices made to perform appropriate clinical evaluation." The draft guidance also addresses the standards for clinical evaluation throughout the entire SaMD life-cycle and not just during development and launch.

The complete text of the draft guidance, can be viewed at: http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm524904.pdf

Submitted by: Christian Perez Font, Esq.

Ten Florida Assisted Living Facility Owners Indicted on Health Care Fraud and Abuse Charges

On October 25th, 2016, after a joint investigation by the FBI, HHS-OIG and Florida's Medicaid Fraud Control Unit, the U.S. Attorney's Office for the Southern District of Florida charged the owners of ten assisted living facilities in Miami-Dade County with participating in a healthcare fraud scheme in violation of the federal Anti-Kickback Statute and False Claims Act. The 30-count complaint alleges that the ten individuals received cash kickbacks and bribes in return for referring individuals residing in their assisted living facilities to the former owner of Florida Pharmacy Inc., a Miami-Dade company, for prescription medications and durable medical equipment reimbursed by Medicare and Florida Medicaid. The complaint further alleges that the ten individuals violated the False Claims Act by submitting Non-Institutional Medicaid Provider Agreements representing to Medicaid that they would comply with state and federal laws and all agency rules contained in the Florida Medicaid Provider Handbook which prohibits the solicitation and receipt of kickbacks. The U.S. Attorney's office has stated that based on these alleged false representations Medicare renewed their provider numbers which allowed them to continue to submit claims and request reimbursement.

More information about this case, including the full indictments can be found on the website of the District Court for the Southern District of Florida at www.flsd.uscourts.gov or at http://pacer.flsd.uscourts.gov.

Submitted by: Christian Perez Font, Esq.

FRAUD & ABUSE

Government's Increased Focus on Soaring Hospice Expenses

An increasing area of focus for government regulators in the healthcare fraud, waste, and abuse arena is hospice care. Hospice was originally intended solely for those patients with a terminal diagnosis. By regulation, that has been defined to mean patients whose doctors certify that they are likely to die within six months, or about 180 days. Today, however, care is routinely being extended to other types of patients such as those with non-specific, but debilitating illnesses including dementia and other mental ailments who often stay in hospice for well over 180 days.

In Florida, recent settlements reflect the government's increased scrutiny of this issue. For example, the United States Attorney's Office for the Middle District of Florida settled two hospice cases last year with both hospice companies paying over $3 million to resolve allegations that it provided medically unnecessary hospice care. In one such case – the matter of Hospice of Citrus County – the government contended that, in a six-year stretch, the company treated at least 52 patients with lengths of stay in excess of 1,000 days. The government alleged that for those 52 patients, Hospice of Citrus County either knowingly or recklessly failed to document a valid basis for the initial start of hospice care and/or subsequent hospice coverage. The failure in documentation included no support for the length of hospice services; patient files that failed to document basic patient characteristics; and patient records that were either unsigned or signed with inconsistent practitioner information. The government agreed to accept $3,022,000 to resolve these allegations.

Submitted by: Mitchell Blum and Jason Mehta[1]

PROFESSIONAL AND FACILITY LICENSURE

AHCA Active in October Licensure Actions

Florida's Agency for Health Care Administration (AHCA) announced that it issued final orders in October to ten (10) facilities and/or providers in Florida for failing to meet certain licensure requirements. Included in these ten orders were seven (7) orders to revoke existing licenses, two (2) final orders to deny certain renewals, and one (1) order that resulted in a provider surrendering their license. AHCA announced that among those that were terminated or non-renewed were providers that were enrolled in the Medicaid program and that AHCA, as a result, has subsequently terminated or is in the process of terminating their participation in the program.

More information on such AHCA licensure actions can be found here: http://ahca.myflorida.com/Executive/Communications/Press_Releases/pdf/OctoberMonthlyActionsPressRelease.pdf

Submitted by: Matthew J. Friendly, Esq.

HEALTH INFORMATION TECHNOLOGY AND PRIVACY

Post-Election Potential Impact on Health Information and Privacy

During his presidential campaign, Donald Trump promised to repeal the Affordable Care Act ('ACA"). The repeal of the ACA could impact certain aspects of the Health Insurance Portability Act of 1996 ("HIPAA"), which was expanded by the ACA. The ACA expanded HIPAA in several ways by (1) requiring the U.S. Department of Health and Human Services ("HHS") to issue operating rules for HIPAA standard transactions, (2) making information and transmission formats more uniform, and (3) reducing the role of plan-specific companion guides.

Healthcare providers may have to adjust some of their policies and procedures implemented post ACA. If the ACA is repealed, the Operating Rules required under the ACA may change as well. The Operating Rules adopted by HHS are considered the necessary business rules and guidelines for the electronic exchange of information that are not defined by a standard or its implementation specifications. The Operating Rules also specify the information that must be included when conducting standard transactions, which makes it simpler for providers to use electronic methods to handle administrative transactions covered under HIPAA.

In addition to some of the specific potential impacts discussed above, we are facing significant uncertainty of what new healthcare related laws and regulations might be forthcoming. The "repeal and replace" mantra is well known to all of us, but what "replace" actually means remains a moving target. Previously proposed Republican backed healthcare legislation could impact health information and privacy as follows:

1) Sections of a larger mental health bill would allow caregivers and family members more information about a mentally ill person's care through changes to HIPAA;
2) Increasing research collaboration into the discovery, development, and delivery of new treatments and cures by breaking down regulatory barriers to sharing and analyzing health data;
3) Advancing the use of electronic health records by spurring innovation and breaking down unnecessary legal and regulatory barriers; and
4) Adjusting the meaningful use program to allow partnerships between technology and health care that will drive toward interoperability and exchange of information.

It is important to note that some of the above measures have not been specifically detailed in full legislation, but statements like "breaking down regulatory barriers to sharing and analyzing health data" would almost certainly implicate changes to HIPAA. It appears that health information and privacy rules and regulations are headed for at least some level of change in the upcoming legislative sessions. Overall, we are in a wait and see position given the various positions lawmakers have been put forth in the past.

Submitted by: Jeffrey Mustari, Esq.

LIFE SCIENCES

Florida Medical Marijuana Constitutional Amendment 2 Passes in General Election

On November 8, 2016, Florida voters approved the medical marijuana constitutional ballot initiative known as Amendment 2. The text of the ballot petition approved in Florida Supreme Court Advisory Opinion No. 15-1796 states that the new amendment will create Article X, Section 29 to the Florida Constitution, titled "Medical marijuana production, possession and use." The amendment expands the use of medical marijuana to patients suffering from a "debilitating medical condition," which is defined as cancer, epilepsy, glaucoma, HIV positive-status, AIDS, PTSD, ALS, Crohn's disease, Parkinson's disease, MS, or "other debilitating medical conditions of the same kind or class as or comparable to those enumerated, and for which a physician believes that the medical use of marijuana would likely outweigh the potential health risks for a patient."
Under the amendment, the term "marijuana" is defined by the same meaning given to "cannabis" in Section 893.02(3), Florida Statutes, the "Florida Comprehensive Drug Abuse Prevention and Control Act" and to "low-THC cannabis" in Section 381.986(1)(b), Florida Statutes, for the "Compassionate use of low-THC and medical cannabis." Only a physician that is licensed to practice medicine and who is certified by the Department of Health ("DOH") may certify a patient as eligible to qualify for the medical use of marijuana by the DOH.

The amendment allows for the administration of medical marijuana by food, tinctures, aerosols, oils, ointments, or related products. The text specifically states that the amendment does not legalize any other use or possession of marijuana, does not require accommodations for patients to use medical marijuana at work, school, or in public places, nor does it require any private or government third-party payer to reimburse a patient for medical marijuana-related expenses.

For the full text of the amendment created by the new Section 29 to Article X of the Florida Constitution, please see Advisory Opinion SC 15-1796 or the approved Constitutional Amendment Petition Form.

Submitted by: Shantal L. Henriquez, Esq.

PUBLIC HEALTH

Report About Opioid Addiction. The Department of Health and Human Services (HHS) has stated that addressing opioid abuse is a high priority, and is promoting access to medication-assisted treatment (MAT)–an approach that combines behavioral therapy and the use of medications–to combat the problem. This study by the US Government Accountability Office (GAO) examines 1) how federal laws and regulations apply when using medications to treat opioid addiction compared to using the same medications for pain management and 2) key factors that can affect access to MAT for opioid addiction.

Online Legal Technical Assistance Knowledge Base. The Network for Public Health Law has released the beta version of a new online tool, the Legal Technical Assistance Knowledge Base, which allows users to access a limited number of records from the Network's extensive database of legal technical assistance. The Network invites users to explore the Knowledge Base and to provide feedback through an online survey.

The end of AIDS' Patient Zero myth shows that history is never complete

Sydney Morning Herald (10/31/2016) Joel Meares

Researchers at the University of Arizona recently published a study concluding that Gaétan Dugas, infamously and erroneously dubbed "Patient Zero" of the AIDS epidemic during the 1980s, could not have been the source of HIV in the United States. The researchers studied HIV genome sequences in blood samples from early HIV/AIDS patients in the United States. When they studied Dugas's blood sample, they found a strain of HIV known to be present in New York years before he visited the city.

This new biological evidence prompts a second look at how the gay community has been portrayed in history. The United Kingdom recently took a step in this direction with the *Turing Law*, allowing thousands of living and deceased gay and bisexual men to be posthumously pardoned for previously criminalized private, consensual sex acts.

Submitted by: Rodney M. Johnson, Esq.

THIRD PARTY PAYORS

Subsidies in Florida Offset the Rise of ACA Premiums for 2017

Under the Affordable Care Act (ACA) the number of uninsured Americans fell to 8.6% in the first quarter of 2016, the lowest in U.S. history. As of March 2016, 1.5 million people had coverage through Florida's exchange, accounting for approximately 14% of the entire country's ACA enrollment. While the number of uninsured Americans has steadily decreased with the enactment of ACA, marketplace premiums continue to rise. The Department of Health and Human Services (HHS) announced that marketplace premiums across states using the Healthcare.gov platform will increase an average of 25% in 2017.

Price hikes for premiums vary widely across the states. In Florida, the average premium increase for 2017 is 19%. However, over 90% of Floridians who enroll in the marketplace will receive subsidies that may offset the premium increase or even lower monthly costs. This is true for both family and individual plans depending on which county the participant resides in. In 2016 over 93% of Florida's enrollees received subsidies. The average pre-subsidy premium was $386 per month. After subsidies, the premium average was just $84 per month. Nationally, 85% of enrollees will receive a tax credit limiting the premium an enrollee will pay.

Florida utilizes the federally-run exchange where open enrollment for 2017 runs from November 1, 2016 to January 31, 2017. Seven carriers, Florida Blue (BCBS of Florida), Florida Blue HMO (Health Option), Florida Health Care Plan, Inc., Humana, Ambetter, Molina and Health First Health Plans are offering coverage in the Florida exchange for 2017.

Submitted by: Ashley Brevda, Esq.

TRANSACTIONS / MISCELLANEOUS

The MACRA Final Rule: 10 Things You Need to Know

The Centers of Medicare and Medicaid Services (CMS) released the much-anticipated *Medicare Access and CHIP Reauthorization Act* (MACRA) final rule this month. The rule makes extensive changes to traditional Medicare Part B reimbursement. MACRA moves Medicare away from a primarily volume based fee-for-service system to a value-based system as part of an overarching strategy to transform how health care is delivered in America by rewarding quality improvement, focusing on patient health outcomes, and reducing unnecessary costs.

The final rule eases the administrative burden for provider transition to MACRA, broadens opportunities for participation in advanced alternative models (APMs) and sets aside funding to provide technical assistance to Merit-Based Incentive Payment System (MIPS) participating clinicians in areas with a shortage of health professionals.

Below are answers to ten frequently asked questions:

1. Who is affected?

Physicians, physician assistants, nurse practitioners, clinical nurse specialists and certified registered nurse anesthetists who participate in Medicare Part B, bill Medicare more than $30,000/year and provide care for more than 100 Medicare patients a year.

Note the proposed rule had set the threshold at $10,000/year.

2. What is the Quality Payment Program?

MACRA's Quality Payment Program (QPP) replaces the sustainable growth rate and continues the agency's shift toward value-based care reimbursement reform. Medicare Part B participating providers must choose between two tracks: APMs or MIPS.

If providers choose to participate in an Advanced APM through Medicare Part B, they will earn an incentive payment. If, instead, a provider chooses to participate in traditional Medicare Part B, he or she will participate in MIPS, and will earn a performance-based payment adjustment.

Providers may participate as an individual (single National Provider Identifier (NPI)) or a group (sharing a common Tax Identification Number).

3. When does the Quality Payment Program start?

The first performance year starts January 1, 2017 and ends December 31, 2017.

If already participating in an Advanced APM, a clinician can provide care during the year through that model and will be eligible for a 5% incentive payment. If not participating in an Advanced APM, clinicians must participate in MIPS, or will receive a negative payment adjustment.

In the first year of the program, 2017, clinicians can pick the pace of participation in MIPS. Clinicians can begin collecting performance data anytime between the first of the year and October 2nd. To earn a positive payment adjustment, data must be submitted to CMS by March 31, 2018.

Medicare will provide feedback to providers after data submission. If a positive MIPS payment adjustment or Advanced APM incentive payment is earned, clinicians will receive the money beginning January 1, 2019.

4. How will my Medicare payments change?

Depending on the data submitted by March 31, 2018, 2019 Medicare payments will be adjusted up, down, or not at all.

- If clinicians choose not to participate, and do not send any data to CMS in 2017, they will receive a negative 4% payment adjustment;
- If clinicians submit some data, they avoid a negative payment adjustment, but will not receive a positive adjustment;
- If clinicians submit 90 days of 2017 data, they can earn a neutral or small positive payment adjustment;
- If clinicians submit a full year of 2017 data, they may earn a moderate positive payment adjustment;
- If clinicians participate in the Advanced APM path (i.e., they receive 25% of payments from Medicare and 20% of Medicare patients are seen through an Advanced APM in 2017), they will earn a 5% incentive payment.

Note: each year of the program, CMS changes the rates of payment adjustments.

5. How does the final rule affect MIPS?

MIPS streamlines prior CMS initiatives (PQRS, Meaningful Use and Value Based Modifier) with four categories: Quality, Improvement Activities, Advancing Care Information and Cost.

In 2017, CMS will not use the Cost category to determine payment adjustments. Instead, the agency will calculate payment adjustments solely based on the Quality (60% of weighted score), Improvement Activities (15% of weighted score) and Advancing Care Information (25% of weighted score) categories.

6. How does the final rule affect APMs?

Advanced APMs allow practices to earn incentive payments for taking on financial risk related to patient outcomes. CMS will announce 2017 qualifying Advanced APMs by January 1, 2017. As of now, the agency has announced 2017 qualifying advanced APMs include:

- Comprehensive ESRD Care (two sided risk model);
- Comprehensive Primary Care Plus (CPC+);
- Next Generation ACO Model;
- Shared Savings Program – Track 2;

- Shared Savings Program – Track 3.

7. How does the final rule impact small practices?

The final rule eases the burden on small practices. In 2017, many small practices are excluded from new requirements, because they see less than or equal to $30,000 in Medicare Part B charges or less than or equal to 100 Medicare patients per year. Although it does not apply in 2017, in future years, MACRA will allow solo and small practices to combine and submit MIPS reporting together as virtual groups of no more than 10 clinicians.

8. How do I know if I'm ready to participate in MIPS?

Determine if you will submit data individually or as a group. Then, consider which measures you will submit to CMS in each of the three categories: quality, improvement activities and advancing care information. Use the QPP Website to explore the MIPS data your practice can choose to submit. Choose quality, advancing care information and improvement activities measures which best fit your practice.

Next, consider how you will submit data: via qualified data registry, registry, CMS web interface (for groups) or electronic health record. If you choose to submit via electronic health record (HER), verify that your EHR is certified by the Office of the National Coordinator for Health Information Technology. If so, CMS indicates your EHR is ready to capture information for the MIPS advancing care information category as well as certain quality category measures.

9. Where can I read the final rule?

The final rule is available here: https://www.federalregister.gov/documents/2016/11/04/2016-25240/medicare-program-merit-based-incentive-payment-system-mips-and-alternative-payment-model-apm.

10. How can I learn more?

On Friday, CMS launched the Quality Payment Program website. The Agency will continue to host listening and learning sessions throughout the country. Additionally, CMS will continue to accept comments on the final rule through December 17, 2016, sixty days after the final rule release date. Comments may be submitted here.

If you have additional questions about how MACRA will affect you and your practice, you should contact a qualified health care attorney or your billing provider.

Submitted By: Elizabeth Scarola M.A., J.D., M.H.S.A.