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INSIDE:

The Costco Choice: Why Florida Chose Medicaid Managed Care

By: Carly Elizabeth Souther[1]

I. The Statewide Medicaid Managed Care Act[2]

In 2011, the Florida Legislature radically altered the delivery of public health insurance programs by enacting the Statewide Medicaid Managed Care Act ("the SMMC Act"),[3] which directed the Agency for Health Care Administration ("AHCA") to implement and administer an innovated, structured health care system by August 1, 2014.[4] *See* Exhibit A. Through a $36 billion procurement process,[5] AHCA contracted with Health Maintenance Organizations ("HMOs" or "Plans") to manage Medicaid health care services across the State. Florida Medicaid, a program that is jointly funded by the federal and State governments, "provides payments for medical assistance to low-income persons who are age 65 or over, blind, disabled, or members of families with dependent children or qualified pregnant women or children."[6] This article explains the advantages and disadvantages of managed health care, describes the differences between Florida's traditional fee-for-service and SMMC models, and summarizes the existing state of public health insurance (e.g., Medicaid) in Florida.

The SMMC program "was designed to emphasize enrollee-centered care and active enrollee participation, provide fully integrated care with access to providers and services through a uniform statewide program, and implement innovations in reimbursement methodologies, plan quality, and plan accountability."[7] SMMC has two components: (1) the Managed Medical Assistance Program ("MMA"), which includes medical services like physician visits, hospital stays, and prescription medicines; and, (2) the Managed Care Long-Term Care Program ("LTC"), which covers institutional care such as nursing and assisted living facilities, hospice, and other home and community-based services.[8] SMMC Program implementation occurred in two phases across 11 regions.[9] Florida Medicaid members who are eligible and enroll in SMMC will receive services through a Plan's network of health care providers.[10] While MMA Plans "cover services such as prescriptions, doctors' visits and hospital stays,"[11] LTC Plans "cover long-term care services ***only*** and do not cover medications, doctor's visits or other healthcare related services" (emphasis added).[12] *See* Figure 1. Accordingly, Medicaid members who qualify for both long-term care and medical managed assistance services may enroll in either (i) a Comprehensive Plan (offering both LTC and MMA services) or, (ii) with both an LTC Plan and an MMA Plan.[13] Florida also has Specialty Plans to serve Medicaid enrollees with specific health conditions like HIV/AIDS or for adults who are eligible for both Medicare and Medicaid ("dual eligible(s)").[14] *See* Figure 2.

II. The Medicaid Models

There are two primary types of health care delivery systems: (1) the traditional fee-for-service model ("FFS"), where the insurer pays the medical provider directly for every covered service an enrollee receives after services have been rendered, and (2) the managed health care model, where the insurer pays the medical provider a capitated rate (a set fee) for each enrollee, in advance, on a monthly basis.[15] Under SMMC, AHCA "will shift from its role as a claims processing service provider under the FFS delivery model to a role of oversight and accountability for the managed care organizations it contracts with under SMMC."[16]

a. Fee-for-Service

In the traditional FFS model, the State

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Update on Florida Sterile Compounding Laws

Michael J. Glazer[1]

In October 2012, an outbreak of fungal meningitis was traced to drugs that were compounded at the New England Compounding Center ("NECC") in Framingham, Massachusetts. Before it was over, more than 700 cases and 64 deaths were reported in the U.S. NECC ultimately agreed to a $100 million settlement as part of its bankruptcy proceedings.[2] Other reports of infections caused by compounded drugs began to surface. While less severe than what originated at NECC, they were equally as concerning due to the lack of oversight of these larger operations that were creating compounded medications. Several infection reports originated in Florida.[3]

In response, Congress passed and the President signed the Drug Quality and Security Act ("DQSA") in late 2013.[4] However, this article will focus on the recent regulatory steps taken by the Florida Legislature and the Florida Board of Pharmacy ("BoP") so that the general health law practitioner can have some 'walking around knowledge' of the changes that have occurred and are still evolving.

More specifically, it is the compounding of sterile products (many of which are hazardous) that has been the subject of regulatory activity. Of course, the first question is what is compounding? The BoP has had a rule defining the term for years[5] but, in 2014, the Florida Legislature defined it more simply in Fla. Stat. § 465.003(18), as follows:

> (18) "Compounding" means combining, mixing, or altering the ingredients of one or more drugs or products to create another drug or product.

Fla. Stat. § 465.003(20) now provides:

> (20) "Compounded sterile product" means a drug that is intended for parenteral administration, an ophthalmic or oral inhalation drug in aqueous format, or a drug or product that is required to be sterile under federal or state law or rule, which is produced through compounding, but is not approved by the United States Food and Drug Administration.[6]

Traditionally, compounded sterile products ("CSPs") were either prepared in larger quantities in centralized and often largely unregulated locations in anticipation of the receipt of routine prescriptions or were prepared in response to specific prescriptions in a local community or hospital pharmacy. Common examples are chemotherapy drugs, anti-rejection drugs, hormone replacement therapy, pain management drugs, neonatal fluids, cardiac drips, antibiotics and others.

The BoP has regulated sterile compounding since 2008 when it adopted Rule 64B16-27.797, Florida Administrative Code. The reference to "797" is no accident. The United States Pharmacopeia ("USP") is a scientific nonprofit corporation founded in 1820 that "sets standards for the identity, strength, quality, and purity of medicines, food ingredients, and dietary supplements manufactured, distributed and consumed worldwide." Its drug standards are used by the U.S. Food and Drug Administration and other countries as well.[7] USP Chapter 797 is entitled "Compounding of Sterile Preparations" and "797" is the shorthand reference to CSP regulation used by pharmacists and others. Until recently, Rule 64B-27.797 contained only a subset of the larger set of guidelines contained in USP Chapter 797. It is also probably fair to say that enforcement in Florida was not as stringent before the concerns surfaced over the NECC incident.

In late 2012, the Department of Health provided its inspectors with additional 797 training. The Department's pharmacy inspectors include both pharmacist and non-pharmacist personnel but the Department directed that only pharmacists could inspect pharmacies that compound. In early 2013, several pharmacies/pharmacists were cited for compounding violations even though those same pharmacies had passed previous inspections. While most of those citations were eventually dropped without sanctions after corrective actions were taken, a new era of enforcement regarding the operational integrity of compounding pharmacies had begun.

In addition to greater oversight and enforcement based on existing laws, the BoP started holding hearings, largely in its Compounding Rules Committee, in late 2012 to determine if changes were needed.

The first change enacted by the BoP was to require pharmacies that compound to obtain a separate permit in addition to their existing pharmacy permits. In mid-2013, the BoP promulgated rules creating the "Special Sterile Compounding Permit" that required, with some limited exceptions, all Florida pharmacies engaged in compounding to obtain the additional permit.[8] Pharmacies were given until March 21, 2014, to secure this permit. These compounding pharmacies have additional standards that they must demonstrate to get and keep this permit as compared to general pharmacy permit requirements.

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Medical Marijuana: What Florida Health Care Providers and Their Attorneys Need to Know

By Jessica M. Smith, Esq.[1]

On June 16, 2014, Governor Rick Scott signed into law Senate Bill 1030, the "Compassionate Medical Cannabis Act of 2014"[2] (the "CMCA"), which will allow registered physicians to order low-THC cannabis for medical use by qualified patients.[3] Slated to go into effect on January 1, 2015, lawmakers are currently working to finalize regulations,[4] establishing five dispensing organizations and creating an online "compassionate use registry" for the registration of ordering physicians and their patients.[5] Additionally, in November, Florida voters will vote on Amendment 2 to Article X of the Florida Constitution, the "Florida Right to Medical Marijuana Initiative" ("Amendment 2"), which would decriminalize medical marijuana on a broader scale.[6] Regardless of whether Amendment 2 passes in November, healthcare providers and their attorneys must be aware of how the CMCA will impact them as of the beginning of the New Year. This article examines the CMCA and Amendment 2 and addresses other important issues practitioners should keep in mind when it comes to medical marijuana and low-THC cannabis.

At the outset, it is critical to recognize that state laws decriminalizing medical marijuana have no effect on federal law, under which all forms of marijuana remain illegal. Specifically, all types of marijuana, even the low-THC cannabis permitted under the CMCA, are considered illegal, Schedule 1 drugs under the Federal Controlled Substances Act, 21 C.F.R. § 1306.04(a) (the "Controlled Substances Act"). Importantly, Deputy Attorney General David Ogden's 2009 memorandum (the "Ogden Memo"), stating that the focus of federal prosecutors should not be on individuals acting in compliance with state laws, did not affect the drug's legality.[7] In fact, in June 2011, Deputy Attorney General James M. Cole released a new memo to clarify the Ogden Memo, explaining:

> [t]he Department of Justice is committed to the enforcement of the Controlled Substances Act in all States. Congress has determined that marijuana is a dangerous drug and that the illegal distribution and sale of marijuana is a serious crime that provides a significant source of revenue to large scale criminal enterprises, gangs, and cartels.[8]

Additionally, an argument that there should be an exception for medical marijuana pursuant to the theory of "medical necessity" was rejected by the Supreme Court.[9] Numerous attempts to pass federal law creating an exception for patients and providers pertaining to medical marijuana have also failed.[10]

Per Florida Bar Rule 4-1.2, a lawyer shall not counsel a client to engage in, or assist a client in, conduct that the lawyer knows or reasonably should know is criminal. In regard to this rule and the new state laws on medical marijuana in Florida, the Florida Bar Board of Governors recently adopted the following policy:

> [t]he Florida Bar will not prosecute a Florida Bar member solely for advising a client regarding the validity, scope, and meaning of Florida statutes regarding medical marijuana or for assisting a client in conduct the lawyer reasonably believes is permitted by Florida statutes, regulations, orders, and other state or local provisions implementing them, as long as the lawyer also advises the client regarding related federal law and policy.

Thus, when advising any client regarding medical marijuana laws, Florida attorneys *must* explain that medical marijuana is illegal under federal law.[11]

The CMCA, codified in Fla. Stat. § 381.986, authorizes osteopathic and allopathic physicians to order low-THC cannabis for qualified patients beginning January 1, 2015. Also known as the "Charlotte's Web" law, the CMCA allows for medical use of a non-euphoric strain of marijuana, taken in the form of oil or vapor, to treat certain conditions such as epilepsy, Lou Gehrig's disease, and cancer.[12] The statute decriminalizes authorized harvesting, ordering, use and possession of low-THC cannabis by creating exceptions to relevant Florida legal provisions, including Fla. Stat. §§ 893.13, 893.135 and 893.147. Authorized use is limited to cannabis containing "0.8 percent or less of tetrahydrocannabinol and more than 10 percent of cannabidiol weight for weight" and administration by smoking is expressly prohibited. Before a physician may order low-THC cannabis for qualified patients, he or she must successfully complete an 8-hour course and subsequent examination to be offered by the Florida Medical Association or the Florida Osteopathic Medical Association.[13] Although the statute states that "[t]he first course and examination shall be presented by October 1, 2014," as of October 6, 2014, no such course is currently available. Physicians must complete the course and examination each time their license is renewed. Failure to comply with these requirements is grounds for disciplinary action under the applicable practice act and under Fla. Stat. § 456.072(1)(k).

A "qualified patient" is defined as a permanent resident of Florida who has been added to the compassionate use registry by a physician to receive low-THC cannabis from a dispensing organization.[14] For minor patients, two physicians must concur on the treatment and document their agreement in the patient's medical record.[15] In all cases, the ordering physician(s) must determine that "the risks of ordering low-THC cannabis are reasonable in light of the potential benefit for that patient," and register the named patient on the compassionate use registry maintained by the Florida Department of Health ("DOH"). Ordering low-THC cannabis without a reasonable belief that the patient is suffering from conditions outlined in Fla. Stat. § 381.986(3)(a) is a first degree misdemeanor, punishable by imprisonment for up to one year or up to $1,000 in fines.[16]

The physician(s) must also update the registry to reflect the contents of the order and deactivate a patient's registration when treatment is discontinued. Ordering physicians are required to maintain a treatment plan "that includes the dose, route of administration, planned duration, and monitoring of the patient's symptoms and other indicators of tolerance or reaction to the low-THC cannabis." On a quarterly basis, the physician(s) must submit the patient treatment plan to the University of Florida College of

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Pharmacy for research on the safety and efficacy of low-THC cannabis. Accordingly, patients will need to be seen once every three months at a minimum. The statute also specifically states that the ordering physician(s) must obtain voluntary informed consent from the patient or legal guardian "after sufficiently explaining the current state of knowledge in the medical community of the effectiveness of treatment of the patient's condition with low-THC cannabis, the medically acceptable alternatives, and the potential risks and side effects" thereof. Presumably, the specifics of adequate informed consent will be addressed in the 8-hour course required by the statute, though this is yet to be determined.

Amendment 2, if accepted, would add Section 29 to Article X of the Florida Constitution, preventing certain qualified individuals from criminal and civil liability under Florida law in relation to prescribing, possessing, or using medical marijuana. In contrast to the CMCA, Amendment 2 does not limit the form or THC level of the marijuana. Significantly, the amendment also allows the use of medical marijuana to treat a wider range of conditions, allowing physicians licensed in Florida to issue "physician certifications" to patients with a "Debilitating Medical Condition," defined as "cancer, glaucoma, positive status for human immunodeficiency virus (HIV), acquired immune deficiency syndrome (AIDS), hepatitis C, amyotrophic lateral sclerosis (ALS), Crohn's disease, Parkinson's disease, multiple sclerosis or other conditions for which a physician believes that the medical use of marijuana would likely outweigh the potential health risks for a patient." Correspondingly, the definition of "Qualifying Patient" in Amendment 2 is broader than under the CMCA, defining such as a person having been "diagnosed with a debilitating medical condition, having a physician certification and a valid qualifying patient identification card." Additionally, the proposed amendment does not include a training requirement for prescribing physicians or constrain production of marijuana to a limited number of dispensaries. It also decriminalizes possession of marijuana by personal caregivers – individuals over the age of 21 who have agreed to assist with a qualifying patient's medical use of marijuana, have been issued a caregiver identification card by the DOH, and assist no more than five patients at one time. If passed, Amendment 2 would require the DOH to issue reasonable regulations necessary for its implementation within six months of the effective date, including but not limited to setting up procedures related to patient identification cards, personal caregiver identification cards, registration of Medical Marijuana Treatment Centers[17], and defining the amount of marijuana presumed to be an adequate supply for qualifying patients' medical use.

As mentioned previously, the CMCA explicitly directs physicians to obtain informed consent from the patient or the patient's guardian prior to ordering low-THC cannabis. Despite this overt requirement, the statute is silent as to the method and exact details of sufficient informed consent. While oral consent *may* be adequate, a wiser approach is to insist upon written informed consent. Likewise, the requisite context of the informed consent is unclear. Though the statute requires that physicians disclose the "current state of knowledge in the medical community" of low-THC cannabis' effectiveness for the patient's condition, possible alternatives, risks and potential side effects, that is easier said than done given the dearth of controlled research on marijuana because of its illegality.[18] It would also seem prudent to inform patients and their guardians that marijuana, even low-THC cannabis, remains illegal under federal law.

In addition to the foregoing, physicians should consider educating their patients about the statute's reporting requirements and disclose the fact that the patient's treatment plan information will be used in studies conducted by the University of Florida. Under HIPAA and Fla. Stat. § 456.057, patients have the right to restrict access to their medical records. Although Fla. Stat. § 381.987 does exempt personal patient information and a physician's identifying information, the DOH is still required to provide access to law enforcement, dispensing organizations, and physicians who have written orders for low-THC cannabis. Interestingly, the text of Amendment 2 states that the DOH "shall protect the confidentiality of all qualifying patients." Thus, privacy issues related to the Compassionate Use Registry and studies at the University of Florida remain unsettled.

Another point that physicians may need to disclose to patients is that health insurance companies are not required to reimburse patients for related expenses. Even in states where medical marijuana has been legalized, insurance companies continue to refuse reimbursement citing the federal regulations.[19] While the CMCA is silent on the issue, Amendment 2 specifically states that "[n]othing in this section shall require any health insurance

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provider or any government agency or authority to reimburse any person for expenses related to the medical use of marijuana." Physicians should also check with their malpractice provider as to such carrier's policy on providing coverage for low-THC cannabis and/or medical marijuana related claims.

Finally, health care providers must be reminded that self-referral and patient brokering are unlawful. Self-referral is prohibited by Stark[20] and the Florida Patient Self-Referral Act of 1992, Fla. Stat. § 456.053. Thus, health care providers are prohibited from referring patients for the provision of any health care item or service from an entity in which the provider is an investor. Given the medical nature of low-THC cannabis and medical marijuana as provided by the CMCA and Amendment 2, health care providers should avoid self-referral to dispending organizations or marijuana treatment centers in which they have an interest.[21] Relatedly, health care providers and health care facilities are prohibited from "patient brokering" by Fla. Stat. § 817.505. The statute makes it unlawful for providers and facilities "to aid, abet, advise, or otherwise participate in an arrangement to offer, pay, solicit, or receive any commission, bonus, rebate, kickback, or bribe, directly or indirectly, in cash or in kind or engage in any split-fee arrangement, in any form whatsoever, in return for referring patients or patronage to or from a health care provider or health care facility." Violation of the anti-kickback statute is a third degree felony, punishable by imprisonment and lofty fines.[22] Providers should be reminded that dispensing organizations and marijuana treatment centers, both of which must register with the DOH, will likely be considered health care providers or health care facilities under the statute.

Endnotes

1 Ms. Smith is an associate attorney at Macfarlane Ferguson & McMullen, P.A. She can be reached at JMS@macfar.com or at (813) 273-4200.

2 *See* Senate Bill 1030 creating Fla. Stat. §§ 381.986, 385.211, 385.212 and 1004.411 and amending Fla. Stat. § 893.02; *See also* companion Senate Bill 1700 creating Fla. Stat § 893.987 (exempting from public records requirements personal identifying information of patients and physicians held by the Department of Health in the compassionate use registry).

3 *See* Nancy Smith, *Bill Signing Makes Florida 22nd State to Pass Medical Marijuana Legislation*, Sunshine State News, (June 16, 2014 4:30 PM), http://www.sunshinestatenews.com/story/bill-signing-makes-florida-22nd-state-pass-medical-marijuana-legislation.

4 The text of the proposed regulations, Chapter 64-4, Florida Administrative Code, and other information regarding the CMCA is available at http://www.floridahealth.gov/programs-and-services/office-of-compassionate-use/.

5 Fla. Stat. § 381.986(5) requires the Department of Health ("DOH") to establish five dispensing organizations to cultivate, produce and supply low-THC cannabis to registered patients and their caretakers, and the development of a secure, electronic and online compassionate use registry. Each dispensing organization must employ a medical director who is a physician. Multiple nurseries have filed challenges to the proposed regulations, based on their opposition to the lottery system outlined therein. *See* Wendy Francois, et. al., *Mounting Legal Challenges to Florida Marijuana Regulations*, National Law Review, (Wednesday, September 24, 2014), http://www.natlawreview.com/article/mounting-legal-challenges-to-florida-medical-marijuana-regulations.

6 The official petition for Amendment 2 is available at http://election.dos.state.fl.us/initiatives/fulltext/pdf/50438-2.pdf.

7 The Ogden memo actually states in part that "…this memorandum does not alter in any way the Department's authority to enforce federal law…Nor does clear and unambiguous compliance with state law or the absence of one or all of the [factors] create a legal defense to a violation of the Controlled Substances Act. Rather this memorandum is intended solely as a guide to the exercise of investigative and prosecutorial discretion." David W. Ogden, Deputy Attorney General, U.S. Department of Justice, *Memorandum for Selected United States Attorneys: Investigations and Prosecutions in States Authorizing Medical Use of Marijuana*, (October 19, 2009), *available at* http://www.justice.gov/sites/default/files/opa/legacy/2009/10/19/medical-marijuana.pdf.

8 James M. Cole, Deputy Attorney General, U.S. Department of Justice, *Memorandum for All United States Attorneys: Guidance Regarding Marijuana Enforcement,* (August 29, 2013), *available at* http://www.justice.gov/iso/opa/resources/3052013829132756857467.pdf.

9 *United States v. Oakland Cannabis Buyers' Cooperative*, 532 U.S. 483 (2001).

10 *See* H.R. 6606, 112th Cong. (2012); H.R. 2306, 112th Cong. (2011); H.R. 1983, 112th Cong. (2011); H.R. 2835, 111th Cong. (2009); H.R. 5842, 110th Cong. (2008); H.R. 5843, 110th Cong. (2008); H.R. 2087, 109th Cong. (2005); H.R. 2233, 108th Cong. (2003); H.R. 1344, 107th Cong. (2001); H.R. 912, 106th Cong. (1999); H.R. 1782, 105th Cong. (1997). However, on July 16, 2014 H.Amdt. 1086 (Heck) to H.R. 5016, 113th Cong. (2014) passed in the House. The amendment would prohibit the use of funds with respect to specified States, to penalize "a financial institution solely because the institution provides financial services to an entity that is a manufacturer, producer, or person that participates in any business or organized activity that involves handling marijuana or marijuana products and engages in such activity pursuant to a law established by a State or a unit of local government."

11 There is also uncertainty about whether the Controlled Substances Act can preempt state medical marijuana laws. *See* Michael A. Cole, Jr., Spring Symposium: Functional Preemption: An Explanation of How State Medicinal Marijuana Laws can Coexist with the Controlled Substances Act, 16 Mich. St. J. Med. & Law 557(Spring 2012).

12 "Charlotte's Web" is a specific strain of low-THC cannabis named after 7 year old Charlotte Figi who suffers from Dravet syndrome. The strain, developed to treat seizures and muscle spasms, reduced the frequency of Charlotte's grand mal seizures from 300 per week to just a few per month. *See* Saundra Young, *Marijuana Stops Child's Severe Seizures*, CNN Health (Wed. Aug. 7, 2013 4:51 PM), http://www.cnn.com/2013/08/07/health/charlotte-child-medical-marijuana/.

13 Interestingly, the Florida Medical Association has come out in opposition of Amendment 2, with spokesperson Dr. Alan B. Pillersdorf stating that the organization believes that "the untended consequences of Amendment 2 are serious and numerous enough for us to believe they constitute a public health risk for Floridians." *See* Scott Powers, *Florida Doctors' Group Comes Out Against Medical Marijuana*, Orlando Sentinel, (Aug. 4, 2014 3:35 PM), http://www.orlandosentinel.com/news/politics/political-pulse/os-florida-medical-association-votes-to-oppose-medical-marijuana-20140804-post.html.

14 Permanent residence is defined as a place where a person has his or her true, fixed and permanent home and principle establishment to which, whenever absent, he or she has the intention of returning. A person may only have one permanent residence at a time, and once a permanent residence is established, it is presumed to continue until he or she shows that a change has occurred. Fla. Stat. § 196.012(18); Fla. Stat. § 381.986(1)(d) (defining "qualified patient").

15 Fla. Stat. § 381.986(2)(b).

16 Fla. Stat. §§ 775.082 and 775.083.

17 "Medical Marijuana Treatment Centers" are distinct from the CMCA's dispensing organizations and are defined in part (b)(5) of Amendment 2 as entities which acquire, cultivate, possess, process (including development of related products such as food, tinctures, aerosols, oils, or ointments), transfer, transport, sell, distribute, dispense, or administer marijuana, products containing marijuana, related supplies, or educational materials to qualifying patients or their personal caregivers and are registered with the DOH.

18 Eric A. Voth, *Guidelines for Prescribing Medical Marijuana*, West J. Med., (Nov. 2001), *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1071601/.

19 Jennifer Mesko, *Health Insurance Companies Refuse to Cover Medical Marijuana*, Drug Watch, (June 16, 2014), http://www.drugwatch.com/2014/06/16/health-insurance-medical-marijuana/.

20 42 U.S.C.S. 1395nn.

21 This is particularly relevant to the physician medical directors of the five dispensing organizations, required under Fla. Stat. § 381.986(5)(b)(7).

22 Imprisonment not to exceed 5 year (or 10 years if a habitual felony offender), and subject to a fine not to exceed $5,000. *See* Fla. Stat. § 775.082 and Fla. Stat. § 775.083.

10 Questions for Dr. Michael F. Gervasi (President and Chief Executive Officer of Florida Community Health Centers, Inc.)

By: Nicholas W. Romanello, Palm Springs, Florida[1]

Author's Note: For more than 10 years, I have enjoyed a different perspective on the practice of health law. As the general counsel of the Health Care District and the Florida Department of Health, I have had the privilege of working with many of the Health Law Section's most experienced members. Be it Code 15s, rule challenges, mergers and acquisitions or emergency suspension orders, I have been fortunate to observe some of the best health lawyers in action. As the liaison to outside counsel (and the one who reviews monthly invoices) my sense is that the very best lawyers all share a common trait – an acute appreciation of the needs of the client. Harder to find is the attorney who understands the intricacies of the client's operations for example, its bond rating and revenue cycle. In an effort to enhance the membership's sensitivity to the client's perspective, it is important to elicit the thoughts and concerns of those we represent. This month, I spoke with Mike Gervasi, the President and Chief Executive Officer of the Florida Community Health Centers, Inc.[2]

The Health Law Section is comprised of attorneys who represent physician practice groups, hospitals and individual practitioners. While these three groups represent cornerstones of the greater health care marketplace, other niche players provide a tremendous amount of clinical care. Among these often overlooked providers are Federally Qualified Health Centers commonly referred to as FQHCs. FQHCs are community-based "safety net" providers that must meet rigorous, if not complex, governance, quality of care, service and cost standards in order to qualify for grant funding under Section 330 of the Public Health Service Act as well as enhanced Medicaid and Medicare reimbursement rates.

While federal grants to open health centers have been available for more than 40 years, the number of FQHCs increased dramatically as a result of President George W. Bush's 2002 Health Center Initiative. "In August 2007, to address continued need and an uneven distribution of health centers, President Bush launched the High Poverty County Presidential Initiative aimed at increasing access to primary health care in some of the poorest counties in the United States."[3] The proliferation of FQHCs continues under the Patient Protection and Affordable Care Act.

Since 2011, Michael Gervasi has served as the President and Chief Executive Officer of the Florida Community Health Centers, Inc. As a practicing physician for over 20 years, Dr. Gervasi enjoys a significant knowledge of FQHCs. Dr. Gervasi is board certified in Family Medicine and has served on the executive committee of the Florida Society of the American College of Osteopathic Family Physicians. He received his certification in Health Care Quality Management from the American Board of Quality Assurance and Utilization Review Physicians, and he frequently lectures on risk management and quality improvement. Dr. Gervasi has received the Samuel L. Salman, D.O. Award for General Practice through Nova Southeastern University where he also serves as Clinical Associate Professor.

What is an FQHC, what role do they play and how do they impact the markets in which they operate? In other words, why should we care about the FQHCs?

FQHCs, are private, non-profit, consumer directed health care organizations with a mission to care for the underserved. They are a crucial part of the medical safety network for millions of Americans. Nationwide, there are just over 1,200 FQHCs with over 9,200 service sites, accounting for over 156,000 jobs. In 2013, FQHCs served over 21 million patients who generated over 86 million patient visits.

FQHCs serve 1 in 15 people living in the United States, including 1 in 6 uninsured persons in the US and 1 in 4 individuals living below the poverty level.

FQHCs are instrumental in eliminating racial/ethnic disparities in such areas as access to primary care and patient satisfaction, cancer screenings, hypertension, diabetes, and other clinical measures. FQHCs often demonstrate equal or superior outcomes in things such as low birth weight babies, women entering prenatal care in the first trimester, diabetes control, blood pressure control, childhood immunizations, tobacco screening and cessation counseling, and other measures.

Tell me about Florida Community Health Centers?

Florida Community Health Centers (FCHC) started in Clewiston (Hendry County) in 1976 to meet the needs of the migrant and farm worker population. Since then, FCHC has grown to a network of 11 practice sites around Lake Okeechobee and coastal St. Lucie and Martin Counties, and a corporate office in West Palm Beach. We currently employ 380 staff to care for over 41,000 patients who generate over 150,000 visits in 2013. We are fully accredited by The Joint Commission and are awaiting our designation as a Patient Centered Medical Home (PCMH).

You, along with some other FQHCs, are now in the insurance business by virtue of your interest in Prestige Health Choice – tell us about the challenges associated with entering into a new business line?

Although FCHC bought shares to become a part owner of Prestige, the decision to do so was much more of a medical decision as opposed to a financial/business decision. Managed care companies are a fact of medical life. Unfortunately, many of them are, when it comes to patient care, difficult to deal with at best, and restrictive at worst. As a part owner of Prestige, we have much more input into the workings of the clinical aspects of patient care/coverage, which makes work flow and patient care easier. From a financial standpoint, Prestige's association with Health Choice Network (HCN) made the investment a "no-brainer" for us since HCN is such a well-run, organized organization.

What do you see as the future for FQHCs and how might health law

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attorneys assist you in fulfilling your vision of that future?

I believe FQHCs will remain not only an integral part of the country's safety net, but will be a major component of the health care delivery system in this country. Their commitment to PCMH, national accreditation, use of electronic medical records and continued focus on the communities they serve will be instrumental in their growth.

The health law landscape is changing rapidly. It is becoming increasingly difficult for FQHCs to keep up with these changes. Health law attorneys must keep up to date with new rules regulations, legislation (especially those specific to FQHCs).

You spend a significant amount of time speaking about quality and treating patients with dignity and respect. If you analogize those concepts to customer service – what suggestions can you offer health law attorneys to more effectively represent their clients?

In medicine, quality is assumed. The problem is the definition of quality. In my opinion, health law attorneys should provide accurate information because that is a key component of quality. Just as patients have varying levels of medical literacy and part of my job is explaining things to them in a language and format that is understandable to them, the same would apply to health laws. Respecting the fact that individuals have varying levels of law literacy, explanations in an understanding, non-judgmental way is critical.

So assuming you had to engage a new attorney – how would you go about it, what would you look for in that attorney and what would some of the determinative factors in selecting counsel be for you?

I subscribe to the three 'A's of business success. I would want the attorney to be Available…return calls and emails timely; they would have to be Affable…someone that I could feel comfortable speaking with and establish a good relationship with; and they would have to be Able… they would have to be knowledgeable in the areas of need.

Without getting into specific facts and circumstances, what legal issues keep you up at night?

By far, the biggest issues that keep me up at night are lawsuits. Even though FQHCs can be covered by the Federal Tort Claims Act[4] (FTCA) for professional liability, I always worry that something might fall through the cracks or the feds might deny coverage based on a technicality. Other suits that keep me up are those pertaining to fraud and abuse violations, and employment law. Additionally, keeping up with the various federal and State regulations causes a fair degree of sleeplessness also.

As we are in the midst of yet another football season – I'd be remiss if I didn't ask: Seminoles, Gators or Hurricanes?

Although I am a FAU alumnus, it is hard to root for the Owls at this time. I have to admit that I do root for the Seminoles since I've done a couple of marathons from their campus in Tallahassee.

Endnotes

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2 The author wishes to acknowledge Bill Dillon, Esq., for providing suggestions for industry leaders to interview to broaden the perspective of members of the Health Law Section by speaking to such industry leaders.

3 Mary Takach *et al.*, Community Health Centers and State Health Policy: A Primer for Policymakers, National Academy for State Health Policy (Jan. 2012) *available at* http://www.nashp.org/sites/default/files/chc.primer.2012.2.pdf.

4 28 U.S.C. §1346(b) (2014).

COMPOUNDING
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However, there was still a big gap in the regulatory scheme. Florida has had a nonresident pharmacy permit category for years but it was not specifically focused on these out-of-state locations that compound commonly used products and ship them into Florida before a specific prescription has been issued. The Legislature enacted what is now Chapter 2014-148, Laws of Florida, the opening clause of which states: "An act relating to nonresident sterile compounding permits…" These new laws became effective October 1, 2014, and created a separate permit for out-of-state organizations that prepared CSPs for shipping into Florida. The BoP and Department now have regulatory oversight and authority that did not previously exist.[9]

While these new permits are important, the most significant change in state law so far has been the amendment of Rule 64B16-27.797. Effective October 1, 2014, after multiple workshops, most of the verbiage of the former rule has been eliminated and instead, USP Chapter 797 as well as three other USP Chapters are incorporated by reference.[10] The incorporated chapters total over sixty single-spaced largely technical pages from the USP.

The new rule includes three specific exceptions that illustrate just how technical CSP regulation is. USP 797 literally dictates the location within the pharmacy where personnel are permitted to put on their gloves. The Florida rule creates an exception that allows gloves to be donned at a place that in most pharmacies will be only several feet closer to where compounding is performed but is an exception that will make compliance with the regulation easier for the pharmacies involved.

USP 797 contains specific air quality standards and dictates the placement of air vents on the wall for the introduction and return of air. As written, many pharmacies would have to engage in extensive and expensive renovations to become compliant regardless of whether the underlying air quality standards are otherwise met. This exception allows those vents to remain in place as long as the pharmacy otherwise meets the air quality requirements.

The third exception may be the most important. In order to protect both patients and the pharmacists, technicians and other personnel in the pharmacy, the compounding of sterile products, particularly those that involve hazardous substances such as chemotherapeutic drugs, require multiple layers of protection. Chief among those is that, under USP 797, drugs are to be compounded in a negative pressure room.[11] To oversimplify, USP 797 provides

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that a full negative pressure room is not required in a facility that prepares a "low volume" of hazardous drugs so long as the facility uses a properly installed and vented biological safety cabinet which resembles a clear plastic box with the long rubber gloves on one side.[12] However, the USP does not define "low volume." After much input and debate, the BoP defined "low volume" as less than forty doses per month. This definition has no doubt saved many pharmacies from the very expensive and disruptive renovations needed to install a negative pressure room.

The Joint Administrative Procedures Committee ("JAPC") conducted a detailed review of the changes to Rule 64B16-27.797. Several letters between JAPC and counsel for the BoP highlights the complexity of this rule and the difficulty associated with incorporating so much material by reference.[13] The incorporation by reference means that the BoP will have to periodically update this rule as the USP is updated.[14]

Even before the revised rule became effective, the BoP has granted two temporary waivers from portions of the new requirements. Several hospital pharmacies are undergoing renovations to become compliant but will not complete them before the effective date. The BoP, recognizing that full compliance will take time, approved those temporary waivers but only on the condition that the pharmacies remain otherwise compliant with the prior version of the rule.

The last item to note deals with "office use compounding," which refers to the provision and administration of a compounded drug to a patient in the practitioner's office or by the practitioner in a health care facility or setting.[15] Historically, pharmacies would prepare a quantity of commonly used compounded drugs and deliver them to practitioners before the pharmacy received a patient-specific prescription. The concept of office use compounding only allows for the administration of the drug to the patient. The practitioner cannot dispense the drug to the patient for later use. In June 2014, the rule regarding office use compounding was amended. Pharmacies that only have a Florida pharmacy permit—even the new compounding pharmacy permit—can no longer prepare and sell compounded products for office use without a patient-specific prescription. Instead, in order to do so, among a number of other requirements, the facility must be an "outsourcing facility" under DQSA.[16] The FDA, and not the Florida BoP, licenses outsourcing facilities. As of the writing of this article, there are only 55 outsourcing facilities authorized by the FDA in the United States with eight of them in Florida.[17]

The work on these Florida compounding rules is not done. Rule 64B16-27.700 contains a far more detailed definition of "compounding" than what is in the statutes enacted by the Florida Legislature in 2014. The BoP will have to address whether there is statutory authority for the more detailed definition in rule or if changes will be necessary. In addition, a public meeting was held on October 9, 2014 in Kissimmee for both Department of Health pharmacy inspectors and the industry to learn more about 797 regulation and enforcement in Florida. Again to demonstrate the change in the level of scrutiny, until recently, the inspection form was a single page document. The most recent draft of the questionnaire the surveyors will use is eleven pages with 125 items. How the inspections will unfold using these standards remains to be seen.

When your clients bring up compounding issues, recognize that they may be complex, the law and regulatory practice is changing and there are state and federal considerations involved.

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Endnotes

1 The author would like to thank Assistant Attorney General David D. Flynn, Counsel to the Florida Board of Pharmacy, for his assistance.

2 Karen Gullo, *New England Compounding Pharmacy In $100 Million Settlement*, Bloomberg Businessweek, (May 7, 2014) http://www.bloomberg.com/news/2014-05-06/new-england-compounding-pharmacy-in-100-million-accord.html.

3 U.S. Food & Drug Admin., *FDA Alerts Health Care Professionals of Infection Risk from Repackaged Avastin Intravitreal Injections*, http://www.fda.gov/drugs/drugsafety/ucm270296.htm.

4 Pub. L. No. 113-54, 127 Stat. 587.

5 Fla. Admin. Code R. 64B16-27.700 (2014).

6 2014 Fla. Laws 148.

7 *See* http://www.usp.org/about-usp.

8 Fla. Admin. Code R. 64B16-28.100(8); 64B16-28.802 (2014).

9 Entities that obtain the nonresident sterile compounding permit may also have to be registered as "outsourcing facilities" which is a new classification under DQSA. An outsourcing facility under DQSA is a location where sterile products are compounded either with or without a prescription for a specific patient. Under federal law, outsourcing facilities do not have to have a state pharmacy permit. However, Florida law now requires the nonresident sterile compounding permit to send those products into this state.

10 The incorporated chapters of the version of the USP in effect as of December 31, 2013 are:

(a) Chapter 797, Pharmaceutical Compounding-Sterile Preparations;

(b) Chapter 71, Sterility Tests;

(c) Chapter 85, Bacterial Endotoxins Test;

(d) Chapter 731, Loss on Drying.

Originally, two other USP chapters were incorporated by reference but were removed by the BoP prior to enactment in response to comments from the Joint Administrative Procedures Committee.

11 Simply stated, in a negative pressure room air can only flow through specific filtered ducks and cannot flow out through doors, windows or other openings.

12 Obviously, a biological safety cabinet is a far more sophisticated piece of equipment than is suggested by this description.

13 Letters from Marjorie C. Holladay, Chief Attorney for JAPC to David D. Flynn, Assistant Attorney General and Counsel to BoP, (March 18, 2014, April 8, 2014, July 7, 2014 and July 11, 2014) (on file with author).

14 *See, e.g., Abbott Laboratories v. Mylan Pharmaceuticals, Inc.*, 15 So. 3d 642 (Fla. 1st DCA 2009), *rev. denied*, 26 So. 3d 582 (Fla. 2009).

15 Fla. Admin. Code R. 64B16-27.700(3).

16 This outsourcing facility requirement applies to drugs compounded for human use. Drugs are also compounded for veterinary use.

17 *See* http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm378645.htm.

Your Clients Know About HIPAA… But Are They Aware of FIPA?

Aldo M. Leiva, Esq.[1]

The healthcare sector has long been aware of the data security and privacy requirements imposed by the Health Insurance Portability and Accountability Act of 1997 ("HIPAA"), and both Covered Entities (primarily health care providers) and Business Associates (service providers to such entities) have been required to update their policies, practices, and applicable contracts (i.e. Business Associate Agreements) to comply with the HIPAA Omnibus Rule enacted in 2013. However, both health care providers and their respective service providers who acquire, maintain or use personal information of individuals located in Florida must now also consider potential compliance measures mandated by Florida's recently enacted Florida Information Protection Act ("FIPA"). Provided below is a summary of FIPA, analysis of potential practical effects on health care providers (and their service providers) both in and outside the State of Florida, and basic FIPA practice tips for counsel.

FIPA was signed into law by Governor Rick Scott on June 20, 2014, and went into effect on July 1, 2014. FIPA repealed Florida's earlier data breach notification statute, Fla. Stat. § 817.5681, which had been in place since 2005, and replaced it with Fla. Stat. § 501.171. The newly enacted law is part of a growing trend among state legislatures that are seeking to update data breach and data security laws in light of well-publicized data breaches that have impacted millions of Americans in recent years.

Expanded Statutory Definitions Trigger Wide-ranging Practical Effects

FIPA includes important definitions that identify individuals and entities that are subject to this law and the type of information that is subject to the law, which trigger practical compliance considerations for any individual or entity engaging in business activities that include personal data of Florida citizens or residents. In contrast to Florida's prior breach notification law, which was limited in application to entities that conducted business in Florida,[2] FIPA's applicability is no longer limited to in-state participation by the regulated entity, but is instead triggered by the use of personal data that is provided by an individual in Florida to the regulated entity. The new focus of FIPA on business practices that include personal data of Florida citizens and residents, as opposed to business presence within the state, expands the application of FIPA to any commercial entity, in any other state and even any other country, provided that a Florida citizen or resident has provided such personal information to that entity. In other words, once an individual located in Florida provides or entrusts their personal information to the entity (whether or not that entity conducts business in the State of Florida), the entity is now subject to FIPA compliance requirements both in the event of a breach and is also now required to enact "reasonable security measures" to protect such data, as further explained below.

FIPA expands compliance obligations of "covered entities" that acquire, maintain, store, or use data containing "personal information" that has been "provided by an individual in this state to a covered entity for the purpose of purchasing or leasing a product or obtaining a service."[3] Although the term "covered entity" is common to both FIPA and HIPAA, the meaning of the term under FIPA is far more expansive, as it is not limited to health care providers or other similar entities as defined under HIPAA.[4] Rather, FIPA's version of a "covered entity" includes any business or government entity[5] that collects or uses "personal information," which is defined as either, (A) an individual's first name or first initial, and last name in combination with any one or more of the following identifying elements:

1. social security number;
2. driver's license number, identification card number, passport number, military ID number, or other similar number issued on a government document used to verify identity;
3. financial account number, such as credit or debit card number, in combination with any security code or password required for access to the account;[6]
4. ANY information regarding an individual's medical history, mental or physical condition, or medical treatment or diagnosis by a health care professional;
5. Health insurance policy number or subscriber identification number and any unique identifier used by a health insurer to identify the individual;[7] OR

(B) a user name or email address in combination with a password or security question and answer that would permit access to an online account.[8]

However, the term "personal information" does NOT include either information that has already been made publicly available by a federal, state, or local government entity, OR information that is encrypted, secured, or modified by any other method or technology that removes elements that will identify the individual or will otherwise render the information unusable.[9]

The application of the above definitions is significant to "covered entities" that are already subject to HIPAA regulations because the new definition of "personal information" under FIPA has been expanded to include health care information, subject to the language that limits the application of FIPA to unencrypted or de-identified information. Healthcare providers that are already "covered entities" under the HIPAA definition are therefore not subject to FIPA if the patient information is encrypted or de-identified. But, for those healthcare practitioners that do not encrypt such data, a breach will trigger a notice requirement under FIPA, in addition to any notice requirements under the HIPAA Omnibus Rule.

New Breach Notification Requirements

FIPA also establishes new notification requirements in the event of a breach of personal information. Under the prior statute, breaches had to be reported to affected individuals within 45 days from the time the breach was discovered.[10] FIPA reduces the reporting period to affected individuals to 30 days, although such notification may be delayed upon

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written request of law enforcement authorities, if it is determined that such notification would interfere with a criminal investigation.[11]

FIPA also provides that data breach notification provided by a covered entity in compliance with its "primary or functional federal regulator" will be deemed to be in compliance with FIPA's notice requirement.[12] As applied to an entity regulated under HIPAA, however, this FIPA provision creates an ambiguity in the law; under HIPAA, a covered entity must provide breach notification "without unreasonable delay" and in no case later than 60 calendar days after discovery of the breach.[13] In contrast, FIPA's notice requirement places a strict limit of 30 days for notice following discovery of the breach; therefore, it is as yet unknown whether a covered entity that notifies affected patients after the 30 day period, but achieves notification prior to HIPAA's 60 day time limit, will be able to avail itself of FIPA's "functional federal regulator" compliance language to retroactively demonstrate compliance with FIPA. To further add to the ambiguity, FIPA requires a covered entity to "timely" provide a copy of the notice it has issued pursuant to applicable federal requirements, in order to be deemed to be in compliance with FIPA's notice requirements; the question arises as to whether "timeliness" will be limited to the 30 days required under FIPA.

In light of these ambiguities, in practice, notification within FIPA's 30 day period will satisfy HIPAA notification requirements, provided other HIPAA notification requirements are also met. In order to ensure proper notification under both FIPA and HIPAA, an independent analysis of notification requirements (and content of same) should be performed under each statute.

A covered entity must notify each individual "in this state" whose personal information was or is believed to have been accessed as a result of a breach, no later than 30 days after determination of a breach or reason to believe a breach occurred. Based on the statutory language limiting notification to individuals "in this state," it appears that FIPA does not require notification of affected individuals who have left Florida as of the time of notification.

In the event the breach affects 500 or more persons, the covered entity must now also notify the Florida Department of Legal Affairs no later than 30 days after determination of the breach or reason to believe a breach occurred, although an additional period of up to 15 days may be granted for good cause, if so authorized by the Florida Department of Legal Affairs.[14] If the breach requires notification to more than 1,000 individuals at a single time, the covered entity must also notify credit reporting agencies "without unreasonable delay."[15]

Notwithstanding FIPA's notification requirement to affected individuals, however, no such notification is required if, after appropriate investigation and consultation with the relevant law enforcement authorities, the covered entity reasonably determines that the breach has not and will not likely result in identity theft or financial harm to affected individuals.[16] Such determination must be reduced to writing and must be submitted to the Florida Department of Legal Affairs within 30 days after the determination, and must be maintained for a period of at least five years after the breach.[17] Counsel for HIPAA covered entities should note that while the above "risk of harm" analysis is applicable within the FIPA compliance context, HIPAA itself no longer applies the "risk of harm" standard and instead, as of enactment of the HIPAA Omnibus Rule in 2013, now emphasizes a "risk of breach to the information" analysis when assessing notification.[18] In practice, the same data breach will trigger independent analysis on the issue of notification under each statute (HIPAA and FIPA), under two different standards.

FIPA also imposes new requirements on covered entities that are notified of a data breach by third party agents that maintain, store or process personal information for a covered entity or governmental entity.[19] As in the prior statute, such agents have no more than 10 days after a data breach to notify the covered entity on whose behalf personal information was maintained.[20] However, FIPA now requires the notified covered entity to provide notification to affected individuals within 30 days of such notification,[21] in contrast to the imprecise requirement in the prior statute, which provided discretion to the covered entity and third party agent to agree on notification or, failing such agreement, imposed notification requirements on whichever person that had the direct business relationship with the affected Florida state resident(s).[22] This new FIPA requirement also contrasts with the 60 day notice period that applies under HIPAA, and may be used by counsel for covered entities in Florida to insist on a shorter notice period in contracts with third party agents (i.e. business associate agreements).

New Requirements for "Reasonable Measures" to Protect, Secure, and Dispose of Data

FIPA also requires that any covered entity, governmental entity, or third party agent that electronically stores regulated personal information "take reasonable measures to protect and secure data."[23] The statute does not define the measures that are deemed to be "reasonable," presumably due to evolving and emerging security threats to such data. In fact, by providing a broad descriptor of measures, it appears that regulated entities must avail themselves of emerging threats and regularly conduct risk assessments of their data storage systems to identify new vulnerabilities.

Covered entities and third party

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FIPA

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agents are now also required to take "all reasonable measures" to dispose of records that are no longer to be retained (except, of course, any records subject to an express or implied litigation).[24] Such measures include shredding, erasing, or otherwise rendering the records unreadable or undecipherable.[25]

Enforcement and Penalties

FIPA does not create a private cause of action and is enforceable only by the Florida Department of Legal Affairs, which may deem any FIPA violations as an unfair or deceptive trade practice, and may lead to imposition of civil penalties as follows: (1) $1,000 per day for the first 30 days, (2) $50,000 for each subsequent 30 day period (up to 180 days), and (3) up to a maximum of $500,000 for any violation. Notably, these civil penalties apply per breach and not per individual affected by the breach.[26]

Summary of FIPA Practice Considerations

1. Confirm whether client has acquired, maintains, or uses unencrypted personal information of individuals in Florida (whether or not client does business in Florida).
2. If FIPA applies, consider advising client to identify and implement "reasonable measures" to secure personal information and adopt "reasonable measures" to dispose of such information as appropriate under applicable law.
3. If FIPA applies, consider adoption by client of policies and procedures reflecting notification requirements and timelines pursuant to FIPA.
4. If FIPA applies, consider requiring third party agents/business associates to adhere to the 30 day FIPA breach notification deadline as opposed to the 60 day HIPAA breach notification deadline.

Endnotes

1 Mr. Leiva is Chair of Data Security and Privacy Practice of Lubell Rosen, in Miami, Florida, and advises domestic and international clients on data protection issues, cybersecurity, and privacy laws. He can be reached via email at aml@lubellrosen.com or at (305) 442-9045.

2 Fla. Stat. § 817.5681(1)(a) (2014).

3 Fla. Stat. § 501.171(1)(c) (2014).

4 45 C.F.R. § 160.103 (2014) defines "covered entity" as any of the following: (1) a health plan; (2) a health care clearinghouse; *or* (3) a health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter.

5 Fla. Stat. § 501.171(1)(b).

6 These definitions were included in the prior data breach notification Stat.ute.

7 FIPA expands upon the prior data breach notification Stat.ute by adding these two new categories of personal information that relate to health care. *See* Fla. Stat. § 501.171(1)(g)(1)(a)(IV) and (V).

8 Fla. Stat. § 501.171(1)(g)(1)(b).

9 Fla. Stat. § 501.171(2).

10 Fla. Stat. § 817.5681(1)(a).

11 Fla. Stat. § 501.171(4)(a) – (c).

12 Fla. Stat. § 501.171(4)(g).

13 44 C.F.R. § 164.404(b).

14 Fla. Stat. § 501.171(3).

15 Fla. Stat. § 501.171(5).

16 Fla. Stat. § 501.171(4)(c).

17 *Id.*

18 44 C.F.R. 164.402(2)(i-iv).

19 Fla. Stat. § 501.171(6)(a).

20 *Id.*

21 *Id.*

22 Fla. Stat. § 817.5681(2)(a).

23 Fla. Stat. § 501.171(2).

24 Fla. Stat. § 501.171(8).

25 *Id.*

26 Fla. Stat. § 501.171(9).

reimbursed credentialed medical providers enrolled in AHCA's provider service network ("PSN") for each service provided to Medicaid recipients. AHCA coordinated Medicaid recipients' health care services through its own contracted network of providers by setting the amount the State would pay for specific medical services. The treating provider would render services upfront and subsequently file a claim for reimbursement from AHCA.

Although one perceived advantage of FFS is increased access to a wide range of high-quality medical providers - over 90% of physicians participated in a provider network as of 2009-,[17] an enrollee may need (or simply want) to visit an out-of-network physician to receive a particular service – however, the costs associated with receiving treatment from a non-participating provider are often exorbitant.[18] In a FFS model, providers have an incentive to provide reactive (rather than preventive) health care treatment and service because any reimbursable procedure is profitable. Providers are therefore motivated to order the maximum number of services and extend the period of care for each enrollee. Because a provider must treat each enrollee as often as possible to capitalize on the FFS billing system, the enrollee could perceive these frequent interactions to mean that "my doctor cares about me and always has my best health care interests in mind."[19] However, if one initial service could have mitigated or altogether prevented an enrollee's disease or condition, then the belief that "my doctor cares" is illusory – all subsequent treatment is rendered at the expense of the Medicaid system. In addition to compromising the enrollee's long-term health, reactive treatment also has the effect of costing the State more money than preventive care.[20] The problems outlined in this section – high reimbursement fees levied by out-of-network providers, and the potential for overutilization of services or billing for unnecessary medical treatment are key reasons why the State decided to pursue an alternative health care delivery system.

b. Managed Care

In the new Medicaid managed care or SMMC program, the State pays a capitation rate (fixed monthly price) to a HMO to provide health care services to Medicaid enrollees. In contrast to FFS, the Plan has agreed to accept each Medicaid enrollee for the capitated fee, regardless of the number of services a particular enrollee receives. The Plan is responsible for coordinating Medicaid enrollees' health care services through its own network of providers.

Inevitably, in an effort to maximize profits, each Plan will seek to eliminate expenses it deems unnecessary. Similar to the concept behind Costco or Sam's Club (i.e., lower prices are available by purchasing products in bulk), Plans receive lower prices with providers by buying a bulk amount of health care services. Plans also cut costs by placing restrictions on enrollees' choice of providers; because each Plan has its own network of providers. Proponents argue, since there are at least two Plans in each of the 11 statewide regions, enrollees' choice is not substantially limited. Although a person could subjectively agree that *Heinz 57 or Kirkland* ketchup* is a satisfactory option because s/he retains the ability to exercise choice (or s/he vehemently defends the position that Kirkland makes the tastiest sauce of tomatoes), that person is nonetheless unable to choose Hunt's, Del Monte, a local gourmet bottle, or any other ketchups. In HMO terms, despite the fact that a Medicaid enrollee could find the choice of two Plans (or two providers) to be satisfactory, his or her choice has still been significantly constricted. As such, many Enrollees may find limited choices to be a downside of SMMC, but many will also find the options offered by the Costco model of health care to be satisfactory.

c. Analysis

Under SMMC, a Florida enrollee is able to select any qualified Plan in his or her region of the State. Many Plans have provided expanded benefits (beyond the baseline Medicaid standard) like equine therapy,[21] and innovations in care coordination to attract enrollees. Not only could such additional services benefit enrollees, they could likewise increase access to care. Robert Book, author of *Benefits and Challenges of Medicaid Managed Care*, explains, "Evidence suggests that, compared to state-run-fee-for-service, managed care can reduce overall Medicaid program costs, while providing better patient outcomes…studies in 24 states found that all states… experience[d]… reduction in per-beneficiary spending due to Medicaid managed care."[22] In response to problems associated with FFS in Florida, MMA Plans are required to offer more preventive care services such as weight loss and smoking cessation programs, and the capitation system incentivizes early detection to prevent or mitigate diseases in order to keep costs below enrollees' capitated rates.[23]

In contrast, evidence also suggests that patients who are treated by low-volume physicians and hospitals have worse health outcomes than patients treated by high-volume providers. Managed care enrollees are commonly treated by low-volume providers, which could mean that enrollees are not "referred as frequently to specialists… or their access to high-volume specialists may be restricted. Such care plans may… have contracts only with low-volume community hospitals… because lower-cost community hospitals tend to charge less for their services than higher-cost teaching hospitals."[24] While proponents would reply that good Plans use referrals to screen inappropriate medical practices, critics retort that the Plan's business people are making decisions regarding the appropriate level of care and they are more concerned about cutting costs than promoting quality of care.[25]

Actuarially sound capitation rates are a critical component to ensuring SMMC does, in fact, succeed. Several unintended, but foreseeable, consequences would likely result from insufficient capitation, including, but not limited to the following: (1) "insufficient rates encourage MCOs to reduce payment rates to providers. This impairs access to care by making it more difficult to enroll providers and thus negates one of the main benefits of Medicaid managed care compared to Medicaid FFS";[26] (2) low capitation may encourage Plans to eliminate expanded benefits to maintain profitability; and, (3) unsound payment may freeze the HMO-market, as current Plans could withdraw from SMMC (or file bankruptcy) and potential participants could opt-out altogether.

III. Conclusion

As of August 1, 2014, Florida's new Medicaid managed health care program has been fully implemented. As the state with the third highest rate of uninsured residents, the success of the SMMC program could have national implications. By implementing the Costco model of health care, the State has the opportunity to improve the overall health outcomes for Florida enrollees while simultaneously cutting Medicaid costs – an opportunity that, in terms of the ketchup analogy, may be the *tastiest*.

continued, next page

EXHIBIT & FIGURES

Exhibit A. Matrix of Florida Medicaid Managed Care

Region	Counties	Long Term Care (LTC) Health Plan	Managed Medical Assistance (MMA) Health Plan	Comprehensive Coverage?	Additional Types of Health Plans *See Key Below*
1	Escambia, Okaloosa, Santa Rosa, Walton	American Elder Care, Sunshine	Humana, Integral	N/A	CH, SH, CM
2	Bay, Calhoun, Franklin, Gulf, Holmes, Jackson, Washington, Gadsden, Jefferson, Leon, Liberty, Madison, Taylor, Wakulla	American Elder Care, UnitedHealth	Prestige, Staywell	N/A	CH, MC, SH, CM
3	Alachua, Bradford, Citrus, Columbia, Dixie, Gilchrist, Hamilton, Hernando, Lafayette, Lake, Levy, Marion, Putnam, Sumter, Suwannee, Union	American Elder Care, Sunshine, UnitedHealth	Prestige, Sunshine, UnitedHealth, Staywell	Sunshine, UnitedHealth	CH, FH, SH, CM
4	Baker, Clay, Duval, Flagler, Nassau, St. Johns, Volusia	American Elder Care, Amerigroup, Humana, Sunshine, UnitedHealth	First Coast Advantage, Sunshine, UnitedHealth, Staywell	Sunshine, UnitedHealth	MC, SH, CM
5	Pasco, Pinellas	American Elder Care, Molina, Sunshine, UnitedHealth	Amerigroup, Prestige, Sunshine, Staywell	Sunshine	CH, FH, MC, SH, CM
6	Hardee, Highlands, Hillsborough, Manatee, Polk	American Elder Care, Coventry, Molina, Sunshine, UnitedHealth	Amerigroup, Better Health, Humana, Integral, Prestige, Sunshine, Staywell	Sunshine	CH, FH, MC, SH, CM
7	Brevard, Orange, Osceola, Seminole	American Elder Care, Coventry, Sunshine, UnitedHealth	Amerigroup, Molina, Prestige, Sunshine, UnitedHealth, Staywell	Sunshine, UnitedHealth	CH, FH, MC, SH, CM
8	Charlotte, Collier, DeSoto, Glades, Hendry, Lee, Sarasota	American Elder Care, Sunshine, UnitedHealth	Integral, Prestige, Sunshine, Staywell	Sunshine	CH, FH, SH, CM
9	Indian River, Martin, Okeechobee, Palm Beach, St. Lucie	American Elder Care, Coventry, Sunshine, UnitedHealth	Humana, Molina, Prestige, Sunshine	Sunshine	CH, FH, MC, SH, CM
10	Broward	American Elder Care, Amerigroup, Humana, Sunshine	Better Health, Humana, SFCNN, Sunshine	Humana, Sunshine	CH, FH, MC, PH, SH, CM
11	Miami-Dade, Monroe	American Elder Care, Amerigroup, Amerigroup, Coventry, Humana, Molina, Sunshine, UnitedHealth	Amerigroup, Coventry, Humana, Molina, Preferred Medical, Prestige, Simply, Sunshine, United Health, Staywell	Amerigroup, Coventry, Humana, Molina, Sunshine, United	CH, FH, MC, PH, SH, CM

CH: Clear Health Alliance HIV/AIDS
FH: Freedom Health- Duals Chronic conditions
MC: Magellan Complete Care – Serious Mental Illness
PH: Positive Heatlhcare Florida HIV/AIDS
SH: Sunshine Health Plan Child Welfare
CM: Children's Welfare Services Children with chronic conditions

Figure 1. Statewide Medicaid Managed Care Programs

	Managed Medical Assistance (MMA)	Long-Term Care (LTC)
Authority	• Federal Approval: Medicaid 1115 waiver • Part IV, Chapter 409, Florida Statutes	• Federal Approval: Medicaid 1915(b) and 1915(c) • Part IV, Chapter 409, Florida Statutes
Characteristics	• Population: low-income families and individuals • Florida offered select managed care service options for Medicaid recipients prior to SMMC implementation • Second phase of AHCA procurement and implementation (Enrollment: 1 May – 1 August 2014)	• Population: smaller group of medically-complex enrollees • No managed LTC services were previously offered by Florida Medicaid • First phase of AHCA procurement and implementation (Enrollment: 1 August 2013 – 1 March 2014)

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Services	• Medical/Acute care: "Medical services for acute and chronic conditions, including prevention, diagnosis, and treatment delivered in a hospital, clinic or doctor's office, or other medical setting."[27]	• Institutional/ long-term care: "Services that assist consumers with activities of daily living such as bathing, dressing, eating, or medication management and are delivered in nursing facilities, assisted living facilities, or at home."[28]
Examples of Specific Services	• Hospital inpatient and outpatient services • Mental health services • Optical services and supplies • Dental services • Chiropractic services • Home health agency services • Birthing center services	• Adult Day Care • Assisted Living Facility Services • Medical Equipment & Supplies • Medication Administration • Nursing Facility Care • Personal Emergency Response System • Physical Therapy

Figure 2. Specialty Plans - Medical Condition/Requirement & Limitations for Enrollment

	All Enrollees	**Children Only (under 21):**	**Dually Eligible Adults (Medicare & Medicaid)**
Medical Condition	• HIV/AIDS • Serious Mental Illness	• Child Welfare (must be in State custody) • Chronic Conditions (as determined by Fla. Dept. of Health)	• Cardiovascular disease • Chronic Obstructive Pulmonary Disease (COPD) • Congestive Heart Failure • Diabetes

Figure 3. Managed Health Care v. Fee-for-Service

	Proponents Say:	Critics Say:
Managed Care	• Cost-effective: capitation allows Florida to control costs & shift financial risk to HMO • Increased accountability to address enrollees' health care • Reduction of number of necessary medical services • Increase enrollees' access to home and community based services (HCBS)	• Limited choice: insufficient access to health care providers • *Potential threat*: reduced payment will lead to reduced quality of services • Actuarial soundness: Difficult to establish payment rates • Lack of Coordination/ continuity of care: inexperienced HMOs in the public managed care market
Fee-for-Service	• Large number of health care providers (expands enrollees' choice) • Affordable access to high-quality, participating medical providers	• High costs associated with visiting out-of-network providers (protection against balance billing does not extend out-of-network) • Over-utilization: enrollees receive more care than necessary due to providers' incentive to render a maximum number of services

Endnotes

1 Carly Elizabeth Souther served as Assistant General Counsel at Florida's Agency for Health Care Administration during the implementation of the Statewide Medicaid Managed Care program. The author extends a heartfelt thanks to Rachel Goldstein and Richard Saliba for providing invaluable [in-Costco] field support. All factual assertions and legal interpretations contained herein are solely those of the author and are not attributable in any way to the State of Florida or the Agency for Health Care Administration. Any questions concerning this Article may be directed to the author at ces11t@my.fsu.edu.

2 Although various parts of SMMC are affected by the Affordable Care Act ("ACA," or, colloquially, "Obamacare"), SMMC is a separate, distinct initiative and the topic herein examined.

3 Fla. Stat. §§ 409.961 – 409.985 (2011); for general information, see *The Statewide Medicaid Managed Care Program*, Agency for Health Care Administration (accessed Aug. 31, 2014), http://www.floridahealth.gov/alternatesites/cms-kids/providers/early_steps/training/documents/presentations2013/SMMC_Overview.pdf

4 Fla. Stat. §§ 409.9122, 409.971 (2011); Chapter 2011-134, Laws of Florida.

5 Stuart F. Williams & William M. Blocker, II, *Building Florida's Medicaid Managed Care Mega-Procurement*, 1 – 23, 5 (April 2014) [hereinafter "Mega-Procurement"].

6 David W. Martin, *Statewide Medicaid Managed Care Program Implementation*, Agency for Health Care Administration, Report No. 2014-193, 1 (May 2014), http://www.myflorida.com/audgen/pages/pdf_files/2014-193.pdf (noting that "[d]uring the 2012–13 fiscal year, the Agency made Medicaid payments totaling approximately $19 billion to medical providers.").

7 Martin, *Statewide Medicaid Managed Care*, *supra* note v.

8 *Statewide Medicaid Managed Care (SMMC) – Managed Medical Assistance (MMA) Program*, Agency for Health Care Administration (accessed Aug. 29, 2014), http://www.flmedicaidmanagedcare.com/MMA/ProgramInformation.aspx.

9 Laura Summer, *Launch of Medicaid Man-*

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10 *Id*; see also *Glossary*, Agency for Health Care Administration (accessed Oct. 5, 2014), http://www.flmedicaidmanagedcare.com/MMA/glossary.aspx (defining "Managed Care Plan" as "an eligible plan under contract with the Agency to provide services in the LTC or Managed Medical Assistance (MMA) part of the Statewide Medicaid Managed Care Program.").

11 *Id*.

12 *Statewide Medicaid Managed Care (SMMC) – Long-Term Care (LTC) Program*, Agency for Health Care Administration (accessed Aug. 29, 2014), http://www.flmedicaidmanagedcare.com/GeneralInfo.aspx.

13 *Frequently Asked Questions*, Agency for Health Care Administration (accessed Aug. 29, 2014), http://www.flmedicaidmanagedcare.com/MMA/faq.aspx

14 *Statewide Medicaid Managed Care: Managed Medical Assistance (MMA) – Choosing an MMA Plan*, Agency for Health Care Administration (accessed Aug. 31, 2014), http://www.flmedicaidmanagedcare.com/SharedFiles/english/SMMC_BrochuresAndLetters/Brochures/MMA%20Brochure.pdf (explaining that all Plans are required to coordinate with Medicare to ensure that dual enrollees receive a continuity of health care services); see also *Glossary*, supra note v (defining "Specialty Plan" as "[a] plan that serves Medicaid recipients who meet certain criteria based on age, medical condition, or diagnosis.").

15 For a detailed explanation on why states should use relevant and sound actuarial data to calculate capitation rates, *see* Robert Book, *Benefits and Challenges of Medicaid Managed Care*, Forbes.com (Oct. 18, 2012, 10:09PM), http://www.forbes.com/sites/aroy/2012/10/18/benefits-and-challenges-of-medicaid-managed-care/.

16 Martin, *Statewide Medicaid Managed Care*, *supra* note v.

17 American Health Insurance Plans, *The Value of Provider Networks and the Role of Out-of-Network Charges in Rising Health Care Costs: A Survey of Charges Billed by Out-of-Network Physicians*, 1 (August 2009) (accessed Oct. 5, 2014), www.ahipresearch.org/PDFs/ValueSurvey/AllStatesReport.pdf.

18 *Id* (noting that "in-network physicians are generally prohibited from charging patients the difference between billed charges and a negotiated rate.").

19 E-mail from Rachel Goldstein, Senior Attorney, Fla. Agency for Health Care Admin., to author (Oct. 10, 2014, 8:36 PM CEST)(on file with author).

20 *Id*.

21 Fla. Agency for Health Care Admin., *SMMC MMA Snapshot*, 2 (Jul. 10, 2014), http://ahca.myflorida.com/Medicaid/statewide_mc/pdf/mma/SMMC_MMA_Snapshot.pdf (noting Staywell plan provides enrollees with the expanded benefit of equine therapy).

22 Robert Book, *Benefits and Challenges of Medicaid Managed Care*, Forbes.com (Oct. 18, 2012, 10:09PM), http://www.forbes.com/sites/aroy/2012/10/18/benefits-and-challenges-of-medicaid-managed-care/.

23 E-mail from Goldstein to author, supra note xix.

24 Matt Nevisky, *Quality Differences in Managed Care and Fee-for-Service*, National Bureau of Economic Research (accessed Oct. 6, 2014), http://www.nber.org/digest/nov98/w6523.html (quoting Sarah Feldman & David Scharfstein, Managed Care Provider Volume, NBER Working Paper 6523 (1998), http://www.nber.org/papers/w65230.

25 Advamak, Inc., *Health Care System – Managed Health Care vs. Fee-for-Service* (accessed Oct. 8, 2014), available at http://www.faqs.org/health/Healthy-Living-V2/Health-Care-Systems-Managed-health-care-vs-fee-for-service.html#ixzz3FHbsVDgz.

26 Book, *Benefits and Challenges*, *supra* note xxii.

27 Summer, Launch of Medicaid Ma*naged Long-Term Care*, supra note v at 1.

28 Id.

E-filing Software Updates to Address Uniformity Concerns

By Gary Blankenship

A coming change to the Florida courts e-filing portal is aimed at making it easier for lawyers to choose the "document type" when they are electronically filing court documents.

The update to portal software, which will be installed after business hours on Friday, October 24, will suggest document categories to users instead of requiring them to conduct a search or scroll through lists to find the correct title for the type of document they are submitting.

The Florida Court E-Filing Authority, which runs the statewide portal through which electronic filing is done, got a look at the upcoming software update at its September 25 meeting in Tallahassee.

Other changes include allowing larger documents to be electronically filed in the appellate courts, making it easier to see who has been served with documents in a case, and making it easier for lawyers to remove themselves from electronic service lists for cases they are no longer involved in.

Jennifer Fishback, portal project manager, presented the upcoming software improvements. She said the assistance on choosing a document type will help address a stubborn problem brought up by users — that the portal functions differently from county to county, primarily in the number and options for document types presented to filers. (The authority took an in-depth look at the lack of uniformity in the document menus among counties later in the meeting. See story, here.)

"What we're trying to do with this [update] is help filers locate the document type they need to file to the county they are filing in, by adding a search feature," Fishback told the authority board.

"We're hoping the next change . . . will help people find their document type more easily."

Currently, the portal's document tab offers to filers a variety of groups to select to find a document type. And each group offers several individual document types that filers can choose.

Carolyn Weber, e-filing portal senior analyst, noted that the number of groups offered and the number of documents in each group varies county to county for historical and other reasons.

Fishback said sometimes the same document will be labeled slightly differently from county to county — "Summons Issued," "Summons Issue To," and "Summons Issued For" are all used by different counties to refer to the same document, she noted.

Also, a document may be listed in several document groups, which can be appropriate but confusing.

Weber said that the current portal offers a search feature that allows users to look for a particular document. The upgrade will allow users to begin typing in a document type, and the portal will automatically provide a list of document types that fit the words being typed, similar to the way many search engines work.

"What we are doing is allowing you to type in a word, put in a common word, and you will get options and get a list," Weber said.

For example, she said typing in "amend" will produce "amended complaint" and any other document types that use the word amend, amended, or similar derivatives.

She said that should reduce some of the difficulties in dealing with county-to-county variances in lists for document groups and document types.

Other changes for filers in the release are:

- The maximum size of documents that can be filed in appellate cases will be increased from 10 megabytes to 25 megabytes.

At the moment, that will only affect the Supreme Court and the Second District Court of Appeal, although the remaining four DCAs are expected to begin taking filings through the portal (they're using an older e-filing system at the moment) in the next several months.

- Information about e-service will be added to a user's "My Filings" screen. Currently, that screen shows documents that have been filed, the status of the filed documents, and the status of fees paid on those documents.

The upgrade, Fishback said, will add an e-service list to that screen so filers can see everyone who has been electronically served with a filed document. To do that now, filers have to check the e-service page and individually check with all parties and lawyers listed on that page.

- A new screen will be added to allow filers to better manage their e-service. Specifically, Fishback said that one screen will show all cases the filer is listed for e-service and allow them to remove themselves from cases they are no longer involved in. Currently, they have to go case by case to each e-service list to remove themselves.

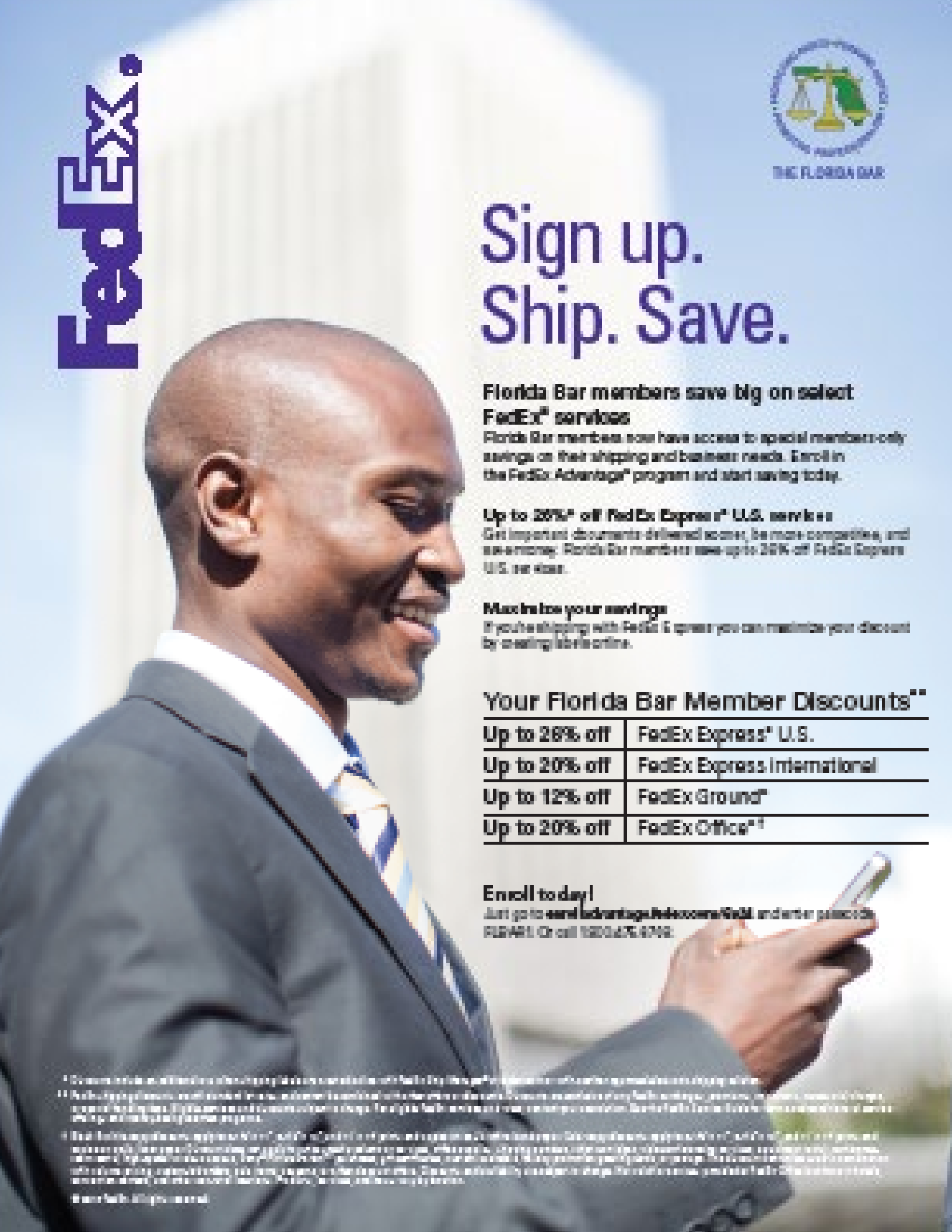
Portal staff has put training materials and videos on the portal's website, www.myflcourtaccess.com, Fishback said. Look under the Help tab on the homepage for training manuals and training videos. Under E-Filing videos on the video page is a 10-minute video on the October 24 update.

Aside from the user improvements in the update, other changes will help clerks, including the ability to electronically send documents to the Department of Corrections.

Fishback also said portal staff is already working on the next software update, tentatively scheduled for April 2015 that will offer a new screen for filers, called "My Fees."

That will show filers what fees have been paid in various cases and documents. She said lawyers are having difficulty because they get bank statements showing the amount of fees paid through the portal, but frequently without detail on which cases and clients the fees were paid for.

Fishback said the goal is to provide information that lawyers can download and import directly into their banking software so they can accurately allocate expenses to clients.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